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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 21

[Docket No. FAA–2019–0280]

Primary Category Design Standards; Cub Crafters, Inc., Model CC21–180 Airplane

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Issuance of final airworthiness design standards.

SUMMARY: These airworthiness design standards are issued to Cub Crafters, Inc., for type certification of the Model CC21–180 airplane under the regulations for primary category aircraft.

DATES: These airworthiness design standards are effective September 9, 2019.

FOR FURTHER INFORMATION CONTACT: Mr. Raymond N. Johnston, AIR–692, Federal Aviation Administration, Policy & Innovation Division, Small Airplane Standards Branch, 901 Locust, Room 301, Kansas City, MO 64106, telephone (816) 329–4159, FAX (816) 329–4090, email *raymond.johnston@faa.gov.*

SUPPLEMENTARY INFORMATION: Any person may obtain a copy of this information by contacting the person named above under **FOR FURTHER INFORMATION CONTACT**.

Background

The ''primary'' category for aircraft was created specifically for the simple, low performance personal aircraft. Section 21.17, Designation of applicable regulations, paragraph (f) provides a means for the FAA to determine appropriate airworthiness standards for the particular primary category aircraft. The FAA procedure establishing appropriate airworthiness standards includes reviewing and possibly revising an applicant's proposal, publication of the submittal in the **Federal Register** for public review and comment, and addressing the comments. After all necessary revisions, the standards are published as approved FAA airworthiness standards. This document prescribes airworthiness standards for the issuance of a type certificate for the Cub Crafters, Inc., Model CC21–180, a primary category airplane. These airworthiness standards have a long safe service history in similar airplanes; therefore, they provide an appropriate level of safety. These airworthiness standards are based on standards that were used to certificate the same design as a normal and utility category airplane, Cub Crafters Model CC19–180, in accordance with FAA Type Certiciate A00053SE.[1]

Comments

Proposed Primary Category Design Standards; Cub Crafters, Inc., Model CC21–180 Airplane was published in the **Federal Register** on April 17, 2019 (84 FR 15992). No comments were received, and the airworthiness design standards are adopted as proposed.

Applicability

These airworthiness design standards under the primary category rule are applicable to the Cub Crafters, Inc., Model CC21–180 airplane. Should Cub Crafters, Inc. wish to apply these airworthiness design standards to other airplane models, it must submit a new airworthiness design standard application under the primary rule category.

Conclusion

This action affects only certain airworthiness design standards on the Cub Crafters, Inc., Model CC21–180 airplane. It is not a standard of general applicability and it affects only the applicant who applied to the FAA for approval of these features on the rotorcraft.

Citation

The authority citation for these airworthiness standards is as follows:

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

Final Airworthiness Standards for Type Certification in the Primary Category

For the airplane:

Title 14, Code of Federal Regulations (14 CFR) part 23, effective December 18, 1964, as amended by 23–1 through 23–62, all sections except § 23.562 Emergency Landing Dynamic Conditions, and as modified by the following:

Equivalent Level of Safety (ELOS) No. TC10279SE–A–C–1 for the emergency exit requirements of § 23.807 [2]

ELOS No. AT12936SE–A–S–1 for the electronic display instrument system requirements of § 23.1311 [3]

ELOS No. TC10279SE–A–G–9 for corrections to technical errors in amendment 23–62 [4]

ELOS No. AT12949SE–A–F–1 for the longitudinal trim requirements of § 23.161 [5]

For noise standards:

14 CFR part 36 as amended by 36–1 through 36–30, appendix G.

Issued in Kansas City, Missouri on August 1, 2019.

Pat Mullen,

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

[FR Doc. 2019–17013 Filed 8–8–19; 8:45 am]

BILLING CODE 4910–13–P

[1] *See http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgMakeModel.nsf/0/CACFCFE4D1346CEB862582D300654D21?OpenDocument&Highlight=a00053se.*

[2] *See http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgELOS.nsf/0/F3FC2C42E551237F86257FC60046467D?OpenDocument&Highlight=tc10279se-a-c-1.*

[3] *See http://rgl.faa.gov/Regulatory_ and _Guidance_Library/rgELOS.nsf/0/E441A4F21736F7E98625814500674B2A?OpenDocument.*

[4] *See http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgELOS.nsf/0/773696FE2DDEA61D86257FF50065B4B6?OpenDocument.*

[5] *See http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgELOS.nsf/0/0D9E358153C4CF028625825D005E5D15?OpenDocument.*

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0352; Product Identifier 2019–NE–09–AD; Amendment 39–19705; AD 2019–16–02]

RIN 2120–AA64

Airworthiness Directives; GE Honda Aero Engines Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all GE Honda Aero Engines (GHAE) HF120 model turbofan engines with a certain fuel pump metering unit (FPMU) assembly. This AD was prompted by damage found on the permanent magnetic alternator (PMA) drive gear within the FPMU assembly. This AD requires removal of a certain FPMU assembly and its replacement with a part eligible for installation. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective September 13, 2019.

ADDRESSES: For service information identified in this final rule, contact GE Honda Aero Engines, LLC, 9050 Centre Pointe Drive, Suite 350, West Chester, OH, 45069; phone 513–552–7820; email: *info@honda-aero.com;* internet: *www.gehonda.com.* You may view this service information at the FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington MA, 01803. 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–2019–0352.

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–2019–0352; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Michael Richardson-Bach, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7747; fax: 781–238–7199; email: *michael.richardson-bach@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all GHAE HF120 model turbofan engines with a certain FPMU assembly. The NPRM published in the **Federal Register** on May 21, 2019 (84 FR 22986). The NPRM was prompted by an incident on a flight test engine that resulted in the loss of over-speed protection warning. GHAE's subsequent investigation found damage on the PMA drive gear teeth within the FPMU assembly, which was likely due to dynamic loads on the drive gear that exceeded the material capability. The NPRM proposed to require removal of a certain FPMU assembly and its replacement with a part eligible for installation. The FAA is issuing this AD to address the unsafe condition on these products.

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Update Service Information

GHAE commented that the Related Service Information section of the NPRM refers to ''GHAE HF120 Service Bulletin (SB) 73–0016 R01, dated November 08, 2018.'' GHAE recommended that the FAA revise the AD to refer to Revision 02, dated May 13, 2019. GHAE noted that GHAE HF120 SB 73–0016 R02 clarifies the interchangeability statement to eliminate confusion as to the FPMU part numbers that are eligible for installation.

The FAA agrees. The FAA revised the Related Service Information paragraph in this AD to refer to GHAE HF120 SB 73–0016 R02, dated May 13, 2019.

Request To Revise JASC Code

GHAE commented that it considers the FPMU an engine fuel control, falling under JASC Code 7321, Fuel Control/Turbine Engines. GHAE classifies the FPMU as 73–21–00 in its Engine Illustrated Parts Catalog. GHAE therefore recommended that the FAA change the JASC Code from 7314, Engine Fuel Pump, to 7321, Fuel Control/Turbine Engines.

The FAA agrees. The FAA revised the JASC Code in this AD as suggested by the commenter.

Request To Update Address

GHAE commented that the GHAE business address listed in the NPRM is incorrect. GHAE indicated its office suite number has changed. GHAE requested that the FAA change the address in this AD to Suite 350.

The FAA agrees. The FAA updated the address in this AD as suggested by the commenter.

Conclusion

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

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

Related Service Information

The FAA reviewed GHAE HF120 SB 73–0016 R02, dated May 13, 2019. The SB describes procedures for replacement of the FPMU assembly with a part eligible for installation.

Costs of Compliance

The FAA estimates that this AD affects 161 engines installed on airplanes of U.S. registry.

The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replace the FPMU	6.5 work-hours × $85 per hour = $552.50	$50,000	$50,552.50	$8,138,952.50

Authority for This Rulemaking

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

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

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to 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) Will not affect intrastate aviation in Alaska, and

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2019–16–02 GE Honda Aero Engines: Amendment 39–19705; Docket No. FAA–2019–0352; Product Identifier 2019–NE–09–AD.

(a) Effective Date

This AD is effective September 13, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all GE Honda Aero Engines (GHAE) HF120 model turbofan engines with fuel pump metering unit (FPMU) assembly, part number (P/N) 24100–Q0A–F000, installed.

(d) Subject

Joint Aircraft System Component (JASC) Code 7321, Fuel Control/Turbine Engines.

(e) Unsafe Condition

This AD was prompted by damage found on the permanent magnetic alternator drive gear within the FPMU assembly. The FAA is issuing this AD to prevent failure of the FPMU assembly. The unsafe condition, if not addressed, could result in failure of one or more engines, loss of thrust control, and loss of the airplane.

(f) Compliance

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

(g) Required Actions

Within 20 engine hours after the effective date of this AD, or before accumulating 600 engine hours since new, whichever occurs later, remove the affected FPMU assembly from service and replace it with a part eligible for installation.

(h) Installation Prohibition

After the effective date of this AD, do not install on any engine an FPMU assembly, P/N 24100–Q0A–F000.

(i) Definition

For the purposes of this AD, a ''part eligible for installation'' is:

(1) an FPMU assembly, P/N 24100–Q0A–G000 or P/N 24100–Q0A–F100; or

(2) an FPMU assembly, P/N 24100–Q0A–F000, that is rebuilt and marked as P/N 24100–Q0A–G000 or P/N 24100–Q0A–F100.

(j) 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 (k) 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.

(k) Related Information

For more information about this AD, contact Michael Richardson-Bach, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7747; fax: 781–238–7199; email: *michael.richardson-bach@faa.gov*.

(l) Material Incorporated by Reference

None.

Issued in Burlington, Massachusetts, on August 6, 2019.

Robert J. Ganley,

Manager, Engine & Propeller Standards Branch, Aircraft Certification Service.

[FR Doc. 2019–17078 Filed 8–8–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2018–0816; Airspace Docket No. 18–AWP–7]

RIN 2120–AA66

Delay of Class E Airspace Effective Date; Boulder City, NV

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule, delay of effective date.

SUMMARY: This action corrects the effective date for the Class E airspace extending upward from 700 feet or more above the surface of the earth at Boulder City, NV. The effective date was listed as August 15, 2019 and should have been October 10, 2019. This does not affect the charted boundaries or operating requirements of the airspace.

DATES: The effective date of the final rule published on July 17, 2019 at 84 FR 34055 is delayed until 0901 UTC, October 10, 2019. The Director of the Federal Register approves this incorporation by reference action under

Title 1 Code of Federal Regulations part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11C, Airspace Designations and Reporting Points, and subsequent amendments can be viewed on line at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC, 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11C at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.* FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Richard Roberts, Federal Aviation Administration, Operations Support Group, Western Service Center, 2200 S 216th Street, Des Moines, WA 98198–6547; telephone (206) 231–2245.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it corrects the effective date of the Class E airspace extending upward from 700 feet or more above the surface of the earth at Boulder City, NV.

History

The FAA noted the effective date for the Class E airspace extending upward from 700 feet or more above the surface of the earth at Boulder City, NV, FAA–2018–0816, was in error. The final rule published on July 17, 2019 (84 FR 34055) and listed the effective date as August 15, 2019 instead of October 10, 2019. The airspace information was issued on July 3, 2019, three weeks after the required submission cutoff date of June 18, 2019. A July 3, 2019 issue date did not allow sufficient time to publish the airspace information in the VFR Sectionals and Chart Supplement for the August 15, 2019 cycle. This action delays the effective date to October 10, 2019 and allows for publication of the Class E airspace extending upward from 700 feet in the VFR Sectional and Chart Supplement before it becomes effective.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11C, dated August 13, 2018, and effective September 15, 2018, which is incorporated by reference in 14 CFR 71.1. The E airspace listed the final rule published on July 17, 2019 (84 FR 34055) will become effective on October 10, 2019 and be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11C dated August 13, 2018, and effective September 15, 2018, which is incorporated by reference in 14 CFR part 71.1. FAA Order 7400.11C is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11C lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

The FAA is amending Title 14, Code of Federal Regulations (14 CFR) part 71 by correcting the effective date of the airspace change.

This is an administrative change and does not affect the boundaries, altitudes, or operating requirements of the airspace, therefore, notice and public procedure under 5 U.S.C. 553(b) is unnecessary.

Regulatory Notices and Analyses

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

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Issued in Seattle, Washington, on July 22, 2019.

Tom Clark,

Group Manager (A), Operations Support Group, Western Service Center.

[FR Doc. 2019–16930 Filed 8–8–19; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 240

[Release No. 34–86031; File No. S7–07–18]

RIN 3235–AM35

Regulation Best Interest: The Broker-Dealer Standard of Conduct

Correction

In rule document 2019–12164, appearing on pages 33318 through 33492, in the issue of Friday, July 12, 2019 make the following corrections:

1. On page 33491, in the center column, on the tenth line, ''240.15*l*–1'' should read, ''240.15l–1''.

2. On the same page, in the same column, on the eleventh line, ''240.15*l*–1'' should read, ''240.15l–1''.

[FR Doc. C1–2019–12164 Filed 8–8–19; 8:45 am]

BILLING CODE 1300–01–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, and 558

[Docket No. FDA–2019–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications; Changes of Sponsorship; Change of Sponsors' Names and Addresses

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during January, February, and March 2019. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. Technical amendments are also being made to improve the accuracy, consistency, and readability of the regulations.

DATES: This rule is effective August 9, 2019, except for amendatory instructions 51 to 21 CFR 524.916 and 63 to 21 CFR 558.325, which are effective August 19, 2019, and instruction 60 to 21 CFR 558.235, which is effective September 9, 2019.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5689, *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Approval Actions

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during January, February, and March 2019, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the office of the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm.* Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: *https://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm.*

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JANUARY, FEBRUARY, AND MARCH 2019

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
January 27, 2019	009–476	Phibro Animal Health Corp., GlenPointe Centre East, 3d Floor, 300 Frank W. Burr Blvd., Suite 21, Teaneck, NJ 07666.	NICARB 25% (nicarbazin) Type A medicated article.	Chickens	Supplemental approval of revised assay limits for nicarbazin (powder) Type A medicated article.	N/A.
January 28, 2019	200–616	Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland.	CEFENIL RTU (ceftiofur hydrochloride sterile suspension).	Swine and cattle	Original approval as a generic copy of NADA 140–890.	FOI Summary.
January 31, 2019	200–450	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin, 18, Ireland.	BIMECTIN PLUS (ivermectin/clorsulon) Injection for Cattle.	Cattle	Original approval as a generic copy of NADA 140–833.	FOI Summary.
February 4, 2019	200–637	Provetica AH LLC, 455 Sovereign Ct., Baldwin, MO 63011.	DOXIDYL (deracoxib) Chewable Tablet.	Dogs	Original approval as a generic copy of NADA 141–203.	FOI Summary.
February 8, 2019	141–297	Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002.	PROZINC (protamine zinc recombinant human insulin) Injectable Suspension.	Dogs	Supplemental approval for the reduction of hyperglycemia and hyperglycemia-associated clinical signs in dogs with diabetes mellitus.	FOI Summary.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JANUARY, FEBRUARY, AND MARCH 2019—Continued

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
March 29, 2019	048–761	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	AUREOMYCIN (chlortetracycline) Type C medicated feeds.	Cattle	Supplemental approval adding replacement dairy heifers to the indications for use of chlortetracycline Type C medicated cattle feeds for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.	N/A.
March 29, 2019	141–517	Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514.	PROIN ER (phenylpropanolamine hydrochloride extended-release tablets) Tablets.	Dogs	Original approval for the control of urinary incontinence due to urethral sphincter hypotonus.	FOI Summary.

II. Changes of Sponsors' Names and Addresses

Aurora Pharmaceutical, LLC, 1196 Highway 3 South, Northfield, MN 55057–3009 has informed FDA that it has changed its name to Aurora Pharmaceutical, Inc.

Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002 has informed FDA that it has changed its name and address to Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096.

Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY 11967 has informed FDA that it has changed its name to American Regent, Inc.

Pharmgate LLC, 1800 Sir Tyler Dr., Wilmington, NC 28405 has informed FDA that it has changed its name to Pharmgate, Inc.

Accordingly, we are amending § 510.600(c) to reflect these changes.

III. Changes of Sponsorship

Provetica AH LLC, 455 Sovereign Ct., Baldwin, MO 63011 has informed FDA that it has transferred ownership of, and all rights and interest in, newly approved ANADA 200–637 for DOXIDYL (deracoxib) Chewable Tablets to Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France. Following this change of sponsorship, Provetica AH LLC is no longer the sponsor of an approved application. Accordingly, it will not be added to the list of sponsors of approved applications in § 510.600(c) (21 CFR 510.600(c)).

Merial, Inc., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640 has informed FDA that it has transferred ownership of, and all rights and interest in, the following applications to Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096:

File No.	Proprietary name
006–623	CAPARSOLATE (arsenamide sodium) Injection.
008–422	SELEEN (selenium disulfide) Suspension.
010–424	NALLINE (nalorphine hydrochloride) Injection.
011–080	HYDELTRONE-TBA (prednisolone and tertiary butylacetate) Suspension.
011–437	HYDELTRONE (prednisolone sodium phosphate and neomycin sulfate) Ointment.
011–532	SULFABROM (sulfabromomethazine sodium) Bolus.
011–678	DIURIL (chlorothiazide) Tablets.
012–734	DIURIL (chlorothiazide) Bolus.
013–022	THIBENZOLE (thiabendazole) Sheep & Goat Wormer.
013–407	EQUIZOLE (thiabendazole) Horse Wormer.
013–674	HYDROZIDE (hydrochlorothiazide) Injection.
013–954	THIBENZOLE (thiabendazole) 20% Swine Premix.
014–350	OMNIZOLE (thiabendazole).
015–123	TBZ® (thiabendazole) Cattle Wormer (Drench).
015–875	TBZ 200 (thiabendazole) Medicated Premix.
030–103	THIBENZOLE (thiabendazole) Suspension.
034–114	EQUIZOLE (thiabendazole).
035–631	THIBENZOLE (thiabendazole) Pig Wormer.
037–410	EQUIZOLE A (thiabendazole and piperazine phosphate).
042–633	TRESADERM (thiabendazole, dexamethasone, neomycin sulfate solution) Dermatologic Solution.
043–141	THIBENZOLE 300 (thiabendazole) Medicated.
044–654	EQUIZOLE (thiabendazole) Horse Wormer Pellets.
047–333	EQUIZOLE A (thiabendazole and piperazine citrate) Liquid.
048–487	TBZ (thiabendazole) Wormer Paste 50%.
042–633	TRESADERM (thiabendazole, dexamethasone, neomycin sulfate solution) Dermatologic Solution.
043–141	THIBENZOLE 300 (thiabendazole) Medicated.
044–654	EQUIZOLE (thiabendazole) Horse Wormer Pellets.
047–333	EQUIZOLE A (thiabendazole and piperazine citrate) Liquid.
048–487	TBZ (thiabendazole) Wormer Paste 50%.
049–461	TBZ (thiabendazole) Wormer Paste 43%.
065–275	Penicillin VK Filmtab (penicillin V potassium) 250 mg.
065–276	VEESYN (penicillin V potassium) Granules for Oral Solution.
094–642	CAMVET (cambendazole) Suspension Horse Wormer.

File No.	Proprietary name
096–506	CAMVET (cambendazole) Horse Wormer Pellets.
096–731	CAMVET (cambendazole) Horse Wormer Paste 45%.
098–379	CYSTORELIN.
098–689	EQUIZOLE (thiabendazole) 50% Wormer Paste; EQUIZOLE 50% Wormer Paste for Horses.
127–443	EQVALAN (ivermectin) Injection.
128–409	IVOMEC (ivermectin) .27% Injection Grower and Feeder Pigs; IVOMEC (ivermectin) 1% Injection; IVOMEC (ivermectin) 1% Injection for Cattle and Swine; IVOMEC (ivermectin) Injection for Cattle.
131–392	IVOMEC (ivermectin) Liquid for Sheep.
134–314	EQVALAN (ivermectin).
134–930	SYNCRO-MATE-B (norgestomet and estradiol valerate) Implant.
136–742	CURATREM (clorsulon) Drench for Cattle.
137–006	IVOMEC (ivermectin) Cattle Paste 0.153%.
138–412	HEARTGARD (ivermectin) Tablets.
140–439	EQVALAN (ivermectin) Oral Liquid for Horses.
140–818	PRODUCIL (efrotomycin) Type A Medicated Article for Swine.
140–833	IVOMEC Plus (ivermectin and clorsulon) Injection For Cattle.
140–841	IVOMEC (ivermectin) Pour-On.
140–883	LEGEND (hyaluronate sodium) Injectable Solution.
140–886	HEARTGARD (ivermectin) Chewables for Dogs.
140–971	HEARTGARD Plus (ivermectin and pyrantel pamoate).
140–974	IVOMEC (ivermectin) Premix for Swine.
140–988	IVOMEC (ivermectin) Sustained-Release Bolus for Cattle.
141–015	ENACARD (enalapril maleate) Tablets for Dogs.
141–042	IMMITICIDE (melarsomine dihydrochloride) Sterile Powder.
141–054	IVOMEC (ivermectin) plus LINCOMIX (lincomycin).
141–078	HEARTGARD (ivermectin) for Cats.
141–079	EPRINEX (eprinomectin) Pour-On for Beef and Dairy Cattle.
141–097	BMD (bacitracin methylendisalicylate)/IVOMEC (ivermectin) Premix for Swine.
141–123	GASTROGARD (omeprazole).
141–188	MARQUIS (ponazuril) Antiprotozoal Oral Paste.
141–214	ZIMECTERIN Gold (ivermectin and praziquantel) Paste.
141–227	ULCERGARD (omeprazole).
141–230	PREVICOX (firocoxib) Chewable Tablets.
141–253	EQUIOXX (firocoxib) Oral Paste.
141–313	EQUIOXX (firocoxib) Injection.
141–327	LONGRANGE (eprinomectin) Injection.
141–328	ZACTRAN (gamithromycin) Injectable Solution.
141–406	NEXGARD (afoxolaner) Chewable Tablet.
141–421	DUOCARE (ivermectin and praziquantel) Paste.
141–458	EQUIOXX (firocoxib) Tablets.
141–492	CENTRAGARD (eprinomectin and praziquantel) Solution.
200–564	Ivermectin Paste 1.87%.

Following this change of sponsorship, Merial, Inc., is no longer the sponsor of an approved application. Accordingly, it will be removed from the list of sponsors of approved applications in § 510.600(c). As provided in the regulatory text, the animal drug regulations are amended to reflect these changes of sponsorship.

IV. Withdrawals of Approval

Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096, has requested that FDA withdraw approval of newly transferred NADA 141–054 for use of LINCOMIX (lincomycin hydrochloride) plus IVOMEC (ivermectin) Type A medicated articles to manufacture 2-way, combination drug Type C medicated feed for swine because the product is no longer manufactured or marketed.

Also, Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140, has requested that FDA withdraw approval of NADA 141–337 for use of RECOVYRA (fentanyl) Transdermal Solution for Dogs because the product is no longer manufactured or marketed.

Elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADAs 141–054 and 141–337, and all supplements and amendments thereto, is withdrawn effective August 19, 2019. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these actions.

V. Technical Amendments

FDA is removing ''IDEXX Pharmaceuticals, Inc.'' from the list of sponsors of approved applications in § 510.600(c). This action is being taken to improve the accuracy of the regulations.

In addition, we are reformatting the regulations to present the approved conditions of use of famphur, morantel, and thiabendazole in tabular format in the respective named sections of subpart B of part 558. This action is being taken to improve the readability and consistency of the regulations.

VI. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C.360b(i)), which requires **Federal Register** publication of ''notice[s] . . . effective as a regulation,'' of the conditions of use of approved new animal drugs. This rule sets forth technical amendments to the regulations to codify recent actions on approved new animal drug applications and corrections to improve the accuracy of the regulations, and as such does not impose any burden on regulated entities.

Although denominated a rule pursuant to the FD&C Act, this document does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a ''rule of particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5

U.S.C. 801–808. Likewise, this is not a rule subject to Executive Order 12866, which defines a rule as ''an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency.''

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, and 524

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 510, 520, 522, 524, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600:
■ a. In the table in paragraph (c)(1):
■ i. Add an entry in alphabetical order for ''American Regent, Inc.'';
■ ii. Revise the entries for ''Aurora Pharmaceutical, LLC'', ''Boehringer Ingelheim Vetmedica, Inc.'';
■ iii. Remove the entries for ''IDEXX Pharmaceuticals, Inc.'', ''Luitpold Pharmaceuticals, Inc.'', and ''Merial, Inc.''; and
■ iv. Revise the entry for ''Pharmgate, LLC''; and
■ b. In the table in paragraph (c)(2):
■ i. Revise the entries for ''000010'' and ''010797'';
■ ii. Remove the entry for ''050604'';
■ iii. Revise the entry for ''051072'';
■ iv. Remove the entry for ''065274''; and
■ v. Revise the entry for ''069254''.

The additions and revisions read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
American Regent, Inc., Animal Health Division, Shirley, NY 11967	010797
* * * * * * *	
Aurora Pharmaceutical, Inc., 1196 Highway 3 South, Northfield, MN 55057–3009	051072
* * * * * * *	
Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096	000010
* * * * * * *	
Pharmgate, Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405	069254
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
000010	Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096.
* * * * * * *	
010797	American Regent, Inc., Animal Health Division, Shirley, NY 11967.
* * * * * * *	
051072	Aurora Pharmaceutical, Inc., 1196 Highway 3 South, Northfield, MN 55057–3009.
* * * * * * *	
069254	Pharmgate, Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405.
* * * * * * *	

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.43 [Amended]

■ 4. In § 520.43, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.284a [Amended]

■ 5. In § 520.284a, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.284b [Amended]

■ 6. In § 520.284b, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.284c [Amended]

■ 7. In § 520.284c, in paragraph (b), remove ''050604'' and in its place add ''000010''.

■ 8. Revise § 520.420 to read as follows:

§ 520.420 Chlorothiazide.

(a) *Specifications*—(1) Each tablet contains 0.25 grams chlorothiazide.

(2) Each bolus contains 2 grams chlorothiazide.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i)—*Amount.* Administer 5 to 10 milligrams per pound of body weight two or three times daily.

(ii) *Indications for use.* For treatment of congestive heart failure and renal edema.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cows*—(i)—*Amount.* Administer 2 grams once or twice daily for 3 or 4 days.

(ii) *Indications for use.* As an aid in reduction of postparturient udder edema.

(iii) *Limitations.* Milk taken from dairy animals during treatment and for 72 hours (six milkings) after latest treatment must not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.462 [Amended]

■ 9. In § 520.462, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.538 [Amended]

■ 10. In § 520.538, in paragraph (b), remove ''No. 058198'' and in its place add ''Nos. 013744 and 058198''.

§ 520.804 [Amended]

■ 11. In § 520.804, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.928 [Amended]

■ 12. In § 520.928, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.930 [Amended]

■ 13. In § 520.930, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.1192 [Amended]

■ 14. In § 520.1192, in paragraph (b)(1), remove ''050604'' and in its place add ''000010''.

§ 520.1193 [Amended]

■ 15. In § 520.1193, in paragraph (b)(1), remove ''050604'' and in its place add ''000010''.

§ 520.1195 [Amended]

■ 16. In § 520.1195, in paragraph (b)(1), remove ''000859, 050604,'' and in its place add ''000010, 000859,''; and in paragraph (b)(3), remove ''050604'' and in its place add ''000010''.

§ 520.1196 [Amended]

■ 17. In § 520.1196, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.1197 [Amended]

■ 18. In § 520.1197, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.1198 [Amended]

■ 19. In § 520.1198, in paragraphs (b)(1) and (3), remove ''050604'' and in its place add ''000010''.

§ 520.1615 [Amended]

■ 20. In § 520.1615, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.1696c [Amended]

■ 21. In § 520.1696c, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.1696d [Amended]

■ 22. In § 520.1696d, in paragraph (b), remove ''050604'' and in its place add ''000010''.

■ 23. In § 520.1760, revise paragraphs (a) and (c)(1) to read as follows:

§ 520.1760 Phenylpropanolamine.

(a) *Specifications*—(1) Each chewable tablet contains 25, 50, or 75 milligram (mg) phenylpropanolamine hydrochloride.

(2) Each extended-release tablet contains 18, 38, 74, or 145 mg phenylpropanolamine hydrochloride.

* * * * *

(c) * * *

(1) *Amount*—Administer orally as follows:

(i) Chewable tablet: 2 mg/kg of body weight twice daily.

(ii) Extended-release tablet: 2 to 4 mg/kg of body weight once daily with food.

* * * * *

§ 520.1855 [Amended]

■ 24. In § 520.1855, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.2170 [Amended]

■ 25. In § 520.2170, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.2380a [Amended]

■ 26. In § 520.2380a, in paragraph (b)(2), remove ''050604'' and in its place add ''000010''.

§ 520.2380b [Amended]

■ 27. In § 520.2380b, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.2380c [Amended]

■ 28. In § 520.2380c, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.2380d [Amended]

■ 29. In § 520.2380d, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§§ 520.2380e and 520.2380f [Redesignated as §§ 520.2380f and 520.2380e]

■ 30. Redesignate §§ 520.2380e and 520.2380f as §§ 520.2380f and 520.2380e, respectively.

§ 520.2380e [Amended]

■ 31. In newly redesignated § 520.2380e, in paragraph (b), remove ''050604'' and in its place add ''000010''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 32. The authority citation for part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.144 [Amended]

■ 33. In § 522.144, in paragraph (b), remove ''050604'' and in its place add ''000010''.

■ 34. In § 522.313b, revise paragraphs (a), (b), and (e)(2)(iii) to read as follows:

§ 522.313b Ceftiofur hydrochloride.

(a) *Specifications.* Each milliliter of suspension contains:

(1) Ceftiofur hydrochloride equivalent to 50 milligrams (mg) of ceftiofur equivalents in the inactive vehicles phospholipan 90H, sorbitan monooleate, and cottonseed oil;

(2) Ceftiofur hydrochloride equivalent to 50 mg ceftiofur equivalents in the inactive vehicle miglyol oil 812; or

(3) Ceftiofur hydrochloride equivalent to 50 mg ceftiofur equivalents in the inactive vehicles aluminum monostearate, sorbitan monooleate, and medium chain triglycerides.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter as follows:

(1) No. 054771 for products described in paragraphs (a)(1) and (2) of this section; and

(2) No. 055529 for the product described in paragraph (a)(3) of this section.

* * * * *

(e) * * *

(2) * * *

(iii) *Limitations*—(A) For products described in paragraphs (a)(2) and (3) of this section: Treated cattle must not be slaughtered for 3 days following the last treatment. For products described in paragraph (a)(2) of this section: Treated cattle must not be slaughtered for 4 days following the last treatment.

(B) A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

§ 522.814 [Amended]

■ 35. In § 522.814, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 522.850 [Amended]

■ 36. In § 522.850, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 522.930 [Amended]

■ 37. In § 522.930, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 522.1014 [Amended]

■ 38. In § 522.1014, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 522.1077 [Amended]

■ 39. In § 522.1077, in paragraph (b)(4), remove ''050604'' and in its place add ''000010''.

§ 522.1145 [Amended]

■ 40. In § 522.1145, in paragraph (e)(2)(i), remove ''050604'' and in its place add ''000010''.

§ 522.1150 [Amended]

■ 41. In § 522.1150, in paragraph (b), remove ''050604'' and in its place add ''000010''.

■ 42. In § 522.1160, revise paragraphs (b)(1) and (2); redesignate the text of paragraph (c)(1)(i) as paragraph (c)(1)(i)(A); add a paragraph heading to newly redesignated paragraph (c)(1)(i)(A); and add paragraph (c)(1)(i)(B).

The revision and addition read as follows:

§ 522.1160 Insulin.

* * * * *

(b) * * *

(1) No. 000061 for use of product described in paragraph (a)(1) as in paragraphs (c)(1)(i)(A), (c)(1)(ii), (c)(1)(iii), (c)(2)(i)(A), (c)(2)(ii), and (c)(2)(iii) of this section.

(2) No. 000010 for use of product described in paragraph (a)(2) as in paragraphs (c)(1)(i)(B), (c)(1)(ii), (c)(1)(iii), (c)(2)(i)(B), (c)(2)(ii), and (c)(2)(iii) of this section.

(c) * * *

(1) * * *

(i) * * *

(A) *Porcine zinc insulin zinc.* * * *

(B) *Protamine zinc recombinant human insulin.* Administer a starting dose of 0.2 to 0.5 IU/pound of body weight (0.5 to 1.0 IU/kg) once daily. When transitioning from another insulin product, this form of insulin should be started once daily, regardless of the frequency of prior insulin use. The dose should be given concurrently with or right after a meal. Reevaluate the dog at appropriate intervals and adjust the dose based on both clinical signs and laboratory test results until adequate glycemic control has been attained. Twice-daily therapy should be initiated if the duration of insulin action is determined to be inadequate. If twice-daily treatment is initiated, the two doses should be 25 percent less than the once daily dose required to attain an acceptable nadir.

* * * * *

§ 522.1192 [Amended]

■ 43. In § 522.1192, in paragraph (b)(1), remove ''050604'' and in its place add ''000010''.

■ 44. In § 522.1193, revise paragraphs (b) and (e)(3) to read as follows:

§ 522.1193 Ivermectin and clorsulon.

* * * * *

(b) *Sponsors.* See Nos. 000010, 055529, 058005, and 061133 in § 510.600(c) of this chapter.

* * * * *

(e) * * *

(3) *Limitations*—(i) Nos. 000010 and 061133: Do not treat cattle within 21 days of slaughter. Nos. 055529 and 058005: Do not treat cattle within 49 days of slaughter.

(ii) Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

§ 522.1362 [Amended]

■ 45. In § 522.1362, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 522.1452 [Amended]

■ 46. In § 522.1452, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 522.1885 [Amended]

■ 47. In § 522.1885, in paragraph (b), remove ''050604'' and in its place add ''000010''.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 48. The authority citation for part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.814 [Amended]

■ 49. In § 524.814, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 524.815 [Amended]

■ 50. In § 524.815, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 524.916 [Removed]

■ 51. Effective August 19, 2019, remove § 524.916.

§ 524.1193 [Amended]

■ 52. In § 524.1193, in paragraph (b)(1), remove ''050604'' and in its place add ''000010''.

§ 524.1484g [Amended]

■ 53. In § 524.1484g, in paragraph (b), remove ''026637 and 050604'' and in its place add ''000010 and 026637''.

§ 524.1484j [Amended]

■ 54. In § 524.1484j, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 524.2101 [Amended]

■ 55. In § 524.2101, in paragraph (b), remove ''000061, 017135, and 050604'' and in its place add ''000010, 000061, and 017135''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc–1, 371.

§ 558.58 [Amended]

■ 57. In § 558.58, redesignate paragraphs (e)(3) through (6) as paragraphs (e)(2) through (5), and redesignate paragraph (e)(9) as new paragraph (e)(6).

§ 558.76 [Amended]

■ 58. In § 558.76, redesignate paragraphs (e)(1)(ix) through (xvi) as paragraphs (e)(1)(vii) through (xiv).

■ 59. In § 558.128, revise paragraphs (b)(1) and (e)(4)(xv), redesignate paragraphs (e)(4)(xvi) through (xxvi) as paragraphs (e)(4)(xvii) through (xxvii), and add new paragraph (e)(4)(xvi).

The revisions and addition read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(b) * * *

(1) *No. 054771:* 50, 70, 80, 90, or 100 grams per pound (g/lb) Type A medicated article.

* * * * *

(e) * * *

(4) * * *

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(xv) 350 mg/head/day.	.....	1. Beef cattle: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.	To sponsor No. 054771 under NADAs 046–699 and 049–287, No. 066104 under NADA 092–286, and No. 069254 under NADA 048–480: Withdraw 48 hours prior to slaughter. To sponsor No. 069254 under NADA 138–935 and ANADA 200–510: Zero withdrawal period.	*
		2. Beef cattle (under 700 lb): For control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline.	To sponsor No. 054771 under NADAs 046–699 and 049–287, No. 066104 under NADA 092–286, and No. 069254 under NADA 048–480: Withdraw 48 h prior to slaughter. To sponsor No. 054771 under NADA 048–761 and No. 069254 under NADA 138–935 and ANADA 200–510: Zero withdrawal time.	*
(xvi) 20 to 350 g/ton.	.....	Beef cattle and replacement dairy heifers: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.	Feed to provide chlortetracycline at the rate of 350 mg per head per day. This drug is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. To sponsor No. 054771 under NADA 048–761: Zero withdrawal period.	054771
*	*	*	*	*

* * * * *

§ 558.235 [Amended]

■ 60. Effective September 9, 2019, in § 558.235, in paragraph (b), remove ''050604'' and in its place add ''000010''.

■ 61. Revise § 558.254 to read as follows:

§ 558.254 Famphur.

(a) *Specifications.* Type A medicated articles containing 13.2 or 33.3 percent famphur.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.273 of this chapter.

(d) *Special considerations.* Famphur is a cholinesterase inhibitor. Do not use this product in animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(e) *Conditions of use.* It is used in cattle feed as follows:

Famphur in grams/ton	Indications for use	Limitations	Sponsor
(i) 1.1 milligrams per pound (mg/lb) body weight per day.	Beef cattle and nonlactating dairy cows: For control of grubs and as an aid in control of sucking lice.	Feed for 30 days. Withdraw from dry dairy cows and heifers 21 days prior to freshening. Withdraw 4 days prior to slaughter.	000061
(ii) 2.3 mg/lb body weight per day.	Beef cattle and nonlactating dairy cows: For control of grubs.	Feed for 10 days. Withdraw from dry dairy cows and heifers 21 days prior to freshening. Withdraw 4 days prior to slaughter.	000061

§ 558.300 [Amended]

■ 62. In § 558.300, in paragraph (b), remove ''050604'' and in its place add ''No. 000010''; in paragraphs (e)(1) through (6), in the ''Sponsor'' column, remove ''050604'' and in its place add ''000010''; and remove paragraph (f).

§ 558.325 [Amended]

■ 63. Effective August 19, 2019, in § 558.325, remove paragraphs (e)(2)(iii), (x), and (xvi); and redesignate paragraphs (e)(2)(iv) through (ix) as paragraphs (e)(2)(iii) through (viii), paragraphs (e)(2)(xi) through (xv) as paragraphs (e)(2)(ix) through (xiii), and paragraph (e)(2)(xvii) as paragraph (e)(2)(xiv).

■ 64. Revise § 558.360 to read as follows:

§ 558.360 Morantel.

(a) *Specifications.* Each pound of Type A medicated article contains 88 grams morantel tartrate.

(b) *Sponsor.* See No. 066104 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.425 of this chapter.

(d) *Special considerations*—(1) Do not use in Type B or Type C medicated feeds containing bentonite.

(2) Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(e) *Conditions of use.* It is used in feed as follows:

Morantel tartrate in grams/ton	Indications for use	Limitations	Sponsor
(1) 0.44 to 4.4 grams of morantel tartrate per pound of feed.	Cattle: For removal and control of mature gastrointestinal nematode infections of cattle including stomach worms (*Haemonchus* spp., *Ostertagia* spp., *Trichostrongylus* spp.), worms of the small intestine (*Cooperia* spp., *Trichostrongylus* spp., *Nematodirus* spp.), and worms of the large intestine (*Oesophagostomum radiatum*).	Feed as a single therapeutic treatment at 0.44 gram of morantel tartrate per 100 pounds of body weight. Fresh water should be available at all times. When medicated feed is consumed, resume normal feeding. Conditions of constant worm exposure may require retreatment in 2 to 4 weeks. Do not treat cattle within 14 days of slaughter.	066104
(2) 0.44 to 4.4 grams of morantel tartrate per pound of feed.	Goats: For removal and control of mature gastrointestinal nematode infections of goats including *Haemonchus contortus, Ostertagia (Teladorsagia) circumcincta,* and *Trichostrongylus axei.*	Feed as a single therapeutic treatment at 0.44 gram of morantel tartrate per 100 pounds of body weight. Fresh water should be available at all times. When medicated feed is consumed, resume normal feeding. Conditions of constant worm exposure may require retreatment in 2 to 4 weeks. Do not treat goats within 30 days of slaughter.	066104

■ 65. Revise § 558.600 to read as follows:

§ 558.600 Thiabendazole.

(a) *Specifications.* Dry Type A medicated articles containing 22, 44.1, 66.1, or 88.2 percent thiabendazole. The 66.1 percent Type A medicated article is solely for the manufacture of cane molasses liquid Type B feed, which is mixed in dry feeds. The 88.2 percent Type A medicated article is used solely for the manufacture of an aqueous slurry for adding to a Type C dry cattle feed.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.730 of this chapter.

(d) Special considerations. Do not use in Type B or Type C medicated feed containing bentonite.

(e) *Conditions of use.* It is used in feed for animals as follows:

(1) *Swine*—

Thiabendazole in grams/ton	Indications for use	Limitations	Sponsor
(i) 45.4 to 908 (0.005 to 0.1 percent).	Swine: As an aid in the prevention of infections of large roundworms (genus *Ascaris*).	Administer continuously in feed containing 0.05 to 0.1 percent thiabendazole per ton for 2 weeks followed by feed containing 0.005 to 0.02 percent thiabendazole per ton for 8 to 14 weeks. Do not treat animals within 30 days of slaughter.	000010
(ii) [Reserved]			

(2) *Cattle*—

Thiabendazole amount	Indications for use	Limitations	Sponsor
(i) 3 grams per 100 lb. body weight.	For control of infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Nematodirus spp., Oesophagostomum radiatum*).	Use 3 grams per 100 lb. body weight at a single dose; may repeat once in 2 to 3 weeks. Do not treat animals within 3 days of slaughter. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.	000010
(ii) 5 grams per 100 lb. body weight.	For control of severe infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Nematodirus spp., Oesophagostomum radiatum*); control of infections of *Cooperia spp.*	Use 5 grams per 100 lb. body weight at a single dose or divided into 3 equal doses, administered 1 dose each day, on succeeding days. May repeat once in 2 to 3 weeks. Do not treat animals within 3 days of slaughter. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.	000010

(3) *Minor species*—

Thiabendazole amount	Indications for use	Limitations	Sponsor
(i) 2 grams per 100 lb. body weight.	Sheep and goats: For control of infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp.; Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.,* and *Oesophagostomum spp.*); also active against ova and larvae passed by sheep from 3 hours to 3 days after the feed is consumed (good activity against ova and larvae of *T. colubriformis* and *axei, Ostertagia spp., Nematodirus spp., Strongyloides spp.;* less effective against those of *Haemonchus contortus* and *Oesophagostomum spp.*).	Use 2 grams per 100 lb. body weight at a single dose. Do not treat animals within 30 days of slaughter. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.	050604
(ii) 3 grams per 100 lb. body weight.	Goats: For control of severe infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.,* and *Oesophagostomum spp.*).	Use 3 grams per 100 lb. body weight at a single dose. Do not treat animals within 30 days of slaughter. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.	050604
(iii) 454 grams per ton of feed.	Pheasants: For the treatment of gapeworms (*Syngamus trachea*).	Feed continuously for 2 weeks (14 days). Do not use treated pheasants for food for 21 days after last day of treatment. Fertility, hatchability, and other reproductive data are not available on use in breeding animals.	050604

Dated: August 1, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16884 Filed 8–8–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 524 and 558

[Docket No. FDA–2019–N–0002]

New Animal Drugs; Withdrawal of Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of two new animal drug applications (NADAs) at the sponsors' request because these products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective August 19, 2019.

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5761, *sujaya.dessai@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Animal Health USA Inc., 3239 Satellite Blvd., Duluth, GA 30096, has requested that FDA withdraw approval of NADA 141–054 for use of LINCOMIX (lincomycin hydrochloride) and IVOMEC (ivermectin) Type A medicated articles in the manufacture of 2-way, combination drug Type C medicated swine feeds because the product is no longer manufactured or marketed.

Also, Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140, has requested that FDA withdraw approval of NADA 141–337 for use of RECOVYRA (fentanyl) Transdermal Solution for Dogs because the product is no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADAs 141–054 and NADA 141–337, and all supplements and amendments thereto, is hereby withdrawn, effective August 19, 2019.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: August 1, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16885 Filed 8–8–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2019–0673]

Special Local Regulations; Annual Les Cheneaux Islands Antique Wooden Boat Show; Hessel, MI.

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a special local regulation for the Annual Les Cheneaux Islands Antique Wooden Boat Show on August 10, 2019, from 7 a.m. to 6:30 p.m. to provide for the safety of life on navigable waterways during this event. During the enforcement period, all vessels will operate at a no wake speed and follow the directions of the on-scene Patrol Commander.

DATES: The regulations in 33 CFR 100.922 will be enforced on August 10, 2019, from 7 a.m. to 6:30 p.m.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email LT Sean Murphy, Coast Guard Sector Sault Sainte Marie Waterways Management, U.S. Coast Guard; telephone 906–635–3223, email *Sean.V.Murphy@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulation in 33 CFR 100.922 for the Annual Les Cheneaux Islands Antique Wooden Boat Show on August 10, 2019

from 7 a.m. to 6:30 p.m. This action is being taken to provide for the safety of life on navigable waterways during this event. The special local regulation, 33 CFR 100.922, specifies the location of the regulated area for the Annual Les Cheneaux Islands Antique Wooden Boat Show which encompasses a portion of the waterway near Hessel, MI. During the enforcement period, as reflected in § 100.922(c), all vessels within the regulated area will operate at a no wake speed and follow the directions of the on-scene Patrol Commander.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners, and marine information broadcasts.

Dated: August 5, 2019.

P.S. Nelson,

Captain, U.S. Coast Guard, Captain of the Port Sault Sainte Marie.

[FR Doc. 2019–17055 Filed 8–8–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 242

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 100

[Docket No. FWS–R7–SM–2018–0003; FXFR13350700640–190–FF07J00000; FBMS# 4500133005]

RIN 1018–BB99

Subsistence Management Regulations for Public Lands in Alaska—Cook Inlet Area Regulations

AGENCY: Forest Service, Agriculture; Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: This final rule revises the regulations for seasons, harvest limits, and methods and means for the subsistence taking of fish in the Cook Inlet Area of Alaska. This action also reorganizes specific regulations addressing the Kenai River, which will provide clarity for the public, and allow the Federal Subsistence Board to correct regulatory conflicts that have arisen based on recent rulemaking.

DATES: This rule is effective August 9, 2019.

ADDRESSES: The Board meeting transcripts are available for review at the Office of Subsistence Management, 1011 East Tudor Road, Mail Stop 121, Anchorage, AK 99503, or on the Office of Subsistence Management website (*https://www.doi.gov/subsistence*). The comments received in response to the proposed rule are available on *www.regulations.gov* in Docket No. FWS–R7–SM–2018–0003.

FOR FURTHER INFORMATION CONTACT: Chair, Federal Subsistence Board, c/o U.S. Fish and Wildlife Service, Attention: Thomas C. J. Doolittle, Office of Subsistence Management; (907) 786–3888 or *subsistence@fws.gov.* For questions specific to National Forest System lands, contact Thomas Whitford, Regional Subsistence Program Leader, USDA, Forest Service, Alaska Region; (907) 743–9461 or *thomas.whitford@usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

Under Title VIII of the Alaska National Interest Lands Conservation Act (ANILCA) (16 U.S.C. 3111–3126), the Secretary of the Interior and the Secretary of Agriculture (Secretaries) jointly implement the Federal Subsistence Management Program. This program provides a preference for take of fish and wildlife resources for subsistence uses on Federal public lands and waters in Alaska. The Secretaries published temporary regulations to carry out this program in the **Federal Register** on June 29, 1990 (55 FR 27114), and published final regulations in the **Federal Register** on May 29, 1992 (57 FR 22940). The Program managers have subsequently amended these regulations a number of times. Because this program is a joint effort between Interior and Agriculture, these regulations are located in two titles of the Code of Federal Regulations (CFR): Title 36, ''Parks, Forests, and Public Property,'' and Title 50, ''Wildlife and Fisheries,'' at 36 CFR 242.1–242.28 and 50 CFR 100.1–100.28, respectively. The regulations contain subparts as follows: Subpart A, General Provisions; Subpart B, Program Structure; Subpart C, Board Determinations; and Subpart D, Subsistence Taking of Fish and Wildlife.

Consistent with subpart B of these regulations, the Secretaries established a Federal Subsistence Board to administer the Federal Subsistence Management Program. The Board comprises:

- A Chair appointed by the Secretary of the Interior with concurrence of the Secretary of Agriculture;
- The Alaska Regional Director, U.S. Fish and Wildlife Service;
- The Alaska Regional Director, National Park Service;
- The Alaska State Director, Bureau of Land Management;
- The Alaska Regional Director, Bureau of Indian Affairs;
- The Alaska Regional Forester, USDA Forest Service; and
- Two public members appointed by the Secretary of the Interior with concurrence of the Secretary of Agriculture.

Through the Board, these agencies participate in the development of regulations for subparts C and D, which, among other things, set forth program eligibility and specific harvest seasons and limits.

In administering the program, the Secretaries divided Alaska into 10 subsistence resource regions, each of which is represented by a Federal Subsistence Regional Advisory Council (Council). The Councils provide a forum for rural residents with personal knowledge of local conditions and resource requirements to have a meaningful role in the subsistence management of fish and wildlife on Federal public lands in Alaska. The Council members represent varied geographical, cultural, and user interests within each region.

Current Rule

The Departments published a proposed rule, ''Subsistence Taking of Fish; Cook Inlet Area,'' on October 1, 2018 (83 FR 49322), to amend 36 CFR 242.27 and 50 CFR 100.27.

The current Cook Inlet area subsistence regulations were revised on May 18, 2015 (80 FR 28187). Two of the revisions addressed community gillnets on the Kasilof and Kenai rivers. While the intent of providing additional opportunities for subsistence users was met, details concerning the harvest limits were difficult and confusing to the public since they overlapped with other active subsistence fisheries on these rivers. In addition, the new regulations were in conflict with existing regulations dealing with early- and late-run Chinook salmon, and various size limits for rainbow trout and Dolly Varden. The Board directed program and field staff to develop recommendations to alleviate these concerns from the Council and members of the public. While some of the size limits are needed as management tools in certain fisheries, the limits are not required in other fisheries. The lack of clarity of season dates with early and late runs of Chinook salmon called for new regulations addressing early-run fish.

The proposed rule opened a comment period, which closed on October 31. 2018. The Departments advertised the proposed rule by mail, email, web page, social media, radio, and newspaper, and comments were submitted via *www.regulations.gov* to Docket No. FWS–R7–SM–2018–0003. During that period, the Southcentral Federal Subsistence Regional Advisory Council met and, in addition to other Council business, received comments from the public and formulated their recommendations to the Board on the proposed rulemaking. The Council had a substantial role in reviewing the proposed rule and making recommendations for the final rule. Moreover, the Council Chair presented the Council's recommendations at the Board's public meeting of April 15–17, 2019. The public received extensive opportunity to review and comment on all changes.

Public Review and Comment

The Southcentral Federal Regional Advisory Council supported the proposed revisions to the Cook Inlet regulations, and they received no negative comments during their meeting on this rulemaking.

The Board received a total of six comments on the proposed rule; this included three comments that were outside the scope of the proposed rulemaking.

The Ninilchik Traditional Council supported the proposed revisions.

The Alaska Department of Fish and Game (ADF&G) had three recommendations. Two were to change the size limits for Chinook salmon (in the Kenai River community gillnet fishery and the Kenai River rod and reel fishery) based on recent Alaska Board of Fish actions.

Response: These recommended actions are outside of the scope of this rulemaking action, and the public did not have an opportunity to comment on a change in size limits. This action would be more appropriate to be submitted as a proposal during the normal cycle for fish regulations.

The ADF&G also recommended that specific language be added to the Kenai River community gillnet regulations that the gillnet must be closely attended while fishing.

Response: This text will be added as part of the permit conditions for this fishery, and there is no need to include this provision in the regulatory language.

A member of the public commented that he was against establishing a subsistence fishery on mile 48 of the Kenai River because this area is considered a trophy rainbow trout fish area and that Chinook salmon populations are threatened and cannot afford additional harvest.

Response: No new fishery is being established on or near mile 48 of the Kenai River. The location of the Kenai River community gillnet fishery has been clarified, however, that fishery occurs in the Moose Range Meadows area of the river and is between river miles 26.5 and 29 (this fishery has been in place since 2015).

These final regulations reflect Board review and consideration of the Council recommendations, Tribal and Alaska Native corporation consultations, and public comments. The only substantive changes in this final rule to the provisions in the proposed rule reflect action by the Board to establish the Ninikchik Traditional Council as the operators of the Kasilof gillnet.

Because this rule concerns public lands managed by an agency or agencies in both the Departments of Agriculture and the Interior, identical text will be incorporated into 36 CFR part 242 and 50 CFR part 100.

Conformance With Statutory and Regulatory Authorities

Administrative Procedure Act Compliance

The Board has provided extensive opportunity for public input and involvement in compliance with Administrative Procedure Act requirements, including publishing a proposed rule in the **Federal Register**, participation in multiple Council meetings, additional public review and comment on all proposed regulatory changes, and opportunity for additional public comment during the Board meeting prior to deliberation. Additionally, an administrative mechanism exists (and has been used by the public) to request reconsideration of the Board's decision on any particular proposal for regulatory change (36 CFR 242.20 and 50 CFR 100.20). Therefore, the Board believes that sufficient public notice and opportunity for involvement have been given to affected persons regarding Board decisions.

In the more than 25 years that the Program has been operating, no benefit to the public has been demonstrated by delaying the effective date of the subsistence regulations. A lapse in regulatory control could affect the continued viability of fish or wildlife populations and future subsistence opportunities for rural Alaskans, and would generally fail to serve the overall public interest. Therefore, the Board finds good cause pursuant to 5 U.S.C. 553(d)(3) to make this rule effective upon the date set forth in **DATES** to ensure continued operation of the subsistence program.

National Environmental Policy Act Compliance

A Draft Environmental Impact Statement that described four alternatives for developing a Federal Subsistence Management Program was distributed for public comment on October 7, 1991. The Final Environmental Impact Statement (FEIS) was published on February 28, 1992. The Record of Decision (ROD) on Subsistence Management for Federal Public Lands in Alaska was signed April 6, 1992. The selected alternative in the FEIS (Alternative IV) defined the administrative framework of an annual regulatory cycle for subsistence regulations.

A 1997 environmental assessment dealt with the expansion of Federal jurisdiction over fisheries and is available at the office listed under **FOR FURTHER INFORMATION CONTACT**. The Secretary of the Interior, with concurrence of the Secretary of Agriculture, determined that expansion of Federal jurisdiction does not constitute a major Federal action significantly affecting the human environment and, therefore, signed a Finding of No Significant Impact.

Section 810 of ANILCA

An ANILCA section 810 analysis was completed as part of the FEIS process on the Federal Subsistence Management Program. The intent of all Federal subsistence regulations is to accord subsistence uses of fish and wildlife on public lands a priority over the taking of fish and wildlife on such lands for other purposes, unless restriction is necessary to conserve healthy fish and wildlife populations. The final section 810 analysis determination appeared in the April 6, 1992, ROD and concluded that the Program, under Alternative IV with an annual process for setting subsistence regulations, may have some local impacts on subsistence uses, but will not likely restrict subsistence uses significantly.

During the subsequent environmental assessment process for extending fisheries jurisdiction, an evaluation of the effects of this rule was conducted in accordance with section 810. That evaluation also supported the Secretaries' determination that the rule will not reach the ''may significantly restrict'' threshold that would require notice and hearings under ANILCA section 810(a).

Paperwork Reduction Act of 1995 (PRA)

An agency may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. This rule does not contain any new collections of information that require OMB approval. OMB has reviewed and approved the collections of information associated with the subsistence regulations at 36 CFR part 242 and 50 CFR part 100, and assigned OMB Control Number 1018–0075 (expires July 31, 2019; in accordance with 5 CFR 1320.10, an agency may continue to conduct or sponsor this collection of information while the renewal submission is pending at OMB).

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires preparation of flexibility analyses for rules that will have a significant effect on a substantial number of small entities, which include small businesses, organizations, or governmental jurisdictions. In general, the resources to be harvested under this rule are already being harvested and consumed by the local harvester and do not result in an additional dollar benefit to the economy. However, we estimate that two million pounds of meat are harvested by subsistence users annually and, if given an estimated dollar value of $3.00 per pound, this amount would equate to about $6 million in food value Statewide. Based upon the amounts and values cited above, the Departments certify that this rulemaking will not have a significant economic effect on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

Small Business Regulatory Enforcement Fairness Act

Under the Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801 *et seq.*), this rule is not a major rule. It does not have an effect on the economy of $100 million or more, will not cause a major increase in costs or prices for consumers, and does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Executive Order 12630

Title VIII of ANILCA requires the Secretaries to administer a subsistence priority on public lands. The scope of this Program is limited by definition to certain public lands. Likewise, these regulations have no potential takings of private property implications as defined by Executive Order 12630.

Unfunded Mandates Reform Act

The Secretaries have determined and certify pursuant to the Unfunded Mandates Reform Act, 2 U.S.C. 1502 *et seq.,* that this rulemaking will not impose a cost of $100 million or more in any given year on local or State governments or private entities. The implementation of this rule is by Federal agencies, and there is no cost imposed on any State or local entities or tribal governments.

Executive Order 12988

The Secretaries have determined that these regulations meet the applicable standards provided in sections 3(a) and 3(b)(2) of Executive Order 12988, regarding civil justice reform.

Executive Order 13132

In accordance with Executive Order 13132, the rule does not have sufficient Federalism implications to warrant the preparation of a Federalism summary impact statement. Title VIII of ANILCA precludes the State from exercising subsistence management authority over fish and wildlife resources on Federal lands unless it meets certain requirements.

Executive Order 13175

The Alaska National Interest Lands Conservation Act, Title VIII, does not provide specific rights to tribes for the subsistence taking of wildlife, fish, and shellfish. However, the Board provided Federally recognized Tribes and Alaska Native corporations opportunities to consult on this rule. Consultation with Alaska Native corporations are based on Public Law 108–199, div. H, Sec. 161, Jan. 23, 2004, 118 Stat. 452, as amended by Public Law 108–447, div. H, title V, Sec. 518, Dec. 8, 2004, 118 Stat. 3267, which provides that: ''The Director of the Office of Management and Budget and all Federal agencies shall hereafter consult with Alaska Native corporations on the same basis as Indian tribes under Executive Order No. 13175.''

The Secretaries, through the Board, provided a variety of opportunities for consultation: Commenting on proposed changes to the existing rule; engaging in dialogue at the Council meetings; engaging in dialogue at the Board's meetings; and providing input in person, by mail, email, or phone at any time during the rulemaking process.

On April 15, 2019, the Board provided Federally recognized Tribes and Alaska Native Corporations a specific opportunity to consult on this rule prior to the start of its public regulatory meeting. Federally recognized Tribes and Alaska Native Corporations were notified by mail and telephone and were given the opportunity to attend in person or via teleconference.

Executive Order 13211

This Executive Order requires agencies to prepare Statements of Energy Effects when undertaking certain actions. However, this rule is not a significant regulatory action under E.O. 13211, affecting energy supply, distribution, or use, and no Statement of Energy Effects is required.

Drafting Information

Theo Matuskowitz drafted these regulations under the guidance of Thomas C.J. Doolittle of the Office of Subsistence Management, Alaska Regional Office, U.S. Fish and Wildlife Service, Anchorage, Alaska. Additional assistance was provided by

- Daniel Sharp, Alaska State Office, Bureau of Land Management;
- Clarence Summers, Alaska Regional Office, National Park Service;
- Dr. Glenn Chen, Alaska Regional Office, Bureau of Indian Affairs;
- Carol Damberg, Alaska Regional Office, U.S. Fish and Wildlife Service; and

• Thomas Whitford, Alaska Regional Office, USDA Forest Service.

List of Subjects

36 CFR Part 242

Administrative practice and procedure, Alaska, Fish, National forests, Public lands, Reporting and recordkeeping requirements, Wildlife.

50 CFR Part 100

Administrative practice and procedure, Alaska, Fish, National forests, Public lands, Reporting and recordkeeping requirements, Wildlife.

Regulation Promulgation

For the reasons set out in the preamble, the Federal Subsistence Board amends title 36, part 242, and title 50, part 100, of the Code of Federal Regulations, as set forth below.

PART___SUBSISTENCE MANAGEMENT REGULATIONS FOR PUBLIC LANDS IN ALASKA

■ 1. The authority citation for both 36 CFR part 242 and 50 CFR part 100 continues to read as follows:

Authority: 16 U.S.C. 3, 472, 551, 668dd, 3101–3126; 18 U.S.C. 3551–3586; 43 U.S.C. 1733.

Subpart D—Subsistence Taking of Fish and Wildlife

■ 2. Amend 36 CFR part 242 and 50 CFR part 100 by revising § __.27(e)(10) to read as follows:

§ __.27 Subsistence taking of fish.

* * * * *

(e) * * *

(10) *Cook Inlet Area.* The Cook Inlet Area includes all waters of Alaska enclosed by a line extending east from Cape Douglas (58°51.10′ N Lat.) and a line extending south from Cape Fairfield (148°50.25′ W Long.).

(i) *General area regulations.* (A) Unless restricted by regulations in this section, or unless restricted under the terms of a subsistence fishing permit, you may take fish at any time in the Cook Inlet Area.

(B) If you take rainbow or steelhead trout incidentally in subsistence net fisheries, you may retain them for subsistence purposes, unless otherwise prohibited or provided for in this section. With jigging gear through the ice or rod-and-reel gear in open waters, there is an annual limit of two rainbow or steelhead trout 20 inches or longer, taken from Kenai Peninsula fresh waters.

(C) Under the authority of a Federal subsistence fishing permit, you may take only salmon, trout, Dolly Varden, and other char. Permits will be issued by the in-season manager or designated representative and will be valid for that regulatory year, except as otherwise provided for in this section, or as stated under the permit conditions, unless the season is closed or restricted by a special action.

(D) All fish taken under the authority of a Federal subsistence fishing permit must be marked and recorded prior to leaving the fishing site.

(*1*) The fishing site includes the particular Federal public waters and/or adjacent shoreline from which the fish were harvested.

(*2*) Marking means removing the dorsal fin.

(E) You may not take grayling or burbot for subsistence purposes.

(F) You may take smelt with dip nets in fresh water only from April 1 through June 15. There are no harvest or possession limits for smelt.

(G) You may take whitefish in the Tyone River drainage using gillnets.

(H) You may take fish by gear listed in this section unless restricted by other regulations in this section or under the terms of a Federal subsistence fishing permit (as may be modified by regulations in this section).

(I) Seasons, harvest and possession limits, and methods and means for take are the same as for the taking of those species under Alaska sport fishing regulations (5 AAC 56 and 5 AAC 57) unless modified herein or by issuance of a Federal special action.

(J) Applicable harvest provisions are as follows:

Location	Methods and means	Permit type
Kasilof River Drainage	Kasilof River dip net or rod and reel for salmon; Kasilof River fish wheel for salmon; Kasilof River gillnet for salmon.	Household Annual Permit.
Kenai River Drainage	Kenai River dip net or rod and reel for salmon; Kenai River gillnet for salmon.	Household Annual Permit.
Kasilof River Drainage	Tustumena Lake rod and reel for salmon; Kasilof River drainage rod and reel for resident species.	General Subsistence Fishing Permit (Daily/Possession Limits).
Kenai River Drainage	Kenai River rod and reel only for salmon; Kenai River and tributaries under ice jigging and rod and reel for resident species.	General Subsistence Fishing Permit (Daily/Possession Limits).
Tustumena Lake	Tustumena Lake under ice fishery	Tustumena Lake Winter Permit.

(*1*) Harvest limits may not be accumulated.

(*2*) Each household may harvest its annual salmon limits in one or more days.

(*3*) All salmon harvested as part of a household annual limit must be reported to the Federal in-season manager within 72 hours of leaving the fishing site.

(*4*) For Ninilchik residents, the household annual limits for Chinook salmon in the Kasilof River and for late-run Chinook salmon in the Kenai River are combined.

(ii) *Seasons, harvest limits, and methods and means for Kasilof River fisheries.* Household annual limits for salmon in Kasilof River fisheries are as follows:

Species	Number of fish allowed for each permit holder	Additional fish allowed for each household member
Sockeye	25	5
Chinook	10	2
Coho	10	2
Pink	10	2

(A) *Kasilof River dip net or rod and reel; salmon.* (*1*) Residents of Ninilchik may take sockeye, Chinook, coho, and pink salmon through a dip net or rod and reel fishery on the upper mainstem of the Kasilof River from a Federal regulatory marker on the river below the outlet of Tustumena Lake downstream to a marker on the river approximately 2.8 miles below the Tustumena Lake boat ramp.

(*2*) Residents using rod-and-reel gear may fish with up to two baited single or treble hooks.

(3) Other species incidentally caught during the dip net and rod and reel fishery may be retained for subsistence uses, including up to 200 rainbow/steelhead trout taken through August 15. After 200 rainbow/steelhead trout have been taken in this fishery or after August 15, all rainbow/steelhead trout must be released unless otherwise provided for in this section.

(*4*) Harvest seasons are as follows:

Species	Season
Sockeye salmon	June 16–August 15.
Chinook salmon	June 16–August 15.
Coho salmon	June 16–October 31.
Pink salmon	June 16–October 31.

(B) *Kasilof River fish wheel; salmon.* (*1*) Residents of Ninilchik may harvest sockeye, Chinook, coho, and pink salmon through a fish wheel fishery in the Federal public waters of the upper mainstem of the Kasilof River.

(*2*) Residents of Ninilchik may retain other species incidentally caught in the Kasilof River fish wheel except for rainbow or steelhead trout, which must be released and returned unharmed to the water.

(*3*) Only one fish wheel may be operated on the Kasilof River. The fish wheel must: Have a live box, be monitored when fishing, be stopped from fishing when it is not being monitored or used, and be installed and operated in compliance with any regulations and restrictions for its use within the Kenai National Wildlife Refuge.

(*4*) One registration permit will be available and will be awarded by the Federal in-season fishery manager, in consultation with the Kenai National Wildlife Refuge manager, based on the merits of the operational plan. The registration permit will be issued to an organization that, as the fish wheel owner, will be responsible for its construction, installation, operation, use, and removal in consultation with the Federal fishery manager. The owner may not rent or lease the fish wheel for personal gain. As part of the permit, the organization must:

(*i*) *Prior to the season.* Provide a written operational plan to the Federal fishery manager including a description of how fishing time and fish will be offered and distributed among households and residents of Ninilchik.

(*ii*) *During the season.* Mark the fish wheel with a wood, metal, or plastic plate that is at least 12 inches high by 12 inches wide, permanently affixed, and plainly visible and that contains the following information in letters and numerals at least 1 inch high: Registration permit number; organization's name and address; and primary contact person name and telephone number.

(*iii*) *After the season.* Provide written documentation of required evaluation information to the Federal fishery manager including, but not limited to, persons or households operating the gear, hours of operation, and number of each species caught and retained or released.

(*5*) People operating the fish wheel must:

(*i*) Have in possession a valid Federal subsistence fishing permit and remain onsite to monitor the fish wheel and remove all fish at least every hour.

(*ii*) In addition, any person operating the fish wheel who is not the owner must attach to the fish wheel an additional wood, metal, or plastic plate that is at least 12 inches high by 12 inches wide, is plainly visible, and contains the person's fishing permit number, name, and address in letters and numerals at least 1 inch high.

(*6*) The organization owning the fish wheel may operate the fish wheel for subsistence purposes on behalf of residents of Ninilchik by requesting a subsistence fishing permit that:

(*i*) Identifies a person who will be responsible for operating the fish wheel; and

(*ii*) Includes provisions for recording daily catches, the household to whom the catch was given, and other information determined to be necessary for effective resource management by the Federal fishery manager.

(*7*) Fishing is allowed from June 16 through October 31 on the Kasilof River unless closed or otherwise restricted by Federal special action.

(C) *Kasilof River gillnet; salmon.*

(*1*) Residents of Ninilchik may harvest sockeye, Chinook, coho, and pink salmon in the Federal public waters of the upper mainstem of the Kasilof River from a Federal regulatory marker on the river below the outlet of Tustumena Lake downstream to the Tustumena Lake boat launch with a single gillnet from June 16 through August 15.

(*2*) Only one community gillnet may be operated on the Kasilof River.

(*i*) The gillnet may not: Be over 10 fathoms in length, be larger than 5.25-inch mesh, and obstruct more than half of the river width with stationary fishing gear.

(*ii*) Subsistence stationary gillnet gear may not be set within 200 feet of other subsistence stationary gear.

(*iii*) The gillnet may be operated as a set gillnet in a fixed location, as a pole-net system drifted through an area while wading, or as a drift net from a boat.

(*3*) One registration permit will be available and will be issued by the Federal in-season fishery manager, in consultation with the Kenai National Wildlife Refuge manager, to the Ninilchik Traditional Council. As the community gillnet owner, the Ninilchik Traditional Council will be responsible for its use and removal in consultation with the Federal in-season manager. As part of the permit, after the season, the Ninilchik Traditional Council must provide written documentation of required evaluation information to the Federal fishery manager including, but not limited to:

(*i*) Persons or households operating the gear;

(*ii*) Hours of operation; and

(*iii*) Number of each species caught and retained or released.

(*4*) The community gillnet is subject to compliance with applicable Kenai National Wildlife Refuge regulations and restrictions.

(*5*) The Ninilchik Traditional Council may operate the net for subsistence purposes on behalf of residents of Ninilchik by requesting a subsistence fishing permit that:

(*i*) Identifies a person who will be responsible for fishing the gillnet; and

(*ii*) Includes provisions for recording daily catches within 72 hours, the household to whom the catch was given, and other information determined to be necessary for effective resource management by the Federal in-season manager.

(*6*) Residents of Ninilchik may retain other species incidentally caught in the Kasilof River community gillnet fishery. The gillnet fishery will be closed when the retention of rainbow or steelhead trout has been restricted under Federal subsistence regulations.

(D) *Tustumena Lake rod and reel; salmon.*

(*1*) In addition to the dip net and rod and reel fishery on the upper mainstem of the Kasilof River described under paragraph (e)(10)(ii)(A)(*1*) of this section, residents of Ninilchik may also take coho and pink salmon through a rod and reel fishery in Tustumena Lake.

Fishing is allowed with up to two baited single or treble hooks.

(*2*) Seasons, areas, harvest and possession limits, and methods and means for take are the same as for the taking of these species under Alaska sport fishing regulations (5 AAC 56), except for the following harvest and possession limits:

Species	Size	Limits
Coho salmon	16 inches and longer	4 per day and 4 in possession.
Pink salmon	16 inches and longer	6 per day and 6 in possession.

(E) *Kasilof drainage rod and reel; resident species.* Resident fish species including lake trout, rainbow or steelhead trout, and Dolly Varden or Arctic char may be harvested by rod and reel in Federally managed waters of the Kasilof River drainage the entire year as follows:

Species	Specifications	Limits
Lake trout	Fish 20 inches and longer	4 per day and 4 in possession.
	Fish less than 20 inches in length	15 per day and 15 in possession.
Dolly Varden and Arctic char	In flowing waters	4 per day and 4 in possession.
	In lakes and ponds	10 per day and 10 in possession.
Rainbow or steelhead trout	In flowing waters	2 per day and 2 in possession.
	In lakes and ponds	5 per day and 5 in possession.

(F) *Tustumena Lake under ice fishery; resident species.*

(*1*) You may fish in Tustumena Lake with a gillnet under the ice, or with jigging gear used through the ice. The gillnet may not be longer than 10 fathoms.

(*2*) Harvest limits are as follows:

Methods	Limits	Additional provisions
Jigging gear through the ice	Household annual limit of 30 fish in any combination of lake trout, rainbow trout, and Dolly Varden or Arctic char.	Household limits are included in the overall total annual harvest quota.
Gillnet under the ice	Total annual harvest quota of 200 lake trout, 200 rainbow trout, and 500 Dolly Varden or Arctic char.	The Federal in-season manager will issue a closure for this fishery once any of these quotas has been met.

(*3*) You may harvest fish under the ice only in Tustumena Lake. Gillnets are not allowed within a ¼ mile radius of the mouth of any tributary to Tustumena Lake, or the outlet of Tustumena Lake.

(*4*) A permit is required. The permit will be issued by the Federal in-season manager or designated representative and will be valid for the winter season unless the season is closed by special action.

(*i*) The permittee must report the following information: The number of each species caught; the number of each species retained; the length, depth (number of meshes deep), and mesh size of gillnet fished; the fishing site; and the total hours fished.

(*ii*) The gillnet must be checked at least once in every 48-hour period.

(*iii*) For unattended gear, the permittee's name and address must be plainly and legibly inscribed on a stake at one end of the gillnet.

(*5*) Incidentally caught fish may be retained and must be recorded on the permit before transporting fish from the fishing site.

(*6*) Failure to return the completed harvest permit by May 31 may result in issuance of a violation notice and/or denial of a future subsistence permit.

(iii) *Seasons, harvest limits, and methods and means for Kenai River fisheries.* Household annual limits for salmon in Kenai River fisheries are as follows:

Species	Number of fish allowed for each permit holder	Additional fish allowed for each household member	Additional provisions
Sockeye salmon	25	5	Chum salmon that are retained are to be included within the annual limit for sockeye salmon.
Chinook salmon— Early-run (July 1 through July 15).	2	1	For the Kenai River community gillnet fishery described under paragraph (e)(10)(iii)(B) of this section.
Chinook salmon—Late-run (July 16 through August 31).	10	2	
Coho salmon	20	5	
Pink salmon	15	5	

(A) *Kenai River dip net or rod and reel; salmon.*

(*1*) You may take only sockeye salmon through a dip net or rod and reel fishery at one specified site on the Russian River.

(*i*) For the Russian River fishing site, incidentally caught fish may be retained for subsistence uses, except for early- and late-run Chinook salmon, coho salmon, rainbow trout, and Dolly Varden, which must be released.

(*ii*) At the Russian River Falls site, dip netting is allowed from a Federal regulatory marker near the upstream end of the fish ladder at Russian River Falls downstream to a Federal regulatory marker approximately 600 yards below Russian River Falls. Residents using rod and reel gear at this fishery site may not fish with bait at any time.

(*2*) You may take sockeye, late-run Chinook, coho, and pink salmon through a dip net or rod and reel fishery at two specified sites on the Kenai River below Skilak Lake and as provided in this section.

(*i*) For both Kenai River fishing sites below Skilak Lake, incidentally caught fish may be retained for subsistence uses, except for early-run Chinook salmon (unless otherwise provided for in this section), rainbow trout 18 inches or longer, and Dolly Varden 18 inches or longer, which must be released.

(*ii*) At the Kenai River Moose Range Meadows site, dip netting is allowed only from a boat from a Federal regulatory marker on the Kenai River at about river mile 29 downstream approximately 2.5 miles to another marker on the Kenai River at about river mile 26.5. Residents using rod and reel gear at this fishery site may fish from boats or from shore with up to two baited single or treble hooks June 15 through August 31.

(*iii*) At the Kenai River mile 48 site, dip netting is allowed while either standing in the river or from a boat, from Federal regulatory markers on both sides of the Kenai River at about river mile 48 (approximately 2 miles below the outlet of Skilak Lake) downstream approximately 2.5 miles to a marker on the Kenai River at about river mile 45.5. Residents using rod and reel gear at this fishery site may fish from boats or from shore with up to two baited single or treble hooks June 15 through August 31.

(*3*) Fishing seasons are as follows:

Species	Season	Location
Sockeye salmon	June 15–August 15	All three sites.
Late-run Chinook salmon	July 16–September 30	Kenai River sites only.
Pink salmon	July 16–September 30	Kenai River sites only.
Coho salmon	July 16–September 30	Kenai River sites only.

(B) *Kenai River gillnet; salmon.*

(*1*) Residents of Ninilchik may harvest sockeye, Chinook, coho, and pink salmon in the Moose Range Meadows area of the Federal public waters of the Kenai River with a single gillnet to be managed and operated by the Ninilchik Traditional Council.

(*2*) Fishing will be allowed July 1 through August 15 and September 10–30 on the Kenai River unless closed or otherwise restricted by Federal special action. The following conditions apply to harvest in the Kenai River community gillnet fishery:

(*i*) Salmon taken in this fishery will be included as household annual limits of participating households.

(ii) The Ninilchik Traditional Council will report all harvested fish within 72 hours of leaving the gillnet location.

(*iii*) Additional harvest restrictions for this fishery are as follows:

Species	Period	Harvest	Fishery limits
Sockeye salmon	July 1–August 15 and September 10–30.		
Early-run Chinook salmon less than 46 inches in length or greater than 55 inches in length.	July 1–15	Fish may be retained if the most current preseason forecast from the State of Alaska Department of Fish and Game projects the in-river run to be within or above the optimal escapement goal range for early-run Chinook salmon; otherwise, live fish must be released.	Fishery will close until July 16 once 50 early-run Chinook salmon have been retained or released.
Late-run Chinook salmon.	July 16–August 15		Fishery will close prior to August 15 if 200 late-run Chinook salmon have been retained or released prior to that date. Fishery will reopen September 10–30 for species available at that time.
Pink salmon	July 16–August 15 and September 10–30.		
Coho salmon	July 16–August 15 and September 10–30.		
Incidentally caught rainbow trout and Dolly Varden.		All live fish must be released. Fish that die in net may be retained.	Fishery will close for the season once 100 rainbow trout or 150 Dolly Varden have been released or retained.

(*iv*) Chinook salmon less than 20 inches in length may be retained and do not count towards retained or released totals.

(*v*) Other incidentally caught species may be retained; however, all incidental fish mortalities, except for Chinook salmon less than 20 inches in length, count towards released or retained totals specified in this section.

(*3*) Only one community gillnet may be operated on the Kenai River.

(i) The gillnet may not: Be over 10 fathoms in length to take salmon; be larger than 5.25-inch mesh; and obstruct more than half of the river width with stationary fishing gear.

(*ii*) Subsistence stationary gillnet gear may not be set within 200 feet of other subsistence stationary gear.

(*4*) One registration permit will be available and will be issued by the Federal in-season manager, in consultation with the Kenai National Wildlife Refuge manager, to the Ninilchik Traditional Council. As the

community gillnet owner, the Ninilchik Traditional Council will be responsible for its use and removal in consultation with the Federal in-season manager. As part of the permit, the Ninilchik Traditional Council must provide post-season written documentation of required evaluation information to the Federal in-season manager including, but not limited to:

(*i*) Persons or households operating the gear;

(*ii*) Hours of operation; and

(*iii*) Number of each species caught and retained or released.

(*5*) The Ninilchik Traditional Council may operate the net for subsistence purposes on behalf of residents of Ninilchik by requesting a subsistence fishing permit that:

(*i*) Identifies a person who will be responsible for fishing the gillnet; and

(*ii*) Includes provisions for recording daily catches, the household to whom the catch was given, and other information determined to be necessary for effective resource management by the Federal in-season manager.

(C) *Kenai River rod and reel only; salmon.*

(*1*) For Federally managed waters of the Kenai River and its tributaries, you may take sockeye, Chinook, coho, pink, and chum salmon through a separate rod and reel fishery in the Kenai River drainage.

(*2*) Seasons, areas, harvest and possession limits, and methods and means for take are the same as for the taking of these salmon species under State of Alaska fishing regulations (5 AAC 56, 5 AAC 57 and 5 AAC 77.540), except for the following harvest and possession limits:

Species	Size	Limits
Chinook salmon— Early-run (January 1 through July 15).	Less than 46 inches or 55 inches and longer.	2 per day and 2 in possession.
Chinook salmon—Late-run (July 16 through August 31).	20 inches and longer	2 per day and 2 in possession.
All other salmon	16 inches and longer	6 per day and 6 in possession, of which no more than 4 per day and 4 in possession may be Coho salmon, except for the Sanctuary Area and Russian River where no more than 2 per day and 2 in possession may be Coho salmon.

(*i*) In the Kenai River below Skilak Lake, fishing is allowed with up to two baited single or treble hooks June 15 through August 31.

(*ii*) Annual harvest limits for any combination of early- and late-run Chinook salmon are four for each permit holder.

(*iii*) Incidentally caught fish, other than salmon, are subject to regulations found in paragraph (e)(10)(iii)(D) of this section.

(D) *Kenai River and tributaries under ice jigging and rod and reel; resident species.*

(*1*) For Federally managed waters of the Kenai River and its tributaries below Skilak Lake outlet at river mile 50, you may take resident fish species including lake trout, rainbow trout, and Dolly Varden or Arctic char with jigging gear through the ice or rod and reel gear in open waters. Seasons, areas, harvest and possession limits, and methods and means for take are the same as for the taking of these resident species under State of Alaska fishing regulations (5 AAC 56, 5 AAC 57, and 5 AAC 77.540), except for the following harvest and possession limits:

Species	Specifications	Limits
Lake trout	20 inches or longer	4 per day and 4 in possession.
	Less than 20 inches	15 per day and 15 in possession.
Dolly Varden or Arctic char	In flowing waters	For fish less than 18 inches, 1 per day and 1 in possession.
	In lakes and ponds	2 per day and 2 in possession, of which only one may be 20 inches or longer, may be harvested daily.
Rainbow or steelhead trout	In flowing waters	For fish less than 18 inches in length, 1 per day and 1 in possession.
	In lakes and ponds	2 per day and 2 in possession, of which only one fish 20 inches or longer may be harvested daily.

(*2*) For Federally managed waters of the upper Kenai River and its tributaries above Skilak Lake outlet at river mile 50, you may take resident fish species including lake trout, rainbow trout, and Dolly Varden or Arctic char with jigging gear through the ice or rod and reel gear in open waters. Seasons, areas, harvest and possession limits, and methods and means for take are the same as for the taking of these resident species under Alaska fishing regulations (5 AAC 56, 5 AAC 57, 5 AAC 77.540), except for the following harvest and possession limits:

Species	Specifications	Limits
Lake trout	20 inches or longer	4 per day and 4 in possession.
	Less than 20 inches	15 per day and 15 in possession.
	From Hidden Lake	2 per day and 2 in possession regardless of length.
Dolly Varden or Arctic char	In flowing waters	For fish less than 16 inches in length, 1 per day and 1 in possession.
	In lakes and ponds	2 per day and 2 in possession, of which only one fish 20 inches or longer may be harvested daily.
Rainbow or steelhead trout	In flowing waters	For fish less than 16 inches in length, 1 per day and 1 in possession.
	In lakes and ponds	2 per day and 2 in possession, of which only one fish 20 inches or longer may be harvested daily.

* * * * *

Dated: August 1, 2019.

Thomas C.J. Doolittle,

Acting Assistant Regional Director, U.S. Fish and Wildlife Service.

Dated: August 1, 2019.

Thomas Whitford,

Subsistence Program Leader, USDA–Forest Service.

[FR Doc. 2019–16870 Filed 8–8–19; 8:45 am]

BILLING CODE 4333–15–P; 3411–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2019–0159; FRL–9997–66–Region 9]

Partial Approval, Partial Disapproval and Limited Approval, Limited Disapproval of Arizona Air Plan Revisions; Pinal County Air Quality Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing a partial approval and partial disapproval of revisions to the Pinal County Air Quality Control District (PCAQCD) portion of the Arizona State Implementation Plan (SIP). This action concerns the District's demonstration regarding reasonably available control technology (RACT) requirements and negative declarations for the 2008 8-hour ozone National Ambient Air Quality Standards (NAAQS or ''standards'') in the portion of the Phoenix-Mesa ozone nonattainment area under the jurisdiction of the PCAQCD. The EPA is also finalizing a limited approval and limited disapproval of two PCAQCD rules that regulate emissions from surface coating operations and gasoline dispensing stations that were submitted with its RACT SIP demonstration. This partial disapproval of the RACT SIP and limited disapproval of two PCAQCD rules will trigger sanctions clocks under the CAA that will be stopped if the EPA approves subsequent SIP revisions that correct the rule and RACT SIP deficiencies within 18 months of the effective date of this final action. Under the authority of the Clean Air Act (CAA or the Act), this action simultaneously approves the PCAQCD rules for surface coating operations and storage and loading of gasoline at gasoline dispensing facilities and directs Arizona to correct the rule deficiencies.

DATES: These rules will be effective on September 9, 2019.

ADDRESSES: The EPA has established a docket for this action under Docket No. EPA–R09–OAR–2019–0159. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the docket, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Stanley Tong, EPA Region IX—(Air 3–2), 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 947–4122 or by email at *tong.stanley@epa.gov.*

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

Table of Contents

I. Proposed Action

On May 13, 2019 (84 FR 20838), the EPA proposed to partially approve and partially disapprove PCAQCD's 2016 RACT SIP (''*2016 RACT SIP*'') demonstration and negative declarations for the 2008 8-hour ozone NAAQS. Our notice also proposed a limited approval and limited disapproval of the following two PCAQCD rules that were submitted with the *2016 RACT SIP:* Chapter 5, Article 13, Surface Coating Operations, and Chapter 5, Article 20, Storage and Loading of Gasoline at Gasoline Dispensing Facilities. Table 1 lists the documents that were submitted by the Arizona Department of Environmental Quality (ADEQ) for incorporation into the Arizona SIP and were the subject of our May 13, 2019 proposed rulemaking action.

TABLE 1—SUBMITTED DOCUMENTS

Local agency	Document	Adopted	Submitted
PCAQCD	Reasonably Available Control Technology (RACT) Analysis, Negative Declaration and Rules Adoption.	11/30/2016	2/3/2017
PCAQCD	Chapter 5, Article 13 Surface Coating Operations	11/30/2016	2/3/2017
	5–13–100, ''General''		
	5–13–200, ''Definitions''		
	5–13–300, ''Standards''		
	5–13–400, ''Administrative Requirements''		
	5–13–500, ''Monitoring and Records''		
	Note: the submittal explicitly excludes 5–13–390 ''Spray Paint and Other Surface Coating Operations'' (as amended 10/12/95)..		
PCAQCD	Chapter 5, Article 20 Storage and Loading of Gasoline at Gasoline Dispensing Facilities	11/30/2016	2/3/2017
	5–20–100 ''General''		
	5–20–200 ''Definitions''		
	5–20–300 ''Standards''		
	5–20–400 ''Administrative Requirements''		
	5–20–500 ''Monitoring and Records''		

PCAQCD's *2016 RACT SIP* provides the District's demonstration that the applicable SIP for the PCAQCD satisfies CAA section 182 RACT requirements for the 2008 8-hour ozone NAAQS. This conclusion is based on the District's analysis of SIP-approved requirements that apply to the following: (1) Source categories for which the EPA has issued a Control Techniques Guidelines (CTG) document, and (2) major non-CTG stationary sources of Volatile Organic

Compounds (VOCs) or oxides of nitrogen (NO_X).

With respect to CTG source categories, PCAQCD determined that it only had sources subject to the CTGs covering surface coating operations and gasoline dispensing stations. PCAQCD submitted for SIP approval two rules to implement RACT for these categories: Chapter 5, Article 13 Surface Coating Operations, and Chapter 5, Article 20 Storage and Loading of Gasoline at Gasoline Dispensing Facilities.

We proposed a limited approval for these two rules because we determined that they improve the SIP and are largely consistent with the relevant CAA requirements. We simultaneously proposed a limited disapproval because some rule provisions conflict with section 110 and part D of the Act. Our proposed action determined that Article 13 did not incorporate all the recommended metal parts coating categories from the Miscellaneous Metal and Plastic Parts CTG and allows some exemptions not found in the CTG. We also determined that Article 20 needed to be strengthened to correct an enforceability issue.

Where there are no existing sources covered by a particular CTG document, or no major non-CTG sources, states may, in lieu of adopting RACT requirements for those sources, adopt negative declarations certifying that there are no such sources in the relevant nonattainment area. Appendix C of the *2016 RACT SIP* lists the District's negative declarations where it has no sources subject to the applicable CTG for the 2008 8-hour ozone NAAQS.

We proposed a partial approval and partial disapproval of the *2016 RACT SIP* because while we determined that the District's negative declarations listed in its *2016 RACT SIP* Appendix C largely addressed the required RACT elements, the District had not adopted a negative declaration or a RACT rule for major stationary sources of VOC or NOx, cutback asphalt, and certain sections of the Miscellaneous Metal and Plastic Parts CTG.

Our proposed action contains more information on the basis for this rulemaking and on our evaluation of the submittal.

II. EPA Action

The EPA's proposed action provided a 30-day public comment period. No comments were submitted. Therefore, as authorized in sections 110(k)(3) and 301(a) of the Act, the EPA is finalizing a limited approval of Articles 13 and 20. This action incorporates the submitted rules into the PCAQCD portion of the Arizona SIP, including those provisions identified as deficient. The approval of Articles 13 and 20 is limited because the EPA is simultaneously finalizing a limited disapproval of Articles 13 and 20 under 110(k)(3). This limited disapproval will trigger sanctions clocks under CAA section 179 and 40 CFR 52.31 that will be stopped if the EPA approves subsequent SIP revisions that correct the rule deficiencies within 18 months of the effective date of today's final action.

Note that Articles 13 and 20 have been adopted by the PCAQCD, and the EPA's final limited disapproval will not prevent the local agency from enforcing them. The limited disapproval also will not prevent any portion of the rules from being incorporated by reference into the federally enforceable SIP as discussed in the memorandum dated July 9, 1992, from John Calcagni, Director, Air Quality Management Division, U.S. EPA, to EPA Regional Air Directors, Regions I–X, Subject: ''Processing of State Implementation Plan (SIP) Submittals,'' currently available at *https://www.epa.gov/sites/production/files/2015-07/documents/procsip.pdf.*

As authorized in sections 110(k)(3) and 301(a) of the Act, the EPA is also finalizing a partial approval of PCAQCD's *2016 RACT SIP.* This action incorporates the *2016 RACT SIP* including the RACT certification and negative declarations into the Pinal County portion of the Arizona SIP. The EPA is simultaneously finalizing a partial disapproval of the *2016 RACT SIP* under 110(k)(3). This partial disapproval of the *2016 RACT SIP* will trigger sanctions clocks under CAA section 179 and 40 CFR 52.31 that will be stopped if the EPA approves subsequent SIP revisions that correct the deficiencies within 18 months of the effective date of today's final action.

The first sanction, the offset sanction in CAA section 179(b)(2), would apply within 18 months of the effective date of today's final action. The highway funding sanctions in CAA section 179(b)(1) would apply in the area six months after the offset sanction is imposed. Neither sanction will be imposed under the CAA if Arizona submits and we approve, prior to the implementation of sanctions, SIP revisions that correct the RACT deficiencies identified in our proposed action. In addition to the sanctions, CAA section 110(c)(1) provides that the EPA must promulgate a federal implementation plan (FIP) addressing the deficient RACT elements two years after the effective date of this rule if we have not approved a SIP revision correcting the deficiencies within two years.

We note that PCAQCD will not be required to submit a revised CAA section 182 RACT SIP demonstration for the 2008 8-hour ozone NAAQS if the rule revisions required by this action correct the identified deficiencies to satisfy current RACT requirements, the District adopts the necessary negative declarations for its *2016 RACT SIP,* and the EPA fully approves the submitted documents into the SIP.

III. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the PCAQCD rules described in the amendments to 40 CFR part 52 set forth below. Therefore, these materials have been approved by the EPA for inclusion in the Arizona SIP, have been incorporated by reference by the 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 the EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[1] The EPA has made, and will continue to make, these documents available through *https://www.regulations.gov* and at the EPA Region IX 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

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

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

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

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not an Executive Order 13771 regulatory action because SIP approvals, including limited approvals, are exempted under Executive Order 12866.

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

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA because this action does not impose additional requirements beyond those imposed by state law.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities beyond those imposed by state law.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action does not impose additional requirements beyond those imposed by state law. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector, will result from this action.

F. Executive Order 13132: Federalism

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

G. Executive Order 13175: Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175, because 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, and will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

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

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

I. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

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

J. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of the NTTAA directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. The EPA believes that this action is not subject to the requirements of section 12(d) of the NTTAA because application of those requirements would be inconsistent with the CAA.

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

The EPA lacks the discretionary authority to address environmental justice in this rulemaking.

L. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

M. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 8, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule 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, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: July 23, 2019.

Michael Stoker,

Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for Part 52 continues to read as follows:

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

Subpart D—Arizona

■ 2. Section 52.120 is amended by:

■ a. In paragraph (c), Table 9, under the heading ''Chapter 5. Stationary Source Performance Standards'' adding entries for ''5–13–100'', ''5–13–200'', ''5–13–300'', ''5–13–400'', ''5–13–500'', ''5–20–100'', ''5–20–200'', ''5–20–300'', ''5–20–400'' and ''5–20–500'' in numerical order, and;

■ b. In paragraph (e), Table 1, under the subheading ''Part D Elements and Plans for the Metropolitan Phoenix and Tucson Areas'' adding an entry for ''Reasonably Available Control Technology (RACT) Analysis, Negative Declaration and Rules Adoption'' after the entry for ''Maricopa Association of Governments (MAG) 1987 Carbon Monoxide (CO) Plan for the Maricopa County Area, MAG CO Plan Commitments for Implementation, and Appendix A through E, Exhibit 4, Exhibit D.''

The additions to read as follows:

§ 52.120 Identification of plan.

* * * * *

(c) * * *

TABLE 9—EPA-APPROVED PINAL COUNTY AIR POLLUTION CONTROL REGULATIONS

County citation	Title/subject	State effective date	EPA approval date	Additional explanation
*	*	*	*	*
Chapter 5. Stationary Source Performance Standards				
5–13–100.	Surface Coating Operations—General.	January 1, 2017	August 9, 2019, [INSERT **Federal Register** CITATION].	Adopted by Pinal County on November 30, 2016. Submitted on February 3, 2017. The RACT rule for Surface Coating Operations consists of Pinal County Air Quality Control District sections 5–13–100, 5–13–200, 5–13–300, 5–13–400, and 5–13–500.
5–13–200.	Definitions	January 1, 2017	August 9, 2019, [INSERT **Federal Register** CITATION].	Adopted by Pinal County on November 30, 2016. Submitted on February 3, 2017. The RACT rule for Surface Coating Operations consists of Pinal County Air Quality Control District sections 5–13–100, 5–13–200, 5–13–300, 5–13–400, and 5–13–500.
5–13–300.	Standards	January 1, 2017	August 9, 2019, [INSERT **Federal Register** CITATION].	Adopted by Pinal County on November 30, 2016. Submitted on February 3, 2017. The RACT rule for Surface Coating Operations consists of Pinal County Air Quality Control District sections 5–13–100, 5–13–200, 5–13–300, 5–13–400, and 5–13–500. Section 5–13–390 is not part of the SIP.
5–13–400.	Administrative Requirements.	January 1, 2017	August 9, 2019, [INSERT **Federal Register** CITATION].	Adopted by Pinal County on November 30, 2016. Submitted on February 3, 2017. The RACT rule for Surface Coating Operations consists of Pinal County Air Quality Control District sections 5–13–100, 5–13–200, 5–13–300, 5–13–400, and 5–13–500.
5–13–500.	Monitoring and Records.	January 1, 2017	August 9, 2019, [INSERT **Federal Register** CITATION].	Adopted by Pinal County on November 30, 2016. Submitted on February 3, 2017. The RACT rule for Surface Coating Operations consists of Pinal County Air Quality Control District sections 5–13–100, 5–13–200, 5–13–300, 5–13–400, and 5–13–500.
*	*	*	*	*
5–20–100.	Storage and Loading of Gasoline at Gasoline Dispensing Facilities—General.	January 1, 2017	August 9, 2019, [INSERT **Federal Register** CITATION].	Adopted by Pinal County on November 30, 2016. Submitted on February 3, 2017. The RACT rule for Storage and Loading of Gasoline at Gasoline Dispensing Facilities consists of Pinal County Air Quality Control District sections 5–20–100, 5–20–200, 5–20–300, 5–20–400, and 5–20–500.
5–20–200.	Definitions	January 1, 2017	August 9, 2019, [INSERT **Federal Register** CITATION].	Adopted by Pinal County on November 30, 2016. Submitted on February 3, 2017. The RACT rule for Storage and Loading of Gasoline at Gasoline Dispensing Facilities consists of Pinal County Air Quality Control District sections 5–20–100, 5–20–200, 5–20–300, 5–20–400, and 5–20–500.
5–20–300.	Standards	January 1, 2017	August 9, 2019, [INSERT **Federal Register** CITATION].	Adopted by Pinal County on November 30, 2016. Submitted on February 3, 2017. The RACT rule for Storage and Loading of Gasoline at Gasoline Dispensing Facilities consists of Pinal County Air Quality Control District sections 5–20–100, 5–20–200, 5–20–300, 5–20–400, and 5–20–500.

TABLE 9—EPA-APPROVED PINAL COUNTY AIR POLLUTION CONTROL REGULATIONS—Continued

County citation	Title/subject	State effective date	EPA approval date	Additional explanation
5–20–400.	Administrative Requirements.	January 1, 2017	August 9, 2019, [INSERT **Federal Register** CITATION].	Adopted by Pinal County on November 30, 2016. Submitted on February 3, 2017. The RACT rule for Storage and Loading of Gasoline at Gasoline Dispensing Facilities consists of Pinal County Air Quality Control District sections 5–20–100, 5–20–200, 5–20–300, 5–20–400, and 5–20–500.
5–20–500.	Monitoring and Records.	January 1, 2017	August 9, 2019, [INSERT **Federal Register** CITATION].	Adopted by Pinal County on November 30, 2016. Submitted on February 3, 2017. The RACT rule for Storage and Loading of Gasoline at Gasoline Dispensing Facilities consists of Pinal County Air Quality Control District sections 5–20–100, 5–20–200, 5–20–300, 5–20–400, and 5–20–500.
*	*	*	*	*	*	*

* * * * *

(e) * * *

TABLE 1—EPA-APPROVED NON-REGULATORY AND QUASI-REGULATORY MEASURES

[Excluding certain resolutions and statutes, which are listed in tables 2 and 3, respectively] [1]

Name of SIP provision	Applicable geographic or nonattainment area or title/subject	State submittal date	EPA approval date	Explanation
The State of Arizona Air Pollution Control Implementation Plan				
*	*	*	*	*	*	*
Part D Elements and Plans for the Metropolitan Phoenix and Tucson Areas				
*	*	*	*	*	*	*
Reasonably Available Control Technology (RACT) Analysis, Negative Declaration and Rules Adoption.	Pinal County portion of Phoenix-Mesa nonattainment area for 2008 8-hour ozone NAAQS.	February 3, 2017	August 9, 2019, [INSERT **Federal Register** CITATION].	RACT SIP submittal for Apache Junction (Pinal County portion of Phoenix-Mesa ozone nonattainment area). Adopted by the Pinal County Air Quality Control District on November 30, 2016.
*	*	*	*	*	*	*

[1] Table 1 is divided into three parts: Clean Air Act Section 110(a)(2) State Implementation Plan Elements (excluding Part D Elements and Plans), Part D Elements and Plans (other than for the Metropolitan Phoenix or Tucson Areas), and Part D Elements and Plans for the Metropolitan Phoenix and Tucson Areas.

* * * * *

■ 3. Section 52.122 is amended by adding paragraph (a)(2) as follows:

§ 52.122 Negative declarations.

* * * * *

(a) * * *

(2) Pinal County Air Quality Control District.

(i) The following negative declarations for the 2008 ozone NAAQS were adopted on November 30, 2016 and submitted on February 3, 2017.

EPA document No.	Title
EPA–450/2–77–008	Surface Coating of Cans.
EPA–450/2–77–008	Surface Coating of Coils.

EPA document No.	Title
EPA–450/2–77–008	Surface Coating of Paper.
EPA–450/2–77–008	Surface Coating of Fabric.
EPA–450/2–77–008	Surface Coating of Automobiles and Light-Duty Trucks.
EPA–450/2–77–022	Solvent Metal Cleaning.
EPA–450/2–77–025	Refinery Vacuum Producing Systems, Wastewater Separators, and Process Unit Turnarounds.
EPA–450/2–77–026	Tank Truck Gasoline Loading Terminals.
EPA–450/2–77–032	Surface Coating of Metal Furniture.
EPA–450/2–77–033	Surface Coating of Insulation of Magnet Wire.
EPA–450/2–77–034	Surface Coating of Large Appliances.
EPA–450/2–77–035	Bulk Gasoline Plants.
EPA–450/2–77–036	Storage of Petroleum Liquids in Fixed-Roof Tanks.
EPA–450/2–78–029	Manufacture of Synthesized Pharmaceutical Products.
EPA–450/2–78–030	Manufacture of Pneumatic Rubber Tires.
EPA–450/2–78–032	Factory Surface Coating of Flat Wood Paneling.
EPA–450/2–78–033	Graphic Arts—Rotogravure and Flexography.
EPA–450/2–78–036	Leaks from Petroleum Refinery Equipment.
EPA–450/2–78–047	Petroleum Liquid Storage in External Floating Roof Tanks.
EPA–450/2–78–051	Leaks from Gasoline Tank Trucks and Vapor Collection Systems.
EPA–450/3–82–009	Large Petroleum Dry Cleaners.
EPA–450/3–83–006	Leaks from Synthetic Organic Chemical Polymer and Resin Manufacturing Equipment.
EPA–450/3–83–007	Leaks from Natural Gas/Gasoline Processing Plants.
EPA–450/3–83–008	Manufacture of High-Density Polyethylene, Polypropylene, and Polystyrene Resins.
EPA–450/3–84–015	Air Oxidation Processes in Synthetic Organic Chemical Manufacturing Industry.
EPA–450/4–91–031	Reactor Processes and Distillation Operations in Synthetic Organic Chemical Manufacturing Industry.
EPA–453/R–96–007	Wood Furniture Manufacturing Operations.
EPA–453/R–94–032	ACT Surface Coating at Shipbuilding and Ship Repair Facilities
61 FR 44050; 8/27/96	Shipbuilding and Ship Repair Operations (Surface Coating).
EPA–453/R–97–004	Aerospace MACT and Aerospace (CTG & MACT).
59 FR 29216; 6/06/94	
EPA–453/R–06–001	Industrial Cleaning Solvents.
EPA–453/R–06–002	Offset Lithographic Printing and Letterpress Printing.
EPA–453/R–06–003	Flexible Package Printing.
EPA–453/R–06–004	Flat Wood Paneling Coatings.
EPA 453/R–07–003	Paper, Film, and Foil Coatings.
EPA 453/R–07–004	Large Appliance Coatings.
EPA 453/R–07–005	Metal Furniture Coatings.
EPA 453/R–08–004	Fiberglass Boat Manufacturing Materials.
EPA 453/R–08–005	Miscellaneous Industrial Adhesives.
EPA 453/R–08–006	Automobile and Light-Duty Truck Assembly Coatings.

(ii) [Reserved]

■ 4. Section 52.124 is amended by adding paragraph (b) to read as follows:

§ 52.124 Part D disapproval.

* * * * *

(b) The following Reasonably Available Control Technology (RACT) determinations are disapproved because they do not meet the requirements of Part D of the Clean Air Act.

(1) Pinal County Air Quality Control District.

(i) RACT determinations for the Control of Volatile Organic Emissions from Use of Cutback Asphalt (EPA–450/2–77–037), major NO_X, and major VOC source categories, in the submittal titled ''Reasonability Available Control Technology (RACT) Analysis, Negative Declaration and Rules Adoption,'' dated November 30, 2016, as adopted on November 30, 2016 and submitted on February 3, 2017.

(ii) [Reserved]

(2) [Reserved]

[FR Doc. 2019–16786 Filed 8–8–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 203 and 252

[Docket DARS–2019–0042]

RIN 0750–AK48

Defense Federal Acquisition Regulation Supplement: Modification of DFARS Clauses Related to the Display of Hotline Posters (DFARS Case 2019–D011)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to update contact information in two DFARS clauses that address the display of hotline posters.

DATES: Effective August 9, 2019.

FOR FURTHER INFORMATION CONTACT: Ms. Carrie Moore, telephone 571–372–6093.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is amending the DFARS to update the DoD hotline poster online address included in DFARS clause 252.203–7004, Display of Hotline Posters, and to update the DoD Office of the Inspector General (OIG) contact information in DFARS clause 252.203–7003, Agency Office of the Inspector General.

DFARS clause 252.203–7004 is included in noncommercial solicitations and contracts with an estimated value exceeding $5 million, in lieu of the clause at Federal Acquisition Regulation (FAR) 52.203–14, Display of Hotline Posters. The DFARS clause requires contractors to display DoD hotline posters when contract performance is in the United States or overseas and provides contractors with an online address to use to obtain the current DoD hotline poster. This rule updates the DoD hotline poster online address in the clause, which is no longer accurate.

Additionally, DoD is amending the DFARS to update the DoD OIG contact information in DFARS clause 252.203–7003 and subpart 203.1003. This rule updates the mailing address to correct the suite number and provides a website for the DoD OIG.

II. Discussion and Analysis

The modification of DFARS clause 252.203–7004 supports a recommendation from the DoD Regulatory Reform Task Force. On February 24, 2017, the President signed Executive Order (E.O.) 13777, ''Enforcing the Regulatory Reform Agenda,'' which established a Federal policy ''to alleviate unnecessary regulatory burdens'' on the American people. In accordance with E.O. 13777, DoD established a Regulatory Reform Task Force to review and validate DoD regulations, including the DFARS. A public notice of the establishment of the DFARS Subgroup to the DoD Regulatory Reform Task Force, for the purpose of reviewing DFARS provisions and clauses, was published in the **Federal Register** at 82 FR 35741 on August 1, 2017, and requested public input. Two respondents submitted public comments on DFARS clause 252.203–7004, which are summarized below:

Comment: The respondents advised that the DFARS clause should be eliminated; or, at a minimum, revised to either allow the electronic poster to suffice, or to allow the contractor's internal anonymous reporting channels to substitute for the DoD hotline poster. The respondents expressed that it is burdensome and costly to hang the posters and translate them into the local language, when necessary. The respondents noted that contractors are required under FAR 52.203–13, Contractor Code of Business Ethics and Conduct, to have robust ethics and compliance programs, reporting channels for misconduct, and to disclose evidence of certain types of misconduct to the Inspector General's office. The respondents state that requiring the distribution and translation of posters does not add benefits that outweigh the costs of the requirement.

Response: In support of the requirements of Executive Order 13627, Strengthening Protections Against Trafficking in Persons in Federal Contracts, it is a DoD initiative to ensure that no taxpayer resources are used to support human trafficking. DFARS clause 252.203–7004 is used in lieu of the FAR clause and requires the display of hotline posters for applicable contracts being performed overseas, as well within the United States. DoD requires posters to be displayed to ensure that contractor employees who do not have access to the internet are aware of their labor rights and have a means of reporting suspected labor violations directly to the DoD OIG. It is also necessary that the posters be translated into the local language so that contractor employees understand the content of the posters.

The DoD Task Force reviewed the requirements of DFARS clause 252.203–7004, and determined that the DFARS clause was out of date and recommended its modification to update the contact information. No change is made to the clause as a result of the public comments received.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule only updates contact information in two existing clauses. The rule does not impose any new requirements on contracts at or below the simplified acquisition threshold and for commercial items, including commercially available off-the-shelf items.

IV. Publication of This Final Rule for Public Comment Is Not Required by Statute

The statute that applies to the publication of the FAR is Office of Federal Procurement Policy statute (codified at title 41 of the United States Code). Specifically, 41 U.S.C. 1707(a)(1) requires that a procurement policy, regulation, procedure or form (including an amendment or modification thereof) must be published for public comment if it relates to the expenditure of appropriated funds, and has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure, or form, or has a significant cost or administrative impact on contractors or offerors. This final rule is not required to be published for public comment, because DoD is not issuing a new regulation; rather, this rule is merely updating contact information already provided for in existing clauses.

V. Executive Orders 12866 and 13563

E.O.s 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

VI. Executive Order 13771

This final rule is not subject to E.O. 13771, because this rule is not a significant regulatory action under E.O. 12866.

VII. Regulatory Flexibility Act

Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under 41 U.S.C. 1707(a)(1) (see section IV. of this preamble), the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Accordingly, no regulatory flexibility analysis is required, and none has been prepared.

VIII. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 203 and 252

Government procurement.

Jennifer Lee Hawes,

Regulatory Control Officer, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 203 and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 203 and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 203—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

■ 2. Amend section 203.1003(b) by—

■ a. Removing ''Investigative Policy and Oversight'' and adding ''Administrative Investigations'' in its place;

■ b. Removing ''Suite 11H25'' and adding ''Suite 14L25'' in its place; and

■ b. Removing ''866–429–8011.'' and adding ''866–429–8011. Website: *https://www.dodig.mil/Programs/Contractor-Disclosure-Program/*.'' in its place.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

252.203–7003 [Amended]

■ 3. Amend section 252.203–7003 by—
■ a. Removing the clause date ''(DEC 2012)'' and adding ''(AUG 2019)'' in its place;
■ a. Removing ''Investigative Policy and Oversight'' and adding ''Administrative Investigations'' in its place;
■ b. Removing ''Suite 11H25'' and adding ''Suite 14L25'' in its place; and
■ b. Removing ''866–429–8011.'' and adding ''866–429–8011. Website: *https://www.dodig.mil/Programs/Contractor-Disclosure-Program/.*'' in its place.

252.203–7004 [Amended]

■ 4. Amend section 252.203–7004 by—
■ a. Removing the clause date ''(MAY 2019)'' and adding ''(AUG 2019)'' in its place; and
■ c. In paragraph (c)(1), removing ''*http://www.dodig.mil/hotline/hotline_posters.htm*'' and adding, ''*https://www.dodig.mil/Resources/Posters-and-Brochures/*'' in its place.

[FR Doc. 2019–16771 Filed 8–8–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 212 and 237

[Docket DARS–2019–0033]

RIN 0750–AJ79

Defense Federal Acquisition Regulation Supplement: Preference for Certain Commercial Services (DFARS Case 2018–D016)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to partially implement a section of the National Defense Authorization Act for Fiscal Year 2017 that provides a preference for the acquisition of certain commercial services in contracts that exceed the simplified acquisition threshold. The statute provides for a two-tier approval process, depending on value of the acquisition, if no commercial items are suitable.

DATES: Effective August 9, 2019.

FOR FURTHER INFORMATION CONTACT: Ms. Amy G. Williams, telephone 571–372–6106.

SUPPLEMENTARY INFORMATION:

I. Background

This final rule partially implements section 876 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2017 (Pub. L. 114–328). Section 876 requires revision of the guidance issued pursuant to section 855 of the NDAA for FY 2016 (Pub. L. 114–92) (final DFARS rule published in the **Federal Register** under DFARS Case 2016–D006 on January 31, 2018 (83 FR 4431)) to provide a preference for certain commercial services, unless the appropriate official determines in writing that no commercial items are suitable to meet the agency's needs. Different approval levels are provided for contracts in excess of $10 million, and contracts that exceed the simplified acquisition threshold but do not exceed $10 million. This rule addresses facilities-related services, knowledge-based services (except engineering services), medical services, and transportation services. Construction services are being addressed under DFARS Case 2019–D034.

II. Discussion and Analysis

The requirements of section 876 have been implemented by adding a new DFARS section 212.272, Preference for certain commercial products and services. A cross-reference to the new section has been added in part 237, Service Contracting, at DFARS 237.102. Also provided in the new DFARS section 212.272, is a cross-reference to the implementation of section 856 of the NDAA for FY 2016 at DFARS 239.101 related to the acquisition of information technology products and services.

III. Publication of This Final Rule for Public Comment Is Not Required by Statute

The statute that applies to the publication of the Federal Acquisition Regulation (FAR) is 41 U.S.C. 1707 entitled ''Publication of Proposed Regulations.'' Paragraph (a)(1) of the statute requires that a procurement policy, regulation, procedure or form (including an amendment or modification thereof) must be published for public comment if it relates to the expenditure of appropriated funds, and has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure or form, or has a significant cost or administrative impact on contractors or offerors. This final rule is not required to be published for public comment, because it only specifies the approval process if acquiring certain noncommercial services. These requirements affect only the internal operating procedures of the Government.

IV. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This final rule does not create any new DFARS provisions or clauses or modify any DFARS existing provision or clauses.

V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

VI. Executive Order 13771

This final rule is not subject to E.O. 13771, because this rule is not a significant regulatory action under E.O. 12866.

VII. Regulatory Flexibility Act

Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under 41 U.S.C. 1707(a)(1) (see section III. of this preamble), the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Accordingly, no regulatory flexibility analysis is required, and none has been prepared.

VIII. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 212 and 237

Government procurement.

Jennifer L. Hawes,

Regulatory Control Officer, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 212 and 237 are amended as follows:

■ 1. The authority citation for 48 CFR parts 212 and 237 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 212—ACQUISITION OF COMMERCIAL ITEMS

■ 2. Add section 212.272 to subpart 212.2 to read as follows:

212.272 Preference for certain commercial products and services.

(a) As required by section 855 of the National Defense Authorization Act for Fiscal Year 2016 (Pub. L. 114–92), for requirements relating to the acquisition of commercial information technology products and services, see 239.101.

(b)(1) As required by section 876 of the National Defense Authorization Act of Fiscal Year 2017 (Pub. L. 114–328), a contracting officer may not enter into a contract above the simplified acquisition threshold for facilities-related services, knowledge-based services (except engineering services), medical services, or transportation services that are not commercial services, unless the appropriate official specified in paragraph (b)(2) of this section determines in writing that no commercial services are suitable to meet the agency's needs as provided in section 10 U.S.C. 2377(c)(2).

(2) The following officials are authorized to make the determination specified in paragraph (b)(1) of this section:

(i) For contracts above $10 million, the head of the contracting activity, the combatant commander of the combatant command concerned, or the Under Secretary of Defense for Acquisition and Sustainment (as applicable).

(ii) For contracts in an amount above the simplified acquisition threshold and at or below $10 million, the contracting officer.

PART 237—SERVICE CONTRACTING

■ 2. Amend section 237.102 by revising paragraph (b) to read as follows:

237.102 Policy.

(b)(1) *Preference for certain commercial services.* See 212.272 for procedures for implementation of the preference for commercial facilities-related services, knowledge-based services (except engineering services), medical services, or transportation services, as required by section 876 of the National Defense Authorization Act for Fiscal Year 2017 (Pub. L. 114–328).

(2) *Public-private competitions.* See PGI 207.302 for information on the Governmentwide moratorium and restrictions on public-private competitions conducted pursuant to Office of Management and Budget (OMB) Circular A–76.

* * * * *

[FR Doc. 2019–16767 Filed 8–8–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 215 and 217

[Docket DARS–2019–0004]

RIN 0750–AJ72

Defense Federal Acquisition Regulation Supplement: Undefinitized Contract Actions (DFARS Case 2018–D008)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement sections of the National Defense Authorization Act for Fiscal Years 2017 and 2018. This rule revises requirements for definitizing undefinitized contract actions.

DATES: Effective August 9, 2019.

FOR FURTHER INFORMATION CONTACT: Ms. Amy G. Williams, telephone 571–372–6106.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 84 FR 4429 on February 15, 2019, to implement section 811 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2017 and section 815 of the NDAA for FY 2018. Section 811 modifies restrictions on undefinitized contractual actions (UCA) regarding risk-based profit, time for definitization, and Foreign Military Sales. Section 815 establishes limitations on unilateral definitizations of UCAs over $50 million. Three respondents provided public comments in response to the proposed rule.

II. Discussion and Analysis

A. Summary of Significant Changes From the Proposed Rule

There are changes to the definition of ''qualifying proposal'' at 217.7401 as a result of public comments. In addition, DoD has delegated some authorities to the head of the contracting activity.

B. Analysis of Public Comments

1. Support for the Rule

Comment: One respondent stated unqualified support for the rule.

Response: Noted.

2. Timely Definitization

Comment: One respondent indicated that the proposed rule impedes the ability of contracting officers to definitize UCAs timely and recommended that the rule be rescinded. The respondent asserted that the application of a higher profit factor after receipt of the qualifying proposal but prior to definitization of the UCA encourages contractors to stall until after the 180-day window has closed, since most contractors are motivated by profit.

Response: This rule modifies the requirements on UCAs related to the calculation of risk-based profit objectives. The language at DFARS 215.404–71–3(d)(2)(i) regarding profit allowed on the contract when a contracting officer definitizes the contract after the end of the 180-day period is consistent with section 811 of the NDAA for FY 2017. However, when definitizing within the 180-day period, the requirement for the contracting officer to assess the extent to which costs have been incurred prior to definitization when determining contract type risk remains unchanged in this rule. When costs have been incurred prior to definitization, DFARS 215.404–71–3(d)(2)(i) states the contracting officer generally regards the contract type risk to be in the low end of the designated range. As such, this rule encourages submission of timely qualifying proposals by contractors and timely definitization by contracting officers.

3. Unilateral Definitization

Comment: One respondent indicated that restricting the authority of a contracting officer to unilaterally definitize a UCA with a value greater than $50 million without the service acquisition executive for the military department approval ensures the UCA will not be definitized within the 180

day window. The respondent also stated that requiring the contracting officer to provide the written approval to the contractor implies that leadership does not trust the contracting officer to be truthful.

Response: The language at DFARS 217.7404(b)(2) and (3) regarding the limitations on unilateral definitization of UCAs over $50 million is a statutory requirement under 10 U.S.C. 2326(c) and is consistent with section 815 of the NDAA for FY 2018. The rule provides greater oversight on UCAs over $50 million in accordance with Congressional intent as set forth in statute.

4. Definition of ''Qualifying Proposal''

Comment: One respondent indicated that their central contention with the proposed rule is the incomplete revision of the definition of ''qualifying proposal'' at DFARS 217.7401(c) to match the statutory revisions of the definition at 10 U.S.C. 2326(g)(2). The respondent also recommended that DoD establish that a proposal submitted in compliance with the Proposal Adequacy Checklist shall be deemed a ''qualifying proposal.''

Response: DoD has revised the definition to conform to the statutory definition as follows: ''Qualifying proposal'' means a proposal that contains sufficient information to enable DoD to conduct meaningful analyses and audits of information contained in the proposal. Although compliance with the proposal adequacy checklist forms a good basis for an adequate proposal, it does not necessarily ensure that the proposal contains sufficient information to enable DoD to conduct meaningful analyses and audits of information contained in the proposal.

C. Other Changes

- At DFARS 217.7401, an editorial change removes paragraph number designations from the definitions.
- At DFARS 217.7402(b), an editorial change updates the titles and address for the Principal Deputy, Defense Pricing and Contracting (Contract Policy).
- At DFARS 217.7404(a), DoD specified the head of the contracting activity as the authority to waive the requirements with regard to entering into a UCA for a foreign military sale.
- At DFARS 217.7404(b)(2), DoD delegated to the head of the contracting activity, without power of redelegation, the authority to approve a unilateral definitization.
- At DFARS 217.7404–3, DoD delegated to the head of the contracting activity, without power of redelegation, the authority to extend the definitization schedule beyond an additional 90 days.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule does not propose to create any new provisions or clauses or impact any existing provisions or clauses.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Executive Order 13771

This rule is not subject to E.O. 13771, because this rule is not a significant regulatory action under E.O. 12866.

VI. Regulatory Flexibility Act

A final regulatory flexibility analysis (FRFA) has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The FRFA is summarized as follows:

DoD is amending the Defense Federal Acquisition Regulation Supplement (DFARS) to modify requirements on undefinitized contract actions (UCAs) regarding calculations of risk-based profit objectives, timing for definitizations, Foreign Military Sales, and limitations on unilateral definitizations of UCAs over $50 million, in accordance with recently enacted statutory requirements. The objective is to implement section 811 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2017, and section 815 of the NDAA for FY 2018.

There were no issues raised by the public in response to the initial regulatory flexibility analysis.

The rule applies to all entities who do business with the Federal Government, including over 327,458 small business registrants in the System for Award Management database. However, DoD does not expect this rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because the rule is primarily implementing internal DoD administrative requirements. With regard to potential profit impacts, DoD estimates that this rule will impact approximately 470 contracts per year, primarily awarded to other than small entities, where definitization is extended beyond 180 days after receipt of a qualifying proposal. This would equate to less than 1/10th of one percent of contracts awarded to small entities.

The rule does not include additional reporting or record keeping requirements.

The rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no available alternatives to the rule to accomplish the desired objective of the statute. We do not expect this rule to have a significant economic impact on a substantial number of small entities because the rule is not implementing any requirements with which small entities must comply.

VII. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 215 and 217

Government procurement.

Jennifer Lee Hawes,

Regulatory Control Officer, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 215 and 217 are amended as follows:

■ 1. The authority citation for 48 CFR parts 215 and 217 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 215—CONTRACTING BY NEGOTIATION

215.404–71–2 [Amended]

■ 2. In section 215.404–71–2 paragraph (e)(2)(iii), remove ''217.7401(c)'' and add ''217.7401'' in its place.

■ 3. In section 215.404–71–3, revise paragraph (d)(2)(i) to read as follows:

215.404–71–3 Contract type risk and working capital adjustment.

* * * * *

(d) * * *

(2) * * *

(i) The contracting officer shall assess the extent to which costs have been incurred prior to definitization of the contract action (also see 217.7404–6(a) and 243.204–70–6). When costs have been incurred prior to definitization, generally regard the contract type risk to be in the low end of the designated range. If a substantial portion of the costs have been incurred prior to definitization, the contracting officer may assign a value as low as zero percent, regardless of contract type. However, if a contractor submits a qualifying proposal to definitize an undefinitized contract action and the contracting officer for such action definitizes the contract after the end of the 180-day period beginning on the date on which the contractor submitted the qualifying proposal (as defined in 217.7401), the profit allowed on the contract shall accurately reflect the cost risk of the contractor as such risk existed on the date the contractor submitted the qualifying proposal.

* * * * *

PART 217—SPECIAL CONTRACTING METHODS

■ 4. Amend section 217.7401 by—

■ a. Removing the alphabetical paragraph designations for each definition and arranging the definitions in alphabetical order;

■ b. In the definition for ''Contract action'', paragraph (3), removing ''Subpart 217.77'' and adding ''subpart 217.77'' in its place; and

■ c. Revising the definition of ''Qualifying proposal'' to read as follows:

217.7401 Definitions.

* * * * *

Qualifying proposal means a proposal that contains sufficient information to enable DoD to conduct meaningful analyses and audits of the information contained in the proposal.

* * * * *

■ 5. Amend section 217.7402 by—

■ a. Removing paragraph (a)(1);

■ b. Redesignating paragraphs (a)(2) through (4) as paragraphs (a)(1) through (3);

■ c. In redesignated paragraphs (a)(1) and (2), removing the semicolons and replacing them with periods; and

■ d. Revising paragraph (b).

The revision reads as follows:

217.7402 Exceptions.

* * * * *

(b) If the contracting officer determines that it is impracticable to adhere to the procedures of this subpart for a particular contract action that falls within one of the categories in paragraph (a)(1), (3), or (4) of this section, the contracting officer shall provide prior notice, through agency channels, electronically via email to the Principal Director, Defense Pricing and Contracting (Contract Policy), at *osd.pentagon.ousd-a-s.mbx.dpc-cp@mail.mil.*

■ 6. Revise section 217.7404 to read as follows:

217.7404 Limitations.

See PGI 217.7404 for additional guidance on obtaining approval to authorize use of an undefinitized contact action, documentation requirements, and other limitations on their use.

(a) *Foreign military sales contracts.*

(1) A contracting officer may not enter into a UCA for a foreign military sale unless—

(i) The UCA provides for agreement upon contractual terms, specifications, and price by the end of the 180-day period beginning on the date on which the contractor submits a qualifying proposal; and

(ii) The contracting officer obtains approval from the head of the contracting activity to enter into a UCA in accordance with 217.7404–1.

(2) The head of the contracting activity may waive the requirements of paragraph (a)(1) of this section, if a waiver is necessary in order to support any of the following operations:

(i) A contingency operation.

(ii) A humanitarian or peacekeeping operation.

(b) *Unilateral definitization by a contracting officer.* Any UCA with a value greater than $50 million may not be unilaterally definitized until—

(1) The earlier of—

(i) The end of the 180-day period, beginning on the date on which the contractor submits a qualifying proposal to definitize the contractual terms, specifications, and price; or

(ii) The date on which the amount of funds expended under the contractual action is equal to more than 50 percent of the negotiated overall not-to-exceed price for the contractual action;

(2) The head of the contracting activity, without power of redelegation, approves the definitization in writing;

(3) The contracting officer provides a copy of the written approval to the contractor; and

(4) A period of 30 calendar days has elapsed after the written approval is provided to the contractor.

■ 7. Amend section 217.7404–3 by revising paragraph (a)(1) to read as follows:

217.7404–3 Definitization schedule.

(a) * * *

(1) The date that is 180 days after the contractor submits a qualifying proposal. This date may not be extended beyond an additional 90 days without a written determination by the head of the contracting activity without power of redelegation, the commander of the combatant command concerned, or the Under Secretary of Defense for Acquisition and Sustainment that it is in the best interests of the military department or the defense agency, the combatant command, or the Department of Defense, respectively, to continue the action; or

* * * * *

217.7404–5 [Amended]

■ 8. Amend section 217.7404–5, paragraph (b) introductory text, by removing ''217.7404–2'' and adding ''217.7404(a), 217.7404–2'' in its place.

■ 9. Amend section 217.7404–6 by–

■ a. Revising paragraph (a); and

■ b. In paragraph (b) removing ''contract;'' and adding ''contract after negotiation of the final price;'' in its place.

The revision reads as follows:

217.7404–6 Allowable profit.

* * * * *

(a) Any reduced cost risk to the contractor for costs incurred during contract performance before negotiation of the final price. However, if a contractor submits a qualifying proposal to definitize a UCA, and the contracting officer for such action definitizes the contract after the end of the 180-day period beginning on the date on which the contractor submitted the qualifying proposal, the profit allowed on the contract shall accurately reflect the cost risk of the contractor as such risk existed on the date the contractor submitted the qualifying proposal;

* * * * *

[FR Doc. 2019–16766 Filed 8–8–19; 8:45 am]

BILLING CODE 6820–ep–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 252

[Docket DARS–2019–0037]

RIN 0750–AK68

Defense Federal Acquisition Regulation Supplement: New World Trade Organization Government Procurement Agreement Country—Australia (DFARS Case 2019–D032)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to add Australia as a new World Trade Organization Government Procurement Agreement (WTO GPA) country.

DATES: Effective August 9, 2019.

FOR FURTHER INFORMATION CONTACT: Ms. Heather Kitchens, telephone 571–372–6104.

SUPPLEMENTARY INFORMATION:

I. Background

On October 17, 2018, the World Trade Organization (WTO) Committee on Government Procurement approved the accession of Australia to the WTO Agreement on Government Procurement (GPA). Australia submitted its instrument of accession to the Secretary-General of the WTO on April 5, 2019. The WTO GPA entered into force for Australia on May 5, 2019. The United States, which is also a party to the WTO GPA, has agreed to waive discriminatory purchasing requirements for eligible products and suppliers of Australia.

The Trade Agreements Act (19 U.S.C. 2501 *et seq.*) provides the authority for the President to waive the Buy American Act and other discriminatory provisions for eligible products from countries that have signed an international trade agreement with the United States (such as the WTO GPA). The President has delegated this authority to the U.S. Trade Representative.

The U.S. Trade Representative has determined that Australia will provide appropriate reciprocal competitive Government procurement opportunities to United States products and services. The U.S. Trade Representative published a notice in the **Federal Register** (84 FR 18110, April 29, 2019) waiving the Buy American Act and other discriminatory provisions for eligible products from Australia.

Therefore, this rule adds Australia to the list of WTO GPA countries wherever it appears in the DFARS, as part of the definition of ''World Trade Organization Government Procurement Agreement Country.''

II. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule does not create any new provisions or clauses or impact any existing provisions or clauses, except for adding ''Australia'' to the definition of ''World Trade Organization Government Procurement Agreement Country'' in the stated DFARS clauses. It does not impact the applicability at or below the simplified acquisition threshold, or applicability to commercial items.

III. Publication of This Final Rule for Public Comment Is Not Required by Statute

The statute that applies to the publication of the Federal Acquisition Regulation (FAR) is 41 U.S.C. 1707 entitled ''Publication of Proposed Regulations.'' Paragraph (a)(1) of the statute requires that a procurement policy, regulation, procedure or form (including an amendment or modification thereof) must be published for public comment if it relates to the expenditure of appropriated funds, and has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure or form, or has a significant cost or administrative impact on contractors or offerors. This final rule is not required to be published for public comment, because it has no significant cost or administrative impact on contractors or offerors. This final rule is just updating the ''World Trade Organization Government Procurement Agreement Country'' lists in order to reflect that Australia is now a member of the WTO GPA to conform to the determination by the U.S. Trade Representative. Australia is already a designated country as it is a ''Free Trade Agreement Country.''

IV. Executive Orders 12866 and 13563

Executive Order (E.O.s) 12866, Regulatory Planning and Review; and E.O. 13563, Improving Regulation and Regulatory Review, direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This is not a major rule under 5 U.S.C. 804.

V. Executive Order 13771

This final rule is not subject to E.O. 13771, because this rule is not a significant regulatory action under E.O. 12866.

VI. Regulatory Flexibility Act

Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under 41 U.S.C. 1707(a)(1) (see section III. of this preamble), the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Accordingly, no regulatory flexibility analysis is required, and none has been prepared.

VII. Paperwork Reduction Act

The Paperwork Reduction Act does apply. However, this rule does not affect the response of an offeror that is offering a product of Australia to the information collection requirements in the provisions at DFARS 252.225–7017, 252.225–7021, and 252.225–7045, currently approved under OMB Control Number 0704–0229, entitled Defense Federal Acquisition Regulation Supplement Part 225, Foreign Acquisition, and related clauses, in accordance with the Paperwork Reduction Act (44 U.S.C. chapter 35). Australia is already a designated country, because it is a Free Trade Agreement country.

List of Subjects in 48 CFR Part 252

Government procurement.

Jennifer Lee Hawes,

Regulatory Control Officer, Defense Acquisition Regulations System.

Therefore, 48 CFR part 252 is amended as follows:

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 1. The authority citation for 48 CFR part 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

252.225–7017 [Amended]

■ 2. Amend section 252.225–7017 by–

■ a. Removing the clause date of ''(DEC 2018)'' and adding ''(AUG 2019)'' in its place; and

■ b. In paragraph (a), in the definition of ''designated country'' in paragraph (1), adding, in alphabetical order, the country of ''Australia''.

252.225–7021 [Amended]

■ 3. Amend section 252.225–7021 by–

■ a. In the basic clause–

■ i. Removing the clause date of ''(DEC 2017)'' and adding ''(AUG 2019)'' in its place;

■ ii. In paragraph (a), in the definition of ''designated country'' in paragraph (i), adding in alphabetical order, the country of ''Australia'';

■ b. In the Alternate II clause–

■ i. Removing the clause date of ''(DEC 2017)'' and adding ''(AUG 2019)'' in its place; and

■ ii. In paragraph (a) in the definition of ''designated country'' in paragraph (i), adding, in alphabetical order, the country of ''Australia''.

252.225–7045 [Amended]

■ 3. Amend section 252.225–7045 by–

■ a. In the basic clause–

■ i. Removing the clause date of ''(SEP 2016)'' and adding ''(AUG 2019)'' in its place;

■ ii. In paragraph (a), in the definition of ''designated country'' in paragraph (i), adding in alphabetical order, the country of ''Australia'';

■ b. In the Alternate I clause–

■ i. Removing the clause date of ''(SEP 2016)'' and adding ''(AUG 2019)'' in its place;

■ ii. In paragraph (a), in the definition of ''designated country'' in paragraph (i), adding, in alphabetical order, the country of ''Australia'';

■ c. In the Alternate II clause–

■ i. Removing the clause date of ''(SEP 2016)'' and adding ''(AUG 2019)'' in its place;

■ ii. In paragraph (a), in the definition of ''designated country'' in paragraph (i), adding, in alphabetical order the country of ''Australia''.

■ d. In the Alternate III clause–

■ i. Removing the clause date of ''(SEP 2016)'' and adding ''(AUG 2019)'' in its place;

■ ii. In paragraph (a), in the definition of ''designated country'' in paragraph (i), adding, in alphabetical order the country of ''Australia''.

* * * * *

[FR Doc. 2019–16772 Filed 8–8–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 180117042–8884–02]

RIN 0648–XT011

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

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

ACTION: Temporary rule; closure of the Harpoon category fishery for 2019.

SUMMARY: NMFS closes the Harpoon category fishery for large medium and giant (*i.e.,* measuring 73 inches curved fork length or greater) Atlantic bluefin tuna (BFT) for the 2019 fishing season and thus until the Harpoon category reopens on June 1, 2020. The intent of this closure is to prevent overharvest of the available Harpoon category BFT quota of 91 metric tons (mt).

DATES: Effective 11:30 p.m., local time, August 8, 2019, through December 31, 2019.

FOR FURTHER INFORMATION CONTACT: Sarah McLaughlin, 978–281–9260, or Larry Redd, 301–420–8503.

SUPPLEMENTARY INFORMATION: Regulations implemented under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) governing the harvest of BFT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 635. Section 635.27 subdivides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) among the various domestic fishing categories, per the allocations established in the 2006 Consolidated Highly Migratory Species Fishery Management Plan (2006 Consolidated HMS FMP) (71 FR 58058, October 2, 2006) and amendments, and in accordance with implementing regulations.

NMFS is required, under § 635.28(a)(1), to file a closure notice with the Office of the Federal Register for publication when a BFT quota (or subquota) is reached or is projected to be reached. On and after the effective date and time of such notification, for the remainder of the fishing year or for a specified period as indicated in the notification, retaining, possessing, or landing BFT under that quota category is prohibited until the opening of the subsequent quota period or until such date as specified in the notice.

The base quota for the Harpoon category is 46 mt. See § 635.27(a). Effective July 18, 2019, NMFS transferred 30 mt from the Reserve category to the Harpoon category, resulting in an adjusted subquota of 76 mt for the Harpoon category and 113 mt for the Reserve category (84 FR 35340, July 23, 2019). Effective August 1, 2019, NMFS transferred an additional 15 mt from the Reserve category to the Harpoon category, resulting in an adjusted subquota of 91 mt for the Harpoon category and 98 mt for the Reserve category (84 FR 38143, August 6, 2019).

Based on the best available landings information for the Harpoon category BFT fishery, NMFS has determined that the adjusted Harpoon category quota of 91 mt is projected to be reached (*i.e.,* as of August 5, reported landings total approximately 83.8 mt) and that the Harpoon category fishery should be closed. Therefore, retaining, possessing, or landing large medium or giant BFT by persons aboard vessels permitted in the Atlantic tunas Harpoon category must cease at 11:30 p.m. local time on August 8, 2019. The Harpoon category will reopen automatically on June 1, 2020, for the 2020 fishing season. This action applies to Atlantic tunas Harpoon category (commercial) permitted and is taken consistent with the regulations at § 635.28(a)(1). The intent of this closure is to prevent overharvest of the available Harpoon category quota.

Monitoring and Reporting

NMFS will continue to monitor the BFT fisheries closely. Dealers are required to submit landing reports within 24 hours of a dealer receiving BFT. Late reporting by dealers compromises NMFS' ability to timely implement actions such as quota and retention limit adjustment, as well as closures, and may result in enforcement actions. Additionally, and separate from the dealer reporting requirement, Harpoon category vessel owners are required to report the catch of all BFT retained or discarded dead within 24 hours of the landing(s) or end of each trip, by accessing *hmspermits.noaa.gov,* using the HMS Catch Reporting app, or calling (888) 872–8862 (Monday through Friday from 8 a.m. until 4:30 p.m.).

Depending on the level of fishing effort and catch rates of BFT, NMFS may determine that additional adjustments are necessary to ensure

available subquotas are not exceeded or to enhance scientific data collection from, and fishing opportunities in, all geographic areas. If needed, subsequent adjustments will be published in the **Federal Register**. In addition, fishermen may call the Atlantic Tunas Information Line at (978) 281–9260, or access *hmspermits.noaa.gov,* for updates on quota monitoring and inseason adjustments.

Classification

The Assistant Administrator for NMFS (AA) finds that it is impracticable and contrary to the public interest to provide prior notice of, and an opportunity for public comment on, this action for the following reasons:

The regulations implementing the 2006 Consolidated HMS FMP and amendments provide for inseason retention limit adjustments and fishery closures to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. This fishery is currently underway and delaying this action would be contrary to the public interest as it could result in BFT landings exceeding the Harpoon category quota. Therefore, the AA finds good cause under 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment. For all of the above reasons, there is good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness.

This action is being taken under § 635.28(a)(1) (BFT fishery closures), and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Jennifer M. Wallace,

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

[FR Doc. 2019–17140 Filed 8–7–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 180713633–9174–02]

0648–XY004

Fisheries of the Exclusive Economic Zone Off Alaska; ''Other Rockfish'' in the Aleutian Islands Subarea of the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting retention of ''other rockfish'' in the Aleutian Islands subarea of the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary because the 2019 ''other rockfish'' total allowable catch (TAC) in the Aleutian Islands subarea of the BSAI has been reached.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), August 6, 2019, through 2400 hours, A.l.t., December 31, 2019.

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

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

The 2019 ''other rockfish'' TAC in the Aleutian Islands subarea of the BSAI is 388 metric tons (mt) as established by the final 2019 and 2020 harvest specifications for groundfish in the BSAI (84 FR 9000, March 13, 2019). In accordance with § 679.20(d)(2), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2019 ''other rockfish'' TAC in the Aleutian Islands subarea of the BSAI has been reached. Therefore, NMFS is requiring that ''other rockfish'' in the Aleutian Islands subarea of the BSAI be treated as prohibited species in accordance with 679.21(b).

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay prohibiting retention of ''other rockfish'' in the Aleutian Islands subarea of the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as August 5, 2019.

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

This action is required by § 679.20 and § 679.21 and is exempt from review under Executive Order 12866.

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

Dated: August 6, 2019.

Jennifer M. Wallace,

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

[FR Doc. 2019–17113 Filed 8–6–19; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 180713633–9174–02]
[RTID 0648–XY005]

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

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting retention of blackspotted/rougheye rockfish in the Western and Central Aleutian Districts of the Bering Sea and Aleutian Islands

management area (BSAI). This action is necessary because the 2019 blackspotted/rougheye rockfish total allowable catch (TAC) in the Western and Central Districts of the BSAI has been reached.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), August 6, 2019, through 2400 hours, A.l.t., December 31, 2019.

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

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

The 2019 blackspotted/rougheye rockfish TAC in the Western and Central Aleutian Districts of the BSAI is 173 metric tons (mt) as established by the final 2019 and 2020 harvest specifications for groundfish in the BSAI (84 FR 9000, March 13, 2019). In accordance with § 679.20(d)(2), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2019 blackspotted/rougheye rockfish TAC in the Western and Central Aleutian Districts of the BSAI has been reached. Therefore, NMFS is requiring that blackspotted/rougheye rockfish in the Western and Central Aleutian Districts of the BSAI be treated as prohibited species in accordance with 679.21(b).

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay prohibiting retention of blackspotted/rougheye rockfish in the Western and Central Aleutian Districts of the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as August 5, 2019.

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

This action is required by § 679.20 and § 679.21 and is exempt from review under Executive Order 12866.

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

Dated: August 6, 2019.

Jennifer M. Wallace,

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

[FR Doc. 2019–17114 Filed 8–6–19; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 84, No. 154
Friday, August 9, 2019

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

DEPARTMENT OF ENERGY

10 CFR Part 430

RIN 1904–AE36

Energy Conservation Program: Test Procedures for Cooking Products

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of proposed rulemaking.

SUMMARY: On April 25, 2018, the U.S. Department of Energy (DOE) published a notification of petition from the Association of Home Appliance Manufacturers (AHAM) to withdraw, and immediately stay the effectiveness of, the conventional cooking top test procedure. Based on the review of public comments and data received in response to this petition, DOE proposes to withdraw the test procedure for conventional cooking tops established under the Energy Policy and Conservation Act (EPCA). DOE has tentatively determined that the conventional cooking top test procedure may not accurately represent consumer use for gas cooking tops, may not be repeatable or reproducible for both gas and electric cooking tops, and is overly burdensome to conduct.

DATES: Written comments and information are requested on or before October 8, 2019. DOE will hold a public meeting on this proposed rule. The details for that public meeting will be provided in a subsequent notice published in the **Federal Register**.

ADDRESSES: Interested persons are encouraged to submit comments, identified by ''[Test Procedure for Cooking Products],'' by any of the following methods:

1. *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

2. *Email: CookProducts2018TP0004@ee.doe.gov.* Include the docket number EERE–2018–BT–TP–0004 and/or RIN 1904–AE36 in the subject line of the message.

3. *Mail:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies.

4. *Hand Delivery/Courier:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW, Suite 600, Washington, DC 20024. Telephone: (202) 586–6636. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

Docket: For access to the docket to read background documents, or comments received, go to the Federal eRulemaking Portal at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Celia Sher, U.S. Department of Energy, Office of the General Counsel, 1000 Independence Avenue SW, Washington, DC 20585. Email: *Celia.Sher@hq.doe.gov;* (202) 287–6122.

SUPPLEMENTARY INFORMATION: DOE intends to include the following industry standards, previously incorporated by reference into 10 CFR part 430:

(1) International Electrotechnical Commission (IEC) Standard 62301, Household electrical appliances—Measurement of standby power,'' Publication 62301 (First Edition 2005–06).

(2) IEC 62301 Household electrical appliances—Measurement of standby power, (Edition 2.0 2011–01).

Copies of IEC 62301 (First Edition) and IEC 62301 (Second Edition) can be obtained from the American National Standards Institute, 25 W 43rd Street, 4th Floor, New York, NY 10036, (212) 642–4900, or go to *http://webstore.ansi.org.*

See Section IV.M. for a further discussion of these standards.

Table of Contents

I. Authority and Background

Kitchen ranges and ovens are included in the list of ''covered products'' for which DOE is authorized to establish and amend energy conservation standards and test procedures. (42 U.S.C. 6292(a)(10)) DOE's regulations at 10 CFR 430.2 include definitions for ''cooking products,'' which cover cooking appliances that use gas, electricity, or microwave energy as the source of heat; as well as specific types of cooking products, including conventional cooking tops, conventional ovens, microwave ovens, and other cooking products. DOE's energy conservation standards and test procedures for cooking products are currently prescribed at 10 CFR 430.32(j) and 10 CFR 430.23(i), respectively. (Note that DOE does not currently have an energy conservation standard for cooktops.) The following sections discuss DOE's authority to establish test procedures for cooking products and relevant background information regarding DOE's consideration to withdraw the test procedures for conventional cooking tops.

A. Authority

Title III, Part B [1] of the Energy Policy and Conservation Act of 1975 (EPCA or the Act), Public Law 94–163 (42 U.S.C. 6291–6309, as codified), established the Energy Conservation Program for Consumer Products Other Than

[1] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

Automobiles,[2] a program covering most major household appliances, which includes cooking products, and specifically conventional cooking tops,[3] the subject of this NOPR. (42 U.S.C. 6292(a)(10))

Under EPCA, DOE's energy conservation program consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of the Act specifically include definitions (42 U.S.C. 6291), test procedures (42 U.S.C. 6293), labeling provisions (42 U.S.C. 6294), energy conservation standards (42 U.S.C. 6295), and the authority to require information and reports from manufacturers (42 U.S.C. 6296).

The Federal testing requirements consist of test procedures that manufacturers of covered products must use as the basis for: (1) Certifying to DOE that their products comply with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6295(s)), and (2) making representations about the efficiency of those consumer products (42 U.S.C. 6293(c)). Similarly, DOE must use these test procedures to determine whether the products comply with relevant standards promulgated under EPCA. (42 U.S.C. 6295(s))

Under 42 U.S.C. 6293, EPCA sets forth the criteria and procedures DOE must follow when prescribing or amending test procedures for covered products. EPCA requires that any test procedures prescribed or amended under this section be reasonably designed to produce test results which measure energy efficiency, energy use or estimated annual operating cost of a covered product during a representative average use cycle or period of use and not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3)) DOE's test procedures for conventional cooking tops are codified at appendix I to subpart B of title 10 of the CFR part 430 (''appendix I'').

B. Background

DOE originally established test procedures for cooking products in a final rule published in the **Federal Register** on May 10, 1978. 43 FR 20108, 20120–20128. DOE revised its test procedures for cooking products to more accurately measure their efficiency and energy use, and published the revisions as a final rule in 1997. 62 FR 51976 (Oct. 3, 1997). These test procedure amendments included: (1) A reduction in the annual useful cooking energy; (2) a reduction in the number of self-clean oven cycles per year; and (3) incorporation of portions of International Electrotechnical Commission (''IEC'') Standard 705–1988, ''Methods for measuring the performance of microwave ovens for household and similar purposes,'' and Amendment 2–1993 for the testing of microwave ovens.[4] The test procedures for consumer cooking products establish provisions for determining estimated annual operating cost, cooking efficiency (defined as the ratio of cooking energy output to cooking energy input), and energy factor (defined as the ratio of annual useful cooking energy output to total annual energy input). 10 CFR 430.23(i); appendix I. Aside from the provisions for measuring standby power of microwave ovens, all other provisions for consumer cooking products are not currently used for compliance with any energy conservation standards because the present standards are design requirements.

DOE subsequently conducted a rulemaking to address standby and off mode energy consumption, as well as certain active mode (*i.e.,* fan-only mode) testing provisions, for consumer cooking products. DOE published a final rule on October 31, 2012 (77 FR 65942, the ''October 2012 TP Final Rule''), adopting standby and off mode provisions that satisfy the EPCA requirement that DOE include measures of standby mode and off mode power in its test procedures for residential products, if technically feasible. (42 U.S.C. 6295(gg)(2)(A))

On January 30, 2013, DOE published a NOPR (78 FR 6232, the ''January 2013 TP NOPR'') proposing amendments to appendix I that would allow for testing the active mode energy consumption of induction cooking products; *i.e.,* conventional cooking tops equipped with induction heating technology for one or more surface units on the cooking top. DOE proposed to incorporate induction cooking tops by amending the definition of ''conventional cooking top'' to include induction heating technology. Furthermore, DOE proposed to require for all cooking tops the use of test equipment compatible with induction technology. Specifically, DOE proposed to replace the solid aluminum test blocks specified at that time in the test procedure for cooking tops with hybrid test blocks comprising two separate pieces: An aluminum body and a stainless steel base. 78 FR 6232, 6234 (Jan. 30, 2013).

On December 3, 2014, DOE published an SNOPR (the ''December 2014 TP SNOPR''), in which DOE modified its proposal from the January 2013 TP NOPR in response to comments from interested parties to specify different test equipment that would allow for measuring the energy efficiency of induction cooking tops, and would include an additional test block size for electric surface units with large diameters (both induction and electric resistance). 79 FR 71894. In addition, DOE proposed methods to test non-circular electric surface units, electric surface units with flexible concentric cooking zones, and full-surface induction cooking tops. *Id.* In the December 2014 TP SNOPR, DOE also proposed amendments to add a larger test block size to test gas cooking top burners with higher input rates. *Id.*

In the December 2014 TP SNOPR, DOE also proposed methods for measuring conventional oven volume, clarification that the existing oven test block must be used to test all ovens regardless of input rate, and a method to measure the energy consumption and efficiency of conventional ovens equipped with an oven separator. 79 FR 71894 (Dec. 3, 2014). DOE published the July 2015 TP Final Rule adopting the test procedure amendments discussed above for conventional ovens only. 80 FR 37954.

On June 10, 2015, DOE published a NOPR (the ''June 2015 NOPR'') proposing new and amended energy conservation standards for consumer conventional ovens. 80 FR 33030. As discussed in the June 2015 NOPR, DOE received a significant number of comments raising issues with the repeatability and reproducibility of the proposed hybrid test block test method for cooking tops in response to the December 2014 TP SNOPR and in separate interviews conducted with consumer cooking product manufacturers in February and March of 2015. 80 FR 33030, 33039–33040 (June 10, 2015). A number of manufacturers that produce and sell products in Europe supported the use of a water-heating test method and harmonization with IEC Standard 60350–2 Edition 2,

[2] All references to EPCA in this document refer to the statute as amended through America's Water Infrastructure Act of 2018, Public Law 115–270 (October 23, 2018).

[3] Conventional cooking top means a class of kitchen ranges and ovens which is a household cooking appliance consisting of a horizontal surface containing one or more surface units which include either a gas flame or electric resistance heating. This includes any conventional cooking top component of a combined cooking product. 10 CFR 430.2.

[4] DOE subsequently withdrew the test procedures for measuring the active mode of microwave ovens in a July 22, 2010 final rule. 75 FR 42579. DOE has adopted test procedure provisions to measure the standby and off mode energy use of microwave ovens. *See* 78 FR 4015.

''Household electric appliances—Part 2: Hobs—Method for measuring performance'' (''IEC Standard 60350–2'') for measuring the energy consumption of electric cooking tops. These manufacturers stated that the test methods in IEC Standard 60350–2 are compatible with all electric cooking top types, specify additional cookware diameters to account for the variety of surface unit sizes on the market, and use test loads that represent real-world cooking top loads. Efficiency advocates also recommended that DOE require water-heating test methods to produce a measure of cooking efficiency for conventional cooking tops that is more representative of actual cooking performance than the hybrid test block method. 80 FR 33030, 33039–33040 (June 10, 2015). For these reasons, DOE decided to defer its decision regarding adoption of energy conservation standards for conventional cooking tops until a representative, repeatable and reproducible test method for cooking tops was finalized. 80 FR 33030, 33040 (June 10, 2015).

DOE published an additional test procedure SNOPR on August 22, 2016 (81 FR 57374) (the ''August 2016 TP SNOPR'') that proposed amendments to the test procedures for conventional cooking tops. Given the feedback from interested parties discussed above and based on the additional testing and analysis conducted for the test procedure rulemaking, in the August 2016 TP SNOPR, DOE withdrew its proposal for testing conventional cooking tops with a hybrid test block. Instead, DOE proposed to amend its test procedure to incorporate by reference the relevant sections of IEC Standard 60350–2, which provide a water-heating test method to measure the energy consumption of electric cooking tops. The test method specifies the quantity of water to be heated in a standardized test vessel whose size is selected based on the diameter of the surface unit under test. 81 FR 57374, 57381–57384.

DOE also proposed to extend the test methods provided in European standard EN 60350–2:2013 ''Household electric cooking appliances Part 2: Hobs—Methods for measuring performance'' EN 60530–2:2013 to measure the energy consumption of gas cooking tops by correlating test equipment diameter to burner input rate, including input rates that exceed 14,000 Btu/h. 81 FR 57374, 57385–57386. In addition, DOE also proposed in the August 2016 TP SNOPR to include methods for both electric and gas cooking tops to calculate the annual energy consumption and the integrated annual energy consumption to account for the proposed water-heating test method. 81 FR 57374, 57387–57388.

In the August 2016 TP SNOPR, DOE proposed to repeal the conventional oven test procedure. DOE determined that the conventional oven test procedure may not accurately represent consumer use, as it favors conventional ovens with low thermal mass and does not capture cooking performance-related benefits due to increased thermal mass of the oven cavity. 81 FR 57374, 57378–57379.

On December 16, 2016, DOE published a final rule (the ''December 2016 TP Final Rule'') repealing the test procedures for conventional ovens for the reasons discussed, and adopting the test procedure amendments for conventional cooking tops proposed in the August 2016 TP SNOPR that, among other things: (1) Incorporated by reference the relevant sections of European Standard EN 60350–2:2013, which uses a water-heating test method to measure the energy consumption of electric cooking tops; (2) extended the water-heating test method specified in EN 60350–2:2013 to gas cooking tops; and (3) clarified that the 20-minute simmering period starts when the water temperature first reaches 90 °C and does not drop below 90 °C for more than 20 seconds after initially reaching 90 °C. 81 FR 91418.

C. AHAM Petition for Reconsideration

The Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.,* provides among other things, that ''[e]ach agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.'' (5 U.S.C. 553(e)) DOE received a petition from AHAM requesting that DOE reconsider its December 2016 TP Final Rule. In its petition, AHAM requested that DOE undertake a rulemaking to withdraw the test procedure for conventional cooking tops, while maintaining the repeal of the oven test procedure that was part of the Final Rule. In the interim, AHAM sought an immediate stay of the effectiveness of the Final Rule, including the requirement that manufacturers use the final test procedure to make energy-related claims. In its petition, AHAM claimed that its analyses showed that the test procedure is not representative for gas cooking tops and, for gas and electric cooking tops, has such a high level of variation it will not produce accurate results for certification and enforcement purposes and will not assist consumers in making purchasing decisions based on energy efficiency. DOE published AHAM's petition on April 25, 2018, and requested comments and information on whether DOE should undertake a rulemaking to consider the proposal contained in the petition. 80 FR 17944.

II. Synopsis of the Notice of Proposed Rulemaking

In this NOPR, DOE proposes to withdraw the test procedure for conventional cooking tops after evaluating new information and data produced by AHAM and other interested parties that suggest the test procedure yields inconsistent results and is unnecessarily burdensome to conduct. The following discussion addresses substantive comments [5] received by DOE on AHAM's petition to withdraw the cooking top test procedure.

III. Discussion

The current test procedure in Appendix I for cooking products measures the integrated annual energy consumption of both gas and electric cooking tops. The integrated annual energy consumption comprises active mode energy consumption of each surface unit on the cooking top, as well as the combined low-power mode energy consumption of the cooking top. In general, to measure the active mode energy consumption of each surface unit, a specified amount of water is heated in a vessel at maximum power (''heat-up'' period) until a threshold temperature is reached, and then the power is turned down such that the water is left to simmer at just above 90 degrees Centigrade (°C) for 20 minutes (''simmering'' period). The active mode energy consumption is the measured energy used during the entire heat-up and simmering periods.

AHAM asserted in its petition that the current test procedure for cooking products is (1) not repeatable or reproducible for both gas and electric cooking tops, (2) is unduly burdensome to conduct, and (3) is not representative for gas cooking tops. In support of its assertions, AHAM submitted results from round-robin testing it conducted and data provided in its petition request. (AHAM, No. 2 at pp. 9, 16, 28, 39) [6]

AHAM asserted in the petition and reiterated in comments that the test procedure is not repeatable nor

[5] DOE received a number of comments that were not relevant to the topic of AHAM's petition. DOE has not addressed these comments, as they are outside the scope of this NOPR.

[6] A notation in the form ''AHAM, No. 2 at pp. 9, 17, 28, 39'' identifies a written comment: (1) Made by AHAM; (2) recorded in document number 2 that is filed in the docket for this rulemaking (Docket No. EERE–2018–BT–TP–0004) and available for review at *www.regulations.gov;* and (3) that appears on pages 9, 17, 28, and 39 of document number 2.

reproducible for gas cooking tops. AHAM's round robin testing of four laboratories showed a level of lab-to-lab variation in the cooking top gas energy consumption among four different cooking top models (3.02%, 3.63%, 9.67%, and 7.99%) that AHAM stated is higher than the acceptable level of variation, which it assumed to be 2 percent. (AHAM, No. 25 at p. 4) AHAM's data showed that a large contributor to this variation was the simmer portion of the test, and AHAM's investigations found that a possible cause is that the gas flow is highly sensitive to the gas burner knob position. (AHAM, No. 25 at p. 5) BSH Home Appliances Corporation (BSH), Whirlpool Corporation (Whirlpool), and GE Appliances (GEA) also commented that determining the simmer setting is difficult. BSH found that four or five trials per burner were necessary to find the correct simmer setting that would keep the water temperature above 90 °C. (BSH, No. 22 at p. 2; Whirlpool, No. 20 at p. 2; GEA, No. 26 at p. 3) GEA found that two to six trials per burner were necessary to find the correct simmer setting. (GEA, No. 26 at p. 3) Whirlpool also commented that it experienced problems with accuracy in determining the turndown temperature, particularly in instances where a technician was performing multiple tasks in the laboratory and not paying strict attention to water temperatures. (Whirlpool, No. 20 at p. 2) AHAM and Whirlpool also commented that DOE did not address pan warpage as a possible factor in repeatability. (AHAM, No. 2 at p. 38; Whirlpool, No. 20 at p. 4)

AHAM asserted in its petition that DOE did not properly conduct a round robin test to ensure the test procedure is reproducible. AHAM commented that DOE only changed testers but used the same laboratory equipment, which AHAM asserted is insufficient for demonstrating reproducibility. (AHAM, No. 2 at p. 17) Whirlpool, BSH, GEA, and Electrolux Home Products (Electrolux) agreed with AHAM's comment regarding DOE's round robin test. (Whirlpool, No. 20 at p. 2; BSH, No. 22 at p. 2; GEA, No. 26 at p. 4; Electrolux, No. 21 at p. 2)

AHAM also asserted in the petition that the current test procedure is not repeatable or reproducible for electric cooking tops. AHAM stated that DOE did not properly evaluate element cycling in electric cooking tops, which could affect the repeatability of the test procedure. (AHAM, No. 2 at p. 34) GEA, Whirlpool, BSH, and Electrolux agreed with this in their comments. (GEA, No. 26 at pp. 3–4; Whirlpool, No. 20 at p. 2; BSH, No. 22 at p. 3; Electrolux, No. 21 at p. 2) Additionally, AHAM noted that new voluntary Underwriters Laboratories (UL) safety standards (UL 858) could require redesigning the element cycling, which could further cause repeatability issues with the test procedure. (AHAM, No. 2 at pp. 36–37) BSH and Electrolux indicated it was unknown at that time how new electric cooking tops would respond due to the new safety standards. (BSH, No. 22 at p. 5; Electrolux, No. 21 at p. 2) Whirlpool indicated design changes to coil elements were required to meet UL 858, which resulted in increased cycling frequency over shorter durations. (Whirlpool, No. 20 at p. 3)

AHAM also asserted in its petition that the test procedure is overly burdensome, and that DOE underestimated the amount of burden imposed by the test procedure. Specifically, AHAM stated that the required test vessels would cost $9,500 per set for each laboratory, and that the laboratory infrastructure would have to be significantly upgraded to maintain the air temperature tolerance of ±2 degrees Fahrenheit (°F),[7] as some current laboratories can only maintain ±5 °F. (AHAM, No. 2 at pp. 20, 42) Felix Storch, Inc. submitted a comment in support of the AHAM petition, and stated that the fixed costs of the test procedure would have a greater impact for small business that produce lower volumes. (Felix Storch, No. 10 at p. 1) BSH and GEA both commented that the test procedure would require substantial improvements to their laboratories to meet these requirements. (BSH, No. 22 at p. 5; GEA, No. 26 at p. 7) Additionally, AHAM reported that testing time for a gas cooking top ranged from 23–26 hours per unit. (AHAM, No. 25 at p. 2) GEA found that the test procedure required 18 hours, on average, to test a four-burner cooking top. (GEA, No. 26 at p. 7)

AHAM also asserted in its petition that the test procedure is not representative for gas cooking tops. It commented that Europe uses a different test standard for gas cooking tops, which differs from the test standard for electric cooking tops, because the simmering and heat-up characteristics vary for different electric cooking top technologies (*e.g.,* coil, smooth-radiant, smooth-induction), whereas there are not different types of gas heating technologies. (AHAM, No. 2 at p. 10) Therefore, according to AHAM, gas cooking top testing does not require a simmer portion in the test. (AHAM, No. 2 at p. 15) Additionally, AHAM asserted that the stainless steel cooking vessels used for electric testing are not appropriate for gas cooking top testing, because stainless steel has a lower level of conduction than aluminum. (AHAM, No. 2 at p. 14) BSH similarly asserted that the cookware used for electric cooking tops would not be representative for gas cooking tops. (BSH, No. 22 at p. 4) AHAM also stated that some burners are optimized for specific cooking purposes, and a water boiling test is not representative of how these burners are actually used. AHAM commented that small burners take 35–37 minutes to reach 90 °C, which is unacceptable for consumers. (AHAM, No. 25 at p. 3) BSH and Electrolux commented that water boiling is not representative of all gas cooking top use. (BSH, No. 22 at p. 4; Electrolux, No. 21 at p. 3)

DOE also received a joint submission from Pacific Gas and Electric Company, San Diego Gas and Electric, and Southern California Edison (California Investor Owned Utilities (CAIOUs)) and a joint submission from Appliance Standards Awareness Project, Consumers Union, National Consumer Law Center, Natural Resources Defense Council, and Northwest Energy Efficiency Alliance (Joint Advocates). The CAIOUs and Joint Advocates stated they are not aware of any information to suggest that consumers actually use gas cooking tops differently from electric cooking tops, and further stated that the test procedure should be aligned between those two products. (CAIOU, No. 15 at p. 2; Joint Advocates, No. 24 at p. 1) The CAIOUs and Joint Advocates support the process DOE went through in developing the test procedure, which they stated was rigorous and which included multiple rounds of comments from stakeholders and appropriate modifications to the test procedure in response to these comments. (CAIOU, No. 15 at p. 1; Joint Advocates, No. 24 at p. 1) The CAIOUs and Joint Advocates also support DOE's original testing and conclusions about repeatability, with the CAIOUs stating that they agree with DOE's data indicating that the coefficient of variation in test results is less than 2.0 percent if the test procedure is followed correctly. (CAIOU, No. 15 at pp. 2, 3; Joint Advocates No. 24 at p. 3) The CAIOUs and Joint Advocates stated that AHAM's round robin testing is different from the actual test procedure, so no conclusion can be drawn from AHAM's data. The CAIOUs and Joint Advocates

[7] The test procedure adopted in the December 2016 TP Final Rule specifies an ambient air temperature tolerance of ±2 °C, which is equivalent to ±3.6 °F.

pointed to round robin testing conducted by the European Committee of Domestic Equipment Manufacturers that DOE evaluated in its rulemaking, with the Joint Advocates suggesting that DOE could conduct its own round robin testing to confirm that the test procedure is repeatable and reproducible. (CAIOU, No. 15 at p. 2; Joint Advocates, No. 24 at pp. 2, 3)

DOE is conducting additional testing, including for gas cooktops, in response to these stakeholder comments. These additional tests will evaluate both test-to-test repeatability and lab-to-lab reproducibility.

To date, DOE has completed testing of ten electric cooking tops to investigate issues raised in AHAM's petition. For a subset of these tests, DOE specifically evaluated repeatability of test results. Table III.1 summarizes the results of testing DOE conducted subsequent to receipt of the AHAM petition in which DOE performed multiple test replications on a single burner (*i.e.* ''surface unit''). Table III.1 indicates that the coefficient of variation for each surface unit's energy consumption was no greater than 2 percent for all the units in the test sample.

TABLE III.1—SUMMARY OF REPEATABILITY TESTS FOR ELECTRIC COOKING TOPS

Cooking top unit	Heating element type	Surface unit location	Number of test replications	Average surface unit test energy consumption *(Wh)*	Coefficient of variation (%)
1	Smooth—Radiant	BL	10	191.7	2.0
2	Smooth—Radiant	BR	4	196.3	1.3
		FL	2	400.6	1.0
3	Smooth—Radiant	FL	2	365.9	0.3
4	Smooth—Induction	FL	2	340.9	1.3
5	Smooth—Induction	BL	3	348.2	0.7

Additionally, DOE examined the specific behavior of electric cooking tops within its test sample that exhibit cycling behavior. For these test units, the control algorithm turns the heating element on and off intermittently during the heat-up period, typically in order to prevent excessive cooking top surface temperatures. Table III.2 summarizes these results for a representative electric cooking top that exhibited varying degrees of cycling behavior during testing.

TABLE III.2—SUMMARY OF CYCLING TESTS ON ELECTRIC COOKING TOP UNIT

Test replication	Cycling speed *	Heat-up energy *(Wh)*
1	Slow	143.3
2	Medium	147.0
3	Fast	147.0
4	Fast	146.2
5	Slow	146.2
6	Slow	144.8
7	Slow	142.7
8	very fast	144.6
9	Fast	145.0
10	medium	146.7
Coefficient of Variation.		1.0%

* The qualitative cycling speed is based on the duty cycle frequency, ranging from around 0.5 cycles/min for ''slow'', to more than 3 cycles/min for ''very fast.''

The results in Table III.2 indicate that the manner in which an electric cooking top surface unit cycled during the heat-up period could vary between tests (*i.e.,* the pattern and frequency of heating element on-off cycles varied).

DOE estimated the time required for performing the test procedure in appendix I. Based on its testing, DOE estimates that a single cooking top surface unit requires around six 90-minute test periods to conduct the complete test procedure, which includes about an hour of cool-down per test period. In total, a cooking top with four surface units requires around 36 work-hours to complete, of which 12 hours require active monitoring by the testing technician.

DOE recognizes that the results of its testing and the results achieved by AHAM show differences have causes yet to be identified. Certainly both sets of tests were conducted by skilled technicians who understand both the product and the test requirements. DOE tentatively determines that existence of these differences suggests that additional investigation of repeatability and reproducibility of the test procedure is warranted. Further, DOE believes that differences in test results are indicative of the test not being representative of energy use or efficiency during an average use cycle. As such, it would be unduly burdensome to subject those manufacturers seeking to make representations as to the efficiency of their products to the requirement to conduct such tests while DOE investigates the issues presented.

Therefore, DOE proposes to withdraw the cooking top test procedure in appendix I to subpart B of part 430. Upon consideration of the comments received, DOE will determine whether to proceed with a final rule to withdraw the test procedure. Because a DOE test method is necessary to develop a performance-based energy conservation standard, if DOE were to ultimately withdraw the test procedure, DOE would need to conduct additional testing and gather additional data to determine any appropriate test procedure for use in developing a subsequent energy conservation standard.

Both the CAIOUs and Joint Advocates asserted that since there is not a performance-based efficiency standard for cooking tops, there is no need to stay the effectiveness of the test procedure. (CAIOU, No. 15 at p. 3; Joint Advocates, No. 24 at pp. 1,4) DOE notes that EPCA requires that a manufacturer making representations of efficiency must use the DOE test procedure, even if there is no standard. Thus, there may be a cost to leaving in place a test procedure that yields inconsistent results and is unnecessarily burdensome to conduct. (42 U.S.C. 6293(c)) Both the CAIOUs and Joint Advocates also stated that the cooking top test procedure is necessary for consumers to make informed purchasing choices relative to energy use and efficiency. (CAIOU, No. 15 at p. 3; Joint Advocates, No. 24 at pp. 1, 4) However, this statement is true only if the test procedure yields accurate results. Multiple commenters have submitted data and information indicating that repeated attempts to follow the test procedure lead to inaccurate results. This suggests that the cooking products test procedure, as conducted by testing laboratories that

may not be familiar with its provisions, does not provide information that is potentially beneficial to consumers.

IV. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866 and 13563

The Office of Management and Budget (OMB) has determined that this NOPR constitutes a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993). Accordingly, this action was subject to review under the Executive Order by the Office of Information and Regulatory Affairs (OIRA) in the OMB.

B. Review Under Executive Orders 13771 and 13777

On January 30, 2017, the President issued Executive Order (E.O.) 13771, ''Reducing Regulation and Controlling Regulatory Costs.'' The E.O. 13771 stated the policy of the executive branch is to be prudent and financially responsible in the expenditure of funds, from both public and private sources. E.O. 13771 stated that it is essential to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations.

Additionally, on February 24, 2017, the President issued E.O. 13777, ''Enforcing the Regulatory Reform Agenda.'' E.O. 13777 required the head of each agency designate an agency official as its Regulatory Reform Officer (RRO). Each RRO oversees the implementation of regulatory reform initiatives and policies to ensure that agencies effectively carry out regulatory reforms, consistent with applicable law. Further, E.O. 13777 requires the establishment of a regulatory task force at each agency. The regulatory task force is required to make recommendations to the agency head regarding the repeal, replacement, or modification of existing regulations, consistent with applicable law. At a minimum, each regulatory reform task force must attempt to identify regulations that:

(i) Eliminate jobs, or inhibit job creation;

(ii) Are outdated, unnecessary, or ineffective;

(iii) Impose costs that exceed benefits;

(iv) Create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies;

(v) Are inconsistent with the requirements of Information Quality Act, or the guidance issued pursuant to that Act, in particular those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility; or

(vi) Derive from or implement Executive Orders or other Presidential directives that have been subsequently rescinded or substantially modified.

DOE initially concludes that this rulemaking, which would repeal the test procedure for cooktops on the basis that it does not meet the EPCA requirement that a test procedure be designed to measure energy use or efficiency during a representative average use cycle or period of use and not be unduly burdensome to conduct, is consistent with the directives set forth in these executive orders. This action is expected to be a deregulatory action consistent with E.O. 13771 because manufacturers wanting to make voluntary representations of energy efficiency would be required to use the test procedure, which DOE has found does not comport with the statutory requirements. Repeal of the test procedure would allow manufacturers making voluntary representations to determine the best way to make such representations, until such time as DOE promulgates, through rulemaking, a new test procedure.

C. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (IRFA) for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's website (*http://energy.gov/gc/office-general-counsel*).

DOE reviewed the proposed withdrawal of the cooking tops test procedure under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003.

DOE uses the Small Business Administration's (SBA) small business size standards to determine whether manufacturers qualify as small businesses, which are listed by the North American Industry Classification System (NAICS). The SBA considers a business entity to be a small business, if, together with its affiliates, it employs less than a threshold number of workers specified in 13 CFR part 121. The 2017 NAICS code for cooking tops is 335210, small electrical appliance manufacturing. The threshold number for NAICS code 335210 is 1,500 employees. This employee threshold includes all employees in a business's parent company and any other subsidiaries.

DOE conducted a focused inquiry into small business manufacturers of products covered by this rulemaking. DOE primarily used the Compliance Certification Database in DOE's Compliance Certification Management System for cooking products to create a list of companies that sell cooking tops. DOE identified a total of 24 distinct companies that sell cooking tops in the United States.

DOE reviewed these companies to determine whether the entities met the SBA's definition of ''small business'' and screened out any companies that do not offer products covered by this rulemaking, do not meet the definition of a ''small business,'' or are foreign-owned and operated. Based on this review, DOE has identified 12 domestic manufacturers of cooking tops that are potential small businesses. Through this analysis, DOE has determined the expected effects of this rulemaking on these covered small businesses and whether an IRFA was needed (*i.e.,* whether DOE could certify that this rulemaking would not have a significant impact).

DOE is proposing to withdraw the cooking tops test procedure for manufacturers. This would not increase manufacturer's testing burden or add any costs to any manufacturers, small or large. Therefore, DOE concludes that the impacts of this proposal would not have a ''significant economic impact on a substantial number of small entities,'' and that the preparation of an IRFA is not warranted. DOE will transmit the certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the Small Business Administration for review under 5 U.S.C. 605(b).

D. Review Under the Paperwork Reduction Act

Manufacturers of cooking tops must certify to DOE that their products comply with any applicable energy conservation standards. In certifying compliance, manufacturers must test their products according to the DOE test procedures for cooking products,

including any amendments adopted for those test procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment. *See generally* 10 CFR part 429. The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This requirement has been approved by OMB under OMB control number 1910–1400. Public reporting burden for the certification is estimated to average 30 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

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

E. Review Under the National Environmental Policy Act of 1969

In this proposed rule, DOE proposes test procedure amendments that it expects will be used to develop and implement future energy conservation standards for cooking products. DOE has determined that this rule falls into a class of actions that are categorically excluded from review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and DOE's implementing regulations at 10 CFR part 1021. Specifically, this proposed rule would revoke the existing test procedures. The existing test procedures are not used for determining compliance with an energy conservation standard and as such, their revocation would not affect the amount, quality or distribution of energy usage, and, therefore, would not result in any environmental impacts. Thus, this rulemaking is covered by Categorical Exclusion A5 under 10 CFR part 1021, subpart D, which applies to any rulemaking that interprets or amends an existing rule without changing the environmental effect of that rule. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

F. Review Under Executive Order 13132

Executive Order 13132, ''Federalism,'' 64 FR 43255 (August 10, 1999), imposes certain requirements on federal agencies formulating and implementing policies or regulations that preempt state law or that have Federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the states and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by state and local officials in the development of regulatory policies that have Federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this proposed rule and has determined that it would not have a substantial direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. EPCA governs and prescribes federal preemption of state regulations as to energy conservation for the products that are the subject of this proposed rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297) Therefore, no further action is required by Executive Order 13132.

G. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' imposes on federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; (3) provide a clear legal standard for affected conduct rather than a general standard; and (4) promote simplification and burden reduction. 61 FR 4729 (Feb. 7, 1996). Regarding the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this proposed rule meets the relevant standards of Executive Order 12988.

H. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each federal agency to assess the effects of federal regulatory actions on state, local, and tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a proposed regulatory action likely to result in a rule that may cause the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a federal agency to develop an effective process to permit timely input by elected officers of state, local, and tribal governments on a proposed ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. DOE's policy statement is also available at *http://energy.gov/gc/office-general-counsel.* DOE examined this proposed rule according to UMRA and its statement of policy and determined that the rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure of $100 million or more in any year, so these requirements do not apply.

I. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This proposed rule would not have any impact on the autonomy or integrity of the family as an institution.

Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

J. Review Under Executive Order 12630

Pursuant to Executive Order 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights,'' 53 FR 8859 (March 15, 1988), DOE has determined that this proposed rule would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

K. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for federal agencies to review most disseminations of information to the public under information quality guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this NOPR under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

L. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires federal agencies to prepare and submit to OMB, a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

This regulatory action to propose the withdrawal of the cooking products test procedure is not a significant regulatory action under Executive Order 12866. Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Therefore, it is not a significant energy action, and, accordingly, DOE has not prepared a Statement of Energy Effects.

M. Description of Materials Incorporated by Reference

In this NOPR, DOE proposes to incorporate by reference the following test standards: (1) IEC 62301, Household electrical appliances—Measurement of standby power,'' Publication 62301 (First Edition 2005–06), section 5; and (2) *IEC 62301* Household electrical appliances—Measurement of standby power, (Edition 2.0 2011–01), sections 4 and 5. These standards include test conditions and testing procedures for measuring the average standby mode and average off mode power consumption of microwaves and were previously incorporated in appendix I.

Copies of IEC 62301 (First Edition) and IEC 62301 (Second Edition) can be obtained from the American National Standards Institute, 25 W 43rd Street, 4th Floor, New York, NY 10036, (212) 642–4900, or go to *http://webstore.ansi.org.*

V. Public Participation

A. Submission of Comments

DOE will accept comments, data, and information regarding this proposed rule before or after the public meeting, but no later than the date provided in the **DATES** section at the beginning of this proposed rule. Interested parties may submit comments, data, and other information using any of the methods described in the **ADDRESSES** section at the beginning of this NOPR.

Submitting comments via *http://www.regulations.gov.* The *http://www.regulations.gov* web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment itself or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Otherwise, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *http://www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as confidential business information or CBI). Comments submitted through *http://www.regulations.gov* cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section below.

DOE processes submissions made through *http://www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *http://www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery/courier, or mail. Comments and documents submitted via email, hand delivery/courier, or mail also will be posted to *http://www.regulations.gov.* If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information in a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via mail or hand delivery/courier, please provide all items on a CD, if feasible, in which case it is not necessary to submit printed copies. No telefacsimiles (faxes) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, that are written in English, and that are free of any defects or viruses.

Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail, or hand delivery/courier two well-marked copies: One copy of the document marked ''confidential'' including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. Submit these documents via email to: *CookProducts2018TP0004@ee.doe.gov* or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include: (1) A description of the items; (2) whether and why such items are customarily treated as confidential within the industry; (3) whether the information is generally known by or available from other sources; (4) whether the information has previously been made available to others without obligation concerning its confidentiality; (5) an explanation of the competitive injury to the submitting person that would result from public disclosure; (6) when such information might lose its confidential character due to the passage of time; and (7) why disclosure of the information would be contrary to the public interest.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

B. Issues on Which DOE Seeks Comment

DOE welcomes comments on any aspect of this proposal, without restriction.

VI. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this notice of proposed rulemaking.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Incorporation by reference, Intergovernmental relations, Small businesses.

Signed in Washington, DC, on: August 1, 2019.

Daniel R Simmons,

Assistant Secretary, Energy Efficiency and Renewable Energy.

For the reasons set forth in the preamble, DOE proposes to amend part 430 of chapter II, subchapter D, of title 10 of the Code of Federal Regulations, as set forth below:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

§ 430.3 [Amended]

■ 2. Section 430.3 is amended by:
■ a. Removing paragraph (l); and
■ b. Redesignating paragraphs (m) through (v) as (l) through (u).
■ 3. Section 430.23 is amended by revising paragraph (i) to read as follows:

§ 430.23 Test procedures for the measurement of energy and water consumption.

* * * * *

(i) *Cooking products.* Determine the standby power for microwave ovens, excluding any microwave oven component of a combined cooking product, according to section 3.2.1 of appendix I to this subpart. Round standby power to the nearest 0.1 watt.

* * * * *

■ 4. Appendix I to subpart B of part 430 is revised to read as follows:

Appendix I to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of Cooking Products

Note: Any representation related to energy or power consumption of cooking products made after June 14, 2017, must be based upon results generated under this test procedure. Upon the compliance date(s) of any energy conservation standard(s) for cooking products, use of the applicable provisions of this test procedure to demonstrate compliance with the energy conservation standard will also be required.

1. Definitions

The following definitions apply to the test procedures in this appendix, including the test procedures incorporated by reference:

1.1 *Active mode* means a mode in which the product is connected to a mains power source, has been activated, and is performing the main function of producing heat by means of a gas flame, electric resistance heating, electric inductive heating, or microwave energy.

1.2 *Built-in* means the product is enclosed in surrounding cabinetry, walls, or other similar structures on at least three sides, and can be supported by surrounding cabinetry or the floor.

1.3 *Combined cooking product* means a household cooking appliance that combines a cooking product with other appliance functionality, which may or may not include another cooking product. Combined cooking products include the following products: Conventional range, microwave/conventional cooking top, microwave/conventional oven, and microwave/conventional range.

1.4 *Drop-in* means the product is supported by horizontal surface cabinetry.

1.5 *IEC 62301 (First Edition)* means the test standard published by the International Electrotechnical Commission, titled ''Household electrical appliances—Measurement of standby power,'' Publication 62301 (First Edition 2005–06) (incorporated by reference; see § 430.3).

1.6 *IEC 62301 (Second Edition)* means the test standard published by the International Electrotechnical Commission, titled ''Household electrical appliances—Measurement of standby power,'' Publication 62301 (Edition 2.0 2011–01) (incorporated by reference; see § 430.3).

1.7 *Normal non-operating temperature* means a temperature of all areas of an appliance to be tested that is within 5 °F (2.8 °C) of the temperature that the identical areas of the same basic model of the appliance would attain if it remained in the test room for 24 hours while not operating with all oven doors closed.

1.8 *Off mode* means any mode in which a cooking product is connected to a mains power source and is not providing any active mode or standby function, and where the mode may persist for an indefinite time. An indicator that only shows the user that the product is in the off position is included within the classification of an off mode.

1.9 *Standby mode* means any mode in which a cooking product is connected to a mains power source and offers one or more of the following user-oriented or protective functions which may persist for an indefinite time:

(1) Facilitation of the activation of other modes (including activation or deactivation of active mode) by remote switch (including remote control), internal sensor, or timer;

(2) Provision of continuous functions, including information or status displays (including clocks) or sensor-based functions. A timer is a continuous clock function (which may or may not be associated with a display) that allows for regularly scheduled tasks and that operates on a continuous basis.

2. Test Conditions

2.1 *Installation.* Install a drop-in or built-in cooking product in a test enclosure in accordance with manufacturer's instructions. If the manufacturer's instructions specify that

the cooking product may be used in multiple installation conditions, install the appliance according to the built-in configuration. Completely assemble the product with all handles, knobs, guards, and similar components mounted in place. Position any electric resistance heaters and baffles in accordance with the manufacturer's instructions.

2.1.1 *Microwave ovens, excluding any microwave oven component of a combined cooking product.* Install the microwave oven in accordance with the manufacturer's instructions and connect to an electrical supply circuit with voltage as specified in section 2.2.1 of this appendix. Install the microwave oven also in accordance with Section 5, Paragraph 5.2 of IEC 62301 (Second Edition) (incorporated by reference; see § 430.3), disregarding the provisions regarding batteries and the determination, classification, and testing of relevant modes. A watt meter shall be installed in the circuit and shall be as described in section 2.6.1.1 of this appendix.

2.2 *Energy supply.*

2.2.1 *Electrical supply.*

2.2.1.1 *Voltage.* For microwave oven testing, maintain the electrical supply to the unit at 240/120 volts ±1 percent. Maintain the electrical supply frequency for all products at 60 hertz ±1 percent.

2.3 *Air circulation.* Maintain air circulation in the room sufficient to secure a reasonably uniform temperature distribution, but do not cause a direct draft on the unit under test.

2.4 *Ambient room test conditions*

2.4.1 *Standby mode and off mode ambient temperature.* For standby mode and off mode testing, maintain room ambient air temperature conditions as specified in Section 4, Paragraph 4.2 of IEC 62301 (Second Edition) (incorporated by reference; see § 430.3).

2.5 *Normal non-operating temperature.* All areas of the appliance to be tested must attain the normal non-operating temperature, as defined in section 1.7 of this appendix, before any testing begins. Measure the applicable normal non-operating temperature using the equipment specified in sections 2.6.2.1 of this appendix.

2.6 *Instrumentation.* Perform all test measurements using the following instruments, as appropriate:

2.6.1 *Electrical measurements.*

2.6.1.1 *Standby mode and off mode watt meter.* The watt meter used to measure standby mode and off mode power must meet the requirements specified in Section 4, Paragraph 4.4 of IEC 62301 (Second Edition) (incorporated by reference; see § 430.3). For microwave oven standby mode and off mode testing, if the power measuring instrument used for testing is unable to measure and record the crest factor, power factor, or maximum current ratio during the test measurement period, measure the crest factor, power factor, and maximum current ratio immediately before and after the test measurement period to determine whether these characteristics meet the requirements specified in Section 4, Paragraph 4.4 of IEC 62301 (Second Edition).

2.6.2 *Temperature measurement equipment.*

2.6.2.1 *Room temperature indicating system.* For the test of microwave ovens, the room temperature indicating system must have an error no greater than ±1 °F (±0.6 °C) over the range 65° to 90 °F (18 °C to 32 °C).

3. Test Methods and Measurements

3.1. *Test methods.*

3.1.1 *Microwave oven.*

3.1.1.1 *Microwave oven test standby mode and off mode power except for any microwave oven component of a combined cooking product.* Establish the testing conditions set forth in section 2, Test Conditions, of this appendix. For microwave ovens that drop from a higher power state to a lower power state as discussed in Section 5, Paragraph 5.1, Note 1 of IEC 62301 (Second Edition) (incorporated by reference; see § 430.3), allow sufficient time for the microwave oven to reach the lower power state before proceeding with the test measurement. Follow the test procedure as specified in Section 5, Paragraph 5.3.2 of IEC 62301 (Second Edition). For units in which power varies as a function of displayed time in standby mode, set the clock time to 3:23 and use the average power approach described in Section 5, Paragraph 5.3.2(a) of IEC 62301 (First Edition), but with a single test period of 10 minutes +0/−2 sec after an additional stabilization period until the clock time reaches 3:33. If a microwave oven is capable of operation in either standby mode or off mode, as defined in sections 1.9 and 1.8 of this appendix, respectively, or both, test the microwave oven in each mode in which it can operate.

3.2 *Test measurements.*

3.2.1 *Microwave oven standby mode and off mode power except for any microwave oven component of a combined cooking product.* Make measurements as specified in Section 5, Paragraph 5.3 of IEC 62301 (Second Edition) (incorporated by reference; see § 430.3). If the microwave oven is capable of operating in standby mode, as defined in section 1.9 of this appendix, measure the average standby mode power of the microwave oven, PSB, in watts as specified in section 3.1.1.1 of this appendix. If the microwave oven is capable of operating in off mode, as defined in section 1.8 of this appendix, measure the average off mode power of the microwave oven, POM, as specified in section 3.1.1.1.

3.3 *Recorded values.*

3.3.1 For microwave ovens except for any microwave oven component of a combined cooking product, record the average standby mode power, PSB, for the microwave oven standby mode, as determined in section 3.2.1 of this appendix for a microwave oven capable of operating in standby mode. Record the average off mode power, POM, for the microwave oven off mode power test, as determined in section 3.2.1 of this appendix for a microwave oven capable of operating in off mode.

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DEPARTMENT OF ENERGY

10 CFR Part 431

[EERE–2017–BT–STD–0021]

RIN 1904–AD90

Energy Conservation Program: Energy Conservation Standards for Unfired Hot Water Storage Tanks

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Request for information.

SUMMARY: The U.S. Department of Energy (''DOE'') is initiating an effort to determine whether to amend the current uniform national standard for unfired hot water storage tanks (''UFHWSTs''). Under the Energy Policy and Conservation Act of 1975, as amended, DOE must review this standard at least once every six years and publish either a notice of proposed rulemaking (''NOPR'') to propose an amended standard (or standards) for UFHWSTs or a notice of determination that the existing standard does not need to be amended. This request for information (''RFI'') seeks to solicit information from the public to help DOE determine whether an amended standard for UFHWSTs would result a significant energy savings and whether such a standard would be technologically feasible and economically justified. DOE welcomes written comments from the public on any subject within the scope of this document (including topics not raised in this RFI).

DATES: Written comments and information are requested and will be accepted on or before September 23, 2019.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2017–BT–STD–0021, by any of the following methods:

1. *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

2. *Email: UnfiredCommercialWH2017STD0021@ee.doe.gov.* Include the docket number EERE–2017–BT–STD–0021 in the subject line of the message.

3. *Postal Mail:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121.

Telephone: (202) 287–1445. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies.

4. *Hand Delivery/Courier:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW, 6th Floor, Washington, DC 20024. Telephone: (202) 287–1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimilies (faxes) will be accepted. For detailed instructions on submitting comments and additional information on this process, see section III of this document.

Docket: The docket for this activity, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at *http://www.regulations.gov.* All documents in the docket are listed in the *http://www.regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket web page can be found at: *http://www.regulations.gov/#!docketDetail;D=EERE-2017-BT-STD-0021.* The docket web page contains instructions on how to access all documents, including public comments, in the docket. See section III of this document for information on how to submit comments through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

Ms. Catherine Rivest, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–7335. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Mr. Eric Stas, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–5827. Email: *Eric.Stas@hq.doe.gov.*

For further information on how to submit a comment or review other public comments and the docket, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

SUPPLEMENTARY INFORMATION:

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I. Introduction

A. Authority and Background

The Energy Policy and Conservation Act of 1975, as amended (''EPCA''),[1] Public Law 94–163 (42 U.S.C. 6291–6317, as codified), among other things, authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. Title III, Part C[2] of EPCA, added by Public Law 95–619, Title IV, § 441(a), established the Energy Conservation Program for Certain Industrial Equipment, which sets forth a variety of provisions designed to improve energy efficiency. This equipment includes UFHWSTs, the subject of this RFI. (42 U.S.C. 6311(1)(K)) EPCA prescribed initial standards for this equipment. (42 U.S.C. 6313(a)(5)(F)–(G))

Under EPCA, DOE's energy conservation program consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA specifically include definitions (42 U.S.C. 6311), energy conservation standards (42 U.S.C. 6313), test procedures (42 U.S.C. 6314), labeling provisions (42 U.S.C. 6315), and the authority to require information and reports from manufacturers (42 U.S.C. 6316).

Federal energy efficiency requirements for covered equipment established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (See 42 U.S.C. 6316(a) and (b); 42 U.S.C. 6297) DOE may, however, grant waivers of Federal preemption in limited instances for particular State laws or regulations, in accordance with the procedures and other provisions set forth under 42 U.S.C. 6316(b)(2)(D).

EPCA contains mandatory standards for commercial heating, air-conditioning, and water-heating equipment. (42 U.S.C. 6313(a)) Specifically, the statute sets standards for small, large, and very large commercial package air-conditioning and heating equipment, packaged terminal air conditioners (PTACs) and packaged terminal heat pumps (PTHPs), warm-air furnaces, packaged boilers, storage water heaters, instantaneous water heaters, and unfired hot water storage tanks (collectively referred to as ''covered ASHRAE equipment''). *Id.* In doing so, EPCA established standards that generally correspond to the efficiency levels in the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) Standard 90.1, ''Energy Standard for Buildings Except Low-Rise Residential Buildings,'' as in effect on October 24, 1992 (*i.e.,* ASHRAE Standard 90.1–1989), for each type of covered equipment listed in 42 U.S.C. 6313(a).

In acknowledgement of technological changes that yield energy efficiency benefits, Congress further directed DOE through EPCA to consider amending the existing Federal standard for each type of equipment listed, each time ASHRAE Standard 90.1 is amended with respect to such equipment. (42 U.S.C. 6313(a)(6)(A)) If ASHRAE Standard 90.1 is amended with respect to the standard levels or design requirements applicable under that standard to any covered ASHRAE equipment, not later than 180 days after the amendment of the standard, DOE must publish in the **Federal Register** for public comment an analysis of the energy savings potential of amended energy efficiency standards. (42 U.S.C. 6313(a)(6)(A)(i)) For each type of equipment, EPCA directs that if ASHRAE Standard 90.1 is amended, DOE must adopt amended energy conservation standards at the new efficiency level in ASHRAE Standard

[1] All references to EPCA in this document refer to the statute as amended through America's Water Infrastructure Act of 2018, Public Law 115–270 (Oct. 23, 2018).

[2] For editorial reasons, upon codification in the U.S. Code, Part C was redesignated Part A–1.

90.1, unless clear and convincing evidence supports a determination that adoption of a more-stringent efficiency level as a national standard would produce significant additional energy savings and be technologically feasible and economically justified.[3] (42 U.S.C. 6313(a)(6)(A)(ii)) If DOE decides to adopt as a national standard the efficiency levels specified in the amended ASHRAE Standard 90.1, DOE must establish such standard not later than 18 months after publication of the amended industry standard. (42 U.S.C. 6313(a)(6)(A)(ii)(I)) If DOE determines that a more-stringent standard is appropriate under the statutory criteria, DOE must establish such more-stringent standard not later than 30 months after publication of the revised ASHRAE Standard 90.1. (42 U.S.C. 6313(a)(6)(A)(ii)(II) and (B))

Although EPCA does not explicitly define the term ''amended'' in the context of what type of revision to ASHRAE Standard 90.1 would trigger DOE's obligation, DOE's longstanding interpretation has been that the statutory trigger is an amendment to the standard applicable to that equipment under ASHRAE Standard 90.1 that increases the energy efficiency level for that equipment. *See* 72 FR 10038, 10042 (March 7, 2007). In other words, if the revised ASHRAE Standard 90.1 leaves the energy efficiency level unchanged (or lowers the energy efficiency level), as compared to the energy efficiency level specified by the uniform national standard adopted pursuant to EPCA, regardless of the other amendments made to the ASHRAE Standard 90.1 requirement (*e.g.,* the inclusion of an additional metric), DOE has stated that it does not have the authority to conduct a rulemaking to consider a higher standard for that equipment pursuant to 42 U.S.C. 6313(a)(6)(A). *See* 74 FR 36312, 36313 (July 22, 2009) and 77 FR 28928, 28937 (May 16, 2012). However, DOE notes that Congress adopted amendments to these provisions related to ASHRAE Standard 90.1 equipment under the American Energy Manufacturing Technical Corrections Act (Pub. L. 112–210 (Dec. 18, 2012); ''AEMTCA''). In relevant part, DOE is prompted to act whenever ASHRAE Standard 90.1 is amended with respect to ''the standard levels or design requirements applicable under that standard'' to any of the enumerated types of commercial air conditioning, heating, or water heating equipment. (42 U.S.C. 6313(a)(6)(A)(i))

EPCA does not detail the exact type of amendment that serves as a triggering event. However, DOE has considered whether its obligation is triggered in the context of whether the specific ASHRAE Standard 90.1 requirement on which the most current Federal requirement is based is amended (*i.e.,* the regulatory metric). For example, if an amendment to ASHRAE Standard 90.1 changed the metric for the standard on which the Federal requirement was based, DOE would perform a crosswalk analysis to determine whether the amended metric under ASHRAE Standard 90.1 resulted in an energy efficiency level that was more stringent than the current DOE standard. Conversely, if an amendment to ASHRAE Standard 90.1 were to add an additional metric by which a class of equipment is to be evaluated, but did not amend the requirement that is in terms of the metric on which the Federal requirement was based, DOE would not consider its obligation triggered.[4]

In addition, DOE has explained that its authority to adopt an ASHRAE amendment is limited based on the definition of ''energy conservation standard.'' 74 FR 36312, 36322 (July 22, 2009). In general, an ''energy conservation standard'' is limited, per the statutory definition, to either a performance standard *or* a design requirement. (42 U.S.C. 6311(18)) Informed by the ''energy conservation standard'' definition, DOE has stated that adoption of an amendment to ASHRAE Standard 90.1 ''that establishes both a performance standard and a design requirement is beyond the scope of DOE's legal authority, as would be a standard that included more than one design requirement.'' 74 FR 36312, 36322 (July 22, 2009).

As noted, the ASHRAE Standard 90.1 provision in EPCA acknowledges technological changes that yield energy efficiency benefits, as well as continuing development of industry standards and test methods. Amendments to a uniform national standard provide Federal requirements that continue to reflect energy efficiency improvements identified by industry. Amendments to a uniform national standard that reflect the relevant amended versions of ASHRAE Standard 90.1 would also help reduce compliance and test burdens on manufacturers by harmonizing the Federal requirements, when appropriate, with industry best practices. This harmonization would be further facilitated by establishing not only consistent energy efficiency levels and design requirements between ASHRAE Standard 90.1 and the Federal requirements, but comparable metrics as well.

As stated previously, DOE has limited its review under the ASHRAE Standard 90.1 provisions in EPCA to the equipment class that was subject to the ASHRAE Standard 90.1 amendment. DOE has stated that if ASHRAE has not amended a standard for an equipment class subject to 42 U.S.C. 6313, there is no change that would require action by DOE to consider amending the uniform national standard to maintain consistency with ASHRAE Standard 90.1. See, 72 FR 10038, 10042 (March 7, 2007); 77 FR 36312, 36320–36321 (July 22, 2009); 80 FR 42614, 42617 (July 17, 2015).

In those situations where ASHRAE has not acted to amend the levels in Standard 90.1 for the equipment types enumerated in the statute, EPCA also provides for a 6-year-lookback to consider the potential for amending the uniform national standards. (42 U.S.C. 6313(a)(6)(C)) Specifically, pursuant to the amendments to EPCA under AEMTCA, DOE is required to conduct an evaluation of each class of covered equipment in ASHRAE Standard 90.1 ''every 6 years'' to determine whether the applicable energy conservation standards need to be amended. (42 U.S.C. 6313(a)(6)(C)(i)) DOE must publish either a notice of proposed rulemaking (NOPR) to propose amended standards or a notice of determination that existing standards do not need to be amended. (42 U.S.C. 6313(a)(6)(C)) In

[3] In determining whether a more-stringent standard is economically justified, EPCA directs DOE to determine, after receiving views and comments from the public, whether the benefits of the proposed standard exceed the burdens of the proposed standard by, to the maximum extent practicable, considering the following:

(1) The economic impact of the standard on the manufacturers and consumers of the products subject to the standard;

(2) The savings in operating costs throughout the estimated average life of the product compared to any increases in the initial cost or maintenance expense;

(3) The total projected amount of energy savings likely to result directly from the standard;

(4) Any lessening of the utility or the performance of the products likely to result from the standard;

(5) The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the standard;

(6) The need for national energy conservation; and

(7) Other factors the Secretary considers relevant. (42 U.S.C. 6313(a)(6)(B)(ii))

[4] See the May 16, 2012, final rule for small, large, and very large water-cooled and evaporatively-cooled commercial package air conditioners, and VRF water-source heat pumps with cooling capacity less than 17,000 Btu/h, in which DOE states that ''if the revised ASHRAE Standard 90.1 leaves the standard level unchanged or lowers the standard, *as compared to the level specified by the national standard adopted pursuant to EPCA,* DOE does not have the authority to conduct a rulemaking to consider a higher standard for that equipment pursuant to 42 U.S.C. 6313(a)(6)(A). 77 FR 28928, 28929 (emphasis added). See also, 74 FR 36312, 36313 (July 22, 2009).

proposing new standards under the 6-year review, DOE must undertake the same considerations as if it were adopting a standard that is more stringent than an amendment to ASHRAE Standard 90.1. (42 U.S.C. 6313(a)(6)(C)(i)(II)) This is a separate statutory review obligation, as differentiated from the obligation triggered by an ASHRAE Standard 90.1 amendment. While the statute continues to defer to ASHRAE's lead on covered equipment subject to Standard 90.1, it does allow for a comprehensive review of all such equipment and the potential for adopting more-stringent standards, where supported by the requisite clear and convincing evidence. That is, DOE interprets ASHRAE's not amending Standard 90.1 with respect to a product or equipment type as ASHRAE's determination that the standard applicable to that product or equipment type is already at an appropriate level of stringency, and DOE will not amend that standard unless there is clear and convincing evidence that a more-stringent level is justified.

As discussed in the paragraphs immediately below, the standard for unfired hot water storage tanks in ASHRAE Standard 90.1 was last updated in October 1999. However, as noted previously, EPCA requires DOE to evaluate the applicable energy conservation standard for unfired hot water storage tanks every 6 years to determine whether it needs to be amended. (42 U.S.C. 6313(a)(6)(C)(i)) Thus, DOE is publishing this RFI to collect data and information to inform its decision consistent with its obligations under EPCA.

As noted previously, the initial Federal standards for UFHWSTs, established by EPCA, corresponded to the efficiency levels contained in the ASHRAE Standard 90.1–1989. On January 12, 2001, DOE amended the standards for UFHWSTs to be equivalent to the efficiency level in ASHRAE Standard 90.1 as revised in October 1999. 66 FR 3336 (''January 2001 final rule''). The January 2001 final rule established an insulation design requirement of a minimum R-value [5] of R–12.5. 66 FR 3336, 3356. This remains the current Federal standard (and the standard level specified in the most recent version of ASHRAE Standard 90.1). The current standard is located in title 10 of the Code of Federal Regulations (''CFR'') part 431, section 110 (10 CFR 431.110). DOE does not prescribe a test procedure for UFHWSTs; however, DOE's regulations define ''R-value,'' in part, as being determined using either ASTM International (''ASTM'') C177–13, ''Standard Test Method for Steady-State Heat Flux Measurements and Thermal Transmission Properties by Means of the Guarded-Hot-Plate Apparatus,'' or ASTM C518–15, ''Standard Test Method for Steady-State Thermal Transmission Properties by Means of the Heat Flow Meter Apparatus.'' 10 CFR 431.102

B. Rulemaking Process

DOE must follow specific statutory criteria for prescribing amended standards for certain covered equipment. EPCA requires that any amended uniform national standard result in significant additional conservation of energy and be technologically feasible and economically justified. (42 U.S.C. 6313(a)(6)(C)(i)(II) and (B)) To determine whether a standard is economically justified, EPCA requires that DOE determine whether the benefits of the standard exceed its burdens by considering, to the maximum extent practicable, the following seven factors:

(1) The economic impact of the standard on manufacturers and consumers of the affected equipment subject to the standard;

(2) The savings in operating costs throughout the estimated average life of the covered equipment in the type (or class) compared to any increase in the prices, initial charges, or maintenance expenses for the covered equipment likely to result from the standard;

(3) The total projected amount of energy savings likely to result directly from the standard;

(4) Any lessening of the utility or the performance of the covered equipment likely to result from the standard;

(5) The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the standard;

(6) The need for national energy conservation; and

(7) Other factors the Secretary of Energy (Secretary) considers relevant.

(42 U.S.C. 6313(a)(6)(B)(ii)(I)–(VII))

DOE fulfills these and other applicable requirements by conducting a series of analyses throughout the rulemaking process. Table I.1 shows the individual analyses that are performed to satisfy each of the requirements within EPCA.

TABLE I.1—EPCA REQUIREMENTS AND CORRESPONDING DOE ANALYSIS

EPCA requirement	Corresponding DOE analysis
Significant Energy Savings	• Energy and Water Use Determination. • Shipments Analysis. • National Impact Analysis.
Technological Feasibility	• Market and Technology Assessment. • Screening Analysis. • Engineering Analysis.
Economic Justification:	
1. Economic impact on manufacturers and consumers	• Manufacturer Impact Analysis. • Life-Cycle Cost and Payback Period Analysis. • Life-Cycle Cost Subgroup Analysis. • Shipments Analysis.
2. Lifetime operating cost savings compared to increased cost for the equipment.	• Mark-ups for Product Price Determination. • Energy and Water Use Determination. • Life-Cycle Cost and Payback Period Analysis.
3. Total projected energy savings	• Shipments Analysis. • National Impact Analysis.
4. Impact on utility or performance	• Screening Analysis. • Engineering Analysis.
5. Impact of any lessening of competition	• Manufacturer Impact Analysis.

[5] DOE defines ''R-value'' as the thermal resistance of insulating material as determined using ASTM C177–13 or C518–15 and expressed in (°F·ft²·h/Btu). 10 CFR 431.102.

TABLE I.1—EPCA REQUIREMENTS AND CORRESPONDING DOE ANALYSIS—Continued

EPCA requirement	Corresponding DOE analysis
6. Need for national energy and water conservation 7. Other factors the Secretary considers relevant	• Shipments Analysis. • National Impact Analysis. • Employment Impact Analysis. • Utility Impact Analysis. • Emissions Analysis. • Monetization of Emission Reductions Benefits. • Regulatory Impact Analysis.

As detailed throughout this RFI, DOE is publishing this document seeking input and data from interested parties to aid in the development of the technical analyses on which DOE will ultimately rely to determine whether (and if so, how) to amend the standards for UFHWSTs.

II. Request for Information and Comments

In the following sections, DOE has identified a variety of issues on which it seeks input to aid in the development of the technical and economic analyses regarding whether an amended uniform national standard for UFHWSTs may be warranted. Additionally, DOE welcomes comments on other issues relevant to this request for information that may not specifically be identified in this document. In particular, DOE notes that under Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs,'' Executive Branch agencies such as DOE are directed to manage the costs associated with the imposition of expenditures required to comply with Federal regulations. See 82 FR 9339 (Feb. 3, 2017). Pursuant to that Executive Order, DOE encourages the public to provide input on measures DOE could take to lower the cost of its energy conservation standards rulemakings, recordkeeping and reporting requirements, and compliance and certification requirements applicable to UFHWSTs while remaining consistent with the requirements of EPCA.

A. Equipment Covered by This Process

This RFI covers equipment that meets the definition for ''unfired hot water storage tank,'' as codified at 10 CFR 431.102.[6] The definition for ''unfired hot water storage tank'' was most recently amended in a 2004 test procedure final rule for commercial water heating (CWH) equipment. 69 FR 61974 (Oct. 21, 2004). Specifically, DOE's regulations define ''unfired hot water storage tank'' as a tank used to store water that is heated externally, and that is industrial equipment. 10 CFR 431.102. UFHWSTs do not use energy (*i.e.,* UFHWSTs do not directly consume electricity or fossil fuel). (42 U.S.C. 6311(4)) Instead, the hot water stored by a UFHWST is supplied by a water heater or boiler that is paired with the UFHWST. Heat loss that occurs in a UFHWST does impact the energy consumption of the paired water heater or boiler.

Neither EPCA nor DOE's regulations include any storage volume criteria for UFHWSTs. Accordingly, UFHWSTs, regardless of storage volume, are subject to the current standard.

Issue A.1 DOE seeks comment on whether, in the context of its consideration of more-stringent standards, there have been sufficient technological or market changes for UFHWSTs since the most recent standards update that may justify a new rulemaking to consider more-stringent standards. Specifically, DOE seeks data and information that could enable the agency to determine whether DOE should propose a ''no new standard'' determination because a more-stringent standard: (1) Would not result in significant additional savings of energy; (2) is not technologically feasible; (3) is not economically justified; or (4) any combination of the foregoing.

Issue A.2 DOE requests comment on whether the definition for UFHWSTs requires any revisions—and if so, how the definition should be revised. DOE also requests feedback on whether any sub-category definitions should be added, and if so, DOE seeks specific input on what terms would be needed and how to define these terms.

Issue A.3 DOE requests comment on whether additional product definitions are necessary to close any potential gaps in coverage between product types. DOE also seeks input on whether such products currently exist in the market or whether they are being planned for introduction.

B. Market and Technology Assessment

The market and technology assessment that DOE routinely conducts when analyzing the impacts of a potential new or amended standard provides information about the UFHWST industry that will be used in DOE's analysis throughout the rulemaking process. DOE uses qualitative and quantitative information to assess the past and present industry structure and market characteristics. DOE identifies manufacturers, estimates market shares and trends, addresses regulatory and non-regulatory initiatives intended to improve energy efficiency or reduce energy consumption, and explores the potential for efficiency improvements in the design and manufacturing of UFHWSTs. To this end, DOE reviews product literature, industry publications, and company websites. Additionally, DOE considers conducting interviews with manufacturers to improve its assessment of the market and available technologies for UFHWSTs.

1. Equipment Classes

When evaluating and establishing energy conservation standards, DOE may divide covered equipment into equipment classes by the type of energy used, or by capacity or other performance-related features that justify a different standard. In making a determination whether capacity or other performance-related feature justifies a different standard, DOE must consider such factors as the utility of the feature to the consumer and other factors DOE deems appropriate.

For UFHWSTs, the current standard at 10 CFR 431.110 is applicable to a single equipment class covering all UFHWSTs.

Issue B.1 DOE requests feedback on whether any division of UFHWSTs into separate equipment classes is warranted, and whether it would impact equipment utility by eliminating any performance-related features or reduce any compliance burdens.

2. Technology Assessment

In analyzing the feasibility of potential new or amended energy conservation standards, DOE uses information about existing and past

[6] The statute defines ''unfired hot water storage tank'' as a tank used to store water that is heated externally. (42 U.S.C. 6311(12)(C))

technology options and prototype designs to help identify technologies that manufacturers could use to meet and/or exceed a given set of standards under consideration. In consultation with interested parties, DOE intends to develop a list of technologies to consider in its analysis. DOE's current standard for UFHWSTs is a prescriptive requirement for minimum tank insulation R-value. Therefore, only technology options that improve tank insulation R-value would be applicable for analyzing more-stringent tank insulation R-value requirements. However, DOE also seeks input on other technologies that can reduce heat loss of UFHWSTs, including those that do not improve R-value.

As described in section II.C of this RFI, some technologies may be removed from consideration during a subsequent screening analysis. The resulting list of technologies that are considered by DOE would be used to establish the maximum technologically feasible design. DOE conducted preliminary market research by examining manufacturer equipment literature and public technical literature (*e.g.,* reports, journal articles, or presentations) which identified the specific technology options listed subsequently. DOE will consider these technologies along with any others identified during the analysis following the RFI, and the rulemaking process should it determine that a rulemaking is necessary.

- Improved insulation R-value
  - Increased insulation thickness
  - Foam insulation
  - Advanced insulation types
    - Aerogel
    - Vacuum panels
    - Inert gas-filled panels
- Pipe and fitting insulation
- Greater coverage of tank surface area with foam insulation (*e.g.,* tank bottom)

Issue B.2 DOE seeks information related to these or other technologies that reduce heat loss. Specifically, DOE is interested in comments regarding the applicability of such technologies to the current market, the associated costs, concerns with incorporating them into UFHWSTs (*e.g.,* impacts on utility, potential safety concerns, manufacturing/production/implementation issues), and how these technologies would reduce the heat loss of UFHWSTs.

C. Screening Analysis

The purpose of the screening analysis is to evaluate the technologies that improve equipment efficiency (or in the present case, reduce heat loss) to determine which technologies will be eliminated from further consideration and which will be passed to the engineering analysis for further consideration.

DOE determines whether to eliminate certain technology options from further consideration based on the following criteria:

(1) *Technological feasibility.* Technologies that are not incorporated in commercial products or in working prototypes will not be considered further.

(2) *Practicability to manufacture, install, and service.* If it is determined that mass production of a technology in commercial products and reliable installation and servicing of the technology could not be achieved on the scale necessary to serve the relevant market at the time of the compliance date of the standard, then that technology will not be considered further.

(3) *Impacts on equipment utility or equipment availability.* If a technology is determined to have significant adverse impact on the utility of the equipment for significant subgroups of consumers, or result in the unavailability of any covered equipment type with performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as equipment generally available in the United States at the time, it will not be considered further.

(4) *Adverse impacts on health or safety.* If it is determined that a technology will have significant adverse impacts on health or safety, it will not be considered further.

10 CFR part 430, subpart C, appendix A, 4(a)(4) and 5(b).

Technology options identified in the technology assessment are evaluated against these criteria using DOE analyses and inputs from interested parties (*e.g.,* manufacturers, trade organizations, and energy efficiency advocates). Technologies that pass through the screening analysis are referred to as ''design options'' in the engineering analysis. Technology options that fail to meet one or more of the four criteria are eliminated from consideration.

Additionally, DOE notes that the four screening criteria do not directly address the proprietary status of technology options. DOE only considers potential efficiency levels achieved through the use of proprietary designs in the engineering analysis if they are not part of a unique pathway to achieve that efficiency level (*i.e.,* if there are other non-proprietary technologies capable of achieving the same efficiency level).

Issue C.1 DOE requests feedback on what impact, if any, the four screening criteria described in this section would have on each of the technology options identified in section II.B.2 of this RFI. Similarly, DOE seeks information regarding how these same criteria would affect any other technology options not already identified in this document with respect to their potential use in UFHWSTs.

D. Engineering Analysis

The engineering analysis estimates the cost-efficiency relationship of equipment at different levels of reduced heat loss (''efficiency levels'').[7] This relationship serves as the basis for the cost-benefit calculations for commercial consumers, manufacturers, and the Nation. In determining the cost-efficiency relationship, DOE estimates the increase in manufacturing production cost (''MPC'') associated with reducing the heat loss of equipment above the baseline, up to the maximum technologically feasible (''max-tech'') efficiency level for each equipment class.

DOE historically has used the following three methodologies to generate incremental manufacturing costs and establish efficiency levels (''ELs'') for analysis: (1) The design-option approach, which provides the incremental costs of adding to a baseline model design options that will improve its efficiency; (2) the efficiency-level approach, which provides the relative costs of achieving increases in energy efficiency levels, without regard to the particular design options used to achieve such increases; and (3) the cost-assessment (or reverse engineering) approach, which provides ''bottom-up'' manufacturing cost assessments for achieving various levels of increased efficiency, based on detailed cost data for parts and materials, labor, shipping/packaging, and investment for models that operate at particular efficiency levels.

1. General Approach

In order to develop the cost-efficiency relationship for UFHWSTs, DOE anticipates that it will structure its engineering analysis using both a reverse-engineering (or cost-assessment) and a catalog teardown approach. The catalog-teardown approach relies on a

[7] While the UFHWSTs standard addresses heat loss through establishing a minimum level of insulation, for the purpose of this analysis, the levels of improvement are referred to generally as ''efficiency levels.''

teardown analysis of representative units at the baseline efficiency level and higher efficiency levels up to the maximum technologically feasible designs. A teardown analysis (or physical teardown) determines the production cost of a product by disassembling the product ''piece-by-piece'' and estimating the material and labor cost of each component. A catalog teardown approach uses published manufacturer catalogs and supplementary component data to estimate the major physical differences between equipment that has been physically disassembled and similar equipment. These two methods would be used together to help DOE estimate the manufacturer production cost of equipment at various efficiency levels.

Issue D.1 DOE requests feedback on the planned approach for the engineering analysis.

2. Representative Equipment

As previously stated, DOE intends to perform a teardown analysis on a set of models with ''representative'' characteristics to estimate the cost-efficiency relationship for UFHWSTs. DOE plans to conduct teardowns at specific storage volumes (referred to as representative storage volumes) that are the most common on the market, and extrapolate those results for the entire market. Based on a survey of models currently on the market, DOE has preliminarily determined the most common characteristics of UFHWSTs in order to identify a representative unit(s). In particular, DOE examined the number of UFHWST models available at distinct rated storage volumes and identified the most common storage volumes on the market as 80 and 119 gallons. DOE is also aware that UFHWSTs can be either vertical or horizontal tanks and recognizes that the tank orientation may affect heat losses from the tank and placement of ports. Based on its market assessment, DOE has found that vertical tanks are more common than horizontal tanks and that horizontal tanks do not have sufficiently different characteristics from vertical tanks to necessitate separate analysis of representative horizontal units. Finally, DOE is aware that the number and location of ports can affect standby heat losses; therefore, DOE may consider a representative configuration of ports.

Issue D.2 DOE requests feedback on the appropriate representative storage volume to use for analysis of UFHWSTs, whether more than one representative storage volume is warranted, and on whether 80 and/or 119 gallons would be appropriate.

Issue D.3 DOE requests comment on whether a vertical tank orientation should be considered representative for the UFHWST market. Such comments may include, but need not be limited to, data as to the fraction of UFHWST shipments that are horizontal tanks, and on whether this fraction depends on storage volume. DOE seeks feedback on whether horizontal tanks have any differences or limitations regarding insulation thickness relative to vertical tanks. DOE also requests comment on whether there is a difference in the utility provided by a vertical tank, as compared to a horizontal tank, that should be considered when identifying representative equipment.

Issue D.4 DOE requests comment on whether there is a configuration of ports (*i.e.,* number and location), or a limited set of port configurations, that is most common for UFHWSTs and that would, therefore, be appropriate to analyze as part of the representative unit(s) in the engineering analysis. DOE further seeks feedback on whether this representative configuration would depend on storage volume.

3. Baseline Efficiency Level

DOE selects a baseline model as a reference point against which any changes resulting from potential new or amended standards can be measured. The baseline model represents the characteristics of common or typical equipment. Typically, a baseline model is one that meets the current minimum standard and provides basic consumer utility.

DOE uses baseline models for comparison in several phases of the analyses, including the engineering analysis, life-cycle cost (''LCC'') analysis, payback period (''PBP'') analysis, and national impact analysis (''NIA''). In the engineering analysis, to determine the changes in price to the commercial consumer that result from amended standards, DOE compares the price of a baseline model to the price of a model at each higher efficiency level.

Consistent with this analytical approach, DOE tentatively plans to consider the current minimum standard (which went into effect October 29, 2003) to establish the baseline efficiency level. The current standard is a prescriptive minimum insulation requirement (R-value of 12.5). 10 CFR 431.110.

Issue D.5 DOE requests feedback on whether using the current established standard for UFHWSTs is an appropriate baseline efficiency level for DOE to apply in evaluating whether to amend the current standard for this equipment. DOE requests data and suggestions to evaluate the baseline efficiency level in order to better evaluate amending the standard for this equipment.

Issue D.6 DOE requests comment on the insulation types and thicknesses typically used in UFHWSTs with R–12.5 tank insulation (*i.e.,* at the current baseline level). DOE also seeks feedback on whether any models with R–12.5 insulation use only fiberglass insulation, and if so, what the maximum feasible R-value is for insulation of UFHWSTs with fiberglass.

4. Maximum Available and Maximum Technologically Feasible Efficiency Levels

As part of DOE's analysis, the maximum available efficiency level is the highest-efficiency model currently available on the market. To identify efficiency levels (including the maximum available efficiency level) and technology options used above the R–12.5 baseline for UFHWSTs, DOE conducted a survey of the UFHWST market, including manufacturer catalogs and other publicly-available literature. Many models are advertised as having a tank insulation R-value that ''meets or exceeds'' R–12.5, without specifying the exact R-value. DOE only identified two model lines for which the manufacturer advertises specific insulation R-values above the R–12.5 baseline, which were advertised as having R–12.9 and R–16 insulation. The product literature for models with these higher insulation R-values identifies the insulation as polyurethane foam insulation but does not provide the insulation thickness.

DOE defines a max-tech efficiency level to represent the theoretical maximum possible efficiency if all available technology options are incorporated in a model. In many cases, the max-tech efficiency level is not commercially available because it is not economically feasible. However, DOE seeks to determine the max-tech level for purposes of its analyses.

Issue D.7 DOE seeks comment on what the range of tank insulation R-values is for the UFHWST market. Such comments may include, but need not be limited to, whether there are models on the market with tank insulation R-values other than R–12.5, R–12.9, and R–16. Further, DOE seeks feedback on the insulation types and thicknesses that typically correspond with any R-values higher than R–12.5.

Issue D.8 DOE requests comment on performance of UFHWSTs currently on the market, including, but not limited to, what the highest tank insulation R-value on the market is (*i.e.,* the maximum available level), and on what

insulation type(s) and thickness(es) typically correspond with this level. DOE also seeks input on whether the maximum available efficiency level is appropriate and technologically feasible for potential consideration as a possible standard for UFHWSTs—and if not, why not. Additionally, DOE seeks feedback on whether there are practical limitations (*e.g.,* shipping or installation concerns) on the thickness of tank insulation that can be applied to UFHWSTs.

Issue D.9 DOE seeks feedback on what design options would be incorporated at a max-tech efficiency level, and the heat losses associated with those levels. More specifically, DOE seeks comment on the theoretical maximum possible tank insulation R-value, and on what insulation type(s) and thickness(es) would correspond with this level. As part of this request, DOE also seeks information as to whether there are limitations on the use of certain combinations of design options.

5. Manufacturer Production Costs and Manufacturer Selling Price

As described at the beginning of this section, the main outputs of the engineering analysis are cost-efficiency relationships that describe the estimated increases in manufacturer production cost associated with higher-efficiency equipment.

Issue D.10 DOE requests feedback on how manufacturers would incorporate the technology options listed in section II.B.2 to increase the tank-insulation R-values in UFHWSTs beyond the baseline. This includes information on the order in which manufacturers would incorporate the different technologies to incrementally improve the R-value (or otherwise reduce the heat loss) of equipment. DOE requests feedback on whether increasing tank insulation R-value would lead to other design changes that would not occur otherwise. DOE is also interested in information regarding any potential impact of increased tank insulation R-value on a manufacturer's ability to incorporate additional functions or attributes in response to consumer demand.

Issue D.11 DOE seeks comment on the increase in MPC associated with incorporating each particular technology option. DOE also requests information on the investments necessary to incorporate specific technology options, including, but not limited to, costs related to new or modified tooling (if any), materials, engineering and development efforts to implement each technology option, and manufacturing/production impacts.

To account for manufacturers' non-production costs and profit margin, DOE applies a non-production cost multiplier (the manufacturer mark-up) to the MPC. The resulting manufacturer selling price (''MSP'') is the price at which the manufacturer distributes a unit into commerce. For a notice of proposed rulemaking for energy conservation standards (''ECS'') for certain classes of commercial water heating equipment published on May 31, 2016, DOE estimated a manufacturer mark-up of 1.41 for commercial electric storage water heaters. 81 FR 34440, 34497 (''May 2016 CWH ECS NOPR''). DOE's market assessment indicates that many manufacturers produce both UFHWSTs and electric storage water heaters and that these equipment categories share many design features. Additionally, some tanks designed for electric storage water heaters are used in UFHWST models (see discussion in section II.D.6 of this RFI). Therefore, DOE has tentatively concluded that the manufacturer mark-up for commercial electric storage water heaters is appropriate to apply for analysis of UFHWSTs.

Issue D.12 DOE requests feedback on whether a manufacturer mark-up of 1.41 is appropriate for UFHWSTs.

6. Additional Engineering Issues

Due to the need for ports and other openings for service/maintenance or repair, the entire surface of an UFHWST cannot be insulated with foam insulation, and, therefore, portions of the UFHWSTs currently on the market are insulated with fiberglass or uninsulated. Additionally, DOE research suggests that manufacturers may use a single tank design for multiple models and plug ports or other openings that are not designed to be used for a given model but that may be used for a similar model. In such cases where a single tank design is used for multiple models, plugged openings sometimes are not covered with tank foam insulation if the foam insulation is applied before any openings are plugged. Further, manufacturers may use a tank designed for electric storage water heaters as the tank for an UFHWST model by plugging the openings for electric resistance heating elements. Electric storage water heaters typically include gaps in tank foam insulation where each heating element and thermostat are located, and these gaps are often insulated with foam or fiberglass insulation inserts. DOE has also observed during testing and examination of water heaters and UFHWSTs that there sometimes are voids in the foam insulation that is applied to some UFHWSTs that form either during or after the foaming process.

Issue D.13 DOE requests comment on the current practices and limitations of foam insulation, including, but not limited to, the approximate fraction of the tank surface area that can typically be insulated with foam. Further, DOE seeks feedback on whether there is significant variation on the market of the fraction of the tank insulated with foam.

Issue D.14 DOE requests comment on the presence of plugged ports, such as how commonly UFHWSTs include plugged ports, and if included, how the plugged ports are insulated (*e.g.,* covered with foam insulation, fiberglass wrap, a fiberglass insert, or not insulated). Further, DOE requests comment on the extent to which electric storage water heater tanks are used for UFHWST models, and when used, how/whether the areas of the tank containing ports for resistance heating elements and thermostats are insulated.

Issue D.15 DOE requests comment on the extent to which voids form in foam insulation on UFHWSTs. Further, DOE seeks comment on the extent to which voids affect the standby losses of UFHWSTs.

In response to the May 9, 2016 CWH TP NOPR (81 FR 28588), several stakeholders stated that many UFHWSTs are customized for specific applications or installations. (Bradford White, Docket No. EERE–2014–BT–TP–0008–0021 at p. 5; AHRI, Docket No. EERE–2014–BT–TP–0008–0026 [8] at p. 12; A.O. Smith, Docket No. EERE–2014–BT–TP–0008–0027 at p. 4; Rheem, Docket No. EERE–2014–BT–TP–0008–0034 at p. 8). However, it is unclear what share of the market consists of custom models, and to what extent UFHWSTs are customized.

Issue D.16 DOE seeks comment on the customization of UFHWSTs, including but not limited to, information as to the fraction of UFHWST shipments that are custom models, and whether this fraction varies by storage volume; and which aspects are customized in UFHWSTs and whether aspects other than number and locations of ports are customized. DOE also seeks feedback on the extent to which the number and location of ports affect standby heat losses of UFHWSTs. Further, DOE seeks feedback on whether UFHWSTs included in publicly-available product literature can be

[8] Docket No. EERE–2014–BT–TP–0008 is available at *https://www.regulations.gov/docket?D=EERE-2014-BT-TP-0008.*

customized or if customizable models are not publicly advertised.

E. Mark-Ups Analysis

The mark-ups analysis develops appropriate mark-ups (*e.g.,* for wholesalers, mechanical contractors, general contractors) in the distribution chain and sales taxes to convert the manufacturer sales prices (MSP) derived in the engineering analysis to consumer prices, which are then used in the LCC and PBP analyses and other analyses. At each step in the distribution channel, companies mark up the price of the equipment to cover business costs and profit margin.

1. Distribution Channels

In generating end-user price inputs for the LCC analysis and the NIA, DOE must identify distribution channels (*i.e.,* how the equipment passes through the chain of commerce from the manufacturer to the customer), and estimate relative sales volumes through each channel. Two different markets exist for UFHWST systems: (1) Replacements and new owners,[9] and (2) new construction. DOE intends to use similar distribution channels as found in the May 2016 CWH ECS NOPR TSD.[10]

Replacement and New Owner

For replacement and new owner applications, manufacturers sell mainly to plumbing distributors. The main distribution path that DOE intends to consider is a plumbing distributor (*i.e.,* a wholesaler) who sells an UFHWST to a contractor, who then sells it to a consumer and installs it. The manufacturer may also utilize a manufacturer's representative to sell the equipment to a plumbing contractor, who then sells it to the commercial consumer. The manufacturer may sell the equipment to a retailer, who in turn may sell it to a plumbing contractor, who in turn sells it to a commercial consumer.

In addition, DOE plans to consider distribution channels where the manufacturer sells the UFHWST a wholesaler or retailer that then sells the equipment to the commercial or industrial consumer. DOE also plans to consider the distribution channel where the manufacturer sells a UFHWST directly to a commercial or industrial consumer through a national account. These three channels reflect those cases where the installation can be accomplished by site personnel.

In summary, DOE plans to characterize the replacement and new owner market distribution channels for UFHWST systems as follows:

Manufacturer → Wholesaler → Plumbing Contractor → Commercial Consumer
Manufacturer → Manufacturer's Representative → Plumbing Contractor → Commercial Consumer
Manufacturer → Retailer → Plumbing Contractor → Commercial Consumer
Manufacturer → Wholesaler → Commercial Consumer
Manufacturer → Retailer → Commercial Consumer
Manufacturer → National Account → Commercial Consumer

New Construction

The new construction distribution channel for UFHWST equipment includes an additional link in the chain—the general contractor. In most new construction applications, the UFHWST is part of the overall plumbing package installed by a plumbing contractor or, in the case of large building companies, by its own master plumber and crew. A plumbing contractor usually purchases the water heater from a plumbing distributor, and in this case, it is appropriate to include a contractor mark-up. In addition, similar to the replacement and new owner distribution channel, DOE plans to consider distribution channels where the manufacturer sells the UFHWST to a wholesaler or retailer that then sells the equipment to the commercial or industrial consumer, and the distribution channel where the manufacturer sells a UFHWST directly to a commercial or industrial consumer through a national account.

In the case of new construction, DOE plans to characterize the distribution channels as follows:

Manufacturer → Wholesaler → Plumbing Contractor → General Contractor → Commercial Consumer
Manufacturer → Manufacturer's Representative → Plumbing Contractor → General Contractor → Commercial Consumer
Manufacturer → Retailer → Plumbing Contractor → General Contractor → Commercial Consumer
Manufacturer → Wholesaler → General Contractor → Commercial Consumer
Manufacturer → Retailer → General Contractor → Commercial Consumer
Manufacturer → Wholesaler → Commercial Consumer
Manufacturer → Retailer → Commercial Consumer
Manufacturer → National Account → Commercial Consumer

Issue E.1 DOE seeks input from stakeholders on whether the distribution channels described above are appropriate for UFHWSTs and are sufficient to characterize this market.

Issue E.2 DOE seeks input on the equipment being distributed through the identified channels, including but not limited to, the percentage of equipment being distributed through the different distribution channels, and whether the share of equipment through each channel varies based on equipment capacity (storage volume).

2. Mark-Ups

To develop mark-ups for the parties involved in the distribution of the equipment, DOE plans to primarily utilize: (1) Form 10–K[11] from the main consumer water heater wholesalers[12] and retailers (for wholesalers and retailers); (2) the Heating, Air Conditioning & Refrigeration Distributors International (''HARDI'') 2013 Profit Report[13] (for wholesalers); (3) the latest U.S. Census Annual Retail Trade Survey data[14] (for retailers), and (4) U.S. Census Bureau 2012 Economic Census data[15] on the residential and commercial building construction industry (for retailers, general contractors, and mechanical contractors). DOE also plans to use the 2005 Air Conditioning Contractors of America's (''ACCA'') Financial Analysis

[9] New owners are defined as existing buildings that acquire a UFHWST for the first time during the analysis period.

[10] Department of Energy, Technical Support Document (TSD): Energy Efficiency Program for Consumer Products and Commercial and Industrial Equipment: Commercial Water Heating Equipment (May 2016) (Available at: *https://www.regulations.gov/document?D=EERE-2014-BT-STD-0042-0016*) (Last accessed April 4, 2019).

[11] U.S. Securities and Exchange Commission, *SEC 10–K Reports* (Available at: *https://www.sec.gov/*) (Last accessed April 4, 2019).

[12] Clear Seas Research, *2017 Top List—Premier Distributors—Plumbing, Heating, Cooling* (Available at: *https://clearseasresearch.com/product/2017-top-list-premier-distributors-plumbing-heating-cooling/*) (Last accessed April 4, 2019).

[13] Heating, Air Conditioning & Refrigeration Distributors International (HARDI), *2013 HARDI Profit Report,* (Available at: *http://hardinet.org/*) (Last accessed April 4, 2019).

[14] U.S. Census Bureau, *2017 Annual Retail Trade Survey Data* (Available at: *https://www.census.gov/programs-surveys/arts.html*) (Last accessed July 8, 2019). At the time this RFI was finalized, the 2017 Annual Retail Trade Survey was the most recent full data release.

[15] U.S. Census Bureau, *2012 Economic Census Data* (Available at: *https://www.census.gov/programs-surveys/economic-census.html*) (Last accessed April 4, 2019). Note that the 2017 Economic Census data are planned to be fully released by late 2020. Until that time, 2012 Economic Census remains the most recent full data release.

on the Heating, Ventilation, Air-Conditioning, and Refrigeration (''HVACR'') contracting industry [16] to disaggregate the mechanical contractor mark-ups into replacement and new construction markets. DOE does not currently have enough information to estimate separate mark-ups for manufacturer's representatives, so DOE plans to assume that the manufacturer's representative mark-up is the same as the wholesaler mark-up.

Issue E.3 DOE seeks recent data and recommendations regarding data sources to establish the mark-ups for the parties involved with the distribution of the UFHWST equipment.

F. Energy Use Analysis

As part of the rulemaking process, DOE conducts an energy use analysis to identify how equipment is used by commercial consumers, and thereby determine the energy savings potential of energy efficiency improvements. As discussed, UFHWSTs store hot water and do not directly consume fuel or electricity for the purpose of heating water, so any potential amendments to the standard target reducing standby loss associated with heat loss from the stored water. The energy use analysis would determine the annual energy consumption of water heaters and boilers due to standby loss of the paired UFHWSTs and to assess the energy savings potential of an amended UFHWST standard, as well as of other technologies that may be applied.

1. Sample Development

DOE intends to base the energy use analysis on key characteristics from the most current version of the Energy Information Administration's (''EIA'') Commercial Building Energy Consumption Survey (''CBECS'') [17] for the subset of commercial building types that use UFHWSTs. DOE also plans to include the industrial sector [18] using EIA's most current Manufacturing Energy Consumption Survey (''MECS'') [19] for the subset of sectors that use UFHWSTs. DOE also plans to look at the use of UFHWSTs in residential applications, for which it plans to include characteristics from EIA's most current Residential Energy Consumption Survey (''RECS'') [20] for a subset of building types (primarily multi-family buildings) that use UFHWSTs.

CBECS and RECS data include information on the physical characteristics of buildings, water heaters and boilers used, fuels used, energy consumption and expenditures, and other relevant characteristics. Neither CBECS nor RECS provide data on whether the building has an UFHWST. Also, MECS does not provide individual sample characteristics. Therefore, DOE intends to develop a methodology for adjusting its building sample to reflect buildings or industrial sectors that are more likely to include UFHWSTs based on the type of water heating and space heating equipment used in the building (for example if the building has a boiler or a commercial water heater). Based on the most current CBECS, MECS, and RECS data, DOE will develop a representative population of buildings for UFHWST equipment. In addition, DOE intends to review other data sets (*e.g.,* data from the 2016 Residential Building Stock Assessment for the Northwest,[21] 2014 Commercial Building Stock Assessment for the Northwest,[22] 2014 Industrial Facilities Site Assessment for the Northwest,[23] 2015 Residential Statewide Baseline Study of New York State,[24] 2006 California Commercial End-Use Survey,[25] and 2009 Residential Appliance Saturation Study [26]) to compare these to the CBECS, MECS, and RECS data for the corresponding region.

Issue F.1 DOE seeks input on the water heating equipment and associated fuels that are used to heat the water stored in UFHWSTs, including, but not limited to, information on the fractions of various space heating and water heating equipment that are associated with UFHWSTs, as follows: Gas-fired hot water boilers, electric hot water boilers, oil-fired hot water boilers, gas-fired steam boilers, electric steam boilers, oil-fired steam boilers, gas-fired storage water heaters, electric storage water heaters, oil-fired storage water heaters, gas-fired tankless water heaters, electric tankless water heaters, heat pump water heaters, solar water heater systems, and heat from other sources (such as industrial processes).

Issue F.2 DOE requests information on the installation applications of UFHWSTs, including, but not limited to the fraction of UFHWSTs that are installed in residential (primarily multi-family buildings), commercial, and industrial applications.

2. Energy Use Calculations

The relevant energy consumption is the site energy use associated with offsetting the standby losses incurred by the UFHWST(s) installed in the building. To determine the field standby loss of the UFHWSTs for the purposes of the energy use analysis, DOE intends to use a methodology based on the ''R-value'' defined by DOE's regulations of UFHWSTs.[27] DOE's methodology will convert the R-value to field standby losses based on tank sizes, tank set point temperature, and surrounding air temperature. The energy use will then be calculated in terms of the fuel type and efficiency of the water heating equipment used to offset the standby losses. DOE intends to also consider any degradation in the R-value over the lifetime of UFHWSTs.

Issue F.3 DOE requests relevant information, such as field or test energy use data, that could assist in the development of an energy use equation to determine field standby loss.

Issue F.4 DOE requests comment on the methodology for determining the standby loss for UFHWSTs based on the

[16] Air Conditioning Contractors of America (ACCA), *Financial Analysis for the HVACR* Contracting Industry (2005) (Available at: *https://www.acca.org/store*) (Last accessed April 4, 2019).

[17] Presently, the 2012 edition of CBECs is the most recent version. Energy Information Administration (EIA), 2012 Commercial Building Energy Consumption Survey (CBECS) (Available at: *http://www.eia.gov/consumption/commercial/*) (Last accessed April 4, 2019).

[18] Industrial sector includes non-manufacturing (agriculture, construction, and mining) and manufacturing sectors.

[19] Presently, the 2014 edition of MECS is the most recent version. Energy Information Administration (EIA), 2014 Manufacturing Energy Consumption Survey (MECS) (Available at: *http://www.eia.gov/consumption/manufacturing/*) (Last accessed April 4, 2019).

[20] Presently the 2015 edition of RECs is the most recent version. Energy Information Administration (EIA), 2015 Residential Energy Consumption Survey (RECS) (Available at: *http://www.eia.gov/consumption/residential/*) (Last accessed April 4, 2019).

[21] Northwest Energy Efficiency Alliance (NEEA), Residential Building Stock Assessment (2016) (Available at: *https://neea.org/data/residential-building-stock-assessment*) (Last accessed April 4, 2019).

[22] Northwest Energy Efficiency Alliance (NEEA), Commercial Building Stock Assessment (2014) (Available at: *https://neea.org/data/commercial-building-stock-assessments*) (Last accessed April 4, 2019).

[23] Northwest Energy Efficiency Alliance (NEEA), Industrial Facilities Site Assessment (2014) (Available at: *https://neea.org/data/industrial-facilties-site-assessment*) (Last accessed April 4, 2019).

[24] New York State Energy Research and Development Authority (NYSERDA), Residential Statewide Baseline Study of New York State (July 2015) (Available at: *https://www.nyserda.ny.gov/About/Publications/Building-Stock-and-Potential-Studies/Residential-Statewide-Baseline-Study-of-New-York-State*) (Last accessed April 4, 2019).

[25] California Energy Commission (CEC), 2006 California Commercial End-Use Survey (CEUS) (2006) (Available at: *http://www.energy.ca.gov/ceus/2006_enduse.html*) (Last accessed April 4, 2019).

[26] California Energy Commission (CEC), 2009 Residential Appliance Saturation Study (RASS) (2009) (Available at: *http://www.energy.ca.gov/appliances/rass/)* (Last accessed April 4, 2019).

[27] DOE defines ''R-value'' as the thermal resistance of insulating material as determined using ASTM C177–13 or C518–15 and expressed in (°F·ft²·h/Btu). 10 CFR 431.102.

R-value and the impact of ambient conditions, tank set-point temperature, and draw patterns.

Issue F.5 DOE seeks data and input on typical tank water temperatures for UFHWSTs used in various residential (primarily multi-family buildings), commercial, and industrial applications to establish the fraction of UFHWSTs storing water at different temperatures.

Issue F.6 DOE seeks input on what are typical storage volumes of UFHWSTs used in various residential (primarily multi-family buildings), commercial, and industrial applications, including, but not limited to the fraction of UFHWSTs at different storage volumes (*i.e.,* equal to or less than 120 gallons, greater than 120 gallons and equal to or less than 500 gallons, greater than 500 gallons).

Issue F.7 DOE requests comment on the installation location of UFHWSTs in the context of the ambient air temperature conditions, including, but not limited to, the fraction of UFHWSTs that are installed outdoors, in an indoor conditioned space, or an indoor unconditioned space.

Issue F.8 DOE requests comment and any data concerning the potential degradation in the R-value over the lifetime of UFHWSTs.

Issue F.9 To better understand the distribution of energy consumption load profiles, DOE seeks comment on the fraction of UFHWSTs that are installed in utility grid-enabled storage applications.

G. Life-Cycle Cost and Payback Period Analysis

DOE plans to conduct LCC and PBP analyses to evaluate the economic impacts on residential (primarily multi-family buildings), commercial, and industrial consumers of potential standards for UFHWSTs. The effect of new or amended standards on residential (primarily multi-family buildings), commercial, and industrial consumers usually involves a reduction in operating cost and an increase in purchase cost.

DOE intends to analyze the potential for variability by performing the LCC and PBP calculations on a representative sample of residential (primarily multi-family buildings), commercial, and industrial consumers. DOE plans to utilize the sample of buildings developed for the energy use analysis and the corresponding simulation results. DOE plans to model uncertainty in many of the inputs to the LCC and PBP analysis using Monte Carlo simulation and probability distributions. As a result, the LCC and PBP results will be displayed as distributions of impacts compared to the no-new-standards case (*i.e.,* the case without amended standards).

Inputs to the LCC and PBP analysis are categorized as: (1) Inputs for establishing the purchase expense, otherwise known as the total installed cost, and (2) inputs for calculating the operating costs. Each type of input is discussed in the paragraphs that follow.

1. Total Installed Cost

The primary inputs for establishing the total installed cost are the baseline customer price, incremental customer price increases resulting from a potential standard, and installation costs. Baseline prices and standard-level price increases will be determined by applying mark-ups to manufacturer selling price estimates and sales tax.

The installation cost is added to the customer price to arrive at a total installed cost. DOE intends to develop installation costs using the most recent RS Means data available.[28] DOE also intends to use regional labor costs to more accurately estimate installation costs by applying the appropriate regional labor cost from RS Means to each sampled household or building.

In conducting its analyses, DOE intends to utilize a basic installation plan that would apply to all UFHWSTs. For UFHWSTs in new installations, DOE plans to include costs such as adding water piping, putting the UFHWST in place, and additional set-up. For replacement cases, in addition to the costs considered for new installations, DOE also plans to include the installation cost associated with disconnecting and removing the old UFHWST, as well as removal/disposal and permit fees, if applicable. In addition, DOE intends to assess whether installation costs vary with insulation levels and storage volume.

Issue G.1 DOE seeks input on any available installation cost data for UFHWSTs. DOE also seeks input on the approach it intends to use to develop UFHWST installation costs.

Issue G.2 DOE seeks input on any additional costs associated with installing UFHWSTs. For example, DOE seeks feedback on any installation costs associated with potential space-constraint issues when the original UFHWST location is too small to accommodate the replacement UFHWST (particularly when installing a UFHWST with a lower heat loss that may have larger physical dimensions).

[28] RS Means, 2019 Mechanical Cost Data (Available at: *https://www.rsmeans.com/products/books/cost-books.aspx*) (Last accessed April 4, 2019).

2. Operating Costs

The primary inputs for calculating the operating costs of UFHWSTs are energy consumption, equipment efficiency, energy prices, maintenance and repair costs, equipment lifetime, and discount rates. Both equipment lifetime and discount rates are used to calculate the present value of future operating costs.

The relevant energy consumption is the site energy use associated with offsetting the standby losses incurred by the UFHWST(s) installed in the building. DOE intends to utilize the standby loss calculation methodology described in section II.F of this document to determine energy use to offset the UFHWST's standby losses.

Maintenance costs are expenses associated with ensuring continued operation of the covered equipment over time. DOE intends to develop maintenance costs using the most recent RS Means data available [29] and manufacturer literature. DOE intends to assess whether maintenance costs vary with equipment heat loss and storage volume. In addition, DOE plans to consider the cases in which the equipment is covered by service and/or maintenance agreements. More specifically, DOE intends to account for the maintenance cost associated with UFHWSTs being drained and flushed annually to minimize deposition of sediment, maintain operating efficiency, and prolong equipment life.

Issue G.3 DOE seeks comment as to whether UFHWST maintenance costs vary as a function of insulation level and storage volume, for the technology options listed in section II.B.2. DOE also requests any data or information on maintenance costs and seeks comment on the extent to which maintenance costs are covered by service and/or maintenance agreements.

Repair costs are expenses associated with repairing or replacing components of the covered equipment that have failed. DOE intends to develop maintenance costs using the most recent RS Means data available [30] and manufacturer literature. DOE intends to assess whether repair costs vary with insulation level and storage volume.

Issue G.4 DOE seeks comment as to whether UFHWST repair costs and frequency of repair vary as a function of insulation level and storage volume, for the technology options listed in section

[29] RS Means, 2019 Facilities Maintenance & Repair Cost Data (Available at: *https://www.rsmeans.com/products/books/cost-books.aspx*) (Last accessed April 4, 2019).

[30] RS Means, 2019 Facilities Maintenance & Repair Cost Data (Available at: *https://www.rsmeans.com/products/books/cost-books.aspx*) (Last accessed April 4, 2019).

II.B.2. DOE also requests any data or information on repair costs and seeks comment on the extent to which repair costs are covered by service and/or maintenance agreements. DOE is also interested in whether consumers simply replace the equipment when they fail as opposed to repairing them.

Equipment lifetime is the age at which a unit is retired from service. DOE intends to conduct a literature review of UFHWST lifetime data together with any stakeholder lifetime data to develop a Weibull probability distribution to characterize UFHWST lifetime.[31]

Issue G.5 DOE requests equipment lifetime data and information on whether equipment lifetime varies based on UFHWST storage volume, application, or insulation level.

DOE measures LCC and PBP impacts of potential standard levels relative to a no-new-standards case that reflects the likely market in the absence of amended standards. DOE plans to develop efficiency market shares (*i.e.,* the distribution of equipment shipments by insulation level) for the UFHWSTs, for the anticipated year in which compliance with any potential amended standards would be required. DOE is not aware of any data to estimate the market shares of different UFHWST insulation levels in the no-new-standards case. DOE is particularly interested in receiving such data. If no market share data become available, DOE intends to use data on the number of water heater models at different insulation levels, as reported in DOE's compliance certification database[32] and from manufacturer literature.

Issue G.6 DOE requests information on the UFHWSTs market, including but not limited to, the current UFHWSTs market share data by different by insulation levels; similar historic data; and information on expected future trends in the efficiency of UFHWSTs.

H. Shipments Analysis

DOE develops shipments forecasts of equipment to calculate the national impacts of potential amended standards on energy consumption, net present value (''NPV''), and future manufacturer cash flows. DOE shipments projections are based on available historical data broken out by equipment class, capacity, and efficiency. Current sales estimates allow for a more accurate model that captures recent trends in the market. However, DOE is not aware of any shipment data for UFHWSTs.

Issue H.1 DOE seeks historical shipments data for UFHWSTs, which may include shipments by storage volume capacity bins.

The shipments model will consider the UFHWSTs in the commercial, industrial, and residential (primarily multi-family buildings) market segments.

Issue H.2 DOE seeks comment, which may include historical data, on the fraction of UFHWST shipments by commercial, industrial, and residential (primarily multi-family buildings) market segments.

The shipments model will consider three market segments: (1) New buildings acquiring UFHWSTs; (2) existing buildings replacing old UFHWSTs; and (3) existing buildings acquiring new UFHWSTs for the first time.

Issue H.3 DOE seeks comment, which may include historical data, on the fraction of UFHWSTs shipments by new buildings, replacements, and new owner market segments.

A table of the types of data requested for historical shipments in Issues H.1, H.2, and H.3 can be found in Table II.1, Table II.2, and Table II.3.

TABLE II.1—HISTORICAL SHIPMENTS BY STORAGE VOLUME CAPACITY BINS

Storage volume (gallons)	Historical shipments (millions)									
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Up to 249 gallons										
250 to 999 gallons										
Above 1000 gallons										
Total										

TABLE II.2—HISTORICAL SHIPMENTS BY COMMERCIAL, INDUSTRIAL, AND RESIDENTIAL MARKET SEGMENTS

Market segment	Historical shipments (millions)									
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Commercial										
Industrial										
Residential *										
Total										

* Primarily muti-family buildings.

[31] A Weibull probability distribution is a continuous distribution function typically used in reliability engineering and equipment failure analysis. If the data are available, DOE also plans to take into account differences in UFHWST lifetime based on usage and application.

[32] U.S. Department of Energy, Compliance Certification Database: Unfired Hot Water Storage Tanks—Commercial (Available at *https://www.regulations.doe.gov/certification-data/products.html*) (Last accessed April 4, 2019).

TABLE II.3—HISTORICAL SHIPMENTS BY NEW BUILDINGS, REPLACEMENT, AND NEW OWNER MARKET SEGMENTS

Market segment	Historical shipments (millions)									
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
New Buildings										
Replacements										
New Owners										
Total										

* Primarily multi-family buildings.

I. Manufacturer Impact Analysis

The purpose of the manufacturer impact analysis (''MIA'') is to estimate the financial impact of amended standards on manufacturers of UFHWSTs, and to evaluate the potential impact of such standards on direct employment and manufacturing capacity. The MIA includes both quantitative and qualitative aspects. The quantitative part of the MIA primarily relies on the Government Regulatory Impact Model (''GRIM''), an industry cash-flow model adapted for this analysis, with the key output being the industry net present value (''INPV''), which is used to assess the financial impact of a potential standard. The qualitative part of the MIA addresses the potential impacts of energy conservation standards on manufacturing capacity and industry competition, as well as factors such as equipment characteristics, impacts on particular subgroups of firms, and important market and product trends.

As part of the MIA, DOE intends to analyze impacts of amended energy conservation standards on subgroups of manufacturers of covered equipment, including small business manufacturers. DOE uses the applicable Small Business Administration's (''SBA'') small business size standards to determine whether manufacturers qualify as small businesses, which are listed by the applicable North American Industry Classification System (''NAICS'') code.[33] Manufacturing of UFHWSTs is classified under NAICS 333318, ''Other Commercial and Service Industry Machinery Manufacturing,'' and the SBA sets a threshold of 1,000 employees or less for a domestic entity to be considered as a small business. This employee threshold includes all employees in a business's parent company and any other subsidiaries.

One aspect of assessing manufacturer burden involves examining the cumulative impact of multiple DOE standards and the equipment-specific regulatory actions of other Federal agencies that affect the manufacturers of covered equipment. While any one regulation may not impose a significant burden on manufacturers, the combined effects of several existing or impending regulations may have serious consequences for some manufacturers, groups of manufacturers, or an entire industry. Assessing the impact of a single regulation may overlook this cumulative regulatory burden. In addition to energy efficiency standards, other regulations can significantly affect manufacturers' financial operations. Multiple regulations affecting the same manufacturer can strain profits and lead companies to abandon product lines or markets with lower expected future returns than competing products. For these reasons, DOE conducts an analysis of cumulative regulatory burden as part of its rulemakings pertaining to appliance efficiency.

Issue I.1 To the extent feasible, DOE seeks company names and contact information for domestic or foreign-based companies that manufacture UFHWSTs for the U.S. market.

Issue I.2 DOE identified small businesses as a subgroup of manufacturers that could be disproportionally impacted by amended standards. DOE requests company names and contact information of small businesses, as defined by the SBA's size threshold, which manufacture UFHWSTs in the United States. In addition, DOE requests comment on any other manufacturer subgroups that could be disproportionally impacted by amended standards for UFHWSTs. DOE also requests feedback on any potential approaches that could be considered to address impacts on manufacturers, including small businesses.

Issue I.3 DOE requests information regarding the impact of cumulative regulatory burden on manufacturers of UFHWSTs associated with: (1) Other DOE standards applying to different products that these manufacturers may also make and (2) product-specific regulatory actions of other Federal agencies. DOE also requests comment on its methodology for computing cumulative regulatory burden and whether there are any flexibilities it can consider that would reduce this burden while remaining consistent with the requirements of EPCA.

In comments submitted to DOE in response to the May 2016 CWH TP NOPR, several stakeholders stated that there are small manufacturers that make UFHWSTs, but that do not manufacture other types of CWH equipment. (Bradford White, Docket No. EERE–2014–BT–TP–0008–0021 at p. 7; A.O. Smith, Docket No. EERE–2014–BT–TP–0008–0027 at p. 16; Raypak, Docket No. EERE–2014–BT–TP–0008–0028 at p. 2; Rheem, Docket No. EERE–2014–BT–TP–0008–0034 at p. 8)

Issue I.4 DOE requests comment on the fraction of UFHWST shipments that are manufactured by small manufacturers who do not manufacture other types of CWH equipment.

J. Other Energy Conservation Standards Topics

1. Market Failures

In the field of economics, a market failure is a situation in which the market outcome does not maximize societal welfare. Such an outcome would result in unrealized potential welfare. DOE welcomes comment on any aspect of market failures, especially those in the context of amended energy conservation standards for UFHWSTs.

2. Network Mode/''Smart'' Equipment

DOE recently published an RFI on the emerging smart technology appliance and equipment market. 83 FR 46886 (Sept. 17, 2018). In that RFI, DOE sought information to better understand market trends and issues in the emerging market for appliances and commercial equipment that incorporate smart technology. DOE's intent in issuing the RFI was to ensure that DOE did not

[33] Available online at *https://www.sba.gov/document/support-table-size-standards.*

inadvertently impede such innovation in fulfilling its statutory obligations in setting efficiency standards for covered products and equipment. Although UFHWSTs themselves do not consume energy or presumably have a network mode capability, they interact with water heaters that may have such capabilities. Consequently, to the extent water heaters have a network mode that may be impacted by a paired UFHWST, DOE seeks comments, data, and information on the issues presented in this RFI as they may be applicable to UFHWSTs.

3. Other

In addition to the issues identified earlier in this document, DOE welcomes comment on any other aspect of uniform national standards for UFHWSTs not already addressed by the specific areas identified in this document.

III. Submission of Comments

DOE invites all interested parties to submit in writing by the date specified previously in the **DATES** section of this document, comments, data, and information on matters addressed in this document and on other matters relevant to DOE's consideration of amended energy conservation standards for UFHWSTs. Interested parties may submit comments, data, and other information using any of the methods described in the **ADDRESSES** section at the beginning of this document. After the close of the comment period, DOE will review the public comments received and may begin collecting data and conducting analyses discussed in this RFI.

Submitting comments via http://www.regulations.gov. The *http://www.regulations.gov* web page requires you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment itself or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Otherwise, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *http://www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (''CBI'')). Comments submitted through *http://www.regulations.gov* cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *http://www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *http://www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery/courier, or postal mail. Comments and documents submitted via email, hand delivery/courier, or postal mail also will be posted to *http://www.regulations.gov.* If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information in a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via postal mail or hand delivery/courier, please provide all items on a CD, if feasible, in which case it is not necessary to submit printed copies. No telefacsimiles (faxes) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English, and free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail, or hand delivery/courier two well-marked copies: One copy of the document marked ''confidential'' including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. Submit these documents via email or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include: (1) A description of the items, (2) whether and why such items are customarily treated as confidential within the industry, (3) whether the information is generally known by or available from other sources, (4) whether the information has previously been made available to others without obligation concerning its confidentiality, (5) an explanation of the competitive injury to the submitting person which would result from public disclosure, (6) when such information might lose its confidential character due to the passage of time, and (7) why disclosure of the information would be contrary to the public interest.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

DOE considers public participation to be a very important part of the process for developing standards. DOE actively encourages the participation and interaction of the public during the comment period in each stage of the rulemaking process. Interactions with and between members of the public provide a balanced discussion of the issues and assist DOE in the rulemaking process. Anyone who wishes to be added to the DOE mailing list to receive future notices and information about

this process should contact Appliance and Equipment Standards Program staff at (202) 287–1445 or via email at *ApplianceStandardsQuestions@ee.doe.gov.*

Signed in Washington, DC, on August 1, 2019.

Alexander N. Fitzsimmons,

Acting Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2019–17084 Filed 8–8–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2019–0329; Notice No. 25–19–06–SC]

Special Conditions: The Boeing Company (Boeing) Model 777–9 Series Airplane; Interior Design To Facilitate Searches for Passenger Cabin High Wall Suites

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed special conditions.

SUMMARY: This action proposes special conditions for The Boeing Company (Boeing) Model 777–9 series airplane. This airplane will have novel or unusual design features when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. These design features are passenger cabins with high wall suites (HWS). The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These proposed 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: Send comments on or before September 23, 2019.

ADDRESSES: Send comments identified by Docket No. FAA–2019–0329 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: Shannon Lennon, Airframe and Cabin Safety Section, AIR–675, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 2200 South 216th Street, Des Moines, Washington 98198; telephone and fax 206–231–3209; email *shannon.lennon@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites 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.

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

Background

On April 24, 2018, Boeing applied for an amendment to Type Certificate No. T00001SE to include the new Model 777–9 series airplane. The Boeing Model 777–9 series airplane, which is a derivative of the 777–300ER currently approved under Type Certificate No. T00001SE, is a twin-engine, transport category airplane with seating for up to 495 passengers depending upon airplane configuration, and a maximum takeoff weight of approximately 775,000 lbs.

Type Certification Basis

Under the provisions of title 14, Code of Federal Regulations (14 CFR) 21.101, Boeing must show that the Model 777–9 series airplane, continues to meet the applicable provisions of part 25, as amended by amendments 139 through 141, and the regulations listed in Type Certificate No. T00001SE, 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 Boeing Model 777–9 series airplane 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, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Boeing Model 777–9 series airplane must comply with the continued airworthiness and safety improvement requirements for transport category airplanes of 14 CFR part 26, 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 Boeing Model 777–9 series airplane will incorporate the following novel or unusual design features:

This airplane will include a passenger cabin with six HWS arranged in two rows of three suites each in a 1–1–1 configuration. Each HWS has a door and walls that extend from the floor to the ceiling or close to the ceiling. The characteristics of the HWS design are unique such that the suites are not fully open to the cabin (such as for

conventional mini-suites with partial height surrounds). They are not remote from the main cabin, as are overhead crew rest areas, for example.

Discussion

This Boeing Model 777–9 series airplane HWS design is unique to part 25 since its design was not specifically considered during the development of § 25.795(c)(3), which requires that the interior design of the airplane deter the easy concealment of weapons, explosives, or other objects, and lessen the likelihood of overlooking such items during a search. Transport category airplanes contain many areas that are not readily visible, but are readily accessible. For example, areas above stowage bins may not be easily visible when conducting a search due to light fixtures that could inhibit both the visual and physical inspection, but these areas could be accessible places to hide an explosive device. The wall-to-blended ceiling interfaces presented in the HWS designs are similar to overhead bin designs with respect to such challenges associated with conducting searches. However, as opposed to areas above overhead bins, which could exist in continuous sections in the passenger cabin, the search challenges associated with HWS designs may be limited when there are a relatively small number of installed suites.

In consideration of the proposed HWS design, an installation incorporating six suites or less limits the search challenges due to the limited overhead area involved, which is similar to the search area presented by installation of a monument complex, for example. Installations incorporating six suites present a large overhead area that closely resembles the large overhead bin areas currently addressed by the rule and associated guidance material. Since the development of HWS designs were not specifically considered during development of the rule, a unique set of special conditions are needed for interior configurations incorporating HWS.

These proposed 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. Existing airworthiness regulations do not contain adequate standards to address this feature.

Applicability

As discussed above, these special conditions are applicable to the Boeing Model 777–9 series airplanes with HWS installed. Should Boeing 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 airplane. 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 Proposed Special Conditions

Accordingly, the Federal Aviation Administration (FAA) proposes the following special conditions as part of the type certification basis for the Boeing Model 777–9 series airplanes with HWS installed. These conditions are in addition to existing FAA Special Condition No. 25–703–SC published in the **Federal Register** on October 26, 2017 (82 FR 49492).

Interior Design To Facilitate Searches for Passenger Cabin High Wall Suites

1. The area above each HWS must be designed such that there should be no hazards to a person performing a physical search above the HWS (*e.g.,* no hot surfaces, no sharp edges, and no corners).

2. Where there are more than six (6) HWS installed on the aircraft, design features must be incorporated that will deter concealment or promote discovery of weapons, explosives, or objects from a simple inspection. Areas above the HWS must be designed to prevent objects from being hidden from view in a simple search from the aisle.

3. Guidance. The associated guidance material presented in Advisory Circular 25.795–8, *Interior Design to Facilitate Searches,* dated October 24, 2008, for airplane interiors can also be applied to HWS designs.

Issued in Des Moines, Washington, on July 22, 2019.

Victor Wicklund,

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

[FR Doc. 2019–17091 Filed 8–8–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2019–0541; Notice No. 25–19–12–SC]

Special Conditions: The Boeing Company Model 777 Series Airplanes; Seats With Inertia Locking Devices

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed special conditions.

SUMMARY: This action proposes special conditions for The Boeing Company (Boeing) Model 777 series airplanes. These airplanes will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. This design feature is an inertia locking device (ILD) installed in passenger seats. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These proposed 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: Send comments on or before September 23, 2019.

ADDRESSES: Send comments identified by Docket No. FAA–2019–0541 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: Shannon Lennon, Cabin and Airframe Safety Section, AIR–675, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 2200 South 216th Street, Des Moines, Washington 98198; telephone and fax 206–231–3209; email *shannon.lennon@faa.gov.*

SUPPLEMENTARY INFORMATION:

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 December 6, 2013, Boeing applied for Type Certificate No. T00001SE for Model 777–9 series airplanes. On September 19, 2018, Boeing applied for a change to Type Certificate No. T00001SE for seats with inertia locking devices in Model 777 series airplanes. The Model 777 series airplane is a twin-engine, transport-category airplane with a maximum takeoff weight of 775,000 pounds and seating for 495 passengers.

Type Certification Basis

Under the provisions of title 14, Code of Federal Regulations (14 CFR) 21.101, Boeing must show that the Model 777 series airplanes, as changed, continue to meet the applicable provisions of the regulations listed in Type Certificate No. T00001SE, 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 Boeing Model 777 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, Boeing Model 777 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

Boeing Model 777 series airplanes will incorporate the following novel or unusual design features:

Seats with inertia locking devices.

Discussion

Boeing has proposed to install, in Model 777 series airplanes, Thompson Aero Seating Ltd. passenger seats that can be translated in the fore and aft direction by an electrically powered motor (actuator) that is attached to the seat primary structure. Under typical service-loading conditions, the motor internal brake is able to translate the seat and hold the seat in the translated position. However, under the inertial loads of emergency-landing loading conditions specified in 14 CFR 25.562, the motor internal brake may not be able to maintain the seat in the required position. The ILD is an ''active'' device intended to control seat movement (*i.e.,* a system that mechanically deploys during an impact event) to lock the gears of the motor assembly in place. The ILD mechanism is activated by the higher inertial load factors that could occur during an emergency landing event. Each seat place incorporates two ILDs; one on either side of the seat pan. Only one ILD is required to hold an occupied seat in position during worst-case dynamic loading specified in § 25.562.

The ILD will self-activate only in the event of a predetermined airplane loading condition such as that occurring during crash or emergency landing, and will prevent excessive seat forward translation. A minimum level of protection must be provided if the seat-locking device does not deploy.

The normal means of satisfying the structural and occupant protection requirements of § 25.562 result in a non-quantified, but nominally predictable, progressive structural deformation or reduction of injury severity for impact conditions less than the maximum specified by the rule. A seat using ILD technology, however, may involve a step change in protection for impacts below and above that at which the ILD activates and deploys to retain the seat pan in place. This could result in structural deformation or occupant injury output being higher at an intermediate impact condition than that resulting from the maximum impact condition. It is acceptable for such step-change characteristics to exist, provided the resulting output does not exceed the maximum allowable criteria at any condition at which the ILD does or does not deploy, up to the maximum severity pulse specified by the requirements.

The ideal triangular maximum severity pulse is defined in Advisory Circular (AC) 25.562–1B. For the evaluation and testing of less-severe pulses for purposes of assessing the effectiveness of the ILD deployment setting, a similar triangular pulse should be used with acceleration, rise time, and velocity change scaled accordingly. The magnitude of the required pulse should not deviate below the ideal pulse by more than 0.5g until 1.33 t_1 is reached, where t_1 represents the time interval between 0 and t_1 on the referenced pulse shape as shown in AC 25.562–1B. This is an acceptable method of compliance to the test requirements of the special conditions.

Proposed conditions 1 through 5 address ensuring that the ILD activates when intended in order to provide the necessary protection of occupants. This includes protection of a range of occupants under various accident conditions. Proposed conditions 6 through 10 address maintenance and reliability of the ILD, including any outside influences on the mechanism, to ensure it functions as intended.

The proposed 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 Boeing Model 777 series airplanes. Should Boeing 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 one novel or unusual design feature 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 Proposed Special Conditions

Accordingly, the Federal Aviation Administration (FAA) proposes the following special conditions as part of the type certification basis for Boeing Model 777 series airplanes.

In addition to the requirements of § 25.562, passenger seats incorporating an inertia locking device (ILD) must meet the following:

1. Level of Protection Provided by ILD—It must be demonstrated by test that the seats and attachments, when subject to the emergency-landing dynamic conditions specified in § 25.562, and with one ILD not deployed, do not experience structural failure that could result in:

a. Separation of the seat from the airplane floor.

b. Separation of any part of the seat that could form a hazard to the seat occupant or any other airplane occupant.

c. Failure of the occupant restraint or any other condition that could result in the occupant separating from the seat.

2. Protection Provided Below and Above the ILD Actuation Condition—If step-change effects on occupant protection exist for impacts below and above that at which the ILD deploys, tests must be performed to demonstrate that the occupant is shown to be protected at any condition at which the ILD does or does not deploy, up to the maximum severity pulse specified by § 25.562. Test conditions must take into account any necessary tolerances for deployment.

3. Protection Over a Range of Crash Pulse Vectors—The ILD must be shown to function as intended for all test vectors specified in § 25.562.

4. Protection During Secondary Impacts—The ILD activation setting must be demonstrated to maximize the probability of the protection being available when needed, considering a secondary impact that is above the severity at which the device is intended to deploy up to the impact loading required by § 25.562.

5. Protection of Occupants other than 50th Percentile—Protection of occupants for a range of stature from a two-year-old child to a ninety-five percentile male must be shown.

6. Inadvertent Operation—It must be shown that any inadvertent operation of the ILD does not affect the performance of the device during a subsequent emergency landing.

7. Installation Protection—It must be shown that the ILD installation is protected from contamination and interference from foreign objects.

8. Reliability—The performance of the ILD must not be altered by the effects of wear, manufacturing tolerances, aging/drying of lubricants, and corrosion.

9. Maintenance and Functional Checks—The design, installation, and operation of the ILD must be such that it is possible to functionally check the device in place. Additionally, a functional check method and a maintenance check interval must be included in the seat installer's instructions for continued airworthiness (ICA) document.

10. Release Function—If a means exists to release an inadvertently activated ILD, the release means must not introduce additional hidden failures that would prevent the ILD from functioning properly.

Issued in Des Moines, Washington, on August 5, 2019.

Victor Wicklund,

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

[FR Doc. 2019–17051 Filed 8–8–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2019–0540; Notice No. 25–19–11–SC]

Special Conditions: The Boeing Company Model 737 Series Airplanes; Seats With Inertia Locking Devices

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed special conditions.

SUMMARY: This action proposes special conditions for The Boeing Company (Boeing) Model 737 series airplanes. These airplanes will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. This design feature is an inertia locking device (ILD) installed in passenger seats. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These proposed 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: Send comments on or before September 23, 2019.

ADDRESSES: Send comments identified by Docket No. FAA–2019–0540 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: Shannon Lennon, Cabin and Airframe Safety Section, AIR–675, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 2200 South 216th Street, Des Moines, Washington 98198; telephone and fax 206–231–3209; email *shannon.lennon@faa.gov.*

SUPPLEMENTARY INFORMATION:

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 January 27, 2012, Boeing applied for Type Certificate No. A16WE for Model 737–8 airplanes. On September 19, 2018, Boeing applied for a change to Type Certificate No. A16WE for seats with inertia locking devices in Model 737 series airplanes. The Model 737 series airplane is a twin-engine, transport-category airplane with a maximum takeoff weight of 194,700 pounds and seating for 220 passengers.

Type Certification Basis

Under the provisions of title 14, Code of Federal Regulations (14 CFR) 21.101, Boeing must show that the Model 737 series airplanes, as changed, continue to meet the applicable provisions of the regulations listed in Type Certificate No. A16WE, 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 Boeing Model 737 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, Boeing Model 737 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

Boeing Model 737 series airplanes will incorporate the following novel or unusual design features:

Seats with inertia locking devices.

Discussion

Boeing has proposed to install, in Model 737 series airplanes, Thompson Aero Seating Ltd. passenger seats that can be translated in the fore and aft direction by an electrically powered motor (actuator) that is attached to the seat primary structure. Under typical service-loading conditions, the motor internal brake is able to translate the seat and hold the seat in the translated position. However, under the inertial loads of emergency-landing loading conditions specified in 14 CFR 25.562, the motor internal brake may not be able to maintain the seat in the required position. The ILD is an ''active'' device intended to control seat movement (*i.e.,* a system that mechanically deploys during an impact event) to lock the gears of the motor assembly in place. The ILD mechanism is activated by the higher inertial load factors that could occur during an emergency landing event. Each seat place incorporates two ILDs; one on either side of the seat pan. Only one ILD is required to hold an occupied seat in position during worst-case dynamic loading specified in § 25.562.

The ILD will self-activate only in the event of a predetermined airplane loading condition such as that occurring during crash or emergency landing, and will prevent excessive seat forward translation. A minimum level of protection must be provided if the seat-locking device does not deploy.

The normal means of satisfying the structural and occupant protection requirements of § 25.562 result in a non-quantified, but nominally predictable, progressive structural deformation or reduction of injury severity for impact conditions less than the maximum specified by the rule. A seat using ILD technology, however, may involve a step change in protection for impacts below and above that at which the ILD activates and deploys to retain the seat pan in place. This could result in structural deformation or occupant injury output being higher at an intermediate impact condition than that resulting from the maximum impact condition. It is acceptable for such step-change characteristics to exist, provided the resulting output does not exceed the maximum allowable criteria at any condition at which the ILD does or does not deploy, up to the maximum severity pulse specified by the requirements.

The ideal triangular maximum severity pulse is defined in Advisory Circular (AC) 25.562–1B. For the evaluation and testing of less-severe pulses for purposes of assessing the effectiveness of the ILD deployment setting, a similar triangular pulse should be used with acceleration, rise time, and velocity change scaled accordingly. The magnitude of the required pulse should not deviate below the ideal pulse by more than 0.5g until 1.33 t_1 is reached, where t_1 represents the time interval between 0 and t_1 on the referenced pulse shape as shown in AC 25.562–1B. This is an acceptable method of compliance to the test requirements of the special conditions.

Proposed conditions 1 through 5 address ensuring that the ILD activates when intended in order to provide the necessary protection of occupants. This includes protection of a range of occupants under various accident conditions. Proposed conditions 6 through 10 address maintenance and reliability of the ILD, including any outside influences on the mechanism, to ensure it functions as intended.

The proposed 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 Boeing Model 737 series airplanes. Should Boeing 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 one novel or unusual design feature 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 Proposed Special Conditions

Accordingly, the Federal Aviation Administration (FAA) proposes the following special conditions as part of the type certification basis for Boeing Model 737 series airplanes.

In addition to the requirements of § 25.562, passenger seats incorporating an inertia locking device (ILD) must meet the following:

1. Level of Protection Provided by ILD—It must be demonstrated by test that the seats and attachments, when subject to the emergency-landing dynamic conditions specified in § 25.562, and with one ILD not deployed, do not experience structural failure that could result in:

a. Separation of the seat from the airplane floor.

b. Separation of any part of the seat that could form a hazard to the seat occupant or any other airplane occupant.

c. Failure of the occupant restraint or any other condition that could result in the occupant separating from the seat.

2. Protection Provided Below and Above the ILD Actuation Condition—If step-change effects on occupant protection exist for impacts below and above that at which the ILD deploys, tests must be performed to demonstrate that the occupant is shown to be protected at any condition at which the ILD does or does not deploy, up to the maximum severity pulse specified by § 25.562. Test conditions must take into account any necessary tolerances for deployment.

3. Protection Over a Range of Crash Pulse Vectors—The ILD must be shown to function as intended for all test vectors specified in § 25.562.

4. Protection During Secondary Impacts—The ILD activation setting must be demonstrated to maximize the probability of the protection being available when needed, considering a secondary impact that is above the severity at which the device is intended to deploy up to the impact loading required by § 25.562.

5. Protection of Occupants other than 50th Percentile—Protection of occupants for a range of stature from a two-year-old child to a ninety-five percentile male must be shown.

6. Inadvertent Operation—It must be shown that any inadvertent operation of the ILD does not affect the performance of the device during a subsequent emergency landing.

7. Installation Protection—It must be shown that the ILD installation is protected from contamination and interference from foreign objects.

8. Reliability—The performance of the ILD must not be altered by the effects of wear, manufacturing tolerances, aging/drying of lubricants, and corrosion.

9. Maintenance and Functional Checks—The design, installation and operation of the ILD must be such that it is possible to functionally check the device in place. Additionally, a functional check method and a maintenance check interval must be included in the seat installer's instructions for continued airworthiness (ICA) document.

10. Release Function—If a means exists to release an inadvertently activated ILD, the release means must not introduce additional hidden failures that would prevent the ILD from functioning properly.

Issued in Des Moines, Washington, on August 5, 2019.

Victor Wicklund,

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

[FR Doc. 2019–17050 Filed 8–8–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0583; Product Identifier 2019–NM–063–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

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

DATES: The FAA must receive comments on this proposed AD by September 23, 2019.

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:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0583.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0583; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

The AD docket contains this NPRM, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Allen Rauschendorfer, Aerospace Engineer, Airframe Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3528; email: *Allen.Rauschendorfer@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2019–0583; Product Identifier 2019–NM–063–AD'' at the beginning of your comments. The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. The FAA will consider all comments received by the closing date and may amend this NPRM because of those comments.

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

Discussion

The FAA received a report of an escapement from the wing spar terminal fitting supplier indicating that the engineering requirements provided by Boeing for controlling machine mismatch were incorrect for part faying surfaces, which can result in a reduced fatigue capability at the interface of the SOB rib. The engineering-defined machined mismatch requirement of 0.001 inch was incorrectly documented as 0.010 inch. Inspection of parts internal to Boeing production found machine mismatch on faying surfaces exceeding the 0.001-inch requirement. This condition, if not addressed, could result in undetected fatigue cracks. Undetected fatigue cracks can grow to weaken primary wing structure where it cannot sustain limit load, which could adversely affect the structural integrity of the airplane.

Related Service Information Under 1 CFR Part 51

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

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

FAA's Determination

The FAA is proposing this AD because the agency evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishment of the actions identified in Boeing Alert Requirements Bulletin B787–81205–SB570036–00 RB, Issue 001, dated December 14, 2018, described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

For information on the procedures and compliance times, see this service information at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0583.

Costs of Compliance

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

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	Up to 32 work-hours × $85 per hour = Up to $2,720 per inspection cycle.	$960	Up to $3,680 per inspection cycle	Up to $3,680 per inspection cycle.

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

According to the manufacturer, some or all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the FAA has included all known costs in our cost estimate.

Authority for This Rulemaking

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

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

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

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not

have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2019–0583; Product Identifier 2019–NM–063–AD.

(a) Comments Due Date

The FAA must receive comments by September 23, 2019.

(b) Affected ADs

None.

(c) Applicability

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

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by a report of an escapement from the wing spar terminal fitting supplier indicating that the engineering requirements provided by Boeing for controlling machine mismatch were incorrect for part faying surfaces, which can result in a reduced fatigue capability at the interface of the side of body (SOB) rib. The FAA is issuing this AD to address fatigue cracks in the left and right SOB rib webs common to the front and rear wing spar terminal fittings. Undetected fatigue cracks can grow to weaken primary wing structure where it cannot sustain limit load, which could adversely affect the structural integrity of the airplane.

(f) Compliance

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

(g) Required Actions

Except as specified by paragraph (h) of this AD: At the applicable times specified in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin B787–81205–SB570036–00 RB, Issue 001, dated December 14, 2018, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin B787–81205–SB570036–00 RB, Issue 001, dated December 14, 2018.

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

(h) Exception to Service Information Specifications

Where Boeing Alert Requirements Bulletin B787–81205–SB570036–00 RB, Issue 001, dated December 14, 2018, specifies contacting Boeing for repair instructions: This AD requires doing the repair using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(j) Related Information

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

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on July 26, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–17008 Filed 8–8–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0602; Product Identifier 2019–NM–016–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2010–26–01, which applies to certain The Boeing Company Model 777–200 series airplanes. AD 2010–26–01 requires installing a new insulation blanket on the latch beam firewall of each thrust reverser (T/R) half. Since AD 2010–26–01 was issued, the agency received a report that the T/R affected by AD 2010–26–01 has the potential to be installed on airplanes outside of the applicability of that AD. This proposed AD would retain the requirements of 2010–26–01. This proposed AD would also add airplanes to the applicability. For those airplanes, this proposed AD would require an inspection to determine if the installed T/R has an affected part number and, if an affected part number is found, installation of a new insulation blanket. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by September 23, 2019.

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:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com*. You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

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–2019–0602; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: James Laubaugh, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3622; email: *james.laubaugh@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2019–0602; Product Identifier 2019–NM–016–AD'' at the beginning of your comments. The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. The FAA will consider all comments received by the closing date and may amend this NPRM because of those comments.

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

Discussion

The FAA issued AD 2010–26–01, Amendment 39–16540 (75 FR 78594, December 16, 2010) (''AD 2010–26–01''), for certain Model 777–200 series airplanes. AD 2010–26–01 requires installing a new insulation blanket on the latch beam firewall of each T/R half. AD 2010–26–01 resulted from an in-flight shutdown due to an engine fire indication; an under-cowl engine fire was extinguished after landing. We issued AD 2010–26–01 to prevent a fire from entering the cowl or strut area, which could weaken T/R parts and result in reduced structural integrity of the T/R, possible separation of T/R parts during flight, and consequent damage to the airplane and injury to people or damage to property on the ground.

Actions Since AD 2010–26–01 Was Issued

Since AD 2010–26–01 was issued, the agency received a report that the T/R affected by AD 2010–26–01 has the potential to be installed on airplanes outside of the applicability of that AD. Therefore, the applicability in this proposed AD has been revised to specify The Boeing Company Model 777–200 series airplanes, equipped with General Electric Company (GE) GE90–76B, –85B, –90B, or –94B engines.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Service Bulletin 777–78A0066, Revision 3, dated April 28, 2011. This service information describes procedures for installing a new insulation blanket on the latch beam firewall of each T/R half. The installation includes, for certain airplanes, inspecting to determine if fitting part number 315W1436–4 is installed on the aft latch beam of the right side T/R and, for affected fittings, cutting the clevis from the affected fitting.

This proposed AD would also require Boeing Alert Service Bulletin 777–78A0066, Revision 2, dated April 8, 2010, which the Director of the Federal Register approved for incorporation by reference as of January 20, 2011 (75 FR 78594, December 16, 2010).

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

FAA's Determination

The FAA is proposing this AD because the agency evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would retain all requirements of AD 2010–26–01. This proposed AD would also add airplanes to the applicability. For those airplanes, this proposed AD would require an inspection to determine if the installed T/R has an affected part number and, if an affected part number is found, installation of a new insulation blanket.

Costs of Compliance

The FAA estimates that this proposed AD affects 25 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Blanket installation (retained actions from AD 2010–26–01) (21 airplanes).	7 work-hours × $85 per hour = $595	Up to $5,253	Up to $5,848	Up to $122,808.
Inspection and blanket installation (new proposed action) (4 airplanes).	Up to 13 work-hours × $85 per hour = Up to $1,105.	Up to $7,529	Up to $8,634	Up to $34,536.

Authority for This Rulemaking

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

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

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

Regulatory Findings

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

For the reasons discussed above, I certify that the proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2010–26–01, Amendment 39–16540 (75 FR 78594, December 16, 2010), and adding the following new AD:

The Boeing Company: Docket No. FAA–2019–0602; Product Identifier 2019–NM–016–AD.

(a) Comments Due Date

The FAA must receive comments on this AD action by September 23, 2019.

(b) Affected ADs

This AD replaces AD 2010–26–01, Amendment 39–16540 (75 FR 78594, December 16, 2010) (''AD 2010–26–01'').

(c) Applicability

This AD applies to The Boeing Company Model 777–200 series airplanes, certificated in any category, equipped with General Electric Company (GE) GE90–76B, –85B, –90B, or –94B engines.

(d) Subject

Air Transport Association (ATA) of America Code 78, Engine exhaust.

(e) Unsafe Condition

This AD was prompted by a report of an in-flight shutdown due to an engine fire indication; an under-cowl engine fire was extinguished after landing and a determination that additional airplanes are affected. The FAA is issuing this AD to prevent a fire from entering the cowl or strut area, which could weaken thrust reverser (T/R) parts and result in reduced structural integrity of the T/R, possible separation of T/R parts during flight, and consequent damage to the airplane and injury to people or damage to property on the ground.

(f) Compliance

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

(g) Retained Installation of Insulation Blanket, With Revised Service Information

This paragraph restates the requirements of paragraph (g) of AD 2010–26–01, with revised service information. For airplanes identified in Boeing Alert Service Bulletin 777–78A0066, Revision 2, dated April 8, 2010: Within 60 months or 4,500 flight cycles after January 20, 2011 (the effective date of AD 2010–26–01), whichever is first, install a new insulation blanket on the latch beam firewall of each T/R half by doing all the applicable actions specified in the Accomplishment Instructions of Boeing Service Bulletin 777–78A0066, Revision 3, dated April 28, 2011.

(h) New Requirement: Installation of Insulation Blanket for Additional Airplanes

For airplanes not identified in paragraph (g) of this AD: Within 60 months or 4,500 flight cycles after the effective date of this AD, whichever is first, inspect to determine if the installed T/R has any affected part number as identified in paragraphs (h)(1) through (h)(5) of this AD. If an affected T/R is found or if it cannot be determined which T/R is installed, within 60 months or 4,500 flight cycles after the effective date of this AD, whichever is first, install a new insulation blanket on the latch beam firewall of each T/R half by doing all the applicable actions specified in the Accomplishment Instructions of Boeing Service Bulletin 777–78A0066, Revision 3, dated April 28, 2011, except as specified in paragraph (i) of this AD. A review of airplane maintenance records is acceptable in lieu of this inspection if it can be conclusively determined from that review that the installed T/R is not an affected T/R. A review of airplane maintenance records is also acceptable in lieu of this inspection if it can be conclusively determined from that review that an affected T/R is installed and the actions specified in Boeing Service Bulletin 777–78A0066, Revision 3, dated April 28, 2011, have already been done on that T/R.

(1) 315W1001–XX (all—where ''XX'' is any combination of numbers and letters that follow the dash).

(2) 315W1295–1 through 315W1295–222 inclusive.

(3) 315W1295–5001 through 315W1295–5222 inclusive.

(4) 315W1295–5501 through 315W1295–5722 inclusive.

(5) 315W1295–6101 through 315W1295–6322 inclusive.

(i) Exceptions to Service Information Specification

(1) Boeing Service Bulletin 777–78A0066, Revision 3, dated April 28, 2011, defines Group 1 as ''all 777–200 airplanes with GE90 engines through line number 413 with a forward insulation blanket;'' however for paragraph (h) of this AD, Group 1 is defined as ''all 777–200 airplanes with GE90 engines with a forward insulation blanket.''

(2) Boeing Service Bulletin 777–78A0066, Revision 3, dated April 28, 2011, defines Group 2 as ''all 777–200 airplanes with GE90 engines through line number 413 without a forward insulation blanket;'' however for paragraph (h) of this AD, Group 2 is defined as ''all 777–200 airplanes with GE90 engines without a forward insulation blanket.''

(3) Boeing Service Bulletin 777–78A0066, Revision 3, dated April 28, 2011, defines Group 2 Configuration 1 as ''all 777–200 airplanes with GE90 engines through line number 413 without a forward insulation blanket and without the fitting assembly at the aft insulation blanket location;'' however for paragraph (h) of this AD, Group 2 Configuration 1 is defined as ''all 777–200

airplanes with GE90 engines without a forward insulation blanket and without the fitting assembly at the aft insulation blanket location.''

(4) Boeing Service Bulletin 777–78A0066, Revision 3, dated April 28, 2011, defines Group 2 Configuration 2 as ''all 777–200 airplanes with GE90 engines through line number 413 without a forward insulation blanket and with the fitting assembly at the aft insulation blanket location;'' however for paragraph (h) of this AD, Group 2 Configuration 2 is defined as ''all 777–200 airplanes with GE90 engines without a forward insulation blanket and with the fitting assembly at the aft insulation blanket location.''

(j) Credit for Previous Actions

This paragraph provides credit for the actions specified in paragraphs (g) and (h) of this AD, if those actions were performed before the effective date of this AD using the service information specified in paragraphs (j)(1), (j)(2), or (j)(3) of this AD.

(1) Boeing Alert Service Bulletin 777–78A0066, dated June 5, 2008.

(2) Boeing Service Bulletin 777–78A0066, Revision 1, dated March 12, 2009.

(3) Boeing Alert Service Bulletin 777–78A0066, Revision 2, dated April 8, 2010.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (l)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov*.

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) AMOCs approved previously for AD 2010–26–01 are approved as AMOCs for the corresponding provisions of paragraph (g) of this AD.

(l) Related Information

(1) For more information about this AD, contact James Laubaugh, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3622; email: *james.laubaugh@faa.gov*.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717. You may view this referenced service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on July 30, 2019.

Dionne Palermo,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–16899 Filed 8–8–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 220

RIN 0596–AD31

National Environmental Policy Act (NEPA) Compliance

AGENCY: Forest Service, USDA.

ACTION: Proposed rule; extension of comment period.

SUMMARY: On June 13, 2019, the U.S. Department of Agriculture, Forest Service (Agency) published a proposed rule to revise its National Environmental Policy Act (NEPA) regulations. The Agency is extending the comment period on the proposed rule, which was scheduled to close on August 12, 2019, for 14 days until August 26, 2019.

DATES: The comment period for the proposed rule published June 13, 2019, at 84 FR 27544, is extended. Comments must be received in writing by August 26, 2019.

ADDRESSES: Please submit comments via one of the following methods:

1. *Public participation portal (preferred): https://www.regulations.gov/.*

2. *Mail:* NEPA Services Group, c/o Amy Barker; USDA Forest Service, 125 South State Street, Suite 1705, Salt Lake City, UT 84138.

3. *Email: nepa-procedures-revision@fs.fed.us.*

All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received online via the public reading room at *https://www.regulations.gov/.*

The proposed rule and supporting information is available at *https://www.fs.fed.us/emc/nepa/revisions/index.shtml.*

FOR FURTHER INFORMATION CONTACT: Christine Dawe; Director, Ecosystem Management Coordination; 406–370–8865. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

Dated: August 6, 2019.

Christopher B. French,

Deputy Chief, National Forest System.

[FR Doc. 2019–17071 Filed 8–8–19; 8:45 am]

BILLING CODE 3411–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51 and 52

[EPA–HQ–OAR–2018–0048; FRL–9997–95–OAR]

RIN 2060–AT89

Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR): Project Emissions Accounting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to revise certain New Source Review (NSR) applicability regulations to clarify the requirements that apply to sources proposing to undertake a physical or operational change (*i.e.,* a project) under the NSR preconstruction permitting program. Under this program, an existing major source proposing to undertake a project must determine whether that project will constitute a major modification following a two-step applicability test and thus be subject to the NSR preconstruction permitting requirements. The first step is to determine if the proposed project will cause a ''significant emissions increase'' of a regulated NSR pollutant (Step 1). If the proposed project is projected to cause such an increase, the second step is to determine if there is a ''significant net emissions increase'' of that pollutant (Step 2). In this action, we are proposing to revise our NSR applicability regulations to make it clear that both emissions increases and emissions decreases that result from a given proposed project are to be considered at Step 1 of the NSR major modification applicability test. In addition, this proposal replaces and withdraws the agency's 2006 Project Netting Proposal.

DATES:

Comments: Comments must be received on or before October 8, 2019.

Public Hearing: If anyone contacts us requesting to speak at a public hearing by August 30, 2019, the EPA will hold a public hearing. Additional information about the hearing will be published in a subsequent **Federal Register** document.

ADDRESSES: *Comments:* Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2018–0048, 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/comments.html*.

FOR FURTHER INFORMATION CONTACT: Jessica Montañez, Air Quality Policy Division, Office of Air Quality Planning and Standards (C504–03), Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number: (919) 541–3407; email address: *montanez.jessica@epa.gov*.

To request a public hearing or information pertaining to a public hearing on this document, contact Ms. Pamela Long, Air Quality Policy Division, Office of Air Quality Planning and Standards (C504–01), Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number (919) 541–0641; fax number (919) 541–4028; email address: *long.pam@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

Entities potentially affected directly by this action include sources in all industry categories. Entities potentially affected by this action also include state, local and tribal air pollution control agencies (air agencies) responsible for permitting sources pursuant to the NSR program.

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

When submitting comments, remember to:

- Identify the rulemaking docket by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions. The proposed rule may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree, suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used to support your comment.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns wherever possible and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

C. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this **Federal Register** document will be posted at *https://www.epa.gov/nsr*.

D. How is this proposed rule organized?

The information presented in this document is organized as follows:

II. Background

A. New Source Review Program

The major NSR provisions of the Clean Air Act (CAA) are a combination of air quality planning and air pollution control technology provisions that require stationary sources of air pollution to obtain a preconstruction permit prior to beginning the construction of a new major stationary source or a major modification of an existing major stationary source. Part C of title I of the CAA contains the requirements for the preconstruction review and permitting of new and modified major stationary sources of air pollution (specifically, regulated NSR pollutants) locating in areas meeting the National Ambient Air Quality Standards (NAAQS) (''attainment'' areas) and, areas for which there is insufficient information to classify an area as either attainment or nonattainment (''unclassifiable'' areas).[1] This program is known as the Prevention of Significant Deterioration (PSD) program.

[1] 40 CFR 52.21(b)(50) defines the term ''regulated NSR pollutant'' for purposes of the Prevention of Significant Deterioration program. The term generally includes pollutants for which a NAAQS has been promulgated and other pollutants subject to regulation under the CAA. This ''regulated NSR pollutant'' definition, however, excludes the Hazardous Air Pollutants regulated under section 112 of the CAA.

Part D of title I of the CAA contains the requirements for the preconstruction review and permitting of new and modified major stationary sources of air pollution locating in areas not meeting the NAAQS (''nonattainment'' areas). This program is known as the Nonattainment New Source Review (NNSR) program.[2]

The permit program for non-major sources and minor modifications to major sources is known as the minor NSR program. CAA section 110(a)(2)(C) requires states to develop a program, which includes a permitting program to regulate the construction and modification of any stationary source ''as necessary to assure that [NAAQS] are achieved.''

To comply with the requirements of the CAA and the major NSR implementing regulations at 40 CFR 51.166 and 51.165 respectively, most states have EPA-approved State Implementation Plans (SIPs) in place to implement the PSD and NNSR preconstruction permit programs. For states and tribes that lack an EPA-approved SIP or Tribal Implementation Plan (TIP) to implement the PSD permit program, the federal PSD program at 40 CFR 52.21 applies. For states that do not have an approved NNSR SIP for a particular nonattainment pollutant, Appendix S to 40 CFR part 51 contains an interim NNSR program. This interim program enables implementation of NNSR permitting in such areas during the time between the date of the relevant nonattainment designation and the date on which the EPA approves into the SIP a NNSR program or additional components of an NNSR program for a particular pollutant. The EPA also has a federal NNSR program at 40 CFR 49.165 that only applies to tribal areas that do not have an EPA-approved TIP in place to implement the NNSR program.[3] For stationary sources whose emissions are lower than the PSD and NNSR applicability thresholds, minor NSR permitting requirements might apply. Sources should consult with the applicable state or local permitting agency, or for most tribal areas the applicable EPA Regional office,[4] to determine if any minor NSR requirements may apply to your stationary source.

The applicability of the PSD, NNSR, or minor NSR programs to a stationary source must be determined in advance of construction and is a pollutant-specific determination. Thus, a stationary source may be subject to the PSD program for certain pollutants, NNSR for some pollutants and minor NSR for others.

B. Major Modifications Under the NSR Program

Our NSR regulations define a major modification[5] as any physical change in or change in the method of operation of an existing major stationary source that would result in a significant emissions increase of a regulated NSR pollutant (known as Step 1) and a significant net emissions increase of that pollutant (known as Step 2) from the major stationary source. This two-step test, which has been an element of the NSR program since the 1980's, was codified by the 2002 NSR Reform Rule[6] to explicitly include the prior EPA practice of looking first at whether any emissions increase that may result from the project[7] by itself would be significant before evaluating whether there would be a significant ''net emission increase''[8] from the major stationary source as a whole. In other words, Step 1 considers the effect of the project alone and Step 2 considers the effect of the project and any *other* emissions changes at the major stationary source that are contemporaneous to the project (*i.e.,* generally within a 5-year period) and creditable. We currently refer to Step 1 applicability procedures as ''project emissions accounting'' (previously known as ''project netting'') and Step 2 as ''contemporaneous netting.''[9]

An emissions increase of a regulated NSR pollutant is considered significant at Step 1 or 2 if the emissions increase would be equal to or greater than any of the pollutant-specific significant emissions rates listed under the definition of ''significant'' in the applicable PSD or NNSR regulations.[10] For those regulated NSR pollutants not specifically listed, any increase in emissions is significant. In addition, the procedure for calculating whether a proposed project would result in a significant emissions increase depends upon the type of emissions unit(s)[11] that would be included in the proposed project. The emissions units involved in a project can be new, existing, or a combination of new and existing units.[12] For new units,[13] the NSR regulations require the difference in pre- and post-project emissions to be calculated based on the difference between baseline actual emissions (as applicable to new emissions units)[14] and potential to emit (PTE)[15] after the project. For existing units,[16] the NSR regulations allow the difference in pre- and post-project emissions to be calculated based on the difference between baseline actual emissions (as

[2] For purposes of NNSR, ''regulated NSR pollutant'' is defined at 40 CFR 51.165(a)(1)(xxxvii).

[3] To date, no tribe has submitted a TIP to administer the NNSR program for any lands under their jurisdiction. Thus, the EPA is currently the NNSR reviewing authority in Indian Country.

[4] To date, most tribes have not submitted a TIP to administer the minor NSR program for any lands under their jurisdiction. Thus, the EPA is currently the minor NSR reviewing authority in Indian country for most tribal areas.

[5] 40 CFR 52.21(b)(2). The regulations at 40 CFR 52.21 apply to the federal PSD program, however, the EPA has other NSR regulations, including 40 CFR 51.165, 51.166, and Appendix S of part 51, that contain analogous provisions. This proposal also applies to those analogous provisions. However, there are certain modification provisions under the Title I, Subpart D of the CAA and the EPA nonattainment NSR regulations that apply to certain nonattainment area classifications (*See, e.g.,* CAA section 182(e)(2); 40 CFR part 51, Appendix S 11.A.5.(v)). This proposal does not cover those provisions.

[6] In 2002, the EPA issued a final rule that revised the regulations governing the major NSR program. The agency refers generally to these rule provisions as the ''NSR Reform Rule.'' As part of this rule, the EPA revised the NSR applicability requirements for modifications to allow sources more flexibility to respond to rapidly changing markets and plan for future investments in pollution control and prevention technologies. 67 FR 80186 (December 31, 2002).

[7] 40 CFR 52.21(b)(52). In general, we use the term ''project'' to mean the physical change or change in method of operation under review, though this can encompass one or more activities at an existing major source. A subsequent section of this rule's preamble discusses how multiple activities should be evaluated to determine whether these activities constitute one project.

[8] 40 CFR 52.21(b)(3).

[9] Contemporaneous netting is voluntary and can add significant complexity to the NSR applicability process in that it requires the additional accounting of all other increases and decreases in actual emissions that are contemporaneous and creditable to the project. Additionally, to be creditable, emissions decreases accounted for under Step 2 must, among other things, be enforceable as a practical matter at and after the time actual construction on the project being evaluated under Step 1 begins. This requirement can limit operational flexibility and increase permitting burden.

[10] 40 CFR 52.21(b)(23) defines when emissions of listed pollutants are considered significant under the federal PSD program. These pollutants include, but are not limited to, the following: Pollutants for which a NAAQS has been promulgated, fluorides, and sulfuric acid mist.

[11] 40 CFR 52.21(b)(7). There are two types of emissions units, new and existing. A ''replacement unit'' as defined in the NSR regulations is an existing emissions unit.

[12] 40 CFR 52.21(a)(2)(iv).

[13] 40 CFR 52.21(b)(7)(i).

[14] The NSR regulations define a ''new emissions unit'' as ''any emissions unit that is (or will be) newly constructed and that has existed for less than two years from the date such emission unit first operated.'' 40 CFR 52.21(b)(7)(i). The ''baseline actual emissions for purposes of determining the emissions increase that will result from the initial construction and operation of such unit shall equal zero; and thereafter, for all other purposes, shall equal the unit's potential to emit.'' 40 CFR 52.21(b)(48)(iii).

[15] 40 CFR 52.21(b)(4).

[16] 40 CFR 52.21(b)(7)(ii).

applicable to existing emissions units) [17] and projected actual emissions.[18] Baseline actual emissions are generally based on the rate of actual emissions a unit has emitted in the past. Projected actual emissions are based on the maximum rate of actual emissions a unit is projected to emit in the future. Potential to emit represents a unit's maximum capacity to emit a pollutant under its physical and operational design.

Step 2, or contemporaneous netting, is described in 40 CFR 52.21(a)(2)(iv)(a). Once a source owner or operator determines that a significant emissions increase would occur at Step 1, then the source owner or operator may perform the Step 2 or contemporaneous netting analysis to determine if there would be a significant net emissions increase. A ''net emissions increase'' is specifically defined at 40 CFR 52.21 (b)(3) [19] and ''means, with respect to any regulated NSR pollutant emitted at a major stationary source, the amount of which the sum of the following exceeds zero: (a) The increase in emissions from a particular physical change or change in the method of operation at a stationary source as calculated pursuant to [40 CFR 52.21] (a)(2)(iv), and (b) any other increases and decreases in actual emissions at the major stationary source that are contemporaneous with the particular change and are otherwise creditable.'' Thus, the Step 2 contemporaneous netting analysis is conducted by adding the resulting emissions changes from the project at Step 1 to all *other* emissions increases and decreases in actual emissions at the major stationary source that are contemporaneous with the Step 1 project and otherwise creditable. If there is a significant net emissions increase after the Step 2 contemporaneous netting analysis, then the project is a major modification.

Emissions increases and decreases are contemporaneous if they occur between ''the date five years before construction of a particular project commences and the date that the increase from a particular change occurs.'' [20] An emissions increase or decrease in actual emissions under Step 2 is creditable only if the EPA Administrator or other reviewing authority has not relied on it in issuing a PSD or NNSR permit for the source and the permit is still in effect at the time of the major modification.[21] Furthermore, emissions increases under Step 2 are only creditable if the new level of actual emissions exceeds the old level of actual emissions.[22] Emissions decreases under Step 2, on the other hand, are creditable only to the extent that the old level of actual emissions or the old level of allowable emissions, whichever is lower, exceeds the new level of actual emissions and the decrease in actual emissions is enforceable as a practical matter at and after the time that actual construction of the particular change begins.[23]

Thus, for a project that results in a significant emissions increase under Step 1 of the major modification applicability test and a significant net emissions increase as determined under Step 2, the modification is a major modification.

C. Regulatory History

In 2002, as part of the NSR Reform Rule, the EPA revised the applicability procedures in its NSR regulations, including procedures for determining whether a project at an existing major stationary source constitutes a major modification. This 2002 rule codified the EPA's prior interpretation that one must first determine whether ''there will be a significant emissions increase from the modification itself,'' [24] and only then move on to assess whether there will be a significant net emissions increase (based on the contemporaneous netting analysis).

In 2006, the EPA issued a proposed rule titled, ''Prevention of Significant Deterioration and Nonattainment New Source Review: Debottlenecking, Aggregation and Project Netting'' (2006 Project Netting Proposal) [25] to address, among other topics, the accounting of emissions under Step 1 of the major modification applicability test. Prior to the 2006 Project Netting Proposal, the agency had come to perceive that there was some uncertainty both within the regulated community and among reviewing authorities with respect to how to account for emissions at Step 1 of the NSR applicability regulations, insofar as some sources and reviewing authorities were counting both emissions decreases and emissions increases from a project at Step 1 of the major modification applicability test, while others were only considering emissions increases from a project at Step 1.[26] In addition, the EPA made applicability determinations before and after this proposal in which it suggested that the NSR applicability regulations could be read as precluding the consideration of emissions decreases at Step 1 of the major modification applicability test.[27] The agency indicated in the 2006 Project Netting Proposal that the current regulatory text for projects that involve multiple types of emissions units,[28] which uses the term ''sum of the emissions increases for each emissions unit,'' ''would not allow a source to include reductions from units that are part of the project until Step 2 of the calculation,'' while the current regulatory text that applies to projects that involve only new or existing units, which uses the term ''sum of the difference,'' would allow for the consideration of both emissions increases and decreases at Step 1 because that ''difference may either be a positive number (representing a projected increase) or a negative number (representing a projected decrease).'' [29]

In the 2006 Project Netting Proposal, we solicited public comment on revising the relevant regulatory text to expressly provide that both emissions increases and decreases that occur within the scope of a project be counted in Step 1 of the major modification applicability test for all project categories. The EPA explained that this was appropriate in order to ''represent the true environmental impact of a project on all involved emissions units.'' [30] In January 2009, however, the EPA announced in a **Federal Register** notice [31] that it was taking no action on the ''project netting'' portion of the 2006 proposal since the agency was still

[17] 40 CFR 52.21(b)(48)(i) and (ii).

[18] 40 CFR 52.21(b)(41). Alternatively, a source may elect to use potential to emit in lieu of projected actual emissions as described in 40 CFR 52.21(b)(41)(ii)(d).

[19] 40 CFR 51.166(b)(3) contains the same definition.

[20] 40 CFR 52.21(b)(3)(ii).

[21] 40 CFR 52.21(b)(3)(iii)(a).

[22] 40 CFR 52.21(b)(3)(v).

[23] 40 CFR 52.21(b)(3)(vi).

[24] Memorandum from Edward E. Reich, Director, Division of Stationary Source Enforcement to Charles Whitmore Chief, Technical Analysis Section, Region VII; ''Re: PSD Applicability,'' January 22, 1981.

[25] 71 FR 54235 (September 14, 2006).

[26] 71 FR 54248 (September 14, 2006) (''The EPA recognizes that in the past some sources and permitting authorities have counted decreases in emissions at the individual units involved in the project when determining an overall project emissions increase (*i.e.,* Step 1 of the NSR test), while some have not.'').

[27] For example, in the 2006 Project Netting Proposal the EPA mentioned that ''In past [permitting applicability] determinations, the EPA has stated that only the increases resulting from the project are considered in determining whether a significant emissions increase has occurred in Step 1.'' 71 FR 54248 (September 14, 2006). In addition, a 2010 letter from Barbara A. Finazzo, U.S. EPA Region 2 to Kathleen Antoine, HOVENSA, LLC, ''Re: HOVENSA Gas Turbine Nitrogen Oxides (GT NO_X) Prevention of Significant Deterioration (PSD) Permit Application-Emission Calculation Clarification,'' March 30, 2010, stated a similar conclusion.

[28] 40 CFR 52.21 (a)(2)(iv)(*f*).

[29] 71 FR 54249 (September 14, 2006).

[30] *Id.*

[31] 74 FR 2376 (January 15, 2009).

considering whether and how to proceed with that proposal.

In early 2017, the new Administration issued a Presidential Memorandum and several Executive Orders initiating a review of regulatory requirements. One of those actions was the Presidential Memorandum on Streamlining Permitting and Reducing Regulatory Burdens for Domestic Manufacturing.[32] The Presidential Memorandum directed the Secretary of Commerce to conduct outreach to stakeholders concerning the impact of federal regulations on domestic manufacturing and solicit comments from the public concerning federal actions to streamline permitting and reduce regulatory burdens for domestic manufacturers.[33] A number of the comments the Department of Commerce subsequently received were related to ''project netting.'' [34] In those comments, the commenters asked the EPA to allow for ''project netting'' in Step 1 of the NSR applicability test because, in general, most of these stakeholders believed that ''project netting'' streamlines permitting. In addition, some of these commenters asked the agency to finalize the 2006 Project Netting Proposal. During the public comment period for another action, Executive Order 13777 on Enforcing the Regulatory Reform Agenda,[35] the agency received over 20 comments specifically on ''project netting.'' [36] As with the commenters on the Presidential Memorandum on Streamlining Permitting, all of these commenters argued that the agency should allow for ''project netting.'' For example, one commenter stated that they had ''recently supported a client in obtaining a PSD permit in which Step 1 of the PSD applicability analysis exceeded the PSD [Significant Emission Rate] (SER) for several pollutants due to the fact that emissions reductions at certain emissions units could not be counted in Step 1.'' [37] This commenter represented that ''if ''project netting'' had been allowed in Step 1, then PSD review would not have been triggered'' and the client would had saved ''four additional months and an additional $80,000 in obtaining a PSD permit.''

After consideration of the ''project netting'' regulatory history, past interpretations, and the recent public comments on this topic, in March 2018, the EPA Administrator issued a memorandum titled ''Project Emissions Accounting Under the New Source Review Preconstruction Permitting Program'' (the ''March 2018 Memorandum'').[38] The March 2018 Memorandum communicated the EPA's current interpretation regarding the consideration of emissions decreases as part of Step 1 of the major modification applicability test. In the memorandum, the agency explained that it interprets the current NSR regulations as providing that emissions decreases as well as increases are to be considered at Step 1 of the NSR applicability process, where those decreases and increases are part of a single project.[39] Unlike in 2006, EPA determined in the March 2018 Memorandum that decreases could be considered at Step 1 for all project categories (*i.e.,* new, existing or projects that involve multiple types of emissions units) . Although the existing language in the NSR regulations supports this interpretation, this rulemaking proposal is intended to eliminate uncertainty regarding this issue. As discussed in more detail below, we propose to revise the NSR applicability procedures for projects that involve multiple types of emissions units to make clear that project emissions accounting should be conducted under Step 1 of the major modification applicability procedures for all project categories, consistent with the interpretation set forth in the March 2018 Memorandum. The EPA is not proposing any changes to the procedures or requirements for Step 2 of the major modification applicability regulations.

III. This Action

A. Overview

In this action, we are proposing revisions to the applicability provisions in the NSR regulations to fully clarify that the regulatory language of 40 CFR 52.21(a)(2)(iv)(*f*) allows the approach set forth in the March 2018 Memorandum. More specifically, we are proposing to revise the regulatory language for projects that involve multiple types of emissions units [40] to more directly state that both emissions increases and decreases are to be considered as part of Step 1 of the major modification applicability test in the same manner as they are for projects that involve only existing emissions units and projects that involve only new emissions units. Furthermore, the EPA is seeking comment on other aspects of the implementation of the concept of project emissions accounting, including how sources should keep records of their emissions increases and decreases. In addition, the EPA is seeking comment on whether states would need to modify their SIPs to accommodate this rule's clarifications if the rule revisions become final. Lastly, this proposal supersedes the agency's 2006 Project Netting Proposal and, as such, this action withdraws the 2006 Project Netting Proposal.

B. Revising the Step 1 Applicability Regulations for Projects That Involve Multiple Types of Emissions Units To Provide Clarity on These Applicability Procedures

As stated previously, the emissions units involved in a project can be new, existing or a combination of new and existing units.[41] For projects that involve only existing emissions units, the applicability procedures at 40 CFR 52.21(a)(2)(iv)(c) state that ''a significant emissions increase of a regulated NSR pollutant is projected to occur if the sum of the difference between the projected actual emissions and the baseline actual emissions for each existing emission unit, equals or exceeds the significant amount for that pollutant.'' For projects that only involve new emissions units, the applicability procedures at 40 CFR52.21(a)(2)(iv)(d) state that ''a significant emissions increase of a regulated NSR pollutant is projected to occur if the sum of the difference between the potential to emit from each new emissions unit following completion of the project and the baseline actual emissions of these units before the project equals or exceeds the significant amount for that pollutant.'' Finally, for projects that involve multiple types of emissions units (*i.e.,* a combination of new and existing units), the applicability procedures at 40 CFR 52.21(a)(2)(iv)(f) state that ''a significant emissions increase of a regulated NSR pollutant is projected to occur if the sum of the emissions increases for each emissions unit, using the method

[32] 82 FR 8667 (January 30, 2017).

[33] 82 FR 12786 (March 7, 2017).

[34] *https://www.regulations.gov/docket?D=DOC-2017-0001.*

[35] 82 FR 17793 (April 13, 2017).

[36] *https://www.regulations.gov/docket?D=EPA-HQ-OA-2017-0190.*

[37] EPA–HQ–OA–2017–0190–53674.

[38] Letter from E. Scott Pruitt, to Regional Administrators, ''Project Emissions Accounting Under the New Source Review Preconstruction Permitting Program,'' March 13, 2018 (''March 2018 Memorandum'').

[39] Furthermore, the memorandum clarified that while this Step 1 had previously been referred to as ''project netting,'' this terminology had caused confusion since the term ''netting'' more properly describes the consideration of other projects that may have been or will be undertaken during the contemporaneous period, which occurs under Step 2 of the major modification applicability test. As such, the memorandum said that since ''netting'' refers to consideration of other projects, its use in Step 1 was misplaced and that the term ''project emissions accounting'' more accurately reflects the purpose of Step 1 which is to account for the emissions impacts from the project itself.

[40] 40 CFR 52.21(a)(2)(iv)(f).

[41] 40 CFR 52.21 (a)(2)(iv).

specified in [40 CFR 52.21] (a)(2)(iv)(c) through (d) as applicable with respect to each emissions unit, for each type of emissions unit equals or exceeds the significant amount for that pollutant.''

In the 2006 Project Netting Proposal, the agency said, consistent with its prior understanding, that the omission of the phrase ''sum of the difference'' and the use of the term ''sum of the emissions increases'' in the regulations for the test for projects involving multiple types of emissions units (*i.e.,* hybrid test) suggested that the current NSR regulations ''would not allow a source to include reductions from units that are part of the project until Step 2 of the calculation.'' [42] However, as reflected in the Administrator's March 2018 Memorandum, the agency has reexamined the existing regulations and their context and has concluded after a more thorough review that, for projects that involve multiple types of emissions units, ''emissions decreases are also to be accounted for.'' [43] The applicability procedures for projects involving multiple types of emissions units state that for each type of unit involved in the modification, the ''method specified in [40 CFR 52.21] (a)(2)(iv)(c) through (d) of this section as applicable with respect to each emission unit'' shall be used and then the sum of the emissions increases for each type of emissions unit is calculated to determine if there is a significant emissions increase for that pollutant. Therefore, since ''the method specified in [40 CFR 52.21] (a)(2)(iv)(c) through (d) with respect to each emission unit'' applies, the EPA has concluded that ''the ''current NSR regulations provide that emissions decreases as well as increases are to be considered at Step 1 of the NSR applicability process . . .'' [44]

The EPA is proposing to revise a portion of the regulations to end any confusion and clarify that project emissions accounting is allowed for all project categories, including projects that involve multiple types of emissions units. Specifically, the EPA is proposing to revise the text ''sum of the emissions increase'' in 40 CFR 52.21(a)(2)(iv)(f) to ''sum of the difference'' as in subparagraphs 40 CFR 52.21(a)(2)(iv)(c) and (d) to make clear that accounting of emissions increases and decreases under Step 1 of the major modification applicability test is allowed for projects that involve multiple types of emissions units. Furthermore, the EPA is proposing to add a subparagraph (g) to 40 CFR 52.21(a)(2)(iv) to further clarify that the term ''sum of the difference,'' as used in 40 CFR 52.21(a)(2)(iv)(c) and (d) and proposed for 40 CFR 52.21(a)(2)(iv)(f), shall include both increases and decreases in emissions calculated in accordance with the procedures specified in those paragraphs. These proposed changes will make clear that projects that involve multiple types of emissions units should treat the calculation of the change in emissions from the project in the same way that projects that only involve new units or only involve existing units. As explained in the March 2018 Memorandum, the history of this provision in the regulations indicates that the EPA originally intended that project emissions accounting be allowed at Step 1 for projects involving different types of units.[45]

The EPA is seeking comment on these clarifying revisions to the regulatory text and whether other clarifications might be more appropriate to convey that consideration of emissions decreases and increases is allowed as part of Step 1 of the major modification applicability test for projects that involve both new and existing emissions units.

C. Legal Analysis and Policy Rationale

The EPA said in its March 2018 Memorandum that we believe that our current NSR applicability regulations, promulgated in 2002 can be reasonably interpreted to allow for project emissions accounting at Step 1.[46] However, the agency made statements in 2006 and earlier that suggested that, at least insofar as the so-called ''hybrid'' applicability test for proposed projects involving both new and existing units is concerned, emissions decreases may not be taken into account at Step 1. Thus, in light of this history, the EPA is proposing to make regulatory revisions that fully clarify that both increases and decreases in emissions from all categories of projects are to be considered at Step 1 of the major NSR applicability regulations.

Fundamentally, the major NSR applicability regulations discussed previously are an interpretation of the statutory phrase ''increases the amount of any air pollutant emitted'' contained in the definition of ''modification.'' [47] This definition is cross referenced in both Part C (PSD) and Part D (NNSR) of the CAA.[48] The United States Court of Appeals for the District of Columbia Circuit has recognized that the CAA ''is silent on how to calculate such 'increases' in emissions.'' [49] Thus, the question of how to determine whether a physical change or change in method of operation ''increases'' emissions is ambiguous.[50] Accordingly, because the statutory text does not itself dictate how to determine whether a physical change or change in the method of operation ''increases'' emissions, under the principles of *Chevron*,[51] the ''EPA has the authority to choose an interpretation'' of the term ''increases'' in ''administering the NSR program and filling in the gaps left by Congress.'' [52]

The EPA believes that allowing for consideration of both increases and decreases from a project is consistent with congressional intent for these preconstruction programs to cover existing sources only when they undertook projects which resulted in a non-*de minimis* increase in emissions.[53] If the full scope of emissions changes from a project were *not* considered at Step 1, the regulations could subject a project to preconstruction review when the actual effect of that project would be to reduce emissions, which would be contrary to congressional intent for this program.[54] The EPA sees little policy

[42] 71 FR 54249 (September 14, 2006).

[43] March 2018 Memorandum at 8.

[44] March 2018 Memorandum at 1.

[45] March 2018 Memorandum at 8.

[46] For example, and as stated in the March 2018 memorandum at 6, ''This interpretation is grounded in the principle that the 'plain language of the CAA indicates that Congress intended to apply NSR to *changes that increase actual emissions.' State of New York* v. *EPA,* 413 F.3d at 40 (emphasis added). Central to the CAA's definition of 'modification' is that there must be a causal link between the physical or operational change at issue—*i.e.,* the 'project'—and any change in emissions that may ensue. In other words, it is necessary to account for the full and direct effect of the proposed change itself. Accordingly, at the very outset of the process for determining whether NSR may be triggered, the EPA should give attention to not only whether emissions may increase from those units that are part of the project but also whether emissions may at the same time decrease at other units that are also part of the project.''

[47] 42 U.S.C. 7411(a)(4).

[48] 42 U.S.C. 7479(2)(C); 42 U.S.C. 7501(4).

[49] *New York* v. *EPA,* 413 F.3d 3, 22 (D.C. Cir. 2005) (*New York I*).

[50] *New York* v. *EPA,* 443 F.3d 880, 888–89 (D.C. Cir. 2006) (*New York II*) (''Congress's use of the word 'increases' necessitated further definition regarding rate and measurement for the term to have any contextual meaning.'').

[51] *Chevron U.S.A.* v. *Natural Resources Defense Council,* 467 U.S. 837, 843 (1984) (Where the ''statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.'')

[52] *New York I,* 413 F.3d at 23, 24.

[53] *Alabama Power* v. *Costle,* 636 F.2d 323, 401 (D.C. Cir. 1979) (''Congress wished to apply the permit process, then, only where industrial changes might increase pollution in an area, not where an existing plant changed its operations in ways that produced no pollution increase.'').

[54] Emissions decreases may also be accounted for under Step 2; however, the language in the NSR regulations makes clear that such decreases are ones ''other'' than those associated with the project being evaluated under Step 1. *See, e.g.,* 40 CFR

Continued

support for such an outcome, while allowing the consideration of both increases and decreases at Step 1 would allow sources to undertake projects that are overall environmentally beneficial that they might forgo if decreases could not be considered at Step 1. Therefore, the EPA believes a two-step process—first determining all of the emissions changes, both increases and decreases, from the project under consideration and second, considering any *other* contemporaneous increases or decreases that are otherwise creditable—is a reasonable and allowable interpretation of the phrase ''increases the amount of any air pollutant emitted'' within the definition of ''modification.''

Furthermore, this approach represents sound policy to the extent it encourages emissions decreases that might not otherwise occur or would be delayed. In discussions with stakeholders, the EPA has come to understand that, given the complexities that Step 2 contemporaneous netting can entail, and given past EPA statements that emissions decreases could not be accounted for at Step 1, there are occasions where sources have experienced significant delays or declined altogether to undertake projects that could have resulted in overall emissions decreases.[55] The agency requests additional information on adverse project impacts that may have occurred and specifically any examples of environmentally beneficial projects that were proposed or under consideration but did not move forward as a result of the apparent unavailability of project emissions accounting.

D. Implementation of Project Emissions Accounting Under Step 1 of the NSR Applicability Regulations

1. Defining the Scope of a Project

In the March 2018 Memorandum, the agency explained that, for purposes of ascertaining whether a proposed project would constitute a major modification at a major stationary source, defining the scope of a project that a source owner or operator is proposing to undertake is a determination that rests within the reasonable discretion of the source owner or operator.[56] Further, while the EPA acknowledged the longstanding principle that, in defining the scope of the project, an owner or operator cannot seek to circumvent NSR permitting by *separating* multiple activities into smaller projects, the EPA did not ''interpret its NSR regulations as directing the agency to preclude a source from reasonably defining its proposed project broadly, to reflect multiple activities.'' [57] The agency concluded by indicating that it would speak more about this concept of grouping multiple activities in a then-planned future action regarding ''project aggregation.'' [58]

Subsequently, the EPA took a final action in November 2018 addressing the subject of ''project aggregation'' in the action titled ''Prevention of Significant Deterioration and Nonattainment New Source Review: Aggregation; Reconsideration.'' [59] In that final action, the agency concluded the reconsideration of an earlier action that the EPA had published on January 15, 2009, titled ''Prevention of Significant Deterioration and Nonattainment New Source Review: Aggregation and Project Netting.'' That 2009 action had provided clarification with respect to when the EPA considered it appropriate to treat nominally separate activities as a single project for the purpose of determining NSR applicability at a stationary source. In the final ''project aggregation'' action, the EPA decided, among other things, not to revoke the 2009 NSR Aggregation Action but to retain both the interpretation and the policy set forth therein.

For purposes of determining the circumstances under which nominally separate activities should reasonably be considered to be a single project, ''the 2009 NSR Aggregation Action called for sources and reviewing authorities to aggregate emissions from nominally-separate activities when they are ''substantially related.'' [60] For a project to be substantially related, the ''interrelationship and interdependence of the activities [is expected], such that substantially related activities are likely to be jointly planned (*i.e.,* part of the same capital improvement project or engineering study), and occur close in time and at components that are functionally interconnected.'' [61] In addition, the November final 2018 project aggregation action adds that in general ''[to] be 'substantially related,' there should be an apparent interconnection—either technically or economically—between the physical and/or operational changes, or a complementary relationship whereby a change at a plant may exist and operate independently, however its benefit is significantly reduced without the other activity.'' [62]

Thus, the main purpose of the November 2018 final project aggregation action was to address situations where a source owner or operator might attempt to circumvent NSR ''through some artificial separation of activities where it would be unreasonable to consider them separate projects.'' [63] This project emissions accounting proposed action, however, addresses the opposite scenario—*i.e.,* ''where a source itself is choosing to group together, as a single project, activities to which a projected emissions decrease is attributable.'' [64]

With respect to this latter scenario, the EPA observed in the March 2018 Memorandum that its ''current view is that the concerns regarding the real possibility that NSR might be circumvented through some artificial separation of activities where it would be unreasonable to consider them separate projects,'' were ''not so obviously presented by the situation where a source itself is choosing to group together, as a single project, activities to which a projected emissions decrease is attributable.'' [65] To the contrary, the EPA observed, the agency ''views this latter situation as one where sources could potentially be incentivized to seek out emission reductions that might otherwise be foregone entirely—*e.g.,* because of perceived complexity with contemporaneous netting under Step 2 of the NSR applicability analysis.'' [66] Nevertheless, we said that in a planned future rulemaking on project emissions accounting, the EPA would take

52.21(b)(3)(i)(b). Furthermore, as explained previously, additional requirements apply for creditability of emissions decreases under Step 2.

[55] For example, National Mining Association Response to Request for Comments on Regulations Appropriate for Repeal, Replacement, or Modification Pursuant to Executive Order 13777, 82 FR 17793, April 13, 2017, at 3–4, EPA–HQ–2017–0190–37770; Testimony of Paul Noe for American Forest & Paper Association (AF&PA) and American Wood Council (AWC), House Committee on Energy & Commerce, Subcommittee on Environment, and Climate Change, Oversight Hearing on ''New Source Review Permitting Challenges for Manufacturing and Infrastructure,'' at 2, 5, 7–8, February 14, 2018; AF&PA and AWC April 25, 2019, Executive Order 12866 meeting materials (EPA–HQ–OAR–2018–0048).

[56] March 2018 Memorandum at 9.

[57] *Id.* The EPA at that same time noted that this NSR ''circumvention'' principle could be seen as giving rise to some ''equivalent understanding that it might be possible to circumvent NSR through some wholly artificial grouping of activities.'' *Id.*

[58] *Id.*

[59] 83 FR 57324 (November 15, 2018).

[60] 83 FR 57326 (November 15, 2018).

[61] 74 FR 2378 (January 15, 2009).

[62] 83 FR 57327 (November 15, 2018). Furthermore, the final ''project aggregation'' action notes that ''these factors are not necessarily determinative of a substantial relationship, but are merely indicators that may suggest that two or more activities are likely to be substantially related and, therefore, candidates for aggregation.'' *Id.*

[63] 83 FR 57331 (November 15, 2018).

[64] *Id.*

[65] *Id.*

[66] *Id.*

comment on our current view of this issue.[67]

The EPA continues to believe that taking account of emissions decreases at Step 1 does not present any reasonable concerns regarding NSR circumvention. Therefore, having analyzed the applicability regulations and having considered the project aggregation final action, we are not proposing to impose additional requirements or find that scrutiny equivalent to that which the EPA's approach to project aggregation requires is warranted with respect to projects where source owners or operators choose to group together activities into a single project. We do not believe it is necessary to adopt the same criteria that apply for separation of activities (*i.e.,* under aggregation) to the grouping of activities, by considering such grouping to potentially constitute ''over aggregation'' that, in turn, may constitute NSR circumvention. The circumvention policy speaks to the situation where a source carves up what is plainly a single project into multiple projects, where each of those separate projects may result in emissions increases below the significance threshold but which, if considered collectively as one project, would result in an emissions increase above the threshold. Separate activities that, when considered together, either decrease emissions or result in an increase that is not significant are not in view in the EPA's circumvention policy. We ask for comment on our position in this regard. In addition, we seek comment on whether, if, in order for an emissions decrease to be accounted for at Step 1, it would be reasonable to require that a source owner or operator determine whether the activity (or activities) to which the emissions decrease is projected to occur is ''substantially related'' to another activity (or activities) to which an emissions increase is projected to occur. We are particularly interested in the impacts that this alternative approach might have on sources' decisions to undertake activities projected to result in emissions decreases (*e.g.,* whether such decisions might be delayed or otherwise foregone). The agency requests public input that would identify examples helpful to inform the agency's judgment on the emissions and cost impacts of this and other potential alternative approaches.

The EPA is currently unable to estimate any cost savings or emissions decreases associated with project emissions accounting because most NSR permits are issued by state and local agencies and the EPA does not have estimates of those permitting statistics. Furthermore, neither the EPA nor state and local permitting agencies have access to any decision-making records made by company owners that would indicate whether a project was or was not undertaken due to the availability of project emissions accounting. NSR permitting is a case-by-case determination and source owners make permitting decisions based on many factors. We do not have access nor require reporting of any decision-making information for permitting projects that were or were not pursued. Thus, any examples on the emissions and cost impacts of project emissions accounting, including the particular cases described above, could be beneficial for the agency to potentially provide some level of qualitative analysis when finalizing this action.

2. Monitoring, Recordkeeping and Reporting of Emissions Decreases During Step 1 of the Applicability Regulations

In the 2006 Project Netting Proposal, the agency proposed a series of steps for implementing project emissions accounting under Step 1 of the major NSR applicability test, including that emissions ''decreases must be enforceable as a practical matter, or there must be another procedure that will ensure the decrease actually occurs and is maintained, and are subject to all the requirements of 40 CFR 52.21(b)(3).'' [68] The 2006 proposal, however, did not provide an explanation as to why the EPA considered this step necessary or warranted. As explained in the March 2018 Memorandum, ''the agency now recognizes that other provisions in existing regulations serve to alleviate concerns that projected emissions decreases would escape the same tracking, documentation and reporting requirement applicable to projected emissions increases.'' [69] The March 2018 Memorandum recognized that the provisions at 40 CFR 52.21(r)(6) are adequate for recording, tracking, documenting, and reporting emissions decreases as well as increases for project emissions accounting. The provisions at 40 CFR 52.21(r)(6) were specifically designed for source owners or operators to document and maintain records when a project that is not a part of a major modification subject to major NSR permitting nonetheless presents a reasonable possibility that it may result in a significant emissions increase of such pollutant after completion. The regulations provide for, among other things: The identification of the emissions units affected by the project; the identification of the applicability test used to determine that the project was not a major modification; and monitoring, recordkeeping, and reporting of emissions from the units involved in the project based on certain criteria.

The agency ''expressly declined to adopt a requirement under which a source's post-project projected actual emissions would have become an enforceable emission limitation'' [70] as part of the 2002 NSR Reform Rule,[71] and the EPA currently believes that ''the same reasoning that underpinned the 2002 NSR Reform Rule's treatment of projected actual increases applies equally to projected emissions decreases at Step 1.'' [72] The EPA continues to believe that ''. . . the combination of the recordkeeping requirements of this rule, along with a requirement to report to the reviewing authority any annual emissions that exceed your baseline actual emissions by a significant amount for the regulated NSR pollutant and differ from your preconstruction projection, is an equally effective way to ensure that a reviewing authority can receive the information necessary to enforce the major NSR requirements.'' [73] In addition, the NSR regulations make enforceability of emissions decreases a requirement of Step 2 and not Step 1.[74] As part of this proposal, we are seeking comment on whether the 40 CFR 52.21(r)(6) provisions provide appropriate monitoring, recordkeeping and reporting requirements for both emissions decreases and increases, as relevant, in the context of Step 1 of the major modification applicability test.

3. Implementation of Projects Emissions Accounting for Delegated and SIP-Approved Programs

The requirements of 40 CFR 52.21 are implemented by the EPA or reviewing authorities that have been delegated federal authority from the EPA to issue PSD permits on behalf of the EPA (via a delegation agreement with an EPA Regional office). Thus, if this regulation is finalized, any revisions to this federal PSD regulation will automatically apply to the EPA and permitting authorities

[67] 83 FR 57331 (November 15, 2018).

[68] 71 FR 54235 (September 14, 2006).

[69] March 2018 Memorandum at 9, footnote 19.

[70] March 2018 Memorandum at 8.

[71] 67 FR 80193, 80197 (December 31, 2002).

[72] March 2018 Memorandum at 8. As also stated in the March 2018 Memorandum, if an emissions decrease is calculated using the potential to emit of a unit after the project, the requirements of 40 CFR 52.21(b)(4) apply.

[73] 67 FR 80193, 80204 (December 31, 2002).

[74] 40 CFR 52.21(a)(2)(iv) and 40 CFR 52.21(b)(3).

that implement a PSD program pursuant to a delegation agreement.

For state and local agencies that implement the NSR program through EPA-approved SIPs, the EPA's regulations for SIP-approved programs in 40 CFR 51.165 and 51.166 include applicability procedures that are analogous to the applicability procedures at 40 CFR 52.21(a)(2)(iv) that have been cited in this preamble. As noted previously, the EPA is also proposing to revise those regulations consistent with the proposed revisions to 40 CFR 52.21(a)(2)(iv).[75]

In light of the agency's interpretation that the existing NSR regulations allow project emissions accounting, and as discussed in the March 2018 Memorandum, the EPA believes that state and local reviewing authorities with approved NSR programs do not need to wait until finalization of this proposal to allow for project emissions accounting if their local rules and SIPs contain the same language as the EPA's regulations. In addition, if the EPA were to finalize the clarifications being proposed in this rulemaking, reviewing authorities may not need to revise their state regulations and submit SIP revisions to adopt those revisions if the current applicability procedures in those regulations can be interpreted to allow for project emissions accounting or these state and local programs incorporate the federal NSR regulations by reference without a date restriction.

Nevertheless, the EPA is currently aware of a few states and locals where the applicable SIP-approved regulations expressly preclude project emissions accounting. With respect to this situation, we request comment on whether the EPA should determine that the revisions to 40 CFR 51.165(2)(ii)(F) and (G); to 40 CFR 51.166(a)(7)(iv)(f) and (g); to (IV)(I)(1)(v) and (vi) to Appendix S to part 51; and to 40 CFR 52.21(a)(2)(iv)(f) and (g) that we are proposing here constitute minimum program elements that must be included in order for state and local agency programs implementing part C or part D to be approvable under the SIP.[76]

[75] There are certain modification provisions under the title I, subpart D of the CAA and the EPA nonattainment NSR regulations that apply to certain nonattainment area classifications (*e.g.,* CAA 182(e)(2); 40 CFR part 51, Appendix S II.A.5.(v)). This proposal, as with the March 2018 Memorandum, does not address those specific modification provisions in the CAA or the EPA regulations for nonattainment areas, and thus, does not communicate any EPA view regarding the interpretation of those provisions.

[76] Such a determination was made with respect to the NSR regulatory revisions the EPA made in 2002. 67 FR 80240 (December 31, 2002).

IV. Withdrawing the 2006 Project Netting Proposal

As mentioned in Section III.A of this notice, this proposal supersedes the 2006 Project Netting Proposal and, as such, this action withdraws the 2006 Project Netting Proposal. As the agency explained in the March 2018 Memorandum, the EPA recently performed a thorough reconsideration of the regulations pertaining to project emissions accounting and found that the statement included in the EPA's 2006 Project Netting Proposal that project emissions accounting was not allowed for projects with multiple types of emissions units [77] was unwarranted as ''other language in clause (f) indicates that emissions decreases are also to be accounted for.'' [78] Therefore, in light of this proposal, we believe the 2006 Project Netting Proposal is no longer necessary and is withdrawn.

V. Environmental Justice Considerations

We do not believe that the proposed clarifying revisions to the NSR applicability regulations would have any effect on environmental justice communities. As indicated in the March 2018 Memorandum, the EPA's NSR regulations in place after the 2002 NSR Reform Rule was finalized allow project emissions accounting and, as such, no increased burden is expected for source owners or operators, permitting authorities or environmental justice communities after finalization of the clarifications included in this rule.

VI. Statutory and Executive Order Reviews

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

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review since it raises policy issues arising from the President's priorities. Any changes made in response to OMB recommendations have been documented in the docket.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This proposed rule is not subject to the requirements of E.O. 13771 (82 FR 9339, February 3, 2017) because this proposed rule would not result in additional costs.

[77] 40 CFR 52.21(a)(2)(iv)(f).

[78] March 2018 Memorandum at 8.

C. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control numbers 2060–0003 for the PSD and NNSR permit programs. The burden associated with obtaining an NSR permit for a major stationary source undergoing a major modification is already accounted for under the approved information collection requests.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. In general, major stationary sources undergoing major modifications are not small entities. In addition, the EPA interprets its current NSR regulations to allow for project emissions accounting and, as such, no increased burden is expected for source owners or operators or permit reviewing authorities after finalization of the clarifications included in this rule.

E. Unfunded Mandates Reform Act (UMRA)

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

F. Executive Order 13132: Federalism

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

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

This action does not have tribal implications as specified in Executive Order 13175. The EPA's NSR applicability regulations in place after the 2002 NSR Reform Rule allow for the consideration of emissions increases and decreases as part of Step 1 of the major NSR applicability test for modifications and, as such, the clarifying revisions being proposed in this rule will not have exclusive tribal implications. Furthermore, the EPA is currently the reviewing authority for PSD and NNSR permits issued in tribal

lands and, as such, the clarifying revisions being proposed will not impose direct burdens on tribal permit reviewing authorities. Thus, Executive Order 13175 does not apply to this action.

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

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

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

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. The EPA interprets its current NSR regulations to allow for project emissions accounting and, as such, no increased burden is expected for source owners or permit reviewing authorities after the finalization of the clarifications included in this rule.

J. National Technology Transfer and Advancement Act

This rulemaking does not involve technical standards.

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

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The EPA interprets its current NSR regulations to allow for project emissions accounting and this action only proposes clarifying revisions to the NSR applicability regulations. Accordingly, no disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples are expected.

VII. Statutory Authority

The statutory authority for this action is provided by 42 U.S.C. 7401, *et seq.*

List of Subjects

40 CFR Part 51

Environmental protection, Air pollution control.

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference.

Dated: August 1, 2019.

Andrew R. Wheeler,

Administrator.

For the reasons stated in the preamble, title 40, chapter I of the Code of Federal Regulations is proposed to be amended as follows:

PART 51—REQUIREMENTS FOR PREPARATION, ADOPTION, AND SUBMITTAL OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 51 continues to read as follows:

Authority: 23 U.S.C. 101; 42 U.S.C. 7401–7671q.

Subpart I—Review of New Sources and Modifications

§ 51.165 [Amended]

■ 2. Section 51.165 is amended by revising paragraph (a)(2)(ii)(F) and adding paragraph (G) to read as follows:

§ 51.165 Permit requirements.

* * * * *

(a) * * *

(2) * * *

(ii) * * *

(F) Hybrid test for projects that involve multiple types of emissions units. A significant emissions increase of a regulated NSR pollutant is projected to occur if the sum of the difference for all emissions units, using the method specified in paragraphs (a)(2)(ii)(C) through (D) of this section as applicable with respect to each emissions unit, equals or exceeds the significant amount for that pollutant (as defined in paragraph (a)(1)(x) of this section).

(G) The ''sum of the difference'' as used in subparagraphs (C), (D) and (F) of this section shall include both increases and decreases in emissions calculated in accordance with those subparagraphs.

* * * * *

■ 3. Section 51.166 is amended by revising paragraph (a)(7)(iv)(*f*) and adding paragraph (*g*) to read as follows:

§ 51.166 Prevention of significant deterioration of air quality.

* * * * *

(a) * * *

(7) * * *

(iv) * * *

(*f*) Hybrid test for projects that involve multiple types of emissions units. A significant emissions increase of a regulated NSR pollutant is projected to occur if the sum of the difference for all emissions units, using the method specified in paragraphs (a)(7)(iv)(c) through (d) of this section as applicable with respect to each emissions unit, equals or exceeds the significant amount for that pollutant (as defined in paragraph (b)(23) of this section).

(*g*) The ''sum of the difference'' as used in subparagraphs (c), (d) and (f) shall include both increases and decreases in emissions calculated in accordance with those subparagraphs.

* * * * *

■ 4. Appendix S to part 51 is amended by revising paragraph IV.I.1.(v) and adding paragraph (vi) to read as follows:

Appendix S to Part 51—Emissions Offset Interpretative Ruling

* * * * *

IV. Sources that Would Locate in a Designated Nonattainment Area

* * * * *

I. *Applicability procedures.*

1. * * *

(v) Hybrid test for projects that involve multiple types of emissions units. A significant emissions increase of a regulated NSR pollutant is projected to occur if the sum of the difference for all emissions units, using the method specified in paragraphs IV.I.1(iii) through (iv) of this Ruling as applicable with respect to each emissions unit, equals or exceeds the significant amount for that pollutant (as defined in paragraph II.A.10 of this Ruling).

(vi) The ''sum of the difference'' as used in subparagraphs (iii), (iv) and (v) shall include both increases and decreases in emissions calculated in accordance with those subparagraphs.

* * * * *

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 5. The authority citation for part 52 continues to read as follows:

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

Subpart A—General Provisions

■ 6. Section 52.21 is amended by revising paragraph (a)(2)(iv)(*f*) and adding paragraph (*g*) to read as follows:

§ 52.21 Prevention of significant deterioration of air quality.

* * * * *

(a) * * *

(2) * * *

(iv) * * *

(*f*) Hybrid test for projects that involve multiple types of emissions units. A

significant emissions increase of a regulated NSR pollutant is projected to occur if the sum of the difference for all emissions units, using the method specified in paragraphs (a)(2)(iv)(c) through (d) of this section as applicable with respect to each emissions unit, equals or exceeds the significant amount for that pollutant (as defined in paragraph (b)(23) of this section).

(*g*) The ''sum of the difference'' as used in subparagraphs (c), (d) and (f) shall include both increases and decreases in emissions calculated in accordance with those subparagraphs.

* * * * *

[FR Doc. 2019–17019 Filed 8–8–19; 8:45 am]

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DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 215 and 252

[Docket DARS–2019–0038]

RIN 0750–AJ78

Defense Federal Acquisition Regulation Supplement: Management of Should-Cost Review Process (DFARS Case 2018–D015)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2018, which requires an amendment to the DFARS to provide for the appropriate use of the should-cost review process of a major weapon system.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before October 8, 2019, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2018–D015, using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Search for ''DFARS Case 2018–D015''. Select ''Submit a Comment Now'' and follow the instructions provided to submit a comment. Please include ''DFARS Case 2018–D015'' on any attached document.
- *Email: osd.dfars@mail.mil.* Include DFARS Case 2018–D015 in the subject line of the message.
- *Fax:* 571–372–6094.
- *Mail:* Defense Acquisition Regulations System, Attn: Ms. Heather Kitchens, OUSD(A&S)DPC/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Heather Kitchens, telephone 571–372–6104.

SUPPLEMENTARY INFORMATION:

I. Background

This rule proposes to amend the DFARS to implement section 837 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2018 (Pub. L. 115–91). Section 837 requires an amendment to the DFARS to provide for the appropriate use of the should-cost review process of a major weapon system in a manner that is transparent, objective, and provides for the efficiency of the systems acquisition process in the Department of Defense. A weapon system is considered to be a ''major weapon system,'' as defined by DFARS 234.7001, when it is ''a weapon system acquired pursuant to a major defense acquisition program.'' At a minimum, DoD is required to address the following:

- A description of the features of the should-cost review process.
- Establishment of a process for communicating with the prime contractor on the program the elements of a proposed should-cost review.
- A method for ensuring that identified should-cost savings opportunities are based on accurate, complete, and current information and can be quantified and tracked.
- A description of the training, skills, and experience that Department of Defense and contractor officials carrying out a should-cost review should possess.
- A method for ensuring appropriate collaboration with the contractor throughout the review process.
- Establishment of review process requirements that provide for sufficient analysis and minimize any impact on program schedule.

II. Discussion and Analysis

Federal Acquisition Regulation (FAR) 15.407–4(b) establishes when a program should-cost review should be considered in the case of a major system acquisition. DoD is proposing to add a new paragraph (b) to DFARS 215.407–4 to address the six elements of a program should-cost review, as required by section 837. In addition, DoD is proposing to add a new contract clause at DFARS 252.215–701X, Program Should-Cost Review, for use in solicitations and contracts for the development or production of a major weapon system, as defined in DFARS 234.7001, to ensure objectivity and efficiency in the should-cost review process, if a program should-cost review is performed.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule does not propose to create any new provisions or clauses or impact any existing provisions or clauses for contracts at or below the simplified acquisition threshold or for contracts for the acquisition of commercial items, including commercially available off-the-shelf items. Contracts for the development and or production of a major weapon system do not include contracts valued at or below the simplified acquisition threshold and are unlikely to include contracts for commercial items.

IV. Executive Orders 12866 and 13563

Executive Order (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This is not a major rule under 5 U.S.C. 804.

V. Executive Order 13771

This rule is not expected to be subject to E.O. 13771, because this rule is not a significant regulatory action under E.O. 12866.

VI. Regulatory Flexibility Act

DoD does not expect this rulemaking to have a significant economic impact on a substantial number of small entities

within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because the rule only applies to major weapon system acquisition programs. However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement to implement section 837 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2018 (Pub. L. 115–91). Section 837 requires an amendment to the DFARS to provide for the appropriate use of the should-cost review process of a major weapon system in a manner that is transparent, objective and provides for the efficiency of the systems acquisition process in the Department of Defense.

The objective of this rulemaking is to incorporate in the DFARS the six elements of a program should-cost review required to be addressed by section 837, and to provide a new contract clause for use in solicitations and contracts for the development or production of a major weapon system, in order to ensure objectivity and efficiency in the should-cost review process. The legal basis for these changes is section 837 of the NDAA for FY 2018.

DoD estimates that there are 150 major systems, which include major weapon systems. DoD further estimates that the prime contractors for major weapon systems are other than small business and only one program should-cost review occurs per year for major weapon systems, so this rule will have minimal impact on small businesses.

This proposed rule does not include any new reporting or recordkeeping requirements for small entities.

The rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no known significant alternative approaches to the proposed rule that would meet the requirements of the applicable statute.

DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2018–D015), in correspondence.

VI. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 215 and 252

Government procurement.

Jennifer Lee Hawes,

Regulatory Control Officer, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 215 and 252 are proposed to be amended as follows:

■ 1. The authority citations for 48 CFR parts 215 and 252 continue to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 215—CONTRACTING BY NEGOTIATION

■ 2. Amend section 215.407–4 by designating the text as paragraph (a), adding a heading to newly designated paragraph (a) and adding paragraph (b) to read as follows:

215.407–4 Should-cost review.

(a) *General.* * * *

(b) *Program should-cost review.* Major weapon system should-cost program reviews shall be conducted in a manner that is transparent, objective, and provides for the efficiency of the DoD systems acquisition process (section 837 of the National Defense Authorization Act for Fiscal Year 2018 (Pub. L. 115–91)).

(i) Major weapon system should-cost reviews may include the following features:

(A) A thorough review of each contributing element of the program cost and the justification for each cost.

(B) An analysis of non-value added overhead and unnecessary reporting requirements.

(C) Benchmarking against similar DoD programs, similar commercial programs (where appropriate), and other programs by the same contractor at the same facility.

(D) An analysis of supply chain management to encourage competition and incentive cost performance at lower tiers.

(E) A review of how to restructure the program (Government and contractor) team in a streamlined manner, if necessary.

(F) Identification of opportunities to break out Government-furnished equipment versus prime contractor-furnished materials;

(G) Identification of items or services contracted through third parties that result in unnecessary pass-through costs.

(H) Evaluation of ability to use integrated developmental and operational testing and modeling and simulation to reduce overall costs.

(I) Identification of alternative technology and materials to reduce developmental or lifecycle costs for a program.

(J) Identification and prioritization of cost savings opportunities.

(K) Establishment of measurable targets and ongoing tracking systems.

(ii) The should-cost review shall provide for sufficient analysis while minimizing the impact on program schedule by engaging stakeholders early, relying on information already available before requesting additional data, and establishing a team with the relevant expertise early.

(iii) The should-cost review team shall be comprised of members, including third-party experts if necessary, with the training, skills, and experience in analysis of cost elements, production or sustainment processes, and technologies relevant to the program under review. The review team may include members from the Defense Contract Management Agency, the department or agency's cost analysis center, and appropriate functional organizations, as necessary.

(iv) The should-cost review team shall establish a process for communicating and collaborating with the contractor throughout the should-cost review, including notification to the contractor regarding which elements of the contractor's operations will be reviewed and what information will be necessary to perform the review, as soon as practicable, both prior to and during the review.

(v) The should-cost review team report shall ensure, to the maximum extent practicable, review of current, accurate, and complete data, and shall identify cost savings opportunities associated with specific engineering or business changes that can be quantified and tracked.

■ 3. Amend section 215.408 by adding paragraph (8) to read as follows:

215.408 Solicitation provisions and contract clauses.

* * * * *

(8) Use the clause at 252.215–701X, Program Should-Cost Review, in all solicitations and contracts for the development or production of a major weapon system, as defined in 234.7001.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 4. Add section 252.215–701X to read as follows:

252.215–701X Program Should-Cost Review.

As prescribed in 215.408(8), use the following clause:

Program Should-Cost Review (Date)

(a) The Government has the right to perform a program should-cost review, as described in Federal Acquisition Regulation (FAR) 15.407–4(b). The review may be conducted in support of a particular contract proposal or during contract performance to find opportunities to reduce program costs. The Government will communicate the elements of the proposed should-cost review to the prime contractor (Pub. L. 115–91).

(b) If the Government performs a program should-cost review, upon the Government's request, the Contractor shall provide access to accurate and complete cost data and Contractor facilities and personnel necessary to permit the Government to perform the program should-cost review.

(c) The Government has the right to use third-party experts to supplement the program should-cost review team. The Contractor shall provide access to the Contractor's facilities and information necessary to support the program should-cost review to any third-party experts who have signed non-disclosure agreements in accordance with the FAR 52.203–16.

(End of Clause)

[FR Doc. 2019–16763 Filed 8–8–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 219

[Docket DARS–2019–0034]

RIN 0750–AK43

Defense Federal Acquisition Regulation Supplement: Review of Defense Solicitations by Procurement Center Representatives (DFARS Case 2019–D008)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2017 that provides limits on the scope of review by the Small Business Administration's procurement center representatives for certain solicitations awarded by or for DoD.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before October 8, 2019, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2019–D008, using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Search for ''DFARS Case 2019–D008.'' Select ''Comment Now'' and follow the instructions provided to submit a comment. Please include ''DFARS Case 2019–D008'' on any attached documents.
- *Email: osd.dfars@mail.mil.* Include DFARS Case 2019–D008 in the subject line of the message.
- *Fax:* 571–372–6094.
- *Mail:* Defense Acquisition Regulations System, Attn: Ms. Jennifer D. Johnson, OUSD(A–S)DPC/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer D. Johnson, telephone 571–372–6100.

SUPPLEMENTARY INFORMATION:

I. Background

This rule proposes to revise the DFARS to implement section 1811 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2017 (Pub. L. 114–328) and the Small Business Administration (SBA) proposed rule published in the **Federal Register** on December 4, 2018, at 83 FR 62516. Section 1811 provides limits on the scope of review by SBA's procurement center representatives for certain solicitations awarded by or for DoD.

Specifically, section 1811 limits the scope of review by procurement center representatives, unless DoD requests a review, if the solicitation is awarded by or for DoD and—

- Is conducted pursuant to section 22 of the Arms Export Control Act (22 U.S.C. 2762);
- Is a humanitarian operation as defined in 10 U.S.C. 401(e);
- Is a contingency operation as defined in 10 U.S.C. 101(a)(13);
- Is to be awarded pursuant to an agreement with the government of a foreign country in which U.S. Armed Forces are deployed; or
- Both the place of award and place of performance outside the United States and its territories.

SBA's proposed rule states that, unless the contracting agency requests a review, procurement center representatives will not review such procurements. Additionally, section 1811 excludes these procurements from DoD's small business goals.

II. Discussion and Analysis

This rule proposes to amend DFARS part 219 to implement section 1811 of the NDAA for FY 2017 and SBA's proposed rule. Specifically, the rule proposes to add text at DFARS 219.402 to inform contracting officers that procurement center representatives will not review acquisitions conducted by or for DoD, unless the contracting activity requests a review, if the acquisition is—

- For foreign military sales (see DFARS 225.7300);
- In support of humanitarian and civic assistance;
- In support of a contingency operation;
- Awarded pursuant to a Status of Forces Agreement or other agreement with the government of a foreign country in which U.S. Armed Forces are deployed; or
- Both awarded and performed outside the United States and its outlying areas.

The proposed text includes a definition of ''humanitarian and civic assistance'' that applies only to the implementation of section 1811. Both section 1811 and SBA's proposed rule refer to ''a humanitarian operation as defined in section 401(e) of title 10, United States Code.'' Although the term ''humanitarian operation'' is used, the type of activities it covers are quite different from the ''humanitarian or peacekeeping operation'' defined in Federal Acquisition Regulation 2.101 and currently used in the DFARS. In 10 U.S.C. 401(e), the term ''humanitarian and civic assistance'' is used to refer to specific activities carried out in conjunction with authorized military operations in a foreign country. Examples of such assistance include construction of rudimentary surface transportation systems, well drilling, and construction of basic sanitation facilities. Therefore, this proposed rule includes a definition to avoid confusion among the contracting workforce.

This rule also proposes to add a reference in DFARS subpart 219.5, Set-Asides for Small Business, to the exclusions in DFARS 219.402.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule does not propose to create any new provisions or clauses or impact any existing provisions or clauses.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Executive Order 13771

This rule is not expected to be subject to E.O. 13771, because this rule is not a significant regulatory action under E.O. 12866.

VI. Regulatory Flexibility Act

DoD does not expect this proposed rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because it is expected to impact primarily Government operations. However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

This rule proposes to revise the DFARS to implement section 1811 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2017 (Pub. L. 114–328) and the SBA proposed rule published in the **Federal Register** on December 4, 2018, at 83 FR 62516. Specifically, the rule informs contracting officers that procurement center representatives will not review acquisitions conducted by or for DoD, unless the contracting activity requests a review, if the acquisition is—

- For foreign military sales (see DFARS 225.7300);
- In support of humanitarian and civic assistance;
- In support of a contingency operation;
- Awarded pursuant to a Status of Forces Agreement or other agreement with the government of a foreign country in which U.S. Armed Forces are deployed; or
- Both awarded and performed outside the United States and its outlying areas.

Additionally, section 1811 of the NDAA for FY 2017 excludes these procurements from DoD's small business goals.

The objective of this rule is to implement, in the DFARS, the limits on the scope of review by procurement center representatives. The legal basis for the rule is section 1811 of the NDAA for FY 2017.

This rule may impact small entities that are interested in performing the types of DoD contracts listed in section 1811 of the NDAA for FY 2017. According to the Federal Procurement Data System (FPDS), DoD awarded an average of 12,658 contracts and orders for performance outside the United States to approximately 1,292 unique small entities per year in FY 2016, 2017, and 2018. Approximately 4 percent of those small entities received awards for foreign military sales. About 8 percent received awards in support of a contingency operation. Approximately 81 percent received awards made pursuant to an agreement such as a Status of Forces Agreement.

FPDS does not currently collect data on the type of humanitarian operation identified in section 1811, which is very different from the ''humanitarian or peacekeeping'' operation defined in Federal Acquisition Regulation (FAR) 2.101 and used in the DFARS. FPDS does collect data on humanitarian or peacekeeping operations, as defined in FAR 2.101, showing that about 1% of the small entities, performing contracts or orders outside the United States, received awards for humanitarian or peacekeeping operations. The data collected may provide some indication of the number of small entities that could perform contracts or orders for the type of humanitarian operation identified in section 1811.

This rule does not impose any new reporting, recordkeeping or other compliance requirements for small entities.

This rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no known alternatives which would accomplish the stated objectives of the applicable statute.

DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C 610 (DFARS Case 2019–D008), in correspondence.

VII. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Part 219

Government procurement.

Jennifer Lee Hawes,

Regulatory Control Officer, Defense Acquisition Regulations System.

Therefore, 48 CFR part 219 is proposed to be amended as follows:

PART 219—SMALL BUSINESS PROGRAMS

■ 1. The authority citation for 48 CFR part 219 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Add section 219.402 to subpart 219.4 to read as follows:

219.402 Small Business Administration procurement center representatives.

(c)(i) *Authority.* This section implements section 1811 of the National Defense Authorization Act for Fiscal Year 2017 (Pub. L. 114–328).

(ii) *Definition.* As used in this section, ''humanitarian and civic assistance'' (10 U.S.C. 401(e)) means any of the following activities carried out in conjunction with authorized military operations in a foreign country:

(A) Medical, surgical, dental, and veterinary care provided in areas of a country that are rural or underserved by professionals in those fields, including education, training, and technical assistance related to the care provided.

(B) Construction of rudimentary surface transportation systems.

(C) Well drilling and construction of basic sanitation facilities.

(D) Rudimentary construction and repair of public facilities.

(iii) *Exclusions.* Unless the contracting activity requests a review, SBA procurement center representatives will not review acquisitions conducted by or for DoD if the acquisition is—

(A) For foreign military sales (see 225.7300);

(B) In support of humanitarian and civic assistance;

(C) In support of a contingency operation;

(D) Awarded pursuant to a Status of Forces Agreement or other agreement

with the government of a foreign country in which U.S. Armed Forces are deployed; or

(E) Both awarded and performed outside the United States and its outlying areas.

■ 3. Revise section 219.502–1 to read as follows:

219.502–1 Requirements for setting aside acquisitions.

Do not set aside acquisitions—

(a) For supplies that were developed and financed, in whole or in part, by Canadian sources under the U.S.-Canadian Defense Development Sharing Program; or

(b) Excluded from procurement center representative review (see 219.402(c)(iii)).

[FR Doc. 2019–16764 Filed 8–8–19; 8:45 am]

BILLING CODE 5001–06–P

Notices

Federal Register
Vol. 84, No. 154
Friday, August 9, 2019

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

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Sugar Charged Against the FY 2019 Raw Sugar Tariff-Rate Quota May be Entered Until October 15, 2019

AGENCY: Office of the Secretary, USDA.

ACTION: Notice.

SUMMARY: The U.S. Department of Agriculture today announced that sugar charged against the FY 2019 raw sugar tariff-rate quota (TRQ) will be permitted to enter U.S. Customs territory until October 15, 2019, two weeks later than usual, to provide more opportunity for supplying countries to fill their import quotas.

Additional U.S. Note 5(a)(iv) of Chapter 17 of the U.S. Harmonized Tariff Schedule provides: ''(iv) Sugar entering the United States during a quota period established under this note may be charged to the previous or subsequent quota period with the written approval of the Secretary.''

Pursuant to the Congressional Review Act, the Office of Information and Regulatory Affairs designated this rule as not a major rule.

DATES: This notice is applicable on August 9, 2019.

FOR FURTHER INFORMATION CONTACT: Souleymane Diaby, Import Policies and Export Reporting Division, Foreign Agricultural Service, Stop 1021, 1400 Independence Avenue SW, Washington, DC 20250–1021; by telephone (202) 720–2916; or by email *Souleymane.Diaby@usda.gov.*

Dated: August 6, 2019.

Ted A. McKinney,

Under Secretary, Trade and Foreign Agricultural Affairs.

[FR Doc. 2019–17130 Filed 8–8–19; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

August 5, 2019.

The Department of Agriculture will submit the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13 on or after the date of publication of this notice. 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 should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, Washington, DC; 725 17th Street NW, Washington, DC 20503. 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.

Comments regarding these information collections are best assured of having their full effect if received by September 9, 2019. Copies of the submission(s) may be obtained by calling (202) 720–8681.

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.

National Agricultural Statistics Service (NASS)

Title: Agricultural Surveys Program—January Sheep Survey—Substantive Change.

OMB Control Number: 0535–0213.

Summary of Collection: General authority for these data collection activities is granted under U.S. Code Title 7, Section 2204 which specifies that ''The Secretary of Agriculture shall procure and preserve all information concerning agriculture which he can obtain . . . by the collection of statistics . . .''. The primary objective of the National Agricultural Statistics Service (NASS) is to provide data users with timely and reliable agricultural production and economic statistics, as well as environmental and specialty agricultural related statistics. To accomplish this objective, NASS relies on the use of diverse surveys that show changes within the farming industry over time.

Using the Sheep and Goat Report—January 1, 2019, NASS collects sheep and goat inventory numbers, lamb and kid births, wool production and prices, death losses, and periodically NASS collects information on inventory losses due to predators. In January 2020 NASS would like to add additional questions to the predator loss section of the questionnaire. This is being done in response to a request by the Animal, Plant Health Inspection Service (APHIS). The majority of the questions that will be added to the January 2020 questionnaire are included in the Master Questionnaire that was included in the original docket that was submitted to OMB for approval in April 2017. In addition there will be a couple of questions that were approved in the previous docket (Oct. 2014) relating to nonlethal predator control methods used on sheep farms. The few new questions that will be added to the survey relate to the movement of sheep from the farm, the use of identification tags on the sheep, the use of government trappers used to control predators and if the operation quit raising sheep, what was the reason.

This substantive change resulted in an overall increase in response burden of approximately 2,800 hours or about 10 minutes per completed questionnaire. The sample size will remain the same.

Need and Use of the Information: In order for APHIS to be able to measure

the effectiveness of previous measures used to curtail sheep and lamb losses due to predators and to determine the need for changes to future measures these additional questions need to be asked.

The additional questions that will be added to the questionnaires will address the following topics:

- Nonlethal predator control methods used on sheep farms,
- the movement of sheep from the farm,
- the use of identification tags on the sheep,
- the use of government trappers used to control predators and
- if the operation quit raising sheep, what was the reason.

Description of Respondents: Farms.

Number of Respondents: 24,000.

Frequency of Responses: Reporting: Once.

Total Burden Hours: 8,640.

Kimble Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2019–17030 Filed 8–8–19; 8:45 am]

BILLING CODE 3410–20–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Tennessee Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights and the Federal Advisory Committee Act, that the Tennessee Advisory Committee will hold a public meeting on Thursday, August 29, 2019, at 1:30 p.m. Eastern Time, to continue discussion of its report on legal financial obligations.

FOR FURTHER INFORMATION CONTACT: Alejandro Ventura (Designated Federal Official) at *aventura@usccr.gov* or (213) 894–3437.

SUPPLEMENTARY INFORMATION:

Public Call Information: Dial: 800–367–2403; Conference ID: 7029307.

This meeting is available to the public through the following toll-free call-in number: 800–367–2403, conference ID number: 7029307. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012. They may be faxed to the Commission at (213) 894–0508, or emailed to *aventura@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (213) 894–3437.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meetings at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzm9AAA.* Please click on the ''Committee Meetings'' tab. Records generated from these meetings may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meetings. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Opening Remarks
II. Discussion of Legal Financial Obligations Report
III. Public Comments
IV. Adjournment

Dated: August 5, 2019.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2019–17039 Filed 8–8–19; 8:45 am]

BILLING CODE P

CIVIL RIGHTS COMMISSION

Sunshine Act Meeting Notice

AGENCY: United States Commission on Civil Rights.

ACTION: Notice of Commission public business meeting.

DATES: Thursday, August 22, 2019, 10:30 a.m. EDT.

ADDRESSES: Meeting to take place by telephone.

FOR FURTHER INFORMATION CONTACT: Brian Walch: (202) 376–8371; TTY: (202) 376–8116; *publicaffairs@usccr.gov.*

SUPPLEMENTARY INFORMATION: This business meeting is open to the public by telephone only: 800–767–8973, Conference ID 203–7785. Persons with disabilities who need accommodation should contact Pamela Dunston at (202) 376–8105 or at *access@usccr.gov* at least seven (7) business days before the date of the meeting.

Meeting Agenda

I. Approval of Agenda
II. Business Meeting
  A. Discussion and Vote on Commission's report, *In the Name of Hate: Examining the Federal Government's Role in Responding to Hate Crimes*
  B. Discussion and vote on Chair for North Dakota State Advisory Committee
  C. Discussion and vote on 2020 Business Meeting Calendar
  D. Management and Operations
  - Staff Director's Report
  E. Meeting of the Commission's Subcommittee on condition of immigration detention centers and treatment of immigrants in detention
  - Discussion and vote on Subcommittee's report to Commission

III. Adjourn Meeting

Dated: August 7, 2019.

Brian Walch,

Director, Communications and Public Engagement.

[FR Doc. 2019–17226 Filed 8–7–19; 4:15 pm]

BILLING CODE 6335–01–P

CIVIL RIGHTS COMMISSION

Sunshine Act Meeting Notice

AGENCY: United States Commission on Civil Rights.

ACTION: Notice of Commission public business meeting.

DATES: Thursday, August 29, 2019, 10:30 a.m. EDT.

ADDRESSES: Meeting to take place by telephone

FOR FURTHER INFORMATION CONTACT: Brian Walch: (202) 376–8371; TTY: (202) 376–8116; *publicaffairs@usccr.gov.*

SUPPLEMENTARY INFORMATION: This business meeting is open to the public

by telephone only: 800–822–2024, Conference ID 955–1456. Persons with disabilities who need accommodation should contact Pamela Dunston at (202) 376–8105 or at *access@usccr.gov* at least seven (7) business days before the date of the meeting.

Meeting Agenda

I. Approval of Agenda
II. Business Meeting
  A. Discussion and Vote on Commission's report, *Are Rights a Reality? Evaluating Civil Rights Enforcement*
  B. Discussion and Vote on Commission's report, *Trauma at the Border: The Human Cost of Inhumane Immigration Policies*
  C. Management and Operations
  • Staff Director's Report
III. Adjourn Meeting

Dated: August 7, 2019.

Brian Walch,

Director, Communications and Public Engagement.

[FR Doc. 2019–17227 Filed 8–7–19; 4:15 pm]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

[Application No. 92–15A001]

Export Trade Certificate of Review

ACTION: Notice of Application for an amended Export Trade Certificate of Review by Aerospace Industries Association of America, Inc., Application No. 92–15A001.

SUMMARY: The Office of Trade and Economic Analysis (''OTEA'') of the International Trade Administration, Department of Commerce, received an application for an amended Export Trade Certificate of Review (''Certificate''). This notice summarizes the proposed amendment and requests comments relevant to whether the amended Certificate should be issued.

FOR FURTHER INFORMATION CONTACT: Joseph Flynn, Director, Office of Trade and Economic Analysis, International Trade Administration, (202) 482–5131 (this is not a toll-free number) or email at *etca@trade.gov.*

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. An Export Trade Certificate of Review protects the holder and the members identified in the Certificate from State and Federal government antitrust actions and from private treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. The regulations implementing Title III are found at 15 CFR part 325. OTEA is issuing this notice pursuant to section 302(b)(1) of the Export Trading Company Act of 1982 (15 U.S.C. 4012(b)(1)) and 15 CFR 325.6(a), which require the Secretary of Commerce to publish a summary of the application in the **Federal Register**, identifying the applicant and each member and summarizing the proposed export conduct.

Request for Public Comments

Interested parties may submit written comments relevant to the determination whether an amended Certificate should be issued. If the comments include any privileged or confidential business information, it must be clearly marked and a nonconfidential version of the comments (identified as such) should be included. Any comments not marked as privileged or confidential business information will be deemed to be nonconfidential.

An original and five (5) copies, plus two (2) copies of the nonconfidential version, should be submitted no later than 20 days after the date of this notice to: Office of Trade and Economic Analysis, International Trade Administration, U.S. Department of Commerce, Room 21028, Washington, DC 20230.

Information submitted by any person is exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552). However, nonconfidential versions of the comments will be made available to the applicant if necessary for determining whether or not to issue the Certificate. Comments should refer to this application as ''Export Trade Certificate of Review, application number 92–15A001.''

The Aerospace Industries Association of America Inc. (''AIA'') original Certificate was issued on September 8, 1992 (57 FR 41920, September 14, 1992). A summary of the application follows.

Summary of the Application

Applicant: AIA, 1000 Wilson Boulevard, Suite 1700, Arlington, VA 20009.

Contact: Matthew F. Hall, General Counsel, Telephone: (202) 862–9700.

Application No.: 92–15A001.

Date Deemed Submitted: July 26, 2019

Proposed Amendment: AIA seeks to amend its Certificate as follows:

1. Add the following companies as new Members of the Certificate within the meaning of section 325.2(l) of the Regulations (15 CFR 325.2(l)):

- Air Liquide USA LLC; Houston, TX (controlling entity Air Liquide; Paris, France)
- Applied Composites; Lake Forest, CA
- Arch Tuscaloosa; Cottondale, AL (controlling entity Arch Global Precision; Bloomfield Hills, MI)
- Booz Allen Hamilton; McLean, VA
- Gamma Aerospace LLC; Mansfield, TX
- Global Partner Solutions LLC; Wichita, KS (controlling entity Global Partner Solutions Inc.; Dorval, Quebec, Canada)
- Hellen Systems LLC; Middleburg, VA
- Limco Airepair, Inc.; Tulsa, OK
- Stratolaunch Systems Corporation; Seattle, WA
- Vantage Associates; National City, CA

2. Delete the following companies as Members of AIA's Certificate:

- American Metal Bearing Company
- Cyient Ltd.
- EPTAM Plastics
- Facebook, Inc.
- Flight Safety International Inc
- Flextronics International USA, Inc.
- GKN Aerospace North America
- Information Services Group, Inc.
- ITT, Inc.
- Job Performance Associates, LLC
- JR Industries, Inc.
- LAI International, Inc.
- L–3 Communications Corporation
- The NORDAM Group, Inc.
- Omega Aerial Refueling Services, Inc.
- Orbital ATK, Inc.
- Pegasus Steel, LLC
- Rockwell Collins
- Universal Protection Services
- Wesco Aircraft Hardware Corporation
- Xerox

3. Change in name for the following Member:

- Altitude Industries in Overland Park, KS is now named Enjet Aero, LLC in Overland Park, KS
- Harris Corporation in Melbourne, FL, is now named L3Harris Technologies, Inc. in Melbourne, FL

AIA's proposed amendment of its Export Trade Certificate of Review would result in the following membership list:

- 3M Company; St. Paul, MN
- AAR Corp.; Wood Dale, IL
- Accenture; Chicago, IL
- Acutec Precision Aerospace, Inc.; Meadville, PA
- ACUTRONIC USA, Inc.; Pittsburgh, PA
- ADI American Distributors LLC; Randolph, NJ

- Advanced Logistics for Aerospace (ALA); New York, NY
- Aerion Corporation; Reno, NV
- Aernnova Aerospace; Ann Arbor, MI
- Aerojet Rocketdyne; Rancho Cordova, CA
- Aero-Mark, LLC; Ontario, CA
- Aero Metals Alliance; Northbrook, IL
- AeroVironment, Inc.; Monrovia, CA
- AGC Aerospace & Defense; Oklahoma City, OK
- Aireon LLC; McLean, VA
- Air Liquide USA LLC; Houston, TX
- AlixPartners, LLP; New York, NY
- Allied Telesis, Inc.; Bothell, WA
- Alta Devices, Inc.; Sunnyvale, CA
- Amazon.com, Inc.; Seattle, WA
- American Pacific Corporation; Las Vegas, NV
- Analytical Graphics, Inc.; Exton, PA
- Arch Tuscaloosa; Cottondale, AL
- Arconic Inc.; New York, NY
- Apex International Management Company; Daytona Beach, FL
- Applied Composites; Lake Forest, CA
- Astronautics Corporation of America; Milwaukee, WI
- Astronics Corporation, East Aurora, NY
- Athena Manufacturing, LP; Austin, TX
- AUSCO, Inc.; Port Washington, NY
- Avascent; Washington, D.C.
- B&E Group, LLC; Southwick, MA
- BAE Systems, Inc.; Rockville, MD
- Ball Aerospace & Technologies Corp.; Boulder, CO
- Belcan Corporation; Cincinnati, OH
- Benchmark Electronics, Inc.; Angleton, TX
- BWX Technologies, Inc.; Lynchburg, VA
- Bombardier; Montreal, Canada
- Boom Technology, Inc.; Denver, CO
- Booz Allen Hamilton; McLean, VA
- Boston Consulting Group; Boston, MA
- BRPH Architects Engineers, Inc.; Melbourne, FL
- Burns & McDonnell Engineering Corporation, Inc.; Kansas City, MO
- CADENAS PARTsolutions, LLC; Cincinnati, OH
- CAE USA; Tampa, FL
- Capgemini; New York, NY
- Celestica Inc.; Toronto, Canada
- Click Bond, Inc.; Carson City, NV
- Cobham; Arlington, VA
- CPI Aerostructures, Inc.; Edgewood, NY
- Crane Aerospace & Electronics; Lynnwood, WA
- Cubic Corporation, Inc.; San Diego, CA
- Cytec Engineered Materials, Inc.; Tempe, AZ
- Deloitte Consulting LLP; New York, NY
- Delta Flight Products; Atlanta, GA
- Denison Industries, Inc.; Denison, TX
- Ducommun Incorporated; Carson, CA
- DuPont Company; New Castle, DE
- DXC Technology Company, Tysons Comer, VA
- Eaton Corporation; Cleveland, OH
- Elbit Systems of America, LLC; Fort Worth, TX
- Embraer Aircraft Holding Inc.; Fort Lauderdale, FL
- Enjet Aero, LLC; Overland Park, KS
- EPS Corporation; Tinton Falls, NJ
- Ernst & Young LLP; New York, NY
- Esterline Technologies; Bellevue, WA
- Exostar LLC; Herndon, VA
- FS Precision Tech, Co. LLC; Compton, CA
- FTG Circuits, Inc.; Chatsworth, CA
- Gamma Aerospace LLC; Mansfield, TX
- Garmin International, Inc.; Olathe, KS
- General Atomics Aeronautical Systems, Inc.; Poway, CA
- General Dynamics Corporation; Falls Church, VA
- General Electric Aviation; Cincinnati, OH
- Global Partner Solutions, LLC; Wichita, KS
- Google, LLC; Mountain View, CA
- GSE Dynamics, Inc.; Hauppauge, NY
- HCL America Inc.; Sunnyvale, CA
- HEICO Corporation; Hollywood, FL
- Hellen Systems LLC; Middleburg, VA
- Hexcel Corporation; Stamford, CT
- Honeywell Aerospace; Phoenix, AZ
- Huntington Ingalls Industries, Inc.; Newport News, VA
- IBM Corporation; Armonk, NY
- Integral Aerospace, LLC; Santa Ana, CA
- Iron Mountain, Inc.; Boston, MA
- Jabil Defense & Aerospace Services LLC; St. Petersburg, FL
- Kaman Aerospace Corporation; Bloomfield, CT
- KPMG LLP; New York, NY
- Kratos Defense & Security Solutions, Inc.; San Diego, CA
- L3Harris Technologies, Inc.; Melbourne, FL
- Leidos, Inc; Reston, VA
- Limco Airepair, Inc.; Tulsa, OK
- Lockheed Martin Corporation; Bethesda, MD
- Lord Corporation; Cary, NC
- LS Technologies, LLC; Fairfax, VA
- Mantech International Corporation; Fairfax, VA
- Marotta Controls, Inc.; Montville, NJ
- Meggitt-USA, Inc.; Simi, CA
- Mercury Systems, Inc.; Andover, MA
- Microsemi Corporation; Aliso Viejo, CA
- Momentum Aviation Group; Woodbridge, VA
- MOOG Inc.; East Aurora, NY
- MTorres Americas; Bothell, WA
- National Technical Systems, Inc.; Calabasas, CA
- NEO Tech.; Chatsworth, CA
- Net-Inspect, LLC; Kirkland, WA
- New England Air Foil Products, Inc.; Farmington, CT
- Nokia US; Murray Hill, NJ
- Norsk Titanium US Inc.; Plattsburgh, NY
- Northrop Grumman Corporation; Los Angeles, CA
- O'Neil & Associates, Inc.; Miamisburg, OH
- Pacific Design Technologies; Goleta, CA
- Parker Aerospace; Irvine, CA
- Plexus Corporation; Neenah, WI
- PPG Aerospace-Sierracin Corporation; Sylmar, CA
- PrecisionHawk Inc.; Raleigh, NC
- Primus Aerospace; Lakewood, CO
- Primus Technologies Corporation; Williamsport, PA
- PTC Inc.; Needham, MA
- PWC Aerospace & Defense Advisory Services; McLean, VA
- Range Generation Next LLC; Sterling, VA
- Raytheon Company; Waltham, MA
- Rhinestahl Corporation; Mason, OH
- Rix Industries; Benecia, CA
- Rolls-Royce North America Inc.; Reston, VA
- salesforce.com, inc.; San Francisco, CA
- SAP America, Inc.; Newtown Square, PA
- Securitas Critical Infrastructure Services, Inc.; Springfield, VA
- Siemens PLM Software; Plano, TX
- Sierra Nevada Corporation, Space Systems; Littleton, CO
- Sparton Corporation; Schaumburg, IL
- Special Aerospace Services, LLC; Boulder, CO
- Spirit AeroSystems; Wichita, KS
- Stratolaunch Systems Corporation; Seattle, WA
- SupplyOn North America, Inc.; San Diego, CA
- Tech Manufacturing, LLC; Wright City, MO
- Textron Inc.; Providence, RI
- The Aerospace Corporation, Civil Systems Group; El Segundo, CA
- The Boeing Company; Chicago, IL
- The Lundquist Group LLC; New York, NY
- The Padina Group, Inc.; Lancaster, PA
- Therm, Incorporated; Ithaca, NY
- Tip Technologies; Waukesha, WI
- Tribus Aerospace Corporation; Poway, CA
- TriMas Aerospace; Los Angeles, CA
- Triumph Group, Inc.; Wayne, PA
- TT Electronics; Perry, OH
- Unitech Aerospace; Hayden, ID
- United Technologies Corporation; Hartford, CT
- Vantage Associates; National City, CA
- Verify, Inc.; Irvine, CA

- Virgin Galactic, LLC; Las Cruces, NM
- Woodward, Inc.; Fort Collins, CO

Dated: August 5, 2019.

Joseph Flynn,

Director, Office of Trade and Economic Analysis, International Trade Administration, U.S. Department of Commerce.

[FR Doc. 2019–17040 Filed 8–8–19; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XR020

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Mukilteo Multimodal Project in Mukilteo, Washington

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

ACTION: Notice; reissuance of incidental harassment authorization.

SUMMARY: NMFS has received a request from the Washington State Department of Transportation (WSDOT) for the re-issuance of a previously issued incidental harassment authorization (IHA) with the only change being effective dates that are ten months later (August 1, 2019–July 31, 2020). The initial IHA authorized take of 12 species of marine mammals, by Level A and Level B harassment, incidental to construction associated with the Mukilteo Multimodal Project in Mukilteo, Washington. The project has been delayed and none of the work covered in the initial IHA (effective October 1, 2018–September 30, 2019) has been conducted. The scope of the activities and anticipated effects remain the same, authorized take numbers would not change, and the required mitigation, monitoring, and reporting would remain the same as authorized in the 2018 IHA referenced above. NMFS is, therefore, issuing a second IHA to cover the identical incidental take analyzed and authorized in the initial IHA.

DATES: This authorization is effective from August 1, 2019 through July 31, 2020.

ADDRESSES: An electronic copy of the final 2018 IHA previously issued to WSDOT, WSDOT's application, and the **Federal Register** notices proposing and issuing the 2018 IHA may be obtained by visiting *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities.* In case of problems accessing these documents, please call the contact listed below (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Amy Fowler, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

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

An 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 takings 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 August 28, 2018, NMFS published final notice of our issuance of an IHA authorizing take of marine mammals incidental to the Mukilteo Multimodal Project at the Mukilteo ferry terminal (83 FR 43849). The effective dates of that IHA were October 1, 2018 through September 30, 2019. On May 8, 2019, WSDOT informed NMFS that the project was being delayed by one year. None of the work identified in the IHA (*i.e.*, pile driving and removal) has occurred and no take of any marine mammals has occurred since the effective date of the initial IHA. WSDOT submitted a formal request for a new identical IHA that would be effective from August 1, 2019 through July 31, 2020, in order to conduct the construction work that was analyzed and authorized through the previously issued IHA. Therefore, an IHA is appropriate.

Summary of Specified Activity and Anticipated Impacts

The planned activities (including mitigation, monitoring, and reporting), authorized incidental take, and anticipated impacts on the affected stocks are the same as those analyzed and authorized through the previously issued IHA.

Planned activities include improving the operations and facilities serving the mainland terminus of the Mukilteo-Clinton ferry route in Washington State. Specifically, the location, timing, and nature of the activities, including the types of equipment planned for use, are identical to those described in the original IHA. The mitigation and monitoring are also identical to the original IHA and will include limiting construction to an in-water work window (July 15–February 15), limiting construction to daylight hours only, using bubble curtains during impact driving of steel piles, using soft-start during impact pile driving, and monitoring and reporting of qualified protected species observers (PSOs).

Species that are expected to be taken by the planned activity include harbor seal (*Phoca vitulina*), California sea lion (*Zalophus californianus*), northern elephant seal (*Mirounga angustirostris*), Steller sea lion (*Eumetopias jubatus*), killer whale (*Orcinus orca*), gray whale (*Eschrichtius robustus*), humpback whale (*Megaptera novaeangliae*), Dall's porpoise (*Phocoenoides dalli*), harbor porpoise (*Phocoena phocoena*), minke whale (*Balaenoptera acutorostrata*), bottlenose dolphin (*Tursiops truncatus*), and long-beaked common dolphin (*Delphinus capensis*). The takes authorized in the 2018 IHA are presented in Table 1.

TABLE 1—AUTHORIZED TAKE AMOUNT BY SPECIES

Species	Level A	Level B	Total take
Harbor seal	93	1,860	1,953
California sea lion	0	868	868
Northern elephant seal	0	7	7
Killer whale (West coast transient)	0	19	19
Steller sea lion	0	154	154
Gray whale	0	2	2
Humpback whale	0	6	6
Dall's porpoise	39	163	202
Harbor porpoise	39	784	823
Minke whale	0	7	7
Bottlenose dolphin	0	49	49
Long-beaked common dolphin	0	49	49

A description of the methods and inputs used to estimate take anticipated to occur and, ultimately, the take that was authorized is found in the previous documents referenced above. The methods of estimating take are identical to those used in the previous IHA, as is the density of marine mammals. NMFS has reviewed recent Stock Assessment Reports, information on relevant Unusual Mortality Events, and recent scientific literature, and determined that no new information affects our original analysis of impacts or take estimate under the original IHA.

We refer to the documents related to the previously issued IHA, which include the **Federal Register** notice of the issuance of the 2018 IHA for WSDOT's construction work (83 FR 43849), WSDOT's application, the **Federal Register** notice of the proposed IHA (83 FR 30421, June 28, 2018), and all associated references and documents.

Determinations

WSDOT will conduct activities identical to those analyzed in the previous 2018 IHA. As described above, the number of authorized takes of the same species and stocks of marine mammals are identical to the numbers that were found to meet the negligible impact and small numbers standards and authorized under the 2018 IHA and no new information has emerged that would change those findings. The re-issued 2019 IHA includes identical required mitigation, monitoring, and reporting measures as the 2018 IHA, and there is no new information suggesting that our analysis or findings should change.

Based on the information contained here and in the referenced documents, NMFS has determined the following: (1) The required mitigation measures will effect the least practicable impact on marine mammal species or stocks and their habitat; (2) the authorized takes will have a negligible impact on the affected marine mammal species or stocks; (3) the authorized takes represent small numbers of marine mammals relative to the affected stock abundances; and (4) WSDOT's activities will not have an unmitigable adverse impact on taking for subsistence purposes as no relevant subsistence uses of marine mammals are implicated by this action.

National Environmental Policy Act

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

Accordingly, NMFS has determined that the issuance of the IHA qualifies to be categorically excluded from further NEPA review. This action is consistent with categories of activities identified in CE B4 of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion.

Endangered Species Act (ESA)

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally, in this case with the West Coast Region Protected Resources Division, whenever we propose to authorize take for endangered or threatened species. The effects of this proposed federal action were adequately analyzed in NMFS' Biological Opinion for the Mukilteo Multimodal Project, dated August 1, 2017, which concluded that the take NMFS proposes to authorize through this IHA would not jeopardize the continued existence of any endangered or threatened species or destroy or adversely modify any designated critical habitat.

Authorization

NMFS has issued an IHA to WSDOT for in-water construction activities associated with the Mukilteo Multimodal Project from August 1, 2019 through July 31, 2020. All previously described mitigation, monitoring, and reporting requirements from the 2018 IHA are incorporated.

Dated: August 6, 2019.

Donna S. Wieting,

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

[FR Doc. 2019–17068 Filed 8–8–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Intent To Prepare a Draft Integrated Feasibility Report-Environmental Impact Statement for the Memphis Metropolitan Stormwater Management Project: North DeSoto County, Mississippi Feasibility Study

AGENCY: U.S. Army Corps of Engineers, Department of Defense.

ACTION: Notice of intent.

SUMMARY: Pursuant to the National Environmental Policy Act (NEPA), the U.S. Army Corps of Engineers (USACE), Memphis District, as the lead agency intends to prepare a Draft Integrated Feasibility Report and Environmental Impact Statement (DIFR–EIS) for the

Memphis Metropolitan Stormwater Management Project: North DeSoto County, Mississippi Feasibility Study. The DIFR–EIS seeks to evaluate the effectiveness of existing Federal and non-Federal improvements; to determine the need for additional improvements to reduce the risk of flooding from storm water, restore environmental resources, and improve the quality of water entering the Mississippi River and its tributaries; and to determine if such improvements are technically feasible, environmentally acceptable, and economically justified.

DATES: This Notice of Intent commences the formal public scoping comment period. No later than August 16, 2019, a scoping meeting notice announcing the location, date, and time for a scoping meeting will be posted on the project website (*https://www.mvm.usace.army.mil/Missions/Projects/North-DeSoto-County-Feasibility-Study/*) and published in local newspapers. Initial scoping comments should be received by October 15, 2019.

ADDRESSES: Written comments may be submitted: (1) To USACE at public scoping meetings; (2) by regular U.S. Mail mailed to: U.S. Army Corps of Engineers, ATTN: CEMVN–PDC–UDC, 167 North Main Street, Room B–202, Memphis, Tennessee 38103–1894; and (3) by email to: *Andrea.L.Carpenter@usace.army.mil*. Please include your name and return address on the first page of your written comments.

FOR FURTHER INFORMATION CONTACT: Questions or comments about the proposed action or requests to be added to the project mailing list should be directed to Andrea Carpenter, 167 North Main Street, Room B202, Memphis, Tennessee 38103, *Andrea.L.Carpenter@usace.army.mil,* or (901) 544–0817. For additional information, please visit the following: *https://www.mvm.usace.army.mil/Missions/Projects/North-DeSoto-County-Feasibility-Study/*.

SUPPLEMENTARY INFORMATION: The lead agency for this proposed action is the USACE. The DeSoto County Government is the non-Federal sponsor.

Authority. The USACE is preparing the DIFR–EIS under the authority of the United States House of Representatives Committee on Transportation and Infrastructure adopted a Resolution on March 7, 1996.

Memphis Metro Area

The Secretary of the Army reviewed the report of the Chief of Engineers on the Wolf River and Tributaries, Tennessee and Mississippi, published as House Document Numbered 76, Eighty-fifth Congress, and other pertinent reports, to determine whether any modifications of the recommendations contained therein are advisable at this time, with particular reference to the need for improvements for flood control, environmental restoration, water quality, and related purposes associated with storm water runoff and management in the metropolitan Memphis, Tennessee, area and tributary basins including Shelby, Tipton, and Fayette counties, Tennessee, and DeSoto and Marshall counties, Mississippi. This area includes the Hatchie River, Loosahatchie River, Wolf River, Nonconnah Creek, Horn Lake Creek, and Coldwater River basins. The review shall evaluate the effectiveness of existing Federal and non-Federal improvements and determine the need for additional improvements to reduce the risk of flooding from storm water, to restore environmental resources, and to improve the quality of water entering the Mississippi River and its tributaries.

1. *Background.* Flooding within DeSoto County, Mississippi, has been an issue of concern and repeated study since at least 1971 with the Soil Conservation Service Watershed Report and continuing through the present. The *Horn Lake Creek and Tributaries, Tennessee and Mississippi Project* was constructed in 1998. Construction of the 1986 authorized project (as revised per the 1988 General Design Memorandum) was completed in 1998 per a Project Cooperation Agreement between the Horn Lake Creek Drainage District Commission and the U.S. Army Corps of Engineers. The completed project included: 3.5 miles of selective channel clearing on Horn Lake Creek from Mile 16.75 downstream to Stateline Road, Mile 13.25; 2.75 miles of vegetative clearing on upper Horn Lake Creek between Mile 16.75 and 19.50 (Highway 51); vegetative clearing on the lower 0.62 miles of Cow Pen Creek; 1.85 miles of channel enlargement on Cow Pen Creek between Mile 0.62 and 2.47, requiring a 35-foot bottom width channel enlargement; 2.1 miles of vegetative clearing on the lower end of Rocky Creek downstream to the mouth. The constructed project provided a 25-year level of protection to existing development along Cow Pen Creek; a 1.1-year level of protection along Horn Lake Creek; and a 1.1 to 2- year level of protection along Rocky Creek. Although hiking/biking trails were proposed along Rocky Creek and Cow Pen Creek, these trails have not been constructed to date. More recently, damaging floods occurred in the area in May 2010, May 2011, September 2014, and March 2016. The area received a Presidential Disaster Declaration in 2011. In DeSoto County, the U.S. Small Business Administration provided federal assistance in the area after the 2014 flood. Flooding inundates major transportation corridors and several neighborhoods, isolates communities, damages public infrastructure and development (residential, commercial and industrial), and threatens life safety. In the area, unstable channels, lack of suitable riparian cover, altered flow regime, and loss of wetlands and floodplains all degrade habitat in the area. Commercial and residential development has reduced floodplain and aquatic habitat. Wetland habitat and bottomland hardwoods have been isolated and degraded. Increased runoff is causing channel instability, scouring and degradation of aquatic habitat.

2. *Alternatives:* The USACE will evaluate a range of alternatives for the proposed action including structural and nonstructural measures within Horn Lake Creek and Tributaries, Hurricane Creek Basin, Johnson Creek Basin, and Coldwater River and Tributaries. Retention and/or detention structures to reduce the flood peak and floodplain restoration in critical reaches are being examined along with other features. Recreation features such as biking and hiking trails will be considered as appropriate.

The USACE will fully evaluate the reasonable and practicable alternatives, including the no action alternative. Alternatives may necessitate avoidance, minimization, and/or compensatory mitigation measures to reduce or offset any impacts. The DIFR–EIS seeks to evaluate the effectiveness of existing Federal and non-Federal improvements and determine the need for additional improvements to reduce the risk of flooding from storm water, to restore environmental resources, and to improve the quality of water entering the Mississippi River and its tributaries and if such improvements are technically feasible, environmentally acceptable, and economically justified. The study will also consider other levels of risk reduction. The significant issues that are likely to be analyzed in depth in the DIFR–EIS include, but are not limited to, the direct, indirect, and cumulative effects on socioeconomics; environmental justice; threatened and endangered species and their critical habitat; other protected species of concern; wildlife resources; air and water quality; prime and unique farmlands; geology and soils; hydrology and hydraulics; cultural resources;

recreation; aesthetics and visual resources; and hazardous, toxic and radioactive waste. USACE will also consider issues identified and comments made throughout scoping, public involvement, and interagency coordination.

3. *Public Involvement:* Public involvement, an essential part of the NEPA process, is integral to assessing the environmental consequences of the proposed action and improving the quality of the environmental decision making. The public includes affected and interested Federal, state, and local agencies; Indian tribes; concerned citizens; stakeholders; and other interested parties. Public participation in the NEPA process will be strongly encouraged, both formally and informally, to enhance the probability of a more technically accurate, economically feasible, and socially acceptable EIS. Public involvement will include, but is not limited to: information dissemination; identification of problems, needs and opportunities; idea generation; public education; problem solving; providing feedback on proposals; evaluation of alternatives; conflict resolution; public and scoping notices and meetings; public, stakeholder and advisory groups consultation and meetings; and making the EIS and supporting information readily available in conveniently located places, such as libraries and on the world wide web at *https://www.mvm.usace.army.mil/Missions/Projects/North-DeSoto-County-Feasibility-Study/*.

4. *Scoping:* Scoping, is the NEPA process utilized for determining the range of alternative and significant issues to be addressed in the EIS. Scoping is used to: (a) Identify the affected public and agency concerns; (b) facilitate an efficient EIS preparation process; (c) define the issues and alternatives that will be examined in detail in the EIS; and (d) save time in the overall process by helping to ensure that the draft EIS adequately addresses relevant issues. USACE invites full public participation to promote open communication on the issues surrounding the proposed action. The public will be involved in the scoping and evaluation process through advertisements, notices, and other means. A Scoping Meeting Notice announcing the locations, dates and times for scoping meetings is anticipated to be posted on the project website, and published in the local newspapers no later than 15 days prior to the meeting dates. Notices of the public scoping meetings will be sent by USACE through email distribution lists, posted on the Project website, and mailed to public libraries, government agencies, and interested groups and individuals. Interested parties unable to attend the scoping meetings can access additional information on DIFR–EIS at: *https://www.mvm.usace.army.mil/Missions/Projects/North-DeSoto-County-Feasibility-Study/*.

5. *Coordination:* The USACE will serve as the lead Federal agency in the preparation of the EIS. Other federal and/or state agencies may participate as cooperating and/or commenting agencies throughout the EIS process.

In accordance with Executive Order 13807, referred to as One Federal Decision (OFD), the USACE and other agencies with environmental review, authorization, or consultation responsibilities for major infrastructure projects should develop a single EIS for such projects, sign a single Record of Decision (ROD) and issue all necessary authorizations within 90 days thereafter, subject to limited exceptions. An essential element of the OFD framework is the development of a schedule, referred to as the ''Permitting Timetable,'' including key milestones critical to completion of the environmental review and issuance of a ROD. Cooperating agencies required by law to develop schedules for environmental review or authorization processes should transmit a summary of such schedules to the lead agency for integration into the Permitting Timetable.

To ensure timely completion of the environmental review and issuance of necessary authorizations, OMB and CEQ recommend the Permitting Timetable for major infrastructure projects provide for environmental review according to the following schedule:

(1) Formal scoping and preparation of a Draft EIS (DEIS) within 14 months, beginning on the date of publication of the NOI to publish an EIS and ending on the date of the Notice of Availability of the DEIS;

(2) Completion of the formal public comment period and development of the Final EIS (FEIS) within eight months of the date of the Notice of Availability of the DEIS; and

(3) Publication of the final ROD within two months of the publication of the Notice of Availability of the FEIS.

While the actual schedule for any given project may vary based upon the circumstances of the project and applicable law, agencies should endeavor to meet the two-year goal established in E.O. 13807.

The USACE is coordinating with the U.S. Fish and Wildlife Service (USFWS) in documenting existing conditions and assessing effects of project alternatives through the Fish and Wildlife Coordination Act and pursuant to Section 7 of the Endangered Species Act. Coordination includes the U.S. Environmental Protection Agency and the Mississippi Department of Environmental Quality pursuant to Section 401 of the Clean Water Act, and the Mississippi Department of Wildlife Fisheries and Parks. The USACE is coordinating with the State Historic Preservation Officer under Section 106 of the National Historic Preservation Act concerning properties listed, or potentially eligible for listing.

6. *Availability:* The DIFR–EIS is expected to be available for public comment and review in January 2020. At that time, a 45-day public review period will be provided for individuals and agencies to review and comment. USACE will notify all interested agencies, organizations, and individuals of the availability of the draft document at that time. All interested parties are encouraged to respond to this notice and provide a current address if they wish to be notified of the DIFR–EIS circulation.

Dated: August 2, 2019. Approved by:

Zachary L. Miller,

Colonel, Corps of Engineers District Commander.

[FR Doc. 2019–17129 Filed 8–8–19; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Personnel Development To Improve Services and Results for Children With Disabilities—Leadership Development Programs: Increasing the Capacity of Leaders To Improve Systems Serving Children With Disabilities

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

SUMMARY: 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. As such, the Department of Education (Department) is issuing a notice inviting applications for new awards for fiscal year (FY) 2019 for Personnel Development to Improve Services and Results for Children with Disabilities—Leadership Development Programs:

Increasing the Capacity of Leaders to Improve Systems Serving Children with Disabilities, Catalog of Federal Domestic Assistance (CFDA) number 84.325L. These grants will fund States to implement leadership development programs that recruit, increase the capacity of, and retain State, regional, and local leaders to promote high expectations and improve early childhood and educational outcomes for children with disabilities and their families by improving the systems that serve them. This notice relates to the approved information collection under OMB control number 1820–0028.

DATES:

Applications Available: August 9, 2019.

Deadline for Transmittal of Applications: September 9, 2019.

Pre-Application Webinar Information: No later than August 14, 2019, OSERS will post pre-recorded informational webinars designed to provide technical assistance to interested applicants. The webinars may be found at *www2.ed.gov/fund/grant/apply/osep/new-osep-grants.html.*

Pre-Application Q & A Blog: No later than August 14, 2019, OSERS will open a blog where interested applicants may post questions about the application requirements for this competition and where OSERS will post answers to the questions received. OSERS will not respond to questions unrelated to the application requirements for this competition. The blog may be found at *www2.ed.gov/fund/grant/apply/osep/new-osep-grants.html* and will remain open until August 28, 2019. After the blog closes, applicants should direct questions to the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf.*

FOR FURTHER INFORMATION CONTACT: Sarah Allen, U.S. Department of Education, 400 Maryland Avenue SW, Room 5160, Potomac Center Plaza, Washington, DC 20202–5076. Telephone: (202) 245–7875. Email: *Sarah.Allen@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 purposes of this program are to (1) help address State-identified needs for personnel preparation in special education, early intervention, related services, and regular education to work with children, including infants and toddlers, and youth with disabilities; and (2) ensure that those personnel have the necessary skills and knowledge, derived from practices that have been determined through scientifically based research, to be successful in serving those children.

Priorities: This competition includes one absolute priority and one competitive preference priority. In accordance with 34 CFR 75.105(b)(2)(v), the absolute priority and competitive preference priority are from allowable activities specified in the statute (see sections 662 and 681 of the Individuals with Disabilities Education Act (IDEA); 20 U.S.C. 1462 and 1481).

Absolute Priority: For FY 2019 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:

Leadership Development Programs: Increasing the Capacity of Leaders to Improve Systems Serving Children with Disabilities.

Background:

State, regional, and local administrators in early intervention and special education serve a critical role in ensuring that infants, toddlers, children, and youth with disabilities (children with disabilities) are provided services and supports to which they are entitled under the Individuals with Disabilities Education Act (IDEA) and in helping improve results for children with disabilities. Given the demands for leading within complex early intervention and special education systems and addressing current issues across systems, administrators must have the skills to collaborate with other agencies and programs. This would help ensure that children with disabilities are held to high standards and that their individualized needs are met across natural environments and educational settings. In addition, the expansion of educational options [1] has also added to special education administrators' responsibilities to ensure that parents of children with disabilities are empowered to choose from a robust range of educational options and supports to identify those that best meet their children's needs.

With the increasing demands placed on State, regional, and local administrators, it is essential that they have the knowledge, skills, and competencies to oversee the administration of early intervention and special education systems. Turnover of administrators and leaders across all levels of the system is high and increasing. In 2018, 70 percent of State Directors of Special Education had less than five years of experience, up from only 15 percent in 2010 (NCSI, 2018a). Similarly, 73 percent of Part C Coordinators had less than 5 years of experience in 2018, up from 39 percent in 2005 (NCSI, 2018b). Approximately 10 to 15 percent of local special education administrator positions turn over each year (Goldring & Taie, 2018).

[1] For the purpose of this priority, ''educational options'' means the opportunity for a child or student (or a family member on their behalf) to create a high-quality personalized path for learning that is consistent with applicable Federal, State, and local laws; is in an educational setting that best meets the child's or student's needs; and, where possible, incorporates evidence-based activities, strategies, or interventions. Opportunities made available to a student through a grant program are those that supplement what is provided by a child's or student's geographically assigned school or the institution in which he or she is currently enrolled and may include one or more of the following options: (1) Public educational programs or courses, including those offered by traditional public schools, public charter schools, public magnet schools, public online education providers, or other public education providers; (2) Private or home-based educational programs or courses, including those offered by private schools, private online providers, private tutoring providers, community or faith-based organizations, or other private education providers; (3) Part-time coursework or career preparation, offered by a public or private provider in person or through the internet or another form of distance learning, that serves as a supplement to full-time enrollment at an educational institution, as a stand-alone program leading to a credential, or as a supplement to education received in a homeschool setting; and (4) Other educational services, including credit-recovery, accelerated learning, or tutoring.

Further, half of the States do not require a special education administration credential for local special education administrators or specifically address the preparation of administrators in the personnel preparation programs offered by institutions of higher education (IHEs) in their States (Boscardin, Weir, & Kusek, 2010). Even when an administration credential is required, preparation programs are at times difficult to find, hard for working professionals to access or complete, and varied in content coverage (Bellamy & Iwaszuk, 2017). Like credentialing programs, professional development programs that help administrators develop the knowledge, skills, and competencies needed for leadership positions often are not available, thus requiring State, regional, and local administrators to learn on the job.

In order to help meet the complex and varied needs of children with disabilities and their families, this priority will fund grants to State educational agencies (SEAs) or lead agencies for Part C to implement high-quality, sustainable leadership development programs to recruit, increase the capacity of, and retain State, regional, and local leaders who have the knowledge, skills, and competencies to improve systems serving children with disabilities and their families. This priority is consistent with Supplemental Priority 2—Promoting Innovation and Efficiency, Streamlining Education with an Increased Focus on Improving Student Outcomes, and Providing Increased Value to Students and Taxpayers; Supplemental Priority 5—Meeting the Unique Needs of Students and Children With Disabilities and/or Those with Unique Gifts and Talents; and Supplemental Priority 8—Promoting Effective Instruction in Classrooms and Schools.

The projects must be operated in a manner consistent with nondiscrimination requirements contained in the U.S. Constitution and the Federal civil rights laws.

Priority:

The purpose of this priority is to fund grants to achieve, at a minimum, the following expected outcomes:

(a) Development, improvement, or expansion of a high-quality, sustainable leadership development program to recruit, increase the capacity of, and retain a network of leaders at the State, regional, or local level to improve systems serving children with disabilities and their families;

(b) Development, improvement, or expansion of infrastructure and implementation supports,[2] including but not limited to partnerships with relevant child-serving agencies and diverse stakeholders (*e.g.,* IHEs, parent centers,[3] State- and local-level administrators, technical assistance providers) to deliver and sustain leadership development programs; and

(c) Increased number of early intervention and special education leaders at the State, regional, or local level with the knowledge, skills, and competencies to improve systems serving children with disabilities and their families.

To be considered for funding under this absolute priority, all applicants must meet the application requirements contained in the priority. All projects funded under this absolute priority also must meet the programmatic and administrative requirements specified in the priority.

To meet the requirements of this priority, an applicant must—

(a) Demonstrate, in the narrative section of the application under ''Significance,'' how the proposed project will—

(1) Address the need for early intervention or special education leaders at the State, regional, or local level with the knowledge, skills, and competencies to improve systems serving children with disabilities and their families. To meet this requirement, the applicant must—

(i) Present applicable data demonstrating the need to increase the number of early intervention or special education leaders with the knowledge, skills, and competencies to improve systems serving children with disabilities and their families;

(ii) Identify the knowledge, skills, and competencies that early intervention or special education leaders need to improve systems serving children with disabilities and their families; and

(iii) Identify current educational issues and policy initiatives at the Federal, State, regional, and local levels that early intervention or special education leaders need to understand, including how innovation and the State's efforts to expand educational options can be supported, and parents can be empowered to choose an education that best meets their children's needs; and

(2) Address the need for infrastructure and implementation supports, including partnerships with relevant child-serving agencies and diverse stakeholders, to effectively develop, deliver, and sustain a leadership development program to recruit, increase the capacity of, and retain a network of leaders at the State, regional, or local level with the knowledge, skills, and competencies to improve systems serving children with disabilities and their families. To meet this requirement, the applicant must—

(i) Present data, if applicable, on the quality of existing leadership development programs or personnel preparation degree programs that prepare leaders to work in administrative or leadership positions in systems where children receive early intervention or special education services, including the effectiveness of the program(s) at (a) increasing the knowledge, skills, and competencies of program completers; and (b) retaining program completers to work in administrative or leadership positions in systems where children receive early intervention or special education services; and

(ii) Present information on the current capacity of the State, regional, or local systems to recruit, increase the capacity of, and retain leaders, including programs IHEs offer to credential or otherwise prepare early intervention and special education administrators, and the likely magnitude or importance of developing a network of leaders with the capacity to improve systems serving children with disabilities.

(b) Demonstrate, in the narrative section of the application under ''Quality of 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;

(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[4] by which the proposed project will

[2] For the purpose of this priority, ''implementation supports'' means effective methods for changing practices, organizational structure, and systems at all levels.

[3] For the purpose of this priority, ''parent centers'' refers to Parent Training and Information Centers and Community Parent Resource Centers funded by OSEP, which can be found at *www.parentcenterhub.org/the-parent-center-network/.*

[4] ''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

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) Develop, improve, or expand a leadership development program or programs to recruit, increase the capacity of, and retain a network of leaders at the State, regional, or local level with the knowledge, skills, and competencies to improve systems serving children with disabilities and their families. To establish the quality of the proposed leadership development program, the applicant must include—

(i) Its proposed plan for partnering with diverse stakeholders to develop, improve, or expand a leadership development program to recruit, increase the capacity of, and retain a network of leaders at the State, regional, or local level to improve systems serving children with disabilities and their families. The stakeholders must include, at a minimum, representatives specifically identified from IHEs. Stakeholders must be involved as decision makers in how the leadership development program is developed, improved, or expanded, and serve as partners in delivering and evaluating the program;

(ii) The intended participants of the leadership development program;

(iii) Its proposed approach for developing or improving the content and delivery of the leadership development program. To meet this requirement the applicant must describe—

(A) The knowledge, skills, and competencies that participants will gain by completing the leadership development program. At a minimum, the applicant must ensure that participants demonstrate knowledge, skills, and competencies in the following areas:

(*1*) Federal laws, State laws, and State policies, procedures, and initiatives that impact children with disabilities and their families;

(*2*) Educational options for children with disabilities and how to support State's efforts to empower parents to choose from a robust range of educational options and supports to identify those that best meet their children's needs;

(*3*) Evidence-based [5] practices to improve academic, learning, and developmental outcomes for children with disabilities, including differentiating interventions and instruction across multi-tiered systems of support;

(*4*) Partnering with parents, families, and diverse stakeholders to improve systems;

(*5*) Systems change, implementation science, and professional development methods to promote the implementation of evidence-based practices and use of data-based decision making; and

(*6*) Leadership practices (*e.g.,* organizational visioning, collaborative decision making, communication and conflict management, relationship building);

(B) The current research and evidence-based practices that will guide the development of the content and delivery of the leadership development program, including but not limited to evidence-based professional development practices for adult learners and resources developed by projects funded by the Departments of Education and Health and Human Services;

(C) How the proposed leadership development program is of sufficient quality, intensity, and duration to prepare a network of leaders with the identified knowledge, skills, and competencies needed to improve systems serving children with disabilities and their families. To meet this requirement, the applicant must describe—

(*1*) The components of the leadership development program, which must include, but are not limited to, face-to-face activities, applied projects, peer interactions and collaboration opportunities, mentoring support, and ongoing coaching, and how these components are sequenced;

(*2*) How participants in the leadership development program will be provided with mentoring, ongoing coaching and performance feedback during the program, and ongoing coaching, networking opportunities, and support following completion of the program, including opportunities to interact with peers who completed the program; and

(*3*) How the proposed leadership development program is aligned to State standards for administrators or meets appropriate national professional organization standards for administrators or leaders;

(5) Implement and sustain the leadership development program to recruit, increase the capacity of, and retain a network of leaders at the State, regional, or local level with the knowledge, skills, and competencies to improve systems serving children with disabilities and their families. To meet this requirement, the applicant must describe its proposed approach to—

(i) Ensuring the infrastructure and implementation supports necessary to effectively build, deliver, and sustain the proposed leadership development program and to retain individuals who complete the leadership development program as a network of leaders at the State, regional, or local level able to improve systems serving children with disabilities and their families. The application must include the proposed approach to partnering with relevant child-serving agencies and diverse stakeholders to deliver and sustain the leadership development program, to retain a network of leaders, and to develop agreements with relevant child-serving agencies and diverse stakeholders that outline responsibilities, sharing of resources, and decision-making and communication processes. The application must include, at a minimum, representatives specifically identified from IHEs as part of its ongoing project leadership or stakeholder group that will build, manage, deliver, evaluate, and sustain the infrastructure and implementation of the proposed program;

(ii) Its proposed approach to recruit participants for the leadership development program; ensure equal access and treatment for eligible participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability; and retain the participants once in the program. To meet this requirement, the applicant must describe—

(A) Recruitment strategies that will be used to attract participants and specific recruitment strategies that will be used to reach potential participants from traditionally underrepresented groups,

operational relationships among the key project components and relevant outcomes.

[5] For the purposes of this priority, ''evidence-based'' means the proposed project component is supported, at a minimum, by evidence that demonstrates a rationale (as defined in 34 CFR 77.1), where 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.

including individuals with disabilities; and

(B) Criteria that will be used to select candidates for participation in the leadership development programs offered, the number of cohorts that will complete the leadership development program, and the number of participants that the applicant proposes will complete program requirements within each cohort during the project period; and

(iii) Strategies for supporting and retaining participants to complete the leadership development program and use the knowledge, skills, and competencies learned following their completion of the program to identify, implement, and evaluate evidence-based practices to improve systems serving children with disabilities; and

(iv) Strategies to fund, manage, and sustain the leadership development program, and retain a network of leaders at the State, regional, or local level once Federal support ends; and

(6) Use technology, as appropriate, to support participants in achieving the outcomes of the proposed project, enhance the efficiency of the project, collaborate with partners, provide the leadership development, mentoring, ongoing coaching, and performance feedback to participants, and support collaboration among the participants once they complete the program.

(c) Demonstrate, in the narrative section of the application under ''Quality of the project evaluation,'' how—

(1) The applicant will use comprehensive and appropriate methodologies to evaluate how well the goals or objectives of the proposed project have been met, including the project processes and intended outcomes. The applicant must describe performance measures for the project that include participants' acquisition of knowledge, skills, and competencies and for the retention of program completers in administrative and leadership positions; and

(2) The applicant will collect, analyze, and use data related to specific and measurable goals, objectives, and intended outcomes of the project. To meet this requirement, the applicant must describe how—

(i) Participants' knowledge, skills, and competencies and other project processes and outcomes will be measured for formative evaluation purposes, including proposed instruments, data collection methods, and possible analyses; and

(ii) It will collect and analyze data on the quality of the leadership development programs offered; the infrastructure and implementation supports in place to deliver the program; the capacity of the State to retain a network of leaders at the State, regional, or local level; and the fidelity and impact of its implementation;

(3) The methods of evaluation will produce quantitative and qualitative data for objective performance measures that are related to the intended outcomes of the proposed project; and

(4) The methods of evaluation will provide performance feedback and allow for periodic assessment of progress towards meeting the project outcomes. To meet this requirement, the applicant must describe how—

(i) Results of the evaluation will be used as a basis for improving the proposed project;

(ii) It will report the evaluation results to OSEP in its annual and final performance reports; and

(iii) Performance information (*e.g.,* annual progress toward program goals) will be made publicly available on the project or State's web page.

(d) Demonstrate, in the narrative section of the application under ''Adequacy of resources and quality of project personnel,'' 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 meet 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 appropriate and adequate to achieve the project's intended outcomes;

(3) The proposed management plan will ensure that the project's products and services 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, faculty, technical assistance and professional development providers, researchers, and policymakers, among others, in its development and operation.

(f) Address the following application requirements. The applicant must—

(1) Demonstrate, in the budget information (ED Form 524, Section B) and budget narrative, matching support for the proposed project at 10 percent of the total amount of the grant;

Note: Matching support can be either cash or in-kind donations. Under 2 CFR 200.306, a cash expenditure or outlay of cash with respect to the matching budget by the grantee is considered a cash contribution. However, certain cash contributions that the organization normally considers an indirect cost should not be counted as a direct cost for the purposes of meeting matching support. Specifically, in accordance with 2 CFR 200.306(c), unrecovered indirect costs cannot be used to meet the non-Federal matching support. Under 2 CFR 200.434, third-party in-kind contributions are services or property (*e.g.,* land, buildings, equipment, materials, supplies) that are contributed by a non-Federal third party at no charge to the grantee.

(2) Include, in Appendix A, personnel-loading charts and timelines, as applicable, to illustrate the management plan described in the narrative;

(3) If the project maintains a website, include relevant information about the revised program and documents in a form that meets government or industry recognized standards of accessibility;

(4) Ensure that annual progress toward meeting project goals is posted on the project website;

(5) Provide an assurance that the project director, key personnel, and representatives from partner agencies will actively participate in the cross-project collaboration and learning opportunities (*e.g.,* webinars, briefings) organized by OSEP. This cross-project collaboration will be used to increase capacity of participants, share resources, increase the impact of funding, and promote innovative leadership development models across projects; and

(6) Include, in the budget, attendance at a two- and one-half day project directors' conference in Washington, DC, during each year of the project period.

Competitive Preference Priority: Within this absolute priority, we give competitive preference to applications that address the following competitive preference priority. Under 34 CFR 75.105(c)(2)(i), we award up to an additional 5 points to an application, depending on how well the application meets the competitive preference priority.

This priority is:

Matching Support (Up to 5 points).

An application that demonstrates matching support for the proposed project at—

(a) 20 percent of the requested Federal award (1 point);

(b) 40 percent of the total amount of the requested Federal award (2 points);

(c) 60 percent of the total amount of the requested Federal award (3 points);

(d) 80 percent of the total amount of the requested Federal award (4 points); or

(e) 100 percent of the total amount of the requested Federal award (5 points).

Applicants must address this competitive preference priority in the budget information (ED Form 524, Section B) and budget narrative.

References:

Bellamy, T., & Iwaszuk, W. (2017, October). *Responding to the need for new local special education administrators: A case study.* CEEDAR Center. Retrieved from University of Florida, Collaboration for Effective Educator, Development, Accountability, and Reform Center website: *http://ceedar.education.ufl.edu/wp-content/uploads/2017/12/Responding-to-the-Need-for-Local-SPED-Admin-Oct-2017.pdf.*

Boscardin, M. L., Weir, K., & Kusek, C. (2010). A national study of State credentialing requirements for administrators of special education. *Journal of Special Education Leadership, 23*(2), 61–75.

Goldring, R., & Taie, S. (2018). Principal attrition and mobility: Results from the 2016–17 principal follow-up survey first look (NCES 2018–066). Washington, DC: U.S. Department of Education, National Center for Education Statistics. Retrieved from *https://nces.ed.gov/pubsearch.*

National Center for Systemic Improvement (NCSI). (2018a). *Leadership turnover: The impact on State special education systems.* Retrieved from *https://ncsi-library.wested.org/resources/201.*

National Center for Systemic Improvement (NCSI). (2018b). *Leadership turnover: The impact on State early intervention systems.* Retrieved from *https://ncsi-library.wested.org/resources/200.*

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. 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. 1462 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. (d) The regulations for this program in 34 CFR part 304.

Note: The regulations in 34 CFR part 86 apply to IHEs only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $2,600,000.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2020 from the list of unfunded applications from this competition.

Estimated Range of Awards: $150,000 to $200,000.

Estimated Average Size of Awards: $200,000.

Maximum Award: We will not make an award exceeding $200,000 for a single budget period of 12 months.

Estimated Number of Awards: 13.

Project Period: 60 months.

Note: The Department is not bound by any estimates in this notice.

III. Eligibility Information

1. *Eligible Applicants:* SEAs or Part C lead agencies.

2. *Cost Sharing or Matching:* Cost sharing or matching is required for this competition.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application. Under 34 CFR 75.708(e), a grantee may contract for supplies, equipment, and other services in accordance with 2 CFR part 200.

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:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf,* which contain requirements and information on how to submit an application.

2. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. However, under 34 CFR 79.8(a), we waive intergovernmental review in order to make an award by the end of FY 2019.

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 50 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 as follows:

(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; and

(ii) The importance or magnitude of the results or outcomes likely to be attained by the proposed project, especially improvements in teaching and student achievement.

(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 the services to be provided by the proposed project reflect up-to-date knowledge from research and effective practice;

(iii) The extent to which the training or professional development services to be provided by the proposed project are of sufficient quality, intensity, and duration to lead to improvements in practice among the recipients of those services;

(iv) The extent to which the services to be provided by the proposed project involve the collaboration of appropriate partners for maximizing the effectiveness of project services; and

(v) The extent to which the proposed activities constitute a coherent, sustained program of training in the field.

(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 goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable;

(iii) 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; and

(iv) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes.

(d) *Adequacy of resources and quality of project personnel (15 points).*

(1) The Secretary considers the adequacy of resources and quality of project personnel for 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 key project personnel;

(ii) The adequacy of support, including facilities, equipment, supplies, and other resources, from the applicant organization or the lead applicant organization; and

(iii) 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; and

(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 (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Additional Review and Selection Process Factors:* In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The standing panel requirements under section 682(b) of IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the

review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications.

4. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose specific conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

5. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.205(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee 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.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

5. *Performance Measures:* Under GPRA, the Department has established a set of performance measures, including long-term measures, that are designed to yield information on the quality of the Personnel Development to Improve Services and Results for Children with Disabilities program. These measures include: (1) The percentage of preparation programs that incorporate scientifically or evidence-based practices into their curricula; (2) the percentage of scholars completing preparation programs who are knowledgeable and skilled in evidence-based practices that improve outcomes for children with disabilities; (3) the percentage of scholars who exit preparation programs prior to completion due to poor academic performance; (4) the percentage of scholars completing preparation programs who are working in the area(s) in which they were prepared upon program completion; and (5) the Federal cost per scholar who completed the preparation program.

In addition, the Department will gather information on the following outcome measures: (1) The percentage of scholars who completed the preparation program and are employed in high-need districts; (2) the percentage of scholars who completed the preparation program and are employed in the field of special education for at least two years; and (3) the percentage of scholars who completed the preparation program and who are rated effective by their employers.

Grantees may be asked to participate in assessing and providing information on these aspects of program quality.

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 5081A, Potomac Center Plaza, Washington, DC 20202–5076. Telephone: (202) 245–7363. If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Johnny W. Collett,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2019–17041 Filed 8–8–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Advanced Scientific Computing Advisory Committee

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Advanced Scientific Computing Advisory Committee (ASCAC). The Federal Advisory Committee Act requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Monday, September 23, 2019, 8:30 a.m. to 5:00 p.m., Tuesday, September 24, 2018, 9:00 a.m. to 12:00 noon.

ADDRESSES: Holiday Inn Washington-Capitol, 550 C Street SW, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Christine Chalk, Office of Advanced Scientific Computing Research; SC–21/Germantown Building; U.S. Department of Energy; 1000 Independence Avenue SW; Washington, DC 20585; Telephone (301) 903–7486; Email: *christine.chalk@science.doe.gov*

SUPPLEMENTARY INFORMATION:

Purpose of the Committee: The purpose of the committee is to provide advice and guidance on a continuing basis to the Office of Science and to the Department of Energy on scientific priorities within the field of advanced scientific computing research.

Purpose of the Meeting: This meeting is the semi-annual meeting of the Committee.

Tentative Agenda Topics:

- View from Washington
- View from Germantown
- Update on Exascale project activities
- Report from Subcommittee on 40 years of investments by the Department of Energy in advanced computing and networking
- Update from Exascale Transition Subcommittee
- In-Situ Data Management Workshop report
- Update on Mathematical Multifaceted Integrated Capability Centers (MMICCs)
- Technical presentations
- Public Comment (10-minute rule)

The meeting agenda includes an update on the budget, accomplishments and planned activities of the Advanced Scientific Computing Research program and the exascale computing project; an update from the Office of Science; technical presentations from funded researchers; updates from subcommittees and there will be an opportunity for comments from the public. The meeting will conclude at 12:00 noon on September 24, 2019. Agenda updates and presentations will be posted on the ASCAC website prior to the meeting: *https://science.osti.gov/ascr/ascac.*

Public Participation: The meeting is open to the public. Individuals and representatives of organizations who would like to offer comments and suggestions may do so during the meeting. Approximately 30 minutes will be reserved for public comments. Time allotted per speaker will depend on the number who wish to speak but will not exceed 10 minutes. The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Those wishing to speak should submit your request at least five days before the meeting. Those not able to attend the meeting, or who have insufficient time to address the committee, are invited to send a written statement to Christine Chalk, U.S. Department of Energy, 1000 Independence Avenue SW, Washington DC 20585, email to: *Christine.Chalk@science.doe.gov.*

Minutes: The minutes of this meeting will be available within 90 days on the Advanced Scientific Computing website at: *https://science.osti.gov/ascr/ascac.*

Signed in Washington, DC, on August 6, 2019.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2019–17101 Filed 8–8–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[Case Number 2018–004; EERE–2018–BT–WAV–0007]

Energy Conservation Program: Petition for Waiver of LG Electronics USA, Inc. From the Department of Energy Portable Air Conditioner Test Procedure and Notice of Grant of Interim Waiver

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of petition for waiver and grant of an interim waiver, and request for comments.

SUMMARY: This document announces receipt of and publishes a petition for waiver from LG Electronics USA, Inc. (''LG''), which seeks an exemption from the U.S. Department of Energy (''DOE'') test procedure used for determining the efficiency of specified portable air conditioner basic models. LG seeks to use an alternate test procedure to address issues involved in testing the basic models identified in its petition. According to LG, the current DOE test procedure for single-duct portable air conditioners does not take into account the benefits of portable air conditioners that use variable-speed compressors (''variable-speed portable air conditioners''), due to their part-load performance characteristics, and misrepresents their actual energy consumption. LG requests use of an alternate test procedure, under which the test unit's final combined energy efficiency ratio (''CEER'') metric would be calculated by multiplying the unit's measured CEER value (as measured according to the existing procedure for a single-duct portable air conditioner) by a ''performance adjustment factor.'' The performance adjustment factor would reflect the performance improvement associated with avoiding

cycling losses as a result of implementing a variable-speed compressor, when tested under the two rating conditions currently used for testing dual-duct portable air conditioners. DOE grants LG an interim waiver from DOE's portable air conditioner test procedure for the basic models listed in the interim waiver, subject to use of the alternate test procedure as set forth in the Interim Waiver Order. DOE solicits comments, data, and information concerning LG's petition and its suggested alternate test procedure to inform its final decision on LG's waiver request.

DATES: Written comments and information are requested and will be accepted on or before September 9, 2019.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *http://www.regulations.gov.* Alternatively, interested persons may submit comments, identified by case number ''2018–004'', and Docket number ''EERE–2018–BT–WAV–0007,'' by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: LG2018WAV0007@ee.doe.gov.* Include the case number [Case No. 2018–004] in the subject line of the message.
- *Postal Mail:* Appliance and Equipment Standards Program. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, Mailstop EE–5B, Petition for Waiver Case No. 2018–004, 1000 Independence Avenue SW, Washington, DC 20585–0121. If possible, please submit all items on a compact disc (''CD''), in which case it is not necessary to include printed copies.
- *Hand Delivery/Courier:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza, SW, 6th floor, Washington, DC, 20024. If possible, please submit all items on a ''CD'', in which case it is not necessary to include printed copies.

No telefacsimilies (faxes) will be accepted. For detailed instructions on submitting comments and additional information on this process, see section V of this document.

Docket: The docket, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at *http://www.regulations.gov.* All documents in the docket are listed in the *http://www.regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket web page can be found at *http://www.regulations.gov/docket?D=EERE-2018-BT-WAV-0007.* The docket web page contains simple instruction on how to access all documents, including public comments, in the docket. See section V for information on how to submit comments through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Lucy deButts, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Email: *AS_Waiver_Request@ee.doe.gov.*

Ms. Sarah Butler, U.S. Department of Energy, Office of the General Counsel, Mail Stop GC–33, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585–0103. Telephone: (202) 586–1777. Email: *Sarah.Butler@hq.doe.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Authority

The Energy Policy and Conservation Act of 1975, as amended (''EPCA''),[1] among other things, authorizes DOE to regulate the energy efficiency of a number of consumer products and industrial equipment. (42 U.S.C. 6291–6317) Title III, Part B [2] of EPCA established the Energy Conservation Program for Consumer Products Other Than Automobiles. In addition to specifying a list of covered products and industrial equipment, EPCA contains provisions that enable the Secretary of Energy to classify additional types of consumer products as covered products. (42 U.S.C. 6292(a)(20)) In a final determination of coverage published in the **Federal Register** on April 18, 2016 (the ''April 2016 Final Coverage Determination''), DOE classified portable air conditioners as covered products under EPCA. 81 FR 22514. The test procedure for portable air conditioners is contained in the Code of Federal Regulations (''CFR'') at 10 CFR part 430, subpart B, appendix CC (''appendix CC'').

Under 42 U.S.C. 6293, EPCA sets forth the criteria and procedures DOE is required to follow when prescribing or amending test procedures for covered products. EPCA requires that any test procedures prescribed or amended under this section must be reasonably designed to produce test results which reflect energy efficiency, energy use or estimated annual operating cost of a covered product during a representative average use cycle or period of use and requires that test procedures not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3))

Under 10 CFR 430.27, any interested person may submit a petition for waiver from DOE's test procedure requirements. DOE will grant a waiver from the test procedure requirements if DOE determines either that the basic model for which the waiver was requested contains a design characteristic that prevents testing of the basic model according to the prescribed test procedures, or that the prescribed test procedures evaluate the basic model in a manner so unrepresentative of its true energy consumption characteristics as to provide materially inaccurate comparative data. 10 CFR 430.27(f)(2). DOE may grant the waiver subject to conditions, including adherence to an alternate test procedure. *Id.*

As soon as practicable after the granting of any waiver, DOE will publish in the **Federal Register** a notice of proposed rulemaking to amend its regulations so as to eliminate any need for the continuation of such waiver. 10 CFR 430.27(l). As soon thereafter as practicable, DOE will publish in the **Federal Register** a final rule. *Id.*

The waiver process also provides that DOE may grant an interim waiver if it appears likely that the underlying petition for waiver will be granted and/or if DOE determines that it would be desirable for public policy reasons to grant immediate relief pending a determination on the underlying petition for waiver. 10 CFR 430.27(e)(2). Within one year of issuance of an interim waiver, DOE will either: (i) Publish in the **Federal Register** a determination on the petition for waiver; or (ii) publish in the **Federal Register** a new or amended test procedure that addresses the issues presented in the waiver. 10 CFR 430.27(h)(1).

When DOE amends the test procedure to address the issues presented in a waiver, the waiver will automatically terminate on the date on which use of that test procedure is required to demonstrate compliance. 10 CFR 430.27(h)(2).

[1] All references to EPCA in this document refer to the statute as amended through America's Water Infrastructure Act of 2018, Public Law 115–270 (October 23, 2018).

[2] For editorial reasons, upon codification in the U.S. Code, Part B was re-designated Part A.

II. LG's Petition for Waiver and Petition for Interim Waiver

On May 15, 2018, LG filed a petition for waiver and a petition for interim waiver from the test procedure for portable air conditioners, set forth in appendix CC. In the petition, LG requested relief for the following portable air conditioner basic models: LP1419IVSM, LP1419HVSM, LP1219IVSM, LP1019IVSM, and LP0819IVSM.[3] LG notes that the current DOE test procedure for portable air conditioners requires testing dual-duct portable air conditioners under two operating conditions, one measuring peak-load performance (*i.e.,* at a high-temperature outdoor operating condition) and another measuring a reduced-load performance (*i.e.,* at a lower outdoor temperature operating condition). For single-duct portable air conditioners, the test procedure requires testing at only the high-temperature outdoor operating condition. LG asserts that the current DOE test procedure for single-duct portable air conditioners does not take into account the specific performance and efficiency benefits associated with single-duct variable-speed portable air conditioners under part-load conditions.

LG stated that single-duct variable-speed portable air conditioners constantly use frequency controls to adjust the compressor rotation speed to maintain the desired temperature in the home without turning the motor on and off; that the compressor responds automatically to surrounding conditions to operate in the most efficient possible manner; and that this results in both significant energy savings and faster cooling compared to a portable air conditioner without a variable-speed compressor. LG asserted that, because the DOE test procedure does not account for the general part-load performance benefits of single-duct variable-speed portable air conditioners or properly account for the favorable difference in cycling losses for single-duct variable-speed portable air conditioners resulting from use of variable-speed technology, the results of the test procedure are not representative of the actual energy consumption of single-duct variable-speed portable air conditioners.

LG also requested an interim waiver from the existing DOE test procedure. DOE will grant an interim waiver if it appears likely that the petition for waiver will be granted, and/or if DOE determines that it would be desirable for public policy reasons to grant immediate relief pending a determination of the petition for waiver. See 10 CFR 430.27(e)(2).

DOE understands that, absent an interim waiver, the test procedure does not accurately measure the energy consumption of single-duct variable-speed portable air conditioners, and without waiver relief, the test results would not reflect the part-load characteristics of the basic models listed above.

III. Requested Alternate Test Procedure

EPCA requires that manufacturers use DOE test procedures when making representations about the energy consumption and energy consumption costs of covered products. (42 U.S.C. 6293(c)) Consistent representations are important when making representations about the energy efficiency of products, including when demonstrating compliance with applicable DOE energy conservation standards. Pursuant to its regulations at 10 CFR 430.27, and after consideration of public comments on the petition, DOE may establish in a subsequent Decision and Order an alternate test procedure for the basic models addressed by the interim waiver.

In its petition, LG requests testing the basic models listed in its petition according to the test procedure for portable air conditioners prescribed by DOE in appendix CC, except that single-duct variable-speed portable air conditioners would be tested at both the high- and low-temperature outdoor operating conditions to measure a weighted-average combined energy efficiency ratio (CEER). LG also suggests an additional set of calculations to model the CEER of a theoretical comparable single-speed portable air conditioner with and without cycling losses.[4] From these results, a ''performance adjustment factor'' would be calculated, representing the performance improvement associated with avoiding cycling losses. The performance adjustment factor would then be multiplied by the measured CEER value for the variable-speed portable air conditioner according to appendix CC to determine the test unit's final rated CEER value. LG states that this approach takes into account performance and efficiency improvements associated with single-duct variable-speed portable air conditioners as compared to single-duct portable air conditioners with single-speed compressors.

IV. Grant of an Interim Waiver

DOE has reviewed the materials submitted in LG's petition. DOE has been unable to identify or review any marketing materials, website, or brochure for basic models LP1419IVSM, LP1419HVSM, LP1219IVSM, LP1019IVSM, and LP0819IVSM because they currently are not available in the U.S. market. The materials submitted support LG's assertion of the part-load characteristics of the single-duct variable-speed portable air conditioners and that the DOE test procedure may yield results that are unrepresentative of their true energy consumption characteristics. In particular, the DOE test procedure does not capture the relative efficiency improvements due to cycling loss avoidance that can be achieved by single-duct variable-speed portable air conditioners over a range of operating conditions compared to single-speed portable air conditioners. Without an alternate test procedure, the CEER values of single-duct variable-speed portable air conditioners would suggest that such portable air conditioners would consume at least as much energy annually as a theoretical comparable single-speed portable air conditioner, despite the anticipated benefits of improved performance under part-load conditions. DOE has reviewed the alternate procedure suggested by LG, along with additional performance modeling and analysis performed by DOE. Based on this review it appears that the suggested alternate test procedure will allow for the generally accurate measurement of efficiency of the specified basic models of single-duct variable-speed potable air conditioners, with certain additional requirements. First, the alternate test procedure provides compressor speed nomenclature and definitions that are derived from those in industry standards for testing consumer central air conditioning products with variable-speed compressors, with additional specificity for the low compressor speed definition that ensures the portable air conditioner provides adequate cooling capacity under reduced loads based on the expected load at those conditions.[5]

[3] LG provided these basic model numbers in its May 15, 2018 petition.

[4] In its suggested alternate test procedure, LG included provisions regarding dual-duct variable-speed portable air conditioners. However, the basic models specified in LG's petition for waiver and petition for interim waiver are single-duct models only. As such, the alternate test procedure specified by DOE addresses only the single-duct variable-speed portable air conditioners listed by LG.

[5] The compressor speed nomenclature and definition clarifications are derived from Air-Conditioning, Heating, and Refrigeration Institute Standard (AHRI) 210/240–2017, ''Performance Rating of Unitary Air-conditioning & Air-source Heat Pump Equipment'', and adapted to be applicable to portable ACs. Equation 11.60 in AHRI 210/240–2017 relates the building load to an AC's full-load cooling capacity and outdoor temperature,

Second, LG must maintain the compressor speed required for each test condition in accordance with the instructions LG has provided to DOE.[6] [7]

Specifically, DOE has found that the suggested alternate test procedure will produce final CEER values for the single-duct variable-speed portable air conditioners that will reflect the average performance improvement associated with variable-speed compressors as compared to theoretical comparable single-speed portable air conditioners under the same test conditions. Consequently, it appears likely that LG's petition for waiver will be granted. Furthermore, DOE has determined that it is desirable for public policy reasons to grant LG immediate relief pending a determination of the petition for waiver.

For the reasons stated, DOE has granted an interim waiver to LG for the specified portable air conditioner basic models in LG's petition. Therefore, DOE has issued an Order stating:

(1) LG must test the following portable air conditioner basic models with the alternate test procedure set forth in paragraph (2):

Brand	Basic model
LG Electronics USA, Inc	LP1419IVSM
LG Electronics USA, Inc	LP1419HVSM
LG Electronics USA, Inc	LP1219IVSM
LG Electronics USA, Inc	LP1019IVSM
LG Electronics USA, Inc	LP0819IVSM

(2) The alternate test procedure for the LG basic models referenced in paragraph (1) is the test procedure for portable air conditioners prescribed by DOE at appendix CC to subpart B of 10 CFR part 430 (Appendix CC), except: (i) Determine the combined energy efficiency ratio (CEER) as detailed below, and (ii) calculate the estimated annual operating cost in 10 CFR 430.23(dd)(2) as detailed below. In addition, for each basic model listed in paragraph (1), maintain the compressor speeds at each test condition, and set the control settings used for the variable components, according to the instructions submitted to DOE by LG. Upon the compliance date of any new energy conservation standards for portable air conditioners, LG must report product specific information pursuant to 10 CFR 429.12(b)(13) and 10 CFR 429.62(b). All other requirements of Appendix CC and DOE's regulations remain applicable. In 10 CFR 430.23, in paragraph (dd) revise paragraph (2) to read as follows:

(2) Determine the estimated annual operating cost for a single-duct variable-speed portable air conditioner, expressed in dollars per year, by multiplying the following two factors:

(i) The sum of AEC_{95} multiplied by 0.2, AEC_{83} multiplied by 0.8, and AEC_T as measured in accordance with section 5.3 of appendix CC of this subpart; and

(ii) A representative average unit cost of electrical energy in dollars per kilowatt-hour as provided by the Secretary.

(iii) Round the resulting product to the nearest dollar per year.

In Appendix CC:

Add in Section 2, *Definitions:*

2.11 *Single-speed* means a type of portable air conditioner that cannot automatically adjust the compressor speed, based on detected conditions.

2.12 *Variable-speed* means a type of portable air conditioner that can automatically adjust the compressor speed, based on detected conditions.

2.13 *Full compressor speed (full)* means the compressor speed specified by the manufacturer at which the unit operates at full load testing conditions.

2.14 *Low compressor speed (low)* means the compressor speed specified by the manufacturer at which the unit operates at low load test conditions, such that the measured cooling capacity at Condition B in Table 1 of this appendix, *i.e.,* $Capacity_{83}$, is not less than 50 percent and not greater than 60 percent of the measured cooling capacity with the full compressor speed at Condition A in Table 1 of this appendix, *i.e.,* $Capacity_{95}$.

Add to the end of Section 3.1.2, *Control settings:*

Set the compressor speed during cooling mode testing as described in section 4.1, as amended by this interim waiver.

Replace Section 4.1, *Cooling mode* with the following:

Cooling mode. Measure the indoor room cooling capacity and overall power input in cooling mode in accordance with Section 7.1.b and 7.1.c of ANSI/AHAM PAC–1–2015 (incorporated by reference; see § 430.3), respectively. Determine the test duration in accordance with Section 8.7 of ASHRAE Standard 37–2009 (incorporated by reference; § 430.3). Apply the test conditions presented in Table 1 of this appendix instead of the test conditions in Table 3 of ANSI/AHAM PAC–1–2015. Measure the indoor room cooling capacity and overall power input in accordance with ambient conditions for Test Configuration 3, Condition A ($Capacity_{95}$, P_{95}) in Table 1 of this appendix, with the compressor speed set to full, for the duration of cooling mode testing, and then measure the indoor room cooling capacity and overall power input a second time in accordance with the ambient conditions for Test Configuration 3, Condition B ($Capacity_{83}$, P_{83}) in Table 1 of this appendix, with the compressor speed set to low, for the duration of cooling mode testing. Set the compressor speed required for each test condition in accordance with instructions provided to DOE. Note that for the purposes of this cooling mode test procedure, evaporator inlet air is considered the ''indoor air'' of the conditioned space and condenser inlet air is considered the ''outdoor air'' outside of the conditioned space.

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and assumes full-load operation at 98 °F outdoor temperature. DOE adjusted (*i.e.* normalized) this equation to reflect full-load operation at 95 °F outdoor temperature, to provide consistency with the full-load test condition for portable ACs. Using the adjusted equation suggests that the representative cooling load at the 83 °F rating condition would be 60 percent of the full-load cooling capacity for portable air conditioners. DOE recognizes that variable-speed portable ACs may use compressors that vary their speed in discrete steps and may not be able to operate at a speed that provides exactly 60 percent cooling capacity; therefore, the defined cooling capacity associated with the low compressor speed is presented as a 10-percent range rather than a single value. 60 percent cooling load is the upper bound of the 10-percent range defining the cooling capacity associated with the lower compressor speed (*i.e.,* the range is defined as 50 to 60 percent). This ensures that the variable-speed portable AC is capable of matching the representative cooling load (60 percent of the maximum) at the 83 °F rating condition, while providing the performance benefits associated with variable-speed operation. In contrast, if the 10-percent range were to be defined as, for example, 55 to 65 percent (with 60 percent as the midpoint), a variable-speed portable AC could be tested at 63 percent, for example, without demonstrating the capability to maintain variable-speed performance down to 60 percent.

[6] Pursuant to 10 CFR 1004.11, if the manufacturer submits information that it believes to be confidential and exempt by law from public disclosure, the manufacturer should submit via email, postal mail, or hand delivery two well-marked copies: One copy of the document marked ''confidential'' including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

[7] The instructions provided by LG were marked as confidential and, as such, the instructions will be treated as confidential. The document is located in the docket at *https://www.regulations.gov/document?D=EERE-2018-BT-WAV-0007.*

TABLE 1—EVAPORATOR (INDOOR) AND CONDENSER (OUTDOOR) INLET TEST CONDITIONS

Test configuration	Evaporator inlet air, °F (°C)		Condenser inlet air, °F (°C)	
	Dry bulb	Wet bulb	Dry bulb	Wet bulb
3 (Condition A)	80 (26.7)	67 (19.4)	95 (35.0)	75 (23.9)
3 (Condition B)	80 (26.7)	67 (19.4)	83 (28.3)	67.5 (19.7)

Revise Section 4.1.1, *Duct Heat Transfer* following ''Calculate the total heat transferred from the surface of the condenser exhaust duct to the indoor conditioned space while operating in cooling mode for the outdoor test conditions in Table 1 of this appendix, as follows.'' to read as follows:

$Q_{duct\_95} = h \times A_{duct} \times (T_{duct\_95} - T_{ei})$

$Q_{duct\_83} = h \times A_{duct} \times (T_{duct\_83} - T_{ei})$

Where:

Q_{duct_95} and Q_{duct_83} = the total heat transferred from the condenser exhaust duct to the indoor conditioned space in cooling mode, in Btu/h, when tested according to the 95 °F dry-bulb and 83 °F dry-bulb outdoor test conditions in Table 1 of this appendix, respectively.

h = convection coefficient, 3 Btu/h per square foot per °F.

A_{duct} = surface area of the condenser exhaust duct, in square feet.

T_{duct_95} and T_{duct_83} = average surface temperature for the condenser exhaust duct, as measured during testing according to the two outdoor test conditions in Table 1 of this appendix, in °F.

T_{ei} = average evaporator inlet air dry-bulb temperature, in °F.

Replace Section 4.1.2, *Infiltration Air Heat Transfer* with the following:

Infiltration Air Heat Transfer. Calculate the heat contribution from infiltration air for both cooling mode outdoor test conditions, as described in this section. Calculate the dry air mass flow rate of infiltration air according to the following equations:

$$\dot{m}_{95} = \left[\frac{V_{co\_95} \times \rho_{co\_95}}{(1 + \omega_{co\_95})}\right] - \left[\frac{V_{ci\_95} \times \rho_{ci\_95}}{(1 + \omega_{ci\_95})}\right]$$

$$\dot{m}_{83} = \left[\frac{V_{co\_83} \times \rho_{co\_83}}{(1 + \omega_{co\_83})}\right] - \left[\frac{V_{ci\_83} \times \rho_{ci\_83}}{(1 + \omega_{ci\_83})}\right]$$

Where:

$\dot{m}_{95}$ and $\dot{m}_{83}$ = dry air mass flow rate of infiltration air, as calculated based on testing according to the test conditions in Table 1 of this appendix, in lb/m.

V_{co_95} and V_{co_83} = average volumetric flow rate of the condenser outlet air during cooling mode testing at the 95 °F and 83 °F dry-bulb outdoor conditions, respectively, in cubic feet per minute (cfm), as determined in section 4.1 of this appendix.

V_{ci_95}, and V_{ci_83} = average volumetric flow rate of the condenser inlet air during cooling mode testing at the 95 °F and 83 °F dry-bulb outdoor conditions, respectively, in cfm, as determined in section 4.1 of this appendix.

ρ_{co_95} and ρ_{co_83} = average density of the condenser outlet air during cooling mode testing at the 95 °F and 83 °F dry-bulb outdoor conditions, respectively, in pounds mass per cubic foot (lb_m/ft^3), as determined in section 4.1 of this appendix.

ρ_{ci_95}, and ρ_{ci_83} = average density of the condenser inlet air during cooling mode testing at the 95 °F and 83 °F dry-bulb outdoor conditions, respectively, in lb_m/ft^3, as determined in section 4.1 of this appendix.

ω_{co_95} and ω_{co_83} = average humidity ratio of condenser outlet air during cooling mode testing at the 95 °F and 83 °F dry-bulb outdoor conditions, respectively, in pounds mass of water vapor per pounds mass of dry air (lb_w/lb_{da}), as determined in section 4.1 of this appendix.

ω_{ci_95} and ω_{ci_83} = average humidity ratio of condenser inlet air during cooling mode testing at the 95 °F and 83 °F dry-bulb outdoor conditions, respectively, in lb_w/lb_{da}, as determined in section 4.1 of this appendix.

Replace Section 5.1, *Adjusted Cooling Capacity* with the following:

Adjusted Cooling Capacity. Calculate the adjusted cooling capacities for portable air conditioners, ACC_{95} and ACC_{83}, expressed in Btu/h, according to the following equations.

$ACC_{83} = Capacity_{95} - Q_{duct\_95} - Q_{infiltration\_95}$

$ACC_{83} = Capacity_{83} - Q_{duct\_83} - Q_{infiltration\_83}$

Where:

$Capacity_{95}$ and $Capacity_{83}$ = cooling capacity measured in section 4.1 of this appendix.

Q_{duct_95} and Q_{duct_83} = duct heat transfer while operating in cooling mode, calculated in section 4.1.1 of this appendix.

$Q_{infiltration\_95}$ and $Q_{infiltration\_83}$ = total infiltration air heat transfer in cooling mode, calculated in section 4.1.2 of this appendix

Replace Section 5.3, *Annual Energy Consumption* with the following:

Annual Energy Consumption. Calculate the annual energy consumption in each operating mode, AEC_m, expressed in kilowatt-hours per year (kWh/year). Use the following annual hours of operation for each mode:

Operating mode	Annual operating hours
Cooling Mode, Dual-Duct 95 °F [1]	750
Cooling Mode, Dual-Duct 83 °F [1]	750
Off-Cycle	880
Inactive or Off	1,355

[1] These operating mode hours are for the purposes of calculating annual energy consumption under different ambient conditions and are not a division of the total cooling mode operating hours. The total cooling mode operating hours are 750 hours.

$AEC_m = P_m \times t_m \times 0.001$

Where:

AEC_m = annual energy consumption in each mode, in kWh/year.

P_m = average power in each mode, in watts.

m represents the operating mode (''95'' and ''83'' cooling mode at the 95 °F and 83 °F dry-bulb outdoor conditions, respectively, ''oc'' off-cycle, and ''ia'' inactive or ''om'' off mode).

t_m = number of annual operating time in each mode, in hours.

0.001 kWh/Wh = conversion factor from watt-hours to kilowatt-hours.

Total annual energy consumption in all modes except cooling, is calculated according to:

$$AEC_T = \sum_m AEC_m$$

Where:

AEC_T = total annual energy consumption attributed to all modes except cooling, in kWh/year;

AEC_m = total annual energy consumption in each mode, in kWh/year.

m represents the operating modes included in AEC_T (''oc'' off-cycle, and ''im'' inactive or ''om'' off mode).

Replace Section 5.4, *Combined Energy Efficiency Ratio* with the following:

Combined Energy Efficiency Ratio. Using the annual operating hours, as outlined in section 5.3 of this appendix, calculate the combined energy efficiency ratio, $CEER_{VS,}$ expressed in Btu/Wh, according to the following:

$$CEER_{VS} = \left[\frac{ACC_{95}}{\left(\frac{AEC_{95} + AEC_T}{750 \times 0.001}\right)}\right] \times 0.2 + \left[\frac{ACC_{83}}{\left(\frac{AEC_{83} + AEC_T}{750 \times 0.001}\right)}\right] \times 0.8$$

Where:

$CEER_{VS}$ = combined energy efficiency ratio for the variable-speed portable air conditioner, in Btu/Wh.

ACC_{95} and ACC_{83} = adjusted cooling capacity, tested at the 95 °F and 83 °F dry-bulb outdoor conditions in Table 1 of this appendix, in Btu/h, calculated in section 5.1 of this appendix.

AEC_{95} and AEC_{83} = annual energy consumption for the two cooling mode test conditions in Table 1 of this appendix, in kWh/year, calculated in section 5.3 of this appendix.

AEC_T = total annual energy consumption attributed to all modes except cooling, in kWh/year, calculated in section 5.3 of this appendix.

750 = number of cooling mode hours per year

0.001 kWh/Wh = conversion factor for watt-hours to kilowatt-hours.

0.2 = weighting factor for the Condition A test.

0.8 = weighting factor for the Condition B test.

Add after Section 5.4, *Combined Energy Efficiency Ratio:*

5.5 *Adjustment of the Combined Energy Efficiency Ratio.* Adjust the combined energy efficiency ratio as follows.

5.5.1 *Theoretical Comparable Single-Speed Portable Air Conditioner Cooling Capacity and Power at the Lower Outdoor Test Condition.* Calculate the cooling capacity and cooling capacity with cycling losses, expressed in British thermal units per hour (Btu/h), and electrical power input, expressed in watts, for a theoretical comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor conditions (Condition B in Table 1 of this appendix). A theoretical comparable single-speed portable air conditioner has the same cooling capacity and electrical power input, with no cycling losses, as the single-duct variable-speed portable air conditioner under test at Condition A in Table 1 of this appendix.

$Capacity_{83\_SS} = Capacity_{95}$

$Capacity_{83\_SS\_CLF} = Capacity_{95} \times CLF$

$P_{83\_SS} = P_{95}$

Where:

$Capacity_{83\_SS}$ = theoretical comparable single-speed portable air conditioner cooling capacity, in Btu/h, calculated for Condition B in Table 1 of this appendix.

$Capacity_{83\_SS\_CLF}$ = theoretical comparable single-speed portable air conditioner cooling capacity with cycling losses, in Btu/h, calculated for Condition B in Table 1 of this appendix.

$Capacity_{95}$ = cooling capacity, in Btu/h, determined in section 4.1 of this appendix for Condition A in Table 1 of this appendix.

P_{83_SS} = theoretical comparable single-speed portable air conditioner electrical power input, in watts, calculated for Condition B in Table 1 of this appendix.

P_{95} = electrical power input, in watts, determined in section 4.1 of this appendix for Condition A in Table 1 of this appendix.

CLF = cycling loss factor for Condition B in Table 1 of this appendix, 0.875.

5.5.2 *Duct Heat Transfer for a Theoretical Comparable Single-Speed Portable Air Conditioner at the Lower Outdoor Test Condition.* Calculate the condenser exhaust duct heat transfer to the conditioned space for a theoretical comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor conditions (Condition B in Table 1 of this appendix), as follows:

$$Q_{duct\_83\_SS} = h \times A_{duct} \times (T_{duct\_95} - T_{ei})$$

Where:

$Q_{duct\_83\_SS}$ = total heat transferred from the ducts to the indoor conditioned space in cooling mode, in Btu/h, for a theoretical comparable single-speed portable air conditioner at Condition B in Table 1 of this appendix.

h = convection coefficient, 3 Btu/h per square foot per °F.

A_{duct} = surface area of the condenser exhaust duct, in square feet, as calculated in section 4.1.1 of this appendix.

T_{duct_95} = average surface temperature for the condenser exhaust duct, as measured during testing at Condition A in Table 1 of this appendix, in °F.

T_{ei} = average evaporator inlet air dry-bulb temperature, in °F.

5.5.3 *Infiltration Air Heat Transfer for a Theoretical Comparable Single-Speed Portable Air Conditioner at the Lower Outdoor Test Condition.* Calculate the heat contribution from infiltration air for a theoretical comparable single-speed portable air conditioner at Condition B in Table 1 of this appendix, as described in this section. Calculate the dry air mass flow rate of infiltration air according to the following equations:

$$\dot{m}_{83\_SS} = \frac{V_{co\_95} \times \rho_{co\_95}}{(1 + \omega_{co\_95})}$$

Where:

$\dot{m}_{83\_SS}$ = dry air mass flow rate of infiltration air for a theoretical comparable single-speed portable air conditioner at Condition B in Table 1 of this appendix, in lb/m.

V_{co_95} = actual average volumetric flow rate of the condenser outlet air during cooling mode testing at Condition A in Table 1 of this appendix, in cubic feet per minute (cfm), as determined in section 4.1 of this appendix.

ρ_{co_95} = actual average density of the condenser outlet air during cooling mode

testing at Condition A in Table 1 of this appendix, in lb_m/ft^3, as determined in section 4.1 of this appendix.

ω_{co_95}= average humidity ratio of condenser outlet air during cooling mode testing at Condition A in Table 1 of this appendix, in pounds mass of water vapor per pounds mass of dry air (lb_w/lb_{da}), as determined in section 4.1 of this appendix.

Calculate the sensible component of infiltration air heat contribution for a theoretical comparable single-speed portable air conditioner at Condition B in Table 1 of this appendix as follows:

$$Q_{s\_83\_SS} = \dot{m}_{83\_SS} \times 60 \times [(0.24 \times (T_{ia\_83} - T_{indoor})) + (0.444 \times (\omega_{ia\_83} \times T_{ia\_83} - \omega_{indoor} \times T_{indoor}))]$$

Where:

$Q_{s\_83\_SS}$ = sensible heat added to the room by infiltration air for a theoretical comparable single-speed portable air conditioner, at Condition B in Table 1 of this appendix, in Btu/h.

0.24 $Btu/lb_m - °F$ = specific heat of dry air.

0.444 $Btu/lb_m - °F$ = specific heat of water vapor.

T_{indoor} = indoor chamber dry-bulb temperature, 80 °F.

T_{ia_95} and T_{ia_83} = infiltration air dry-bulb temperatures for Condition A and Condition B in Table 1 of this appendix, 95 °F and 83 °F, respectively.

ω_{ia_95} and ω_{ia_83} = humidity ratios of the infiltration air at Condition A and Condition B in Table 1 of this appendix, 0.0141 and 0.01086 lb_w/lb_{da}, respectively.

ω_{indoor} = humidity ratio of the indoor chamber air, 0.0112 lb_w/lb_{da}.

60 = conversion factor from minutes to hours.

$\dot{m}_{83\_SS}$ as previously defined in this section.

Calculate the latent component of infiltration air heat contribution for a theoretical comparable single-speed portable air conditioner at Condition B in Table 1 of this appendix as follows:

$$Q_{l\_83\_SS} = \dot{m}_{83\_SS} \times 60 \times 1061 \times (\omega_{ia\_83} - 0.0112)$$

Where:

$Q_{l\_83\_SS}$ = latent heat added to the room by infiltration air for a theoretical comparable single-speed portable air conditioner, at Condition B in Table 1 of this appendix, in Btu/h.

1061 Btu/lb_m = latent heat of vaporization for water vapor.

0.0112 lb_w/lb_{da} = humidity ratio of the indoor chamber air.

60 = conversion factor from minutes to hours.

$\dot{m}_{83\_SS}$, ω_{ia_95}, and ω_{ia_83} as previously defined in this section.

The total heat contribution of the infiltration air for a theoretical comparable single-speed portable air conditioner at Condition B in Table 1 of this appendix is the sum of the sensible and latent heat calculated above in this section:

$$Q_{infiltration\_83\_SS} = Q_{s\_83\_SS} + Q_{l\_83\_SS}$$

Where:

$Q_{infiltration\_83\_SS}$ = total infiltration air heat in cooling mode for a theoretical comparable single-speed portable air conditioner at Condition B in Table 1 of this appendix, in Btu/h.

$Q_{s\_83\_SS}$, $Q_{l\_83\_SS}$ as previously defined.

5.5.4 *Adjusted Cooling Capacity for a Theoretical Comparable Single-Speed Portable Air Conditioner at the Lower Outdoor Test Condition.* Calculate the adjusted cooling capacity for a theoretical comparable single-speed portable air conditioner at Condition B in Table 1 of this appendix with and without cycling losses, ACC_{83_SS} and $ACC_{83\_SS\_CLF}$, respectively, expressed in Btu/h, according to the following equations:

$$ACC_{83\_SS} = Capacity_{83\_SS} - Q_{duct\_83\_SS} - Q_{infiltration\_83\_SS}$$

$$ACC_{83\_SS\_CLF} = Capacity_{83\_SS\_CLF} - Q_{duct\_83\_SS} - Q_{infiltration\_83\_SS}$$

Where:

ACC_{83_SS} and $ACC_{83\_SS\_CLF}$ = adjusted cooling capacity for a theoretical comparable single-speed portable air conditioner at Condition B in Table 1 of this appendix without and with cycling losses, respectively, in Btu/h.

$Capacity_{83\_SS}$ and $Capacity_{83\_SS\_CLF}$ = theoretical comparable single-speed portable air conditioner cooling capacity without and with cycling losses, respectively, in Btu/h, at Condition B in Table 1 of this appendix, calculated in section 5.5.1 of this appendix.

$Q_{duct\_83\_SS}$ = total heat transferred from the ducts to the indoor conditioned space in cooling mode for a theoretical comparable single-speed portable air conditioner at Condition B in Table 1 of this appendix, in Btu/h, calculated in section 5.5.2 of this appendix.

$Q_{infiltration\_83\_SS}$ = total infiltration air heat in cooling mode for a theoretical comparable single-speed portable air conditioner at Condition B in Table 1 of this appendix, in Btu/h, calculated in section 5.5.3 of this appendix.

5.5.5 *Annual Energy Consumption in Cooling Mode for a Theoretical Comparable Single-Speed Portable Air Conditioner at the Lower Outdoor Test Condition.* Calculate the annual energy consumption in cooling mode for a theoretical comparable single-speed portable air conditioner at Condition B in Table 1 of this appendix, expressed in kWh/year, according to the following equations:

$$AEC_{83\_SS} = P_{83\_SS} \times 750 \times 0.001$$

Where:

AEC_{83_SS} = annual energy consumption for a theoretical comparable single-speed portable air conditioner in cooling mode at Condition B in Table 1 of this appendix, in kWh/year.

P_{83_SS} = theoretical comparable single-speed portable air conditioner electrical power input at Condition B in Table 1 of this appendix, in watts, calculated in section 5.5.1 of this appendix.

750 = number of cooling mode hours per year.

0.001 kWh/Wh = conversion factor from watt-hours to kilowatt-hours.

5.5.6 *Combined Energy Efficiency Ratio for a Theoretical Comparable Single-Speed Portable Air Conditioner.* Calculate the combined energy efficiency ratio for a theoretical comparable single-speed portable air conditioner without and with cycling losses considered, $CEER_{SS}$ and $CEER_{SS\_CLF}$, respectively, expressed in Btu/Wh, according to the following equations:

$$CEER_{SS} = \left[\frac{ACC_{95}}{\left(\frac{AEC_{95} + AEC_T}{750 \times 0.001}\right)}\right] \times 0.2 + \left[\frac{ACC_{83\_SS}}{\left(\frac{AEC_{83\_SS} + AEC_T}{750 \times 0.001}\right)}\right] \times 0.8$$

$$CEER_{SS\_CLF} = \left[\frac{ACC_{95}}{\left(\frac{AEC_{95} + AEC_T}{750 \times 0.001}\right)}\right] \times 0.2 + \left[\frac{ACC_{83\_SS\_CLF}}{\left(\frac{AEC_{83\_SS} + AEC_T}{750 \times 0.001}\right)}\right] \times 0.8$$

Where:

$CEER_{SS}$ and $CEER_{SS\_CLF}$ = combined energy efficiency ratio for a theoretical

comparable single-speed portable air conditioner without and with cycling losses considered, respectively, in Btu/Wh.

ACC_{95} = adjusted cooling capacity, tested for the single-duct variable-speed portable air conditioner at Condition A in Table 1 of this appendix, in Btu/h, calculated in section 5.1 of this appendix.

ACC_{83_SS} and $ACC_{83\_SS\_CLF}$ = adjusted cooling capacity for a theoretical comparable single-speed portable air conditioner at Condition B in Table 1 of this appendix without and with cycling losses, respectively, in Btu/h, calculated in section 5.5.4 of this appendix.

AEC_{95} = annual energy consumption for the sample unit at Condition A in Table 1 of this appendix, in kWh/year, calculated in section 5.3 of this appendix.

AEC_{83_SS} = annual energy consumption for a theoretical comparable single-speed portable air conditioner in cooling mode at Condition B in Table 1 of this appendix, in kWh/year, calculated in section 5.5.5 of this appendix.

AEC_T = total annual energy consumption attributed to all modes except cooling for the sample unit, in kWh/year, calculated in section 5.3 of this appendix.

750 and 0.001 as defined previously in this section.

0.2 = weighting factor for the Condition A test.

0.8 = weighting factor for the Condition B test.

5.5.7 *Single-Duct Variable-Speed Portable Air Conditioner Performance Adjustment Factor.* Calculate the single-duct variable-speed portable air conditioner performance adjustment factor, F_p, according to the following equation:

$$F_p = \frac{(CEER_{SS} - CEER_{SS\_CLF})}{CEER_{SS\_CLF}}$$

Where:

$CEER_{SS}$ and $CEER_{SS\_CLF}$ = combined energy efficiency ratio for a theoretical comparable single-speed portable air conditioner without and with cycling losses considered, respectively, in Btu/Wh, calculated in section 5.5.6 of this appendix.

5.5.8 *Single-Duct Variable-Speed Portable Air Conditioner Combined Energy Efficiency Ratio.* Calculate the final combined energy efficiency ratio, CEER, expressed in Btu/Wh, according to the following equation:

$$CEER = CEER_{VS} \times (1 + F_p)$$

Where:

CEER = combined energy efficiency ratio for the sample unit, in Btu/Wh.

$CEER_{VS}$ = combined energy efficiency ratio initially determined for the sample unit, in Btu/Wh, calculated in section 5.4 of this appendix.

F_p = single-duct variable-speed portable air conditioner performance adjustment factor, determined in section 5.5.7 of this appendix.''

(3) *Representations.* LG may not make representations about the energy efficiency of the basic models listed in paragraph (1) for compliance, marketing, or other purposes unless the basic model has been tested in accordance with the provisions in this alternate test procedure and such representations fairly disclose the results of such testing.

(4) This interim waiver shall remain in effect according to the provisions of 10 CFR 430.27.

(5) This interim waiver is issued to LG on the condition that the statements, representations, and information provided by LG are valid. DOE may revoke or modify this waiver at any time if it determines the factual basis underlying the petition for waiver is incorrect, or the results from the alternate test procedure are unrepresentative of a basic model's true energy consumption characteristics. 10 CFR 430.27(k)(1). Likewise, LG may request that DOE rescind or modify the interim waiver if LG discovers an error in the information provided to DOE as part of its petition, determines that the interim waiver is no longer needed, or for other appropriate reasons. 10 CFR 430.27(k)(2).

(6) LG remains obligated to fulfill any certification requirements set forth at 10 CFR part 429.

DOE makes decisions on waivers and interim waivers for only those basic models specifically set out in the petition, not future models that may be manufactured by the petitioner. LG may submit a new or amended petition for waiver and request for grant of interim waiver, as appropriate, for additional basic models of portable air conditioners. Alternatively, if appropriate, LG may request that DOE extend the scope of a waiver or an interim waiver to include additional basic models employing the same technology as the basic models set forth in the original petition consistent with 10 CFR 430.27(g).

V. Request for Comments

DOE is publishing LG's petition for waiver in its entirety, pursuant to 10 CFR 430.27(b)(1)(iv).[8] The petition includes a suggested alternate test procedure, as specified in the petition and summarized in section IV of this document, to determine the efficiency of LG's specified portable air conditioners. DOE may consider including the alternate procedure specified in the Interim Waiver Order, and restated in section IV of this document, in a subsequent Decision and Order.

[8] The petition did not identify any of the information contained therein as confidential business information.

DOE invites all interested parties to submit in writing by September 9, 2019, comments and information on all aspects of the petition, including the alternate test procedure. Pursuant to 10 CFR 430.27(d), any person submitting written comments to DOE must also send a copy of such comments to the petitioner. The contact information for the petitioner is Scott Blake Harris, Harris, Wiltshire & Grannis LLP, 1919 M Street NW, Eighth Floor, Washington, DC 20036.

Submitting comments via *http://www.regulations.gov.* The *http://www.regulations.gov* web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *http://www.regulations.gov* information for which disclosure is restricted by statute,

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DOE processes submissions made through *http://www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *http://www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery, or mail. Comments and documents submitted via email, hand delivery, or mail also will be posted to *http://www.regulations.gov.* If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information on a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via mail or hand delivery, please provide all items on a CD, if feasible. It is not necessary to submit printed copies. No facsimiles (faxes) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are written in English, free of any defects or viruses, and are not secured. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. According to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail, or hand delivery two well-marked copies: One copy of the document marked confidential including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. Submit these documents via email or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include (1) a description of the items, (2) whether and why such items are customarily treated as confidential within the industry, (3) whether the information is generally known by or available from other sources, (4) whether the information has previously been made available to others without obligation concerning its confidentiality, (5) an explanation of the competitive injury to the submitting person which would result from public disclosure, (6) when such information might lose its confidential character due to the passage of time, and (7) why disclosure of the information would be contrary to the public interest.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

Signed in Washington, DC, on July 30, 2019.

Alexander N. Fitzsimmons,

Acting Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

Before the

United States Department of Energy

Washington, DC 20585

In the Matter of: Energy Efficiency Program: Test Procedure for Portable Air Conditioners

Petition of LG Electronics, Inc. for Waiver and Application for Interim Waiver of Test Procedure for Portable Air Conditioners

LG Electronics, Inc. (LG) respectfully submits this Petition for Waiver and Application for Interim Waiver [1] from DOE's test procedure for portable air conditioners (PACs). LG seeks a waiver because the current test procedure for PACs does not accurately measure the energy consumption of single-duct PACs with variable speed compressors (VSCs). LG requests expedited treatment of the Petition and Application.

LG is a manufacturer of PACs and other products sold worldwide, including in the United States. LG's United States affiliate is LG Electronics USA, Inc., with headquarters at 1000 Sylvan Avenue, Englewood Cliffs, NJ 07632 (tel. 201–816–2000).

I. Basic Models for Which a Waiver Is Requested

The basic models for which a waiver is requested are set forth in the Appendix. They are single-duct PACs distributed in commerce under the LG brand name.

II. Need for the Requested Waiver

The LG PACs with VSC technology are advanced, energy efficient products. A VSC (inverter compressor) uses frequency controls constantly to adjust the compressor's rotation speed to maintain the desired temperature in the home without turning the motor on and off. The compressor responds automatically to surrounding conditions to operate in the most efficient possible manner. This results in both dramatic energy savings and faster cooling compared to products without VSCs. PACs with VSCs also have a higher/lower operating range (10 Hz to 120 Hz) than those without VSC.[2]

Unfortunately, while the current DOE test procedure for dual-duct PACs provides that they be tested in two conditions, the test procedure provides for testing only with full-load performance for single-duct PACs.[3] Thus, the PAC test procedure as applied to single-duct PACs does not take into account the benefits of VSC, with its part-load performance characteristics. This is also unlike the DOE test procedure for central air conditioners, which provides for testing with part-load performance for VSCs. Additionally, the PAC test procedure as applied to single-duct PACs does not properly account for the favorable difference in cycling losses resulting

[1] *See* 10 CFR 430.27 (petitions for waiver and interim waiver).

[2] To the best of LG's knowledge, LG is the only manufacturer of PAC basic models distributed in commerce in the United States to incorporate design characteristic(s) similar to those found in the basic models that are the subject of this petition, namely, PAC VSC technology.

[3] 10 CFR Pt. 430, Subpart B, App. CC, § 4.1, Tbl.1.

from use of VSC technology. This technology limits the inefficiencies associated performance degradation from cycling losses. Cycling losses are avoided when the unit modulates its speed to meet a partial load rather than cycles on and off.

DOE has recognized this serious shortcoming in the context of its test procedure for room air conditioners (RACs).[4] It has stated that the RAC test procedure ''does not measure the benefits of technologies that improve part-load performance.'' [5]

> The current room AC test procedure measures only the full-load performance at outdoor ambient conditions of 95 °F dry-bulb and 75 °F wet-bulb. Therefore, technologies that improve part-load performance, such as multiple-speed compressors and variable-opening expansion devices, will not improve the rated performance of a room AC under the current test procedure.[6]

Indeed, DOE has correctly stressed that, ''[i]n contrast, central ACs and heat pumps are rated'' using ''multiple rating points at different conditions.'' [7] DOE has said it intends to investigate potential revision of the test procedure ''to account for any benefits of technologies that improve part-load performance.'' [8] DOE is currently considering a waiver request by LG for RACs with VSCs.

These considerations apply to single-duct PACs as well as dual-duct PACs and RACs. At the moment, however, the DOE test procedure for PACs as applied to single-duct PACs does not include any provision to account for the benefits of the part-load performance of VSCs or properly account for the favorable difference in cycling losses resulting from use of VSC technology. Therefore, the test procedure evaluates the LG models with VSCs in a manner that misrepresents their actual energy consumption. LG urges that a waiver be granted, for the basic models in the Appendix, that will allow use of the alternate test procedure discussed below. The alternate test procedure is designed to take into account the energy savings characteristics of VSCs, properly account for the favorable difference in cycling losses, and yield results more representative of the actual energy consumption of these products than the current DOE test procedure. And the rules provide that DOE ''will grant a waiver from the test procedure requirements'' in these circumstances.[9] The waiver should continue until DOE adopts an applicable amended test procedure.

III. Proposed Alternate Test Procedure

LG proposes the following alternate test procedure to evaluate the performance of the basic models listed in the Appendix. The alternate test procedure is the same as the existing test procedure for PACs except that it takes into account VSC part-load characteristics for single-duct PACs. It does so by providing for tests at multiple load conditions. Specifically:

LG shall be required to test the performance of the basic models listed in the Appendix hereto according to the test procedure for portable air conditioners in 10 CFR part 430, subpart B, Appendix CC, except as follows:

Add new Section 2.10 to Appendix CC as follows:

''2.10 *Single-speed* means a type of portable air conditioner that does not automatically adjust either the compressor or fan speed, or both, based on the detected outdoor conditions.''

Add new Section 2.12 to Appendix CC as follows:

''2.12 *Variable-speed* means a type of portable air conditioner that can automatically adjust compressor and fan speed, only compressor speed, or only fan speed, based on the detected outdoor conditions.''

Add the following at the end of Section 3.1.2 of Appendix CC:

''For a variable-speed portable air conditioner, the compressor speed shall be set during cooling mode testing as described in section 4.1 of this appendix.''

Add the following at the end of Section 4.1 of Appendix CC:

''For a single-duct or dual-duct variable-speed portable air conditioner, measure the indoor room cooling capacity and overall power input in accordance with ambient conditions for Test Configuration 3, Condition A ($Capacity_{95}$, P_{95}) with the compressor speed set to maximum, and then measure the indoor room cooling capacity and overall power input a second time in accordance with the ambient conditions for Test Configuration 3, Condition B ($Capacity_{83}$, P_{83}) with the compressor speed set to minimum, for the duration of cooling mode testing.''

Add in Section 4.1.1, Duct Heat Transfer following ''Calculate the total heat transferred from the surface of the duct(s) to the indoor conditioned space while operating in cooling mode for the outdoor test conditions in Table 1 of this appendix, as follows.'':

''Variable-speed portable air conditioners shall use the dual-duct portable air conditioner calculations.''

Add in Section 4.1.2, Infiltration Air Heat Transfer after ''Calculate the heat contribution from infiltration air for single-duct and dual-duct portable air conditioners for both cooling mode outdoor test conditions, as described in this section.:

''Variable-speed portable air conditioners shall use the dual-duct portable air conditioner calculations, except that the condenser inlet terms shall not be included for single-duct variable-speed portable air conditioners.''

Add in Section 4.1.2, Infiltration Air Heat Transfer after ''Calculate the dry air mass flow rate of infiltration air according to the following equations.'':

''For single-duct portable air conditioners:''

Add in Section 5.1, Adjusted Cooling Capacity after ''Calculate the adjusted cooling capacities for portable air conditioners, ACC_{95} and ACC_{83}, expressed in Btu/h, according to the following equations.'':

''Variable-speed portable air conditioners shall use the dual-duct portable air conditioner calculations.''

Add in Section 5.3, Annual Energy Consumption after ''Calculate the annual energy consumption in each operating mode, AEC_m, expressed in kilowatt-hours per year (kWh/year).'':

''Variable-speed portable air conditioners shall use the dual-duct portable air conditioner annual operating hours and calculations.''

Add in Section 5.4, Combined Energy Efficiency Ratio after ''expressed in Btu/Wh,'':

''which shall be the combined energy efficiency ratio reported in § 429.62(b)(2) for single-speed portable air conditioners,''

Add the following after ''according to the following:'' in Section 5.4 of Appendix CC:

''Variable-speed portable air conditioners shall use the dual-duct portable air conditioner calculation.''

Add the following after Section 5.4 of Appendix CC:

''5.5 *Adjustment of the Combined Energy Efficiency Ratio for Variable-Speed Portable Air Conditioners.* Adjust the combined energy efficiency ratio for variable-speed portable air conditioners as follows, which shall be the combined energy efficiency ratio reported in § 429.62(b)(2) for variable-speed portable air conditioners.

5.5.1 *Comparable Single-Speed Portable Air Conditioner Cooling Capacity and Power at the Lower Outdoor Test Condition.* Calculate the

[4] *Id.* App. F.

[5] 80 FR 34843, 34848 (June 18, 2015).

[6] *Id.*

[7] *Id.*

[8] *Id.*

[9] 10 CFR 430.27(f)(2).

cooling capacity and cooling capacity with cycling losses, expressed in British thermal units per hour (Btu/h), and electrical power input, expressed in watts, for a comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor conditions (Condition B in Table 1 of this appendix).

For a single-duct variable-speed portable air conditioner:

$Capacity_{83\_SS} = Capacity_{95}$

$Capacity_{83\_SS\_CLF} = Capacity_{95} \times CLF$

$P_{83\_SS} = P_{95}$

For a dual-duct variable-speed portable air conditioner:

$Capacity_{83\_SS} = Capacity_{95} \times (1 + (M_c \times (T_{95} - T_{83})))$

$Capacity_{83\_SS\_CLF} = [Capacity_{95} \times (1 + (M_c \times (T_{95} - T_{83})))] \times CLF$

$P_{83\_SS} = P_{95} \times (1 - (M_p \times (T_{95} - T_{83})))$

Where:

$Capacity_{83\_SS}$ = comparable single-speed portable air conditioner cooling capacity, in Btu/h, calculated for Condition B in Table 1.

$Capacity_{83\_SS\_CLF}$ = comparable single-speed portable air conditioner cooling capacity with cycling losses, in Btu/h, calculated for Condition B in Table 1.

$Capacity_{95}$ = variable-speed portable air conditioner cooling capacity, in Btu/h, determined in section 4.1 of this appendix for Condition A in Table 1.

P_{83_SS} = comparable single-speed portable air conditioner electrical power input, in watts, calculated for Condition B in Table 1.

P_{95} = variable-speed portable air conditioner electrical power input, in watts, determined in section 4.1 of this appendix for Condition A in Table 1.

M_c = adjustment factor to determine the increased cooling capacity at lower outdoor test conditions, 0.0099.

M_p = adjustment factor to determine the reduced electrical power input at lower outdoor test conditions, 0.0076.

T_{95} = outdoor dry-bulb temperature for Condition A in Table 1, 95 °F.

T_{83} = outdoor dry-bulb temperature for Condition B in Table 1, 83 °F.

CLF = cycling loss factor for Condition B, 0.875.

5.5.2 *Duct Heat Transfer for a Comparable Single-Speed Portable Air Conditioner at the Lower Outdoor Test Condition.* Calculate the condenser exhaust duct and condenser inlet duct heat transfer to the conditioned space for a comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor conditions (Condition B in Table 1 of this appendix).

For a single-duct variable-speed portable air conditioner:

$Q_{duct\_83\_SS} = h \times A_{duct\_exhaust} \times (T_{duct\_95\_exhaust} - T_{ei})$

For a dual-duct variable-speed portable air conditioner:

$Q_{duct\_95\_inlet} = h \times A_{duct\_inlet} \times (T_{duct\_95\_inlet} - T_{ei})$

$Q_{duct\_95\_exhaust} = h \times A_{duct\_exhaust} \times (T_{duct\_95\_exhaust} - T_{ei})$

$Q_{duct\_83\_SS} = M_D \times Q_{duct\_95\_inlet} + Q_{duct\_95\_exhaust}$

Where:

$Q_{duct\_95\_inlet}$ and $Q_{duct\_95\_exhaust}$ = the heat transferred from the variable-speed portable air conditioner condenser inlet duct and condenser exhaust duct to the indoor conditioned space in cooling mode, in Btu/h, at the 95 °F dry-bulb outdoor test conditions in Table 1 of this appendix, respectively.

$Q_{duct\_83\_SS}$ = total heat transferred from the ducts to the indoor conditioned space in cooling mode, in Btu/h, for a comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor test conditions in Table 1 of this appendix.

h = convection coefficient, 3 Btu/h per square foot per °F.

A_{duct_inlet} and $A_{duct\_exhaust}$ = surface area of the variable-speed portable air conditioner condenser inlet and condenser exhaust ducts, respectively, in square feet, as calculated in section 4.1.1 of this appendix.

$T_{duct\_95\_inlet}$ and $T_{duct\_95\_exhaust}$ = average surface temperature for the variable-speed portable air conditioner condenser inlet and exhaust ducts, respectively, as measured during testing according to the 95 °F outdoor test condition (Condition A in Table 1 of this appendix), in °F.

T_{ei} = variable-speed portable air conditioner average evaporator inlet air dry-bulb temperature, in °F.

M_D = adjustment factor to determine the comparable single-speed portable air conditioner inlet condenser duct heat transfer at the lower outdoor test condition, 0.241.

5.5.3 *Infiltration Air Heat Transfer for a Comparable Single-Speed Portable Air Conditioner at the Lower Outdoor Test Condition.* Calculate the heat contribution from infiltration air for a comparable single-speed portable air conditioner at Condition B in Table 1 of this appendix, as described in this section. Calculate the dry air mass flow rate of infiltration air according to the following equations:

For a single-duct variable-speed portable air conditioner:

$$\dot{m}_{83\_SS} = \frac{V_{co\_95} \times \rho_{co\_95}}{(1 + \omega_{co\_95})}$$

For a dual-duct variable-speed portable air conditioner:

$$\dot{m}_{83\_SS} = \left[\frac{V_{co\_95} \times \rho_{co\_95}}{(1 + \omega_{co\_95})}\right] - \left[\frac{V_{ci\_95} \times \rho_{ci\_83}}{(1 + \omega_{ci\_83})}\right]$$

Where:

$\dot{m}_{83\_SS}$ = dry air mass flow rate of infiltration air for a comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor conditions (Condition B in Table 1 of this appendix), in lb/m.

V_{co_95} = average volumetric flow rate of the condenser outlet air during cooling mode testing for the variable-speed portable conditioner at the 95 °F dry-bulb outdoor conditions, in cubic feet per minute (cfm).

ρ_{ci_95} and ρ_{ci_83} = average density of the condenser inlet air during cooling mode testing for the variable-speed portable air conditioner at the 95 °F and 83 °F dry-bulb outdoor conditions, respectively, in lb_m/ft^3.

ω_{co_95}, and ω_{co_83} = average humidity ratio of condenser outlet air during cooling mode testing for the variable-speed portable air conditioner at the 95 °F and 83 °F dry-bulb outdoor conditions, respectively, in pounds mass of water vapor per pounds mass of dry air (lb_w/lb_{da}).

Calculate the sensible component of infiltration air heat contribution for a comparable single-speed portable air conditioner at Condition B in Table 1 of this appendix as follows:

$Q_{s\_83\_SS} = \dot{m}_{83\_SS} \times 60 \times [(c_{p\_da} \times (T_{ia\_83} - T_{indoor})) + (c_{p\_wv} \times (\omega_{ia\_83} \times T_{ia\_83} - \omega_{indoor} \times T_{indoor}))]$

Where:

$Q_{s\_83\_SS}$ = sensible heat added to the room by infiltration air for a comparable single-speed portable air conditioner, at

the 83 °F dry-bulb outdoor condition in Table 1 of this appendix, in Btu/h.

$\dot{m}_{83\_SS}$ = dry air mass flow rate of infiltration air for a comparable single-speed portable air conditioner, at the 83 °F dry-bulb outdoor condition in Table 1 of this appendix, in lb/m.

c_{p_da} = specific heat of dry air, 0.24 Btu/lb_m − °F.

c_{p_wv} = specific heat of water vapor, 0.444 Btu/lb_m − °F.

T_{indoor} = indoor chamber dry-bulb temperature, 80 °F.

T_{ia_95} and T_{ia_83} = infiltration air dry-bulb temperatures for the two test conditions in Table 1 of this appendix, 95 °F and 83 °F, respectively.

ω_{ia_95} and ω_{ia_83} = humidity ratios of the 95 °F and 83 °F dry-bulb infiltration air, 0.0141 and 0.01086 lb_w/lb_{da}, respectively.

ω_{indoor} = humidity ratio of the indoor chamber air, 0.0112 lb_w/lb_{da}.

60 = conversion factor from minutes to hours.

Calculate the latent component of infiltration air heat contribution for a comparable single-speed portable air conditioner at Condition B in Table 1 of this appendix as follows:

$$Q_{l\_83\_SS} = \dot{m}_{83\_SS} \times 60 \times H_{fg} \times (\omega_{ia\_83} - \omega_{indoor})$$

Where:

$Q_{l\_83\_SS}$ = latent heat added to the room by infiltration air for a comparable single-speed portable air conditioner, at the 83 °F dry-bulb outdoor condition in Table 1 of this appendix, in Btu/h.

$\dot{m}_{83\_SS}$ = dry air mass flow rate of infiltration air for a comparable single-speed portable air conditioner, at the 83 °F dry-bulb outdoor condition in Table 1 of this appendix, in lb/m.

$H_{fg.}$ = latent heat of vaporization for water vapor, 1061 Btu/lb_m.

ω_{ia_95} and ω_{ia_83} = humidity ratios of the 95 °F and 83 °F dry-bulb infiltration air, 0.0141 and 0.01086 lb_w/lb_{da}, respectively.

ω_{indoor} = humidity ratio of the indoor chamber air, 0.0112 lb_w/lb_{da}.60 = conversion factor from minutes to hours.

The total heat contribution of the infiltration air for a comparable single-speed portable air conditioner at Condition B in Table 1 of this appendix is the sum of the sensible and latent heat calculated above in this section:

$$Q_{infiltration\_83\_SS} = Q_{s\_83\_SS} + Q_{l\_83\_SS}$$

Where:

$Q_{infiltration\_83\_SS}$ = total infiltration air heat in cooling mode for a comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor condition in Table 1 of this appendix, in Btu/h.

$Q_{s\_83\_SS}$ = sensible heat added to the room by infiltration air for a comparable single-speed portable air conditioner, at the 83 °F dry-bulb outdoor condition in Table 1 of this appendix, in Btu/h.

$Q_{l\_83\_SS}$ = latent heat added to the room by infiltration air for a comparable single-speed portable air conditioner, at the 83 °F dry-bulb outdoor condition in Table 1 of this appendix, in Btu/h.

5.5.4 *Adjusted Cooling Capacity for a Comparable Single-Speed Portable Air Conditioner at the Lower Outdoor Test Condition.* Calculate the adjusted cooling capacity for a comparable single-speed portable air conditioner at Condition B in Table 1 of this appendix with and without cycling losses, ACC_{83_SS} and $ACC_{83\_SS\_CLF}$, respectively, expressed in Btu/h, according to the following equations.

$$ACC_{83\_SS} = Capacity_{83\_SS} - Q_{duct\_83\_SS} - Q_{infiltration\_83\_SS}$$

$$ACC_{83\_SS\_CLF} = Capacity_{83\_SS\_CLF} - Q_{duct\_83\_SS} - Q_{infiltration\_83\_SS}$$

Where:

ACC_{83_SS} and $ACC_{83\_SS\_CLF}$ = adjusted cooling capacity for a comparable single-speed portable air conditioner at Condition B in Table 1 of this appendix without and with cycling losses, respectively, in Btu/h.

$Capacity_{83\_SS}$ and $Capacity_{83\_SS\_CLF}$ = comparable single-speed portable air conditioner cooling capacity without and with cycling losses, respectively, in Btu/h, at Condition B in Table 1, calculated in section 5.5.1 of this appendix.

$Q_{duct\_83\_SS}$ = total heat transferred from the ducts to the indoor conditioned space in cooling mode for a comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor test condition, in Btu/h, calculated in section 5.5.2 of this appendix.

$Q_{infiltration\_83\_SS}$ = total infiltration air heat in cooling mode for a comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor condition, in Btu/h, calculated in section 5.5.3 of this appendix.

5.5.5 *Annual Energy Consumption in Cooling Mode for a Comparable Single-Speed Portable Air Conditioner at the Lower Outdoor Test Condition.* Calculate the annual energy consumption in cooling mode for a comparable single-speed portable air conditioner at Condition B in Table 1 of this appendix, expressed in kWh/year, according to the following equations.

$$AEC_{83\_SS} = P_{83\_SS} \times t \times k$$

Where:

AEC_{83_SS} = annual energy consumption for a comparable single-speed portable air conditioner in cooling mode at the 83 °F dry-bulb outdoor condition, in kWh/year.

P_{83_SS} = comparable single-speed portable air conditioner electrical power input, in watts, calculated for the 83 °F dry-bulb outdoor condition in section 5.5.1.

t = number of cooling mode hours per year, 750.

k = 0.001 kWh/Wh conversion factor from watt-hours to kilowatt-hours.

5.5.6 *Combined Energy Efficiency Ratio for a Comparable Single-Speed Portable Air Conditioner.* Calculate the combined energy efficiency ratio for a comparable single-speed portable air conditioner without and with cycling losses considered, $CEER_{SS}$ and $CEER_{SS\_CLF}$, respectively, expressed in Btu/Wh, according to the following:

$$CEER_{SS} = \left[\frac{ACC_{95}}{\left(\frac{AEC_{95} + AEC_T}{k \times t}\right)}\right] \times 0.2 + \left[\frac{ACC_{83\_SS}}{\left(\frac{AEC_{83\_SS} + AEC_T}{k \times t}\right)}\right] \times 0.8$$

$$CEER_{SS\_CLF} = \left[\frac{ACC_{95}}{\left(\frac{AEC_{95} + AEC_T}{k \times t}\right)}\right] \times 0.2 + \left[\frac{ACC_{83\_SS\_CLF}}{\left(\frac{AEC_{83\_SS} + AEC_T}{k \times t}\right)}\right] \times 0.8$$

Where:

$CEER_{SS}$ and $CEER_{SS\_CLF}$ = combined energy efficiency ratio for a comparable single-speed portable air conditioner without and with cycling losses considered, respectively, in Btu/Wh.

ACC_{95} = adjusted cooling capacity, tested for the variable-speed portable air conditioner at the 95 °F outdoor condition in Table 1 of this appendix, in Btu/h, calculated in section 5.1 of this appendix.

ACC_{83_SS} and $ACC_{83\_SS\_CLF}$ = adjusted cooling capacity for a comparable single-

speed portable air conditioner at the 83 °F outdoor condition in Table 1 of this appendix without and with cycling losses, respectively, in Btu/h, calculated in section 5.5.4 of this appendix.

AEC_{95} = annual energy consumption for the variable-speed portable air conditioner at the 95 °F outdoor conditions in Table 1 of this appendix, in kWh/year, calculated in section 5.3 of this appendix.

AEC_{83_SS} = annual energy consumption for a comparable single-speed portable air conditioner in cooling mode at the 83 °F dry-bulb outdoor condition, in kWh/year, calculated in section 5.5.5 of this appendix.

AEC_T = total annual energy consumption for the variable-speed portable air conditioner attributed to all modes except cooling, in kWh/year, calculated in section 5.3 of this appendix.

t = number of cooling mode hours per year, 750.

k = 0.001 kWh/Wh conversion factor for watt-hours to kilowatt-hours.

0.2 = weighting factor for the 95 °F dry-bulb outdoor condition test.

0.8 = weighting factor for the 83 °F dry-bulb outdoor condition test.

5.5.7 *Variable-Speed Portable Air Conditioner Performance Adjustment Factor.* Calculate the variable-speed portable air conditioner performance adjustment factor, F_p.

$$F_p = \frac{\left(CEER_{SS} - CEER_{SS\_CLF}\right)}{CEER_{SS\_CLF}}$$

Where:

F_p = variable-speed portable air conditioner performance adjustment factor.

$CEER_{SS}$ and $CEER_{SS\_CLF}$ = combined energy efficiency ratio for a comparable single-speed portable air conditioner without and with cycling losses considered, respectively, in Btu/Wh.

5.5.8 *Variable-Speed Portable Air Conditioner Combined Energy Efficiency Ratio.* For single-duct and dual-duct variable-speed portable air conditioners, multiply the combined energy efficiency ratio, $CEER_{DD}$, expressed in Btu/Wh, determined in section 5.4 by $(1 + F_p)$ to obtain the final CEER for variable-speed portable air conditioners.

Where:

F_p = variable-speed portable air conditioner performance adjustment factor, determined in section 5.5.7 of this appendix.''

IV. Application for Interim Waiver

LG also hereby applies for an interim waiver of the applicable test procedure requirements for the LG basic models set forth in the Appendix. LG meets the criteria for an interim waiver.

LG's Petition for Waiver is likely to be granted because the test method contained in 10 CFR part 430, subpart B, Appendix CC clearly does not address the VSC characteristics of these LG basic models and does not properly account for the favorable difference in cycling losses resulting from use of VSC technology. Thus, the test procedure does not accurately measure these models' energy consumption. Without waiver relief, LG would be subject to requirements that are inapplicable to these products. Additionally, LG will suffer economic hardship and be at a competitive disadvantage if it must wait to rate these basic models pending a determination on the petition for waiver.

DOE approval of LG's interim waiver application is also supported by sound public policy. These LG products employ advanced technology that increases efficiency and reduces energy consumption, while offering a new level of affordable comfort to consumers.

V. Conclusion

LG respectfully requests that DOE grant its Petition for Waiver of the applicable test procedure for specified basic models, and also grant its Application for Interim Waiver.

LG requests expedited treatment of the Petition and Application.

Respectfully submitted,

Scott Harris/s/,

Richard C. Wingate,

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Counsel to LG Electronics USA, Inc.

May 15, 2018.

Appendix

The waiver and interim waiver requested herein should apply to testing and rating of the following basic models that are manufactured by LG:
LP1419IVSM
LP1419HVSM
LP1219IVSM
LP1019IVSM
LP0819IVSM

[FR Doc. 2019–17083 Filed 8–8–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[Case Number 2018–002; EERE–2018–BT–WAV–002]

Energy Conservation Program: Decision and Order Granting a Waiver Store It Cold From the Department of Energy Walk-in Cooler Refrigeration System Test Procedure

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of decision and order.

SUMMARY: The U.S. Department of Energy (''DOE'') gives notice of a Decision and Order (Case Number 2018–002) that grants Store It Cold a waiver from specified portions of the DOE test procedure for determining the energy efficiency of specified walk-in refrigeration system models. Store It Cold is required to test and rate specified basic models of its walk-in cooler refrigeration system in accordance with the alternate test procedure specified.

DATES: The Decision and Order is effective on August 9, 2019. The Decision and Order will terminate upon the compliance date of any future amendment to the test procedure for walk-in cooler refrigeration systems located at 10 CFR part 431, subpart R, appendix C that addresses the issues presented in this waiver. At such time, Store It Cold must use the relevant test procedure for this equipment for any testing to demonstrate compliance with the applicable standards, and any other representations of energy use.

FOR FURTHER INFORMATION CONTACT:

Ms. Lucy deButts, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue, SW, Washington, DC, 20585–0121. Email: *AS_Waiver_Requests@ee.doe.gov.*

Mr. Michael Kido, U.S. Department of Energy, Office of the General Counsel, Mail Stop GC–33, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585–0103. Telephone: (202) 586–8145. Email: *Michael.Kido@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: In accordance with Title 10 of the Code of Federal Regulations (10 CFR 431.401(f)(2)), DOE gives notice of the issuance of its Decision and Order as set forth below. The Decision and Order grants Store It Cold a waiver from the applicable test procedure at 10 CFR part 431, subpart R, appendix C for specified basic models of walk-in cooler refrigeration systems provided that

Store It Cold tests and rates such equipment using the alternate test procedure specified in the Decision and Order. Store It Cold's representations concerning the energy efficiency of the specified basic models must be based on testing according to the provisions and restrictions in the alternate test procedure set forth in the Decision and Order, and the representations must fairly disclose the test results. Distributors, retailers, and private labelers are held to the same requirements when making representations regarding the energy efficiency of this equipment. (42 U.S.C. 6314(d))

Consistent with 10 CFR 431.401(j), not later than October 8, 2019, any manufacturer currently distributing in commerce in the United States equipment employing a technology or characteristic that results in the same need for a waiver from the applicable test procedure must submit a petition for waiver. Manufacturers not currently distributing such equipment in commerce in the United States must petition for and be granted a waiver prior to the distribution in commerce of that equipment in the United States. Manufacturers may also submit a request for interim waiver pursuant to the requirements of 10 CFR 431.401.

Signed in Washington, DC, on July 30, 2019.

Alexander N. Fitzsimmons,

Acting Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

I. Background and Authority

The Energy Policy and Conservation Act of 1975, as amended (''EPCA''),[1] authorizes the U.S. Department of Energy (''DOE'') to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317) Title III, Part C[2] of EPCA established the Energy Conservation Program for Consumer Products Other Than Automobiles, which sets forth a variety of provisions designed to improve energy efficiency for certain types of consumer products. These products include walk-in cooler refrigeration systems, the focus of this document. (42 U.S.C. 6311(1)(G))

The energy conservation program under EPCA consists essentially of four parts: (1) testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA include definitions (42 U.S.C. 6311), energy conservation standards (42 U.S.C. 6313), test procedures (42 U.S.C. 6314), labeling provisions (42 U.S.C. 6315), and the authority to require information and reports from manufacturers (42 U.S.C. 6316).

The Federal testing requirements consist of test procedures that manufacturers of covered equipment must use as the basis for: (1) certifying to DOE that their equipment complies with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6316(a); 42 U.S.C. 6295(s)), and (2) making representations about the efficiency of that equipment (42 U.S.C. 6314(d)). Similarly, DOE must use these test procedures to determine whether the equipment complies with relevant standards promulgated under EPCA. (42 U.S.C. 6316(a); 42 U.S.C. 6295(s)).

Under 42 U.S.C. 6314, EPCA sets forth the criteria and procedures DOE is required to follow when prescribing or amending test procedures for covered equipment. EPCA requires that any test procedures prescribed or amended under this section must be reasonably designed to produce test results which reflect energy efficiency, energy use or estimated annual operating cost of covered equipment during a representative average use cycle and requires that test procedures not be unduly burdensome to conduct. (42 U.S.C. 6314(a)(2)) The test procedure for walk-in cooler refrigeration systems is contained in the Code of Federal Regulations (''CFR'') at 10 CFR part 431, subpart R, appendix C, – ''Uniform Test Method for the Measurement of Net Capacity and AWEF of Walk-In Cooler and Walk-In Freezer Refrigeration Systems'' (''Appendix C'').

Under 10 CFR 431.401, any interested person may submit a petition for waiver from DOE's test procedure requirements for commercial and industrial equipment. DOE will grant a waiver from the test procedure requirements if DOE determines either that the basic model for which the waiver was requested contains a design characteristic that prevents testing of the basic model according to the prescribed test procedures, or that the prescribed test procedures evaluate the basic model in a manner so unrepresentative of its true energy consumption characteristics as to provide materially inaccurate comparative data. 10 CFR 431.401(f)(2). DOE may grant the waiver subject to conditions, including adherence to an alternate test procedure. *Id.*

II. Store It Cold's Petition for Waiver: Assertions and Determinations

By letter dated March 9, 2018, Store It Cold filed a petition for waiver and petition for interim waiver from the test procedure for walk-in refrigeration systems set forth in Appendix C, and in response to DOE requests for technical clarification, Store It Cold submitted a revised petition for waiver and petition for interim waiver on May 16, 2018.[3] In the petition, Store It Cold requested relief for the following walk-in cooler refrigeration system basic models: CBLW08, CBLW10, CBLW12, CBLW15, CBLW18, CBLW25. Store It Cold identified these models as single-package dedicated refrigeration systems comprised of a controller (*i.e.,* the °CoolBot® controller) and a room air conditioner (''RAC''), which are combined to form a walk-in refrigeration system. Store It Cold stated in its petition that the resulting walk-in refrigeration systems are designated for both indoor and outdoor use. According to Store It Cold's petition, the CoolBot's technology controls a window air conditioner that maintains desired temperatures, as opposed to a much larger traditional walk-in cooler refrigeration system that would utilize large compressors, large surface area coils, multiple fans, and large volumes of refrigerant to do the same. Store It Cold asserted in its petition that, for the basic models listed in its petition, the refrigerant enthalpy method (referred to as the '''refrigerant-side' gross capacity'' method by Store It Cold) yields inconsistent refrigerant mass flow rates and lower than expected capacities. Store It Cold explained in its petition that the installation of the refrigerant mass flow meters used under this method significantly increased the refrigerant circuit's internal volume, requiring the system to be charged with approximately twice the amount of refrigerant as was present from the factory. Store It Cold requested that it be allowed to test its models using an alternate '''air-side' gross capacity'' method, in which the capacity would be determined by measuring the enthalpy change and mass flow rate of the air passing through both the evaporator side and condenser side, resulting in two capacity measurements that would have to match within a designated tolerance for the test to be considered valid. Store It Cold also requested an interim waiver for this equipment.

[1] All references to EPCA in this document refer to the statute as amended through America's Water Infrastructure Act of 2018, Public Law 115-270 (October 23, 2018).

[2] For editorial reasons, upon codification in the U.S. Code, Part C was redesignated as Part A-1.

[3] The docket, including Store It Cold's submissions is located at: *https://www.regulations.gov/docket?D=EERE-2018-BT-WAV-0002.*

After reviewing Store It Cold's application, the alternate test procedure requested by Store It Cold, the company's testing and performance data, product characteristics, and product specification sheets published online by Store It Cold, DOE published a notice that announced its receipt of the petition for waiver and granted Store It Cold an interim waiver. 84 FR 11944 (March 29, 2019) (''Notice of Petition for Waiver''). In the Notice of Petition for Waiver, DOE presented Store it Cold's claim that the results from testing the specified basic models according to ''refrigerant-side'' measurements provide results unrepresentative of the °CoolBot® walk-in cooler refrigeration system's actual energy consumption characteristics and that such testing would provide materially inaccurate comparative data. A test photo provided by Store It Cold shows that the refrigerant tubing exiting the unit has multiple bends in it without any extended straight sections upstream and downstream of the refrigerant mass flow meters, which could very well have affected the accuracy of the mass flow measurements. Additionally, Store It Cold stated the refrigerant tubing as configured increased the refrigerant circuit's internal volume, requiring the system to be charged with approximately twice the amount of refrigerant as was present from the factory.

DOE stated in the Notice of Petition for Waiver that for refrigeration systems in general, it is expected that the capacity of the system would monotonically increase as the condenser air temperature decreases (until further increases are limited by refrigerant mass flow restriction of the expansion device for the lower condensing pressures that would occur for lower condenser air temperatures). 84 FR 11944, 11946. This is because the cooler condenser air temperature can further cool the refrigerant such that it leaves the condenser at lower temperature and enthalpy, and similarly enters the evaporator at lower enthalpy. This increases the amount of heat the refrigerant absorbs from the refrigerated space as it flows through the evaporator coil, increasing the capacity of the evaporator. DOE noted that the ''refrigerant-side'' method test data in Store It Cold's petition do not follow this trend, and that the inconsistent results suggest that the capacity measurements are not accurate. *Id.* DOE also stated the data from testing using the ''air side'' method follows the expected trend, showing increasing refrigeration capacity as condenser air temperature decreases for both tested units, giving much greater confidence that the measurements are accurate. *Id.*

DOE granted Store It Cold an interim waiver requiring testing of the specified walk-in cooler refrigeration systems using the alternate ''air-side'' test procedure as requested by Store It Cold. Under the ''air-side'' method, the refrigeration capacity is determined by measuring the enthalpy change and mass flow rate of the air passing through the evaporator side (*i.e.*, Indoor Air Enthalpy Method) and condenser side (*i.e.*, Outdoor Air Enthalpy Method). The condenser side measurement is adjusted by subtracting the system input power to determine refrigeration capacity.

In the Notice of Petition for Waiver, DOE also solicited comments from interested parties on all aspects of the petition and the specified alternate test procedure *Id.* DOE received comments from three commenters: (1) a group of utilities including Pacific Gas and Electric Company (''PG&E''), San Diego Gas and Electric (''SDG&E''), and Southern California Edison (''SCE'') (hereinafter the ''California IOUs''), (2) the Air-Conditioning, Heating, and Refrigeration Institute (''AHRI''), and (3) BMIL Technologies, LLC.[4]

The California IOUs recommended that DOE deny the current version of the petition for waiver and instead recommended DOE require that Store It Cold determine the refrigeration capacity of the specified equipment using a ''dual Calibrated Box'' approach, as is prescribed by DOE for RACs, with appropriate modifications. (California IOUs, No. 0017 at p. 1) The California IOUs stated that the air-side enthalpy methods proposed in the petition for waiver is not used for the DOE capacity rating test procedure of either WICF or RAC. (California IOUs, No. 0017 at p. 2) The CA IOUs stated that the test procedure suggested by Store It Cold is widely used for testing ducted unit air-conditioners and heat pumps, and not appropriate for non-ducted equipment, such as the Store It Cold models. The California IOUs also stated that the equipment for which the waiver is sought is an RAC with a modified controller to make it a WICF, rather than a piece of unitary air-conditioning equipment with ducts, and thus the RAC capacity test is more appropriate for evaluating the application. (California IOUs, No. 0017 at p. 3) They further stated that a dual Calibrated Box approach would allow the airflows to freely circulate in both the hot side and cold side enclosures, reflecting the actual application of the models in question. (California IOUs, No. 0017 at p. 3) Alternatively, they suggested that DOE at a minimum require testing under both the air-side enthalpy and dual calibrated box methods and submit the resulting data as confirmation of the air-side enthalpy measurements.[5](California IOUs, No. 0017 at p. 4)

The California IOUs also expressed concern that if the alternate test procedure changes the rated capacity and creates a lower bar to meet the WICF standards (especially for a low-cost off-the-shelf product) it could significantly shift segments of the market away from compliant efficient equipment towards equipment that would not be compliant if tested using the consensus test method prescribed by DOE. (California IOUs, No. 0017 at p. 2) The California IOUs also expressed concern that, being based on RACs that were not designed for walk-in applications, the Store It Cold models may not meet safety and consumer protection standards and may have reduced life as compared with the 10.5 years estimated by DOE for medium temperature refrigeration systems. (California IOUs, No. 0017 at pp. 4-5)

As noted in the Notice of Petition for Wavier, the equipment for which Store It Cold has requested a waiver are walk-in cooler refrigeration systems that are comprised, in part, of a RAC. 84 FR 11944, 11946. DOE recognizes that Store It Cold also separately distributes in commerce the °CoolBot® controller, i.e., not as part of a walk-in cooler refrigeration system, and reiterates that the grant of a waiver only applies to the walk-in cooler refrigeration system basic models identified by Store It Cold, i.e., the specific models listed in the Waiver order, which contain °CoolBot® controllers integrated by Store It Cold with the specified RAC models.

As explained in the Notice of Petition for Waiver, the test procedure for determining the rated capacity under the WICF test procedure provides results that are unrepresentative of the specified models' true performance capabilities. The test data provided by Store It Cold indicated that the air-side enthalpy test suggested by Store It Cold yields more accurate results for the basic models listed in its petition. Additionally, multiple organizations have established test procedures for determining the capacity of single-

[4] All comments are in the docket located at: *https://www.regulations.gov/docket?D=EERE-2018-BT-WAV-0002.*

[5] The California IOUs comment is available in the docket at: *https://www.regulations.gov/docket?D=EERE-2018-BT-WAV-0002.*

package air-conditioners and refrigeration systems using the psychrometric approach, which uses the indoor air enthalpy method and/or the outdoor air enthalpy method. Examples include the following:

• ANSI/ASHRAE 58-1986 (RA 1999), ''Method of Testing for Rating Room Air Conditioner and Packaged Terminal Air Condition Heating Capacity'' prescribes the use of the air enthalpy test method to measure heating capacity of room air conditioners and packaged terminal air conditioners with reverse-cycle operation to allow heating.

• ANSI/ASHRAE 16 (2016), ''Method of Testing for Rating Room Air Conditioners and Packaged Terminal Air Conditioners'', the updated version of ASHRAE 16-1983 (RA 2009), allows both calorimetric methods similar to ASHRAE 16-1983 (RA 2009) as well as the psychrometric approach using the air enthalpy method.

• DOE's test procedure for packaged terminal air conditioners and heat pumps (10 CFR 431.96), allows use of both calorimetric and psychrometric test methods to determine cooling capacity.

• AHRI has published for comment a draft revision of AHRI 1250, ''Standard for Performance Rating of Walk-In Coolers and Freezers'', which allows use of air enthalpy methods for measurement of refrigeration capacity for single-package walk-in refrigeration systems. (AHRI 1250 Draft, NO. 18 at p. 60)

Regarding the California IOUs suggestion that the indoor air enthalpy method is suitable only for capacity measurement for ducted systems, DOE notes that many non-ducted systems are tested using this test method, for example Central Air Conditioners and Heat Pumps, Variable Refrigerant Flow units, and Packaged Terminal Air Conditioners. In addition to the systems noted above, non-ducted systems such as mini-split air conditioners multi-split air conditioners also are tested using the indoor air enthalpy method. See 10 CFR part 430 subpart B appendix M.

Finally, with respect to the potential food safety and product life implications raised by the California IOUs, DOE notes that the waiver process addresses instances in which a basic model contains one or more design characteristics that prevent testing of the basic model according to the DOE prescribed test procedures or cause the prescribed test procedures to evaluate the basic model in a manner so unrepresentative of its true energy consumption characteristics as to provide materially inaccurate comparative data. 10 CFR 431.401(a)(1). Accordingly, these particular concerns raised by the California IOUs lie beyond the much more limited scope of the waiver process. We also note that, while DOE takes no position as to the safety performance or longevity of the subject basic models, the relevant portions of the test procedure that Store It Cold must follow as part of this waiver order require that the equipment's interior box maintain a temperature of 35°F, which would fall within the recommended food storage temperature range. (NSF/ANSI 7- 2009, at p. 13 (specifying that refrigeration equipment must be capable of maintaining air temperature of 40°F (4°C) or lower in all refrigerated compartment interiors).

AHRI stated that the models for which the waiver is requested appear to meet the legal definition of a walk-in cooler, and that its primary component—the RAC—is also a DOE-covered product that can be tested pursuant to air-conditioning methods of test. AHRI further explained that, although its members have raised generalized concerns about whether the waiver seeks to sanction what its members view as the misapplication of a RAC as a walk-in cooler, they do not object to the waiver, as long as it is consistent with relevant industry-standard performance tests for equipment. Specifically, AHRI requested that the waiver stipulate a 75 °F wet bulb condition be applied. (AHRI, No. 0016 at p. 1) AHRI asserted that, similar to a room air conditioner, the °CoolBot® system would reject condensate to the outdoor coil, using it to enhance outdoor coil cooling. AHRI further states that variations in outdoor air wet bulb temperature would lead to inconsistent test results when compared to the performance of a typical evaporative condensing unit. (AHRI, No. 0016 at pp. 1-2) Specifically, AHRI suggested that the Note 1 of Tables 3 and 4 in the Store It Cold waiver be updated to read ''Required only for evaporative Dedicated Condensing Units or Single-Package Dedicated Systems that reject the condensate to the outdoor coil.'' [6] (AHRI, No. 0016 at p. 2)

DOE agrees that maintaining a 75 °F wet bulb condition for the outdoor air would be important for evaporative condensers and units that reject condensate to the outdoor coil. However, DOE notes that the test procedure for walk-in refrigeration systems requires maintaining the evaporator-side inlet air at a low-humidity condition such that frost would not form on the evaporator. Consequently, at steady-state operating conditions, there would be no moisture collecting on the °CoolBot® system evaporator. Further, since the system would have to stop operation and undergo defrost for the moisture to melt and turn into condensate that can be transferred to the condenser coil, the possibility for enhancing condenser cooling using condensate collected at the evaporator is even less likely.

DOE acknowledges that it is possible that some moisture could be present—for example, the °CoolBot® system could be used prior to a test to help cool the test chamber down to 35 °F. In this case, moisture present in the room before cooldown could collect on the evaporator. This moisture could possibly drain off the evaporator before the evaporator surface is cold enough to freeze it, or the system's operation could be interrupted briefly before a test is conducted, either of which would lead to drainage of the moisture and transfer to the condenser side. DOE is concerned that the quantity of this moisture collection would be highly dependent on the uncontrolled circumstances occurring before the test measurement begins (e.g., whether the unit was used to help cool down the test chamber, whether or not the test was conducted during humid summer conditions when a higher level of moisture could have been in the chamber prior to cooldown, whether the unit operation was stopped to allow defrost before conducting the test), and hence, even if the outdoor side wet bulb temperature is maintained at 75 °F, as recommended by AHRI, the amount of condenser cooling enhancement could vary. DOE concludes that a better approach to address AHRI's concern about the variability is to ensure that there is no moisture in the condensate pan on the condenser side during the test. In this case, the outdoor wet bulb temperature would not affect the test result, because there would be no evaporative cooling—thus the outdoor wet bulb temperature would not have to be controlled, other than to prevent it from exceeding the maximum limits specified for single-package units. Ensuring that there is no moisture in the condenser-side condensate pan could be done in different ways, for example, drilling a small hole in the bottom of the pan to let the moisture drain out, running the unit for a long time to evaporate any collected moisture, or preventing the collection of moisture in the first place by drying out the indoor room prior to starting operation of the test unit. The alternate test procedure in this Order has been modified from the procedure in the interim waiver, to include this

[6] AHRI comment is available in the docket at: *https://www.regulations.gov/docket?D=EERE-2018-BT-WAV-0002.*

requirement to make sure that there is no moisture in the condenser-side condensate pan during performance measurement test periods. It does not specify how to ensure that the condensate pan is dry in order to retain flexibility in test approach.

BMIL Technologies, LLC questioned the granting of a waiver that would enable testing the application of air conditioning units within an operating range that the manufacturer does not rate, *i.e.,* refrigeration.[7] (BMIL Technologies, LLC, No. 0014 at p. 1)

DOE acknowledges that an RAC is not routinely considered to be a refrigeration system used for commercial or industrial cooling applications. However, in the circumstances presented here, where a manufacturer's own materials and statements assert that the pairing of its refrigeration controls (i.e., °CoolBot® controller) with a specified off-the-shelf RAC satisfies the relevant walk-in regulatory definitions and refrigerates at a 35 °F walk-in temperature, DOE accepts the manufacturer's submissions in its request for a waiver, absent evidence to the contrary. Accordingly, when faced with the current set of facts, Store It Cold's equipment is subject to the test procedures and energy conservation standards established for WICF at 10 CFR part 431, subpart R. The fact that one of the components used in each of the specified Store It Cold basic models can also operate as a RAC at warmer temperatures is not relevant under the facts at hand to the question of whether the alternate test procedure is appropriate for measuring the system capacity of these models.

For the reasons explained here and in the Notice of Petition for Waiver, absent a waiver the basic models identified by Store It Cold in its petition cannot be tested and rated for energy consumption on a basis representative of their true energy consumption characteristics. DOE has reviewed the recommended procedure suggested by Store It Cold and concludes that it will allow for the accurate measurement of the energy use of the equipment, subject to the modification discussed in the prior paragraphs, while alleviating the testing problems associated with Store It Cold's implementation of DOE's applicable walk-in cooler refrigeration system test procedure for the specified basic models.

Thus, DOE is requiring that Store It Cold test and rate the identified walk-in cooler refrigeration system basic models according to the alternate test procedure specified in this Decision and Order. The alternate test procedure in this Order is a modified version of the procedure in the interim waiver.

This Decision and Order is applicable only to the basic models listed in the Order and does not extend to any other basic models. Store It Cold may request that the scope of this waiver be extended to include additional basic models that employ the same technology as those listed in this waiver. 10 CFR 431.401(g). Store It Cold may also submit another petition for waiver from the test procedure for additional basic models that employ a different technology and meet the criteria for test procedure waivers. 10 CFR 431.401(a)(1).

DOE notes that it may modify or rescind the waiver at any time upon DOE's determination that the factual basis underlying the petition for waiver is incorrect, or upon a determination that the results from the alternate test procedure are unrepresentative of the basic models' true energy consumption characteristics. 10 CFR 430.401(k)(1). Likewise, Store It Cold may request that DOE rescind or modify the waiver if the company discovers an error in the information provided to DOE as part of its petition, determines that the waiver is no longer needed, or for other appropriate reasons. 10 CFR 430.401(k)(2). As set forth above, the test procedure specified in this Decision and Order is not the same as the test procedure offered by Store It Cold. If Store It Cold believes that the alternate test method it suggested provides representative results and is less burdensome than the test method required by this Decision and Order, Store It Cold may submit a request for modification under 10 CFR 431.401(k)(2) that addresses the concerns that DOE has specified with that procedure. Store It Cold may also submit another less burdensome alternative test procedure not expressly considered in this notice under the same provision.

III. Order

After careful consideration of all the material that was submitted by Store It Cold, product specification sheets published online by Store It Cold, and comments received in this matter, it is ORDERED that:

(1) Store It Cold must, as of the date of publication of this Order in the *Federal Register*, test and rate the following walk-in cooler refrigeration system basic models with the alternate test procedure as set forth in paragraph (2):

Brand	Basic Model Number
CoolBot	CBLW08
CoolBot	CBLW10
CoolBot	CBLW12
CoolBot	CBLW15
CoolBot	CBLW18
CoolBot	CBLW25

(2) The alternate test procedure for the Store It Cold basic models listed in paragraph (1) of this Order is the test procedure for walk-in cooler refrigeration systems prescribed by DOE at 10 CFR part 431, subpart R, appendix C,[8] except as detailed below. All other requirements of 10 CFR part 431, subpart R, appendix C, and DOE's regulations remain applicable, with the following modifications:

In 10 CFR part 431, subpart R, appendix C, section 3.1. *General modifications: Test Conditions and Tolerances*, revise sections 3.1.1. and 3.1.4., and add instructions in a new section 3.1.6. regarding Tables 3 and 4 of AHRI 1250-2009, to read:

3.1.1. In Table 1, Instrumentation Accuracy, refrigerant temperature measurements shall have a tolerance of ±0.5 F for unit cooler in/out. Temperature measurements used to determine water vapor content of the air shall be accurate to within ±0.4 F, ±1.0 F for all other temperature measurements.

3.1.4. In Tables 2 through 14, the Test Condition Outdoor Wet Bulb Temperature requirement and its associated tolerance apply only to units with evaporative cooling and single-packaged dedicated systems. The condenser-side condensate pan must be dry during performance measurement test periods.

3.1.6. Tables 3 and 4 shall be modified to read as follows:

[7] BMIL Technologies, LLC comment is available in the docket at*: https://www.regulations.gov/docket?D=EERE-2018-BT-WAV-0002.*

[8] AHRI Standard 1250P (I-P)-2009 (''AHRI 1250-2009'') titled ''Standard for Performance Rating of Walk-in Coolers and Freezers'' is incorporated by reference in the federal test procedure at 10 CFR 431.303(b)(2). The alternate test procedure provides amendments to 10 CFR part 431, subpart R, appendix C that include required modifications to AHRI 1250-2009.

TABLE 3—FIXED CAPACITY MATCHED REFRIGERATOR SYSTEM AND SINGLE-PACKAGED DEDICATED SYSTEM, CONDENSING UNIT LOCATED INDOOR

Test description	Unit cooler air entering dry-bulb, °F	Unit cooler air entering relative humidity, (%)	Condenser air entering dry-bulb, (°F)	Condenser air entering wet-bulb, (°F)	Compressor capacity	Test objective
Off-cycle Fan Power	35	<50	–	–	Compressor Off	Measure fan input wattage during compressor off cycle.
Refrigeration Capacity	35	<50	90	[1] 75, [2] 65	Compressor On	Determine Net Refrigeration Capacity of Unit Cooler, input power, and EER at Rating Condition.

Note:
1. Required only for evaporative Dedicated Condensing Units.
2. Maximum allowable value for Single-Packaged Dedicated Systems that do not use evaporative Dedicated Condensing Units, where all or part of the equipment is located in the outdoor room.

TABLE 4—FIXED CAPACITY MATCHED REFRIGERATOR SYSTEM AND SINGLE-PACKAGED DEDICATED SYSTEM, CONDENSING UNIT LOCATED OUTDOOR

Test description	Unit cooler air entering dry-bulb, °F	Unit cooler air entering relative humidity, (%)	Condenser air entering dry-bulb, (°F)	Condenser air entering wet-bulb, (°F)	Compressor capacity	Test objective
Off Cycle Fan Power	35	<50	–	–	Compressor Off	Measure fan input wattage during compressor off cycle.
Refrigeration Capacity A	35	<50	95	75[1], [2] 68	Compressor On	Determine Net Refrigeration Capacity of Unit Cooler, input power, and EER at Rating Condition.
Refrigeration Capacity B	35	<50	59	54[1], [2] 46	Compressor On	Determine Net Refrigeration Capacity of Unit Cooler and system input power at moderate condition.
Refrigeration Capacity C	35	<50	35	[1] 34, [2] 29	Compressor On	Determine Net Refrigeration Capacity of Unit Cooler and system input power at cold condition.

Note:
1. Required only for evaporative Dedicated Condensing Units.
2. Maximum allowable value for Single-Packaged Dedicated Systems that do not use evaporative Dedicated Condensing Units, where all or part of the equipment is located in the outdoor room.

In 10 CFR part 431, subpart R, appendix C, section 3.2. *General Modifications: Methods of Testing* add the following instructions regarding additional modifications to appendix C of AHRI 1250-2009:

3.2.6 In appendix C, section C1. reads: *Purpose.* The purpose of this appendix is to provide a method of testing for Matched-pair, single-packaged dedicated systems, as well as Unit coolers and Dedicated Condensing Units tested alone.

3.2.7 In appendix C, section C5. and C5.1 read as follows:

3.2.7.1 C5 reads: C5. *Methods of Testing for walk-in cooler and freezer systems that have matched unit coolers and condensing units.* The testing of the walk-in cooler and freezer systems include a steady state test, defrost test and off-cycle fan power test. For single-packaged dedicated systems, calculate the refrigeration capacity and power consumption using the Indoor Air Enthalpy test method and the Outdoor Air Enthalpy test method. The Indoor Air Enthalpy test method shall be considered the primary measurement and used to report capacity. The Outdoor Air Enthalpy test method shall be considered the secondary measurement and used to calculate the Refrigeration Capacity Heat Balance. See Section C10 of this appendix for complete details on each test method.

3.2.7.2 C5.1 reads: The Gross Total Refrigeration Capacity of Unit Coolers for matched-pairs (not including single-packaged dedicated systems) from steady state test shall be determined by either one of the following methods.

3.2.8 In appendix C, section C7.1 reads: Refer to the standard rating conditions for a particular application listed in Section 5 of this standard. Test acceptance criteria listed in Table 2 in section 4 of this standard apply to the Dual Instrumentation and Calibrated Box methods of test. Single-packaged dedicated system test tolerances are listed in each applicable Method of Test outlined in section C10.

3.2.9 In appendix C, section C7.2 reads: Data that need to be recorded during the test are listed in Table C2. For single-packaged dedicated systems tested in accordance with ASHRAE 37-2009, data that need to be recorded during the test are listed in ASHRAE 37-2009.

3.2.10 In appendix C, section C6. *Test Chambers Requirements,* add C6.3 to read as follows:

C6.3 For all system constructions (Split systems, Single-packaged dedicated systems, Unit Cooler tested alone, and Dedicated Condensing Unit tested alone), the Unit Cooler under test may be used to aid in achieving the required test chamber ambient temperatures prior to beginning any Steady-state test. However, the unit under test must be free from frost before initiating any Steady-state testing.

For single-packaged dedicated systems, refer to the applicable methods of test for single-packaged dedicated systems listed in section C10 of this appendix.

In 10 CFR part 431, subpart R, appendix C, section 3.3. *Matched systems, single-packaged dedicated systems, and unit coolers tested alone,* revise the language to read:

3.3 *Matched systems, single-packaged dedicated systems, and unit coolers tested alone*: Use the test method in AHRI 1250-2009 (incorporated by reference; see §431.303), appendix C as the method of test for matched refrigeration systems, single-packaged dedicated systems, or unit coolers tested alone, with the modifications listed below in sections 3.3.1 through 3.3.7.2.:

In appendix C of AHRI 1250-2009, renumber the following sections and equations, and references to the following sections and equations, as follows:

Section C10 to C11;
Section C11 to C12;
Section C11.1 to C12.1;
Section C11.1.1 to C12.1.1;
Equation C11 to C12;
Equation C12 to C13;
Section C11.2 to C12.2;
Section C11.3 to C12.3;
Equation C13 to C14;
Equation C14 to C15;
Equation C15 to C16;
Equation C16 to C17;
Section C12 to C13; and
Section C13 to C14.

Insert the following as sections C10 through C10.2.3, and equation C11:

C10. *Single-packaged Test Methods and Allowable Refrigeration Capacity Heat Balance.*

C10.1 *Single-packaged Test Methods.*

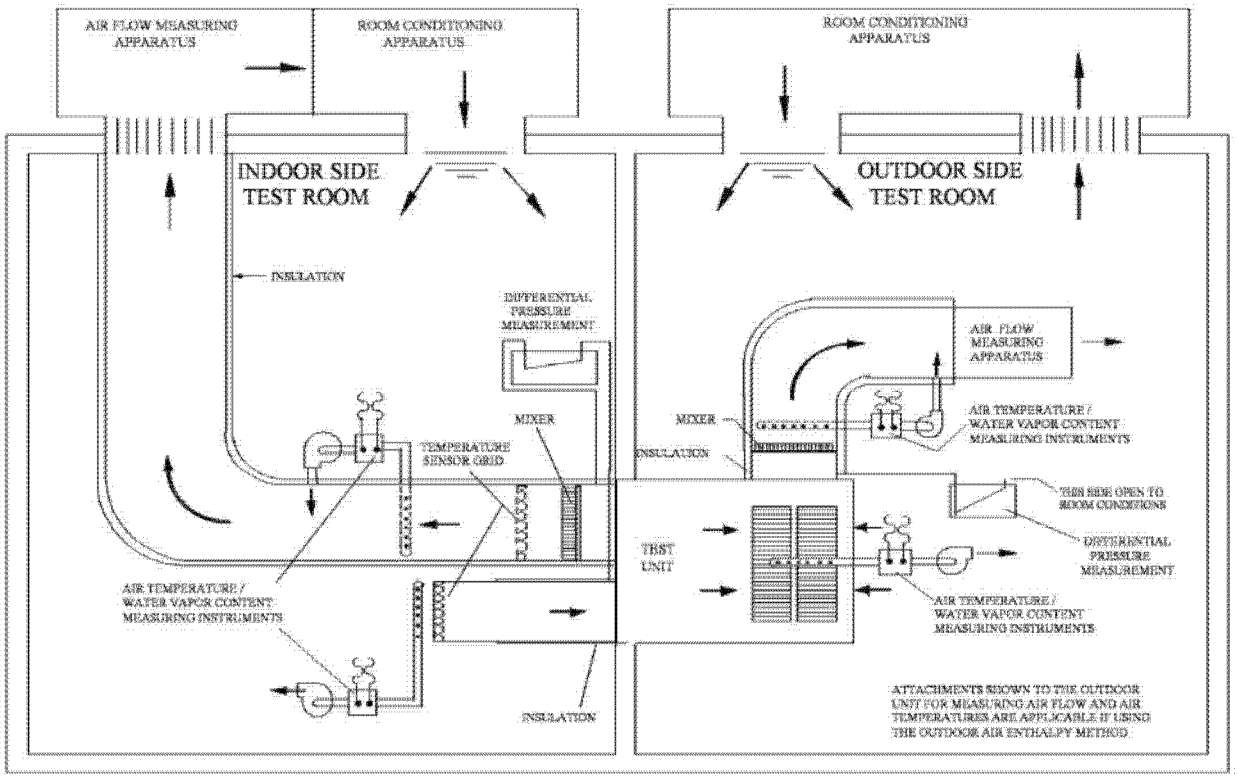

Figure C3 - Air Enthalpy Method

Also see the following website for Figure C3: *https://www.regulations.gov/document?D=EERE-2018-BT-WAV-0002-0009*.

C10.1.1 *Indoor Air Enthalpy Method.* Determine Net Refrigeration Capacity of Unit Cooler and input power in accordance with ASHRAE 37-2009, Figure C3, and the following modifications.

C10.1.1.1 Space conditioning capacity is determined by measuring airflow rate and the dry-bub temperature and water vapor content of the air that enters and leaves the coil. Air enthalpies shall be determined in accordance with ANSI ASHRAE 41.6. Entering air is to be sufficiently dry as to not produce frost on the Unit Cooler coil. Therefore, only sensible capacity measured by dry bulb change shall be used to calculate capacity.

C10.1.1.2 Test Setup for Non-Ducted Unit Coolers. A single outlet plenum box shall be constructed in a cubic arrangement. The length of the longest dimension of the Unit Cooler outlet shall be used to determine the dimension of the cube outlet plenum. Four static pressure taps shall be installed in the center of each face. A 6″ inlet plenum skirt shall be installed with four static pressure taps at each center face as well. Airflow shall be adjusted by the exhaust fan on the airflow plenum to achieve 0.00″WC (± 0.02″WC).

C10.1.2 *Outdoor Air Enthalpy Method.* Determine Net Refrigeration Capacity of Unit Cooler and input power in accordance with ASHRAE 37-2009, Figure C3, and the following modifications.

C10.1.2.1 Outdoor Air Enthalpy is only applicable on Dedicated Condensing Units for which the leaving air can be fully captured. Space conditioning capacity is determined by measuring airflow rate and the dry-bub temperature and water vapor content of the air that enters and leaves the coil. Air enthalpies shall be determined in accordance with ANSI ASHRAE 41.6. Line loss adjustments in section 7.3.3.4 of ASHRAE 37-2009 are not applicable to package units.

C10.2 *Allowable Refrigeration Capacity Heat Balance.*

C10.2.1 Following the completion of the Steady-state capacity test, for each rating condition, the measured net capacities of the primary and secondary test methods must balance within 6%, per Equation C11 [9]

$$-6\% \leq \frac{\dot{Q}_{net,primary} - \dot{Q}_{net,secondary}}{\dot{Q}_{net,primary}} \times 100\% \leq 6\% \qquad C11$$

C10.2.2 If measured net capacities do not balance per Equation C11, investigate all potential test facility leaks and/or non-conformances. If no leaks or non-conformances are detected, proceed to Section C10.2.3. If any leaks or non-conformances are detected, remedy the concerns and rerun the Steady-state test at all applicable rating condition(s). If the measured net capacities balance per Equation C11, then the test is considered valid and capacity and power measurements from the

[9] The suggested alternate test procedure in Store It Cold's petition for waiver referenced equation C24. DOE understands this to be an error and that the appropriate equation to reference is C11.

primary method of the second test will be used. If the measured net capacities still do not balance per Equation C11, proceed to Section C10.2.3

C10.2.3 To achieve a capacity heat balance, the test lab may modify the exterior of the unit under test to reduce leakage and surface losses. Specifically, the lab may add insulation to the outside surface of the single-packaged dedicated system and/or tape and seal sheet metal edges to minimize outdoor ambient air intrusion to the Unit Cooler. After the unit is insulated, rerun the Steady-state test at all applicable rating condition(s). If the measured net capacities balance per Equation C11, then the lab facility and instrumentation are verified as complying with the applicable method of test. However, capacity, power, and all downstream calculations will be based on the results of the primary method from the first test, which occurred before the unit was altered. If the measured net capacities still do not balance per Equation C11, then the lab facility and instrumentation are considered non-compliant, must be remedied, and all prior tests for the unit under test are considered invalid.

In 10 CFR part 431, subpart R, appendix C, sections 3.3 through 3.3.7.2 replace references to AHRI-1250-2009 sections C10, C11, C11.1, C11.1.1, C11.2, and C11.3, with C11, C12, C12.1, C12.1.1, C12.2, and C12.3, respectively; and replace references to AHRI-1250-2009 equations C13 and C14 with equations C14 and C15, respectively.

(3) *Representations.* Store It Cold may not make representations about the energy use, including the refrigeration capacity (in Btu/h), of a basic model listed in paragraph (1) of this Order for compliance, marketing, or other purposes unless such basic model has been tested in accordance with the provisions set forth above and such representations fairly disclose the results of such testing.

(4) This waiver shall remain in effect according to the provisions of 10 CFR 431.401.

(5) This waiver is issued on the condition that the statements, representations, and documents provided by Store It Cold are valid. If Store It Cold makes any modifications to the controls or configurations of these basic models, the waiver will no longer be valid and Store It Cold will either be required to use the current Federal test method or submit a new application for a test procedure waiver. DOE may rescind or modify this waiver at any time if it determines the factual basis underlying the petition for waiver is incorrect, or the results from the alternate test procedure are unrepresentative of a basic model's true energy consumption characteristics. 10 CFR 430.401(k)(1). Likewise, Store It Cold may request that DOE rescind or modify the waiver if Store It Cold discovers an error in the information provided to DOE as part of its petition, determines that the waiver is no longer needed, or for other appropriate reasons. 10 CFR 430.401(k)(2).

(6) Granting of this waiver does not release Store It Cold from the certification requirements set forth at 10 CFR part 429.

Signed in Washington, DC, on July 30, 2019.

Alexander N. Fitzsimmons,

Acting Deputy Assistant Secretary for Energy Efficiency Energy Efficiency and Renewable Energy.

[FR Doc. 2019–17082 Filed 8–8–19; 8:45 am]

BILLING CODE 6450–01–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: ER19–2065–001.

Applicants: Midcontinent Independent System Operator, Inc. Ameren Illinois Company.

Description: Tariff Amendment: 2019–08–05 SA 2026 Ameren-Hannibal Substitute 2nd Rev WDS to be effective 12/31/9998.

Filed Date: 8/5/19.

Accession Number: 20190805–5053.

Comments Due: 5 p.m. ET 8/26/19.

Docket Numbers: ER19–2252–001.

Applicants: Stanton Energy Reliability Center, LLC.

Description: Tariff Amendment: SERC Amendment to Application for Market Based Rate Authorization to be effective 8/25/2019.

Filed Date: 8/5/19.

Accession Number: 20190805–5017.

Comments Due: 5 p.m. ET 8/26/19.

Docket Numbers: ER19–2529–000.

Applicants: Black Hills Wyoming, LLC.

Description: § 205(d) Rate Filing: Request for Authorization of Affiliate Transactions and Revisions to MBR Tariff to be effective 10/2/2019.

Filed Date: 8/2/19.

Accession Number: 20190802–5157.

Comments Due: 5 p.m. ET 8/23/19.

Docket Numbers: ER19–2531–000.

Applicants: DesertLink, LLC.

Description: § 205(d) Rate Filing: Amendments to DesertLinks Formula Rate Protocols and Template to be effective 8/2/2019.

Filed Date: 8/5/19.

Accession Number: 20190805–5038.

Comments Due: 5 p.m. ET 8/26/19.

Docket Numbers: ER19–2532–000.

Applicants: Duke Energy Progress, LLC.

Description: Tariff Cancellation: DEP-Notice of Cancellation of CIAC w/ Fayetteville to be effective 10/5/2019.

Filed Date: 8/5/19.

Accession Number: 20190805–5052.

Comments Due: 5 p.m. ET 8/26/19.

Docket Numbers: ER19–2533–000.

Applicants: Vermont Transco LLC.

Description: Notice of Cancellation of executed Large Generator Interconnection Service Agreement No. 17 of Vermont Transco LLC.

Filed Date: 8/5/19.

Accession Number: 20190805–5068.

Comments Due: 5 p.m. ET 8/26/19.

Take notice that the Commission received the following qualifying facility filings:

Docket Numbers: QF19–1373–000; QF19–1374–000; QF19–1375–000; QF19–1376–000; QF19–1377–000; QF19–1378–000; QF19–1379–000; QF19–1380–000; QF19–1381–000; QF19–1382–000; QF19–1383–000; QF19–1384–000; QF19–1386–000; QF19–1387–000; QF19–1388–000; QF19–1389–000; QF19–1390–000; QF19–1391–000.

Applicants: WGL Energy Systems, Inc.

Description: Refund Report of WGL Energy Systems, Inc., et al.

Filed Date: 8/5/19.

Accession Number: 20190805–5031.

Comments Due: 5 p.m. ET 8/26/19.

Take notice that the Commission received the following PURPA 210(m)(3) filings:

Docket Numbers: QM19–3–000.

Applicants: Prairie Power, Inc.

Description: Supplement to July 11, 2019 Application of Prairie Power, Inc. to Terminate Mandatory PURPA Purchase Obligation.

Filed Date: 7/30/19.

Accession Number: 20190730–5128.

Comments Due: 5 p.m. ET 8/27/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests,

service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 5, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–17045 Filed 8–8–19; 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 Number: PR19–69–000.
Applicants: Cypress Gas Pipeline, LLC.
Description: Tariff filing per 284.123(e)+(g)/: Notice of Cancellation to be effective 10/1/2019.
Filed Date: 8/2/19.
Accession Number: 201908025032.
Comments Due: 5 p.m. ET 8/23/19.
284.123(g) Protests Due: 5 p.m. ET 9/30/19.

Docket Numbers: RP19–343–000.
Applicants: Texas Eastern Transmission, LP.
Description: Report Filing: TETLP Refund Report—RP19–343–000.
Filed Date: 7/19/19.
Accession Number: 20190719–5000.
Comments Due: 5 p.m. ET 8/7/19.

Docket Numbers: RP10–996–000.
Applicants: Dominion Cove Point LNG, LP.
Description: Report Filing: DECP—2019 Report of Operational Sales and Purchases of Gas.
Filed Date: 7/31/19.
Accession Number: 20190731–5148.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1432–000.
Applicants: Golden Pass Pipeline LLC.
Description: § 4(d) Rate Filing: GPPL Tariff Clean up 2019 07 to be effective 9/1/2019.
Filed Date: 8/1/19.
Accession Number: 20190801–5000.
Comments Due: 5 p.m. ET 8/13/19.

Docket Numbers: RP19–1433–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rate—MC Global to Cima Energy 8958810 to be effective 8/1/2019.
Filed Date: 8/1/19.
Accession Number: 20190801–5001.
Comments Due: 5 p.m. ET 8/13/19.

Docket Numbers: RP19–1434–000.
Applicants: Equitrans, L.P.
Description: § 4(d) Rate Filing: Negotiated Capacity Release Agreements—8/1/2019 to be effective 8/1/2019.
Filed Date: 8/1/19.
Accession Number: 20190801–5041.
Comments Due: 5 p.m. ET 8/13/19.

Docket Numbers: RP19–1435–000.
Applicants: Florida Gas Transmission Company, LLC.
Description: § 4(d) Rate Filing: Reticulated Area and Definition to be effective 9/1/2019.
Filed Date: 8/1/19.
Accession Number: 20190801–5048.
Comments Due: 5 p.m. ET 8/13/19.

Docket Numbers: RP19–1436–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Osaka 46429 to Spotlight 51422) to be effective 8/1/2019.
Filed Date: 8/1/19.
Accession Number: 20190801–5078.
Comments Due: 5 p.m. ET 8/13/19.

Docket Numbers: RP19–1437–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Constellation 51333 to Exelon 51418) to be effective 8/1/2019.
Filed Date: 8/1/19.
Accession Number: 20190801–5079.
Comments Due: 5 p.m. ET 8/13/19.

Docket Numbers: RP19–1438–000.
Applicants: RH energytrans, LLC.
Description: Compliance filing RH energytrans, LLC—Filing of Negotiated Rate Agrmt, Dkt No CP18–6 Compliance to be effective 9/1/2019.
Filed Date: 8/1/19.
Accession Number: 20190801–5089.
Comments Due: 5 p.m. ET 8/13/19.

Docket Numbers: RP19–1439–000.
Applicants: Columbia Gas Transmission, LLC.
Description: § 4(d) Rate Filing: TCO Citadel Neg Rate Agreement Filing to be effective 8/1/2019.
Filed Date: 8/1/19.
Accession Number: 20190801–5097.
Comments Due: 5 p.m. ET 8/13/19.

Docket Numbers: RP19–1440–000.
Applicants: Columbia Gulf Transmission, LLC.
Description: § 4(d) Rate Filing: CGT Citadel Negotiated Rate Agreement to be effective 8/1/2019.
Filed Date: 8/1/19.
Accession Number: 20190801–5098.
Comments Due: 5 p.m. ET 8/13/19.

Docket Numbers: RP19–1441–000.
Applicants: Columbia Gas Transmission, LLC.
Description: § 4(d) Rate Filing: TCO Essential Power Neg Rate Amendment to be effective 8/1/2019.
Filed Date: 8/1/19.
Accession Number: 20190801–5099.
Comments Due: 5 p.m. ET 8/13/19.

Docket Numbers: RP19–1442–000.
Applicants: ANR Pipeline Company.
Description: § 4(d) Rate Filing: ANR Exelon Negotiated Rate Amendments to be effective 8/1/2019.
Filed Date: 8/1/19.
Accession Number: 20190801–5100.
Comments Due: 5 p.m. ET 8/13/19.

Docket Numbers: RP19–1443–000.
Applicants: Kern River Gas Transmission Company.
Description: § 4(d) Rate Filing: 2019 Housekeeping Original Volume 1A to be effective 9/1/2019.
Filed Date: 8/1/19.
Accession Number: 20190801–5104.
Comments Due: 5 p.m. ET 8/13/19.

Docket Numbers: RP19–1444–000.
Applicants: Texas Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Permanent Release CNE 35007 to Exelon 38117 to be effective 8/1/2019.
Filed Date: 8/1/19.
Accession Number: 20190801–5105.
Comments Due: 5 p.m. ET 8/13/19.

Docket Numbers: RP19–1445–000.
Applicants: Rockies Express Pipeline LLC.
Description: § 4(d) Rate Filing: Neg Rate 2019–08–01 Encana to be effective 8/1/2019.
Filed Date: 8/1/19.
Accession Number: 20190801–5107.
Comments Due: 5 p.m. ET 8/13/19.

Docket Numbers: RP19–1446–000.
Applicants: Equitrans, L.P.
Description: § 4(d) Rate Filing: Negotiated Rate Service Agreement—Revised Peoples EFT Agreement to be effective 8/1/2019.
Filed Date: 8/1/19.
Accession Number: 20190801–5110.
Comments Due: 5 p.m. ET 8/13/19.

Docket Numbers: RP19–1447–000.
Applicants: Enable Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate Filing—August 2019 to be effective 8/1/2019.
Filed Date: 8/1/19.
Accession Number: 20190801–5122.
Comments Due: 5 p.m. ET 8/13/19.

Docket Numbers: RP19–1448–000.
Applicants: Dominion Energy Transmission, Inc.
Description: § 4(d) Rate Filing: DETI—August 1, 2019 Nonconforming Service Agreements to be effective 9/1/2019.

Filed Date: 8/1/19.

Accession Number: 20190801–5126.

Comments Due: 5 p.m. ET 8/13/19.

Docket Numbers: RP19–1449–000.

Applicants: Colorado Interstate Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Non Conforming Negotiated Rate Agreement Filing (RMM) to be effective 9/1/2019.

Filed Date: 8/1/19.

Accession Number: 20190801–5127.

Comments Due: 5 p.m. ET 8/13/19.

Docket Numbers: RP19–1450–000.

Applicants: Dominion Energy Cove Point LNG, LP.

Description: § 4(d) Rate Filing: DECP—Eastern Market Access Project (CP17–15) to be effective 9/1/2019.

Filed Date: 8/1/19.

Accession Number: 20190801–5141.

Comments Due: 5 p.m. ET 8/13/19.

Docket Numbers: RP19–1451–000.

Applicants: Equitrans, L.P.

Description: § 4(d) Rate Filing: Negotiated Retainage Updates to be effective 9/1/2019.

Filed Date: 8/1/19.

Accession Number: 20190801–5149.

Comments Due: 5 p.m. ET 8/13/19.

Docket Numbers: RP19–445–000.

Applicants: Iroquois Gas Transmission System, L.P.

Description: Report Filing: 080119 Refund Report, RP19–445 Settlement.

Filed Date: 8/1/19.

Accession Number: 20190801–5080.

Comments Due: 5 p.m. ET 8/13/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified date(s). Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 5, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–17043 Filed 8–8–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP19–492–000]

Columbia Gas Transmission, LLC; Notice of Request Under Blanket Authorization

Take notice that on July 25, 2019, Columbia Gas Transmission, LLC (Columbia), 700 Louisiana Street, Houston, Texas 77002–2700, filed in the above referenced docket, a prior notice request pursuant to sections 157.205 and 157.216 of the Commission's regulations under the Natural Gas Act (NGA) and Columbia's blanket certificate issued in Docket No. CP83–76–000, for authorization to abandon three injection/withdrawal wells number 8972, 9029, 9083 and a total of 1,854 feet of associated 4.5-inch-diameter pipelines and appurtenances, all located in its Laurel Storage Field in Hocking County, Ohio. Columbia states that the proposed abandonment will not affect Columbia's ability to continue to maintain the current quality of service to its storage customers. Furthermore, there will be no change to the existing boundary, total inventory, reservoir pressure, reservoir and buffer boundaries, or the certificated capacity of the Laurel Storage Field as a result of this abandonment, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

The filing may also be viewed on the web at *http://www.ferc.gov* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or TTY, contact (202) 502–8659.

Any questions regarding this prior notice request should be directed to Sorana Linder, Director, Modernization & Certificates, Columbia Gas Transmission, LLC, 700 Louisiana Street, Suite 700, Houston, Texas 77002–2700, or call (832) 320–5209, or by email *sorana_linder@transcanada.com.*

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's EA.

Any person may, within 60 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention. Any person filing to intervene or the Commission's staff may, pursuant to section 157.205 of the Commission's Regulations under the NGA (18 CFR 157.205) file a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the internet in lieu of paper. See 18 CFR 385.2001(a) (1) (iii) and the instructions on the Commission's website (*http://www.ferc.gov*) under the ''e-Filing'' link.

Dated: August 5, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–17044 Filed 8–8–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. Er19–2527–000]

Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization; Prevailing Wind Park, LLC

This is a supplemental notice in the above-referenced Prevailing Wind Park, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of

future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 26, 2019.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also 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.

Dated: August 5, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–17042 Filed 8–8–19; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9046–2]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa/.*

Weekly receipt of Environmental Impact Statements

Filed 07/29/2019 Through 08/02/2019 Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20190179, Final, USFWS, CA, Delta Research Station Project: Estuarine Research Station and Fish Technology Center, Review Period Ends: 09/09/2019, Contact: Robert Clarke 916–414–6581

EIS No. 20190180, Draft, BLM, NM, Borderlands Wind Project Draft Environmental Impact Statement and Resource Management Plan Amendment, Comment Period Ends: 11/07/2019, Contact: James Stobaugh 775–861–6478

EIS No. 20190181, Draft, NRC, PA, Generic Environmental Impact Statement for License Renewal of Nuclear Plants, Supplement 10, Second Renewal, Regarding Subsequent License Renewal for Peach Bottom Atomic Power Station Units 2 and 3, Comment Period Ends: 09/23/2019, Contact: David Drucker 301–415–6223

EIS No. 20190182, Draft, USFS, NM, Carson National Forest Revision of Land Management Plan, Comment Period Ends: 11/07/2019, Contact: Peter Rich 575–758–6277

EIS No. 20190183, Draft, USAF, WI, United States Air Force F–35A Operational Beddown Air National Guard, Comment Period Ends: 09/27/2019, Contact: Ramon Ortiz 240–612–7042

EIS No. 20190184, Draft, USFS, NM, Cibola National Forest Draft Land Management Plan Draft Environmental Impact Statement, Comment Period Ends: 11/07/2019, Contact: Sarah Browne 505–346–3812

EIS No. 20190185, Draft, USFS, NM, Santa Fe National Forest Land Management Plan Revision, Comment Period Ends: 11/07/2019, Contact: Jennifer Cramer 505–438–5449

EIS No. 20190186, Draft, BIA, NV, Eagle Shadow Mountain Solar Project, Comment Period Ends: 09/23/2019, Contact: Chip Lewis 602–379–6750

EIS No. 20190187, Draft, NPS, CA, Point Reyes National Seashore General Management Plan Amendment, Comment Period Ends: 09/23/2019, Contact: Cicely Muldoon 415–464–5101

EIS No. 20190188, Final, USFS, CA, San Gabriel River Confluence With Cattle Canyon Improvements Project, Review Period Ends: 09/09/2019, Contact: Jeremy Sugden 626–335–1251 x222

EIS No. 20190189, Draft, USFS, AZ, Resolution Copper Project and Land Exchange, Comment Period Ends: 11/07/2019, Contact: Mary C. Rasmussen 602–225–2500

Amended Notice

EIS No. 20190170, Draft, BR, CA, San Luis Low Point Improvement Project Draft Environmental Impact Statement/Environmental Impact Report, Comment Period Ends: 09/24/2019, Contact: Nicole S. Johnson 916–978–5085

Revision to FR Notice Published 07/26/2019; Extending the Comment Period from 09/09/2019 to 09/24/2019.

Dated: August 5, 2019.

Candi Schaedle,

Acting Director, Office of Federal Activities.

[FR Doc. 2019–17048 Filed 8–8–19; 8:45 a.m.]

BILLING CODE 6560–50–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 September 9, 2019.

A. Federal Reserve Bank of Minneapolis (Mark A. Rauzi, Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Bancommunity Service Corporation, St. Peter, Minnesota*; to acquire 100 percent of the voting shares of State Bank of Belle Plaine, Belle Plaine, Minnesota.

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. *Simmons First National Corporation, Pine Bluff, Arkansas*; to merge with The Landrum Company, and thereby indirectly acquire Landmark Bank, both of Columbia, Missouri.

C. Federal Reserve Bank of Atlanta (Kathryn Haney, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *West Florida Bank Corporation, Palm Harbor, Florida*; to become a bank holding company by acquiring 100 percent of the voting shares of Flagship Community Bank, Clearwater, Florida.

Board of Governors of the Federal Reserve System, August 6, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019–17107 Filed 8–8–19; 8:45 am]

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FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than August 23, 2019.

A. Federal Reserve Bank of Atlanta (Kathryn Haney, Assistant Vice President) 1000 Peachtree Street, NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *Anna Laurie Bryant McKibbens, Eutaw, Alabama; Mae Martin Bryant Murray, Mobile, Alabama; and Stella Gray Bryant Sykes, Madison, Mississippi;* as a group to acquire voting shares of First Dozier Bancshares, Inc., and thereby indirectly acquire shares of First National Bank of Dozier, both of Dozier, Alabama.

B. Federal Reserve Bank of Philadelphia (William Spaniel, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105–1521. Comments can also be sent electronically to *Comments.applications@phil.frb.org:*

1. *Andrew S. Samuel, Jane Samuel, both of Dillsburg, Pennsylvania; individually and as a group acting in concert with Alexandria Hart, Shane Sinclair and Beulha Sigamony, all of Dillsburg, Pennsylvania;* to acquire voting shares of LINKBANCORP, Inc., Camp Hill, Pennsylvania, and thereby indirectly acquire shares of LINKBANK, West Chester, Pennsylvania.

Board of Governors of the Federal Reserve System, August 6, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019–17106 Filed 8–8–19; 8:45 am]

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FEDERAL RESERVE SYSTEM

[Docket No. OP–1670]

Federal Reserve Actions To Support Interbank Settlement of Faster Payments

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice and request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) has determined that the Federal Reserve Banks (Reserve Banks) should develop a new interbank 24x7x365 real-time gross settlement service with integrated clearing functionality to support faster payments in the United States. The new service would support depository institutions' provision of end-to-end faster payment services and would provide infrastructure to promote ubiquitous, safe, and efficient faster payments in the United States. In addition, the Federal Reserve intends to explore expanded hours for the Fedwire® Funds Service and the National Settlement Service, up to 24x7x365, to support a wide range of payment activities, including liquidity management in private-sector real-time gross settlement services for faster payments. Subject to the outcome of additional analysis of relevant operational, risk, and policy considerations, the Board will seek public comment separately on plans to expand hours for the Fedwire Funds Service and the National Settlement Service.

DATES: Comments on the proposed actions must be received on or before November 7, 2019.

ADDRESSES: You may submit comments, identified by Docket No. OP–1670, by any of the following methods:

- Agency website: *http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*
- Email: *regs.comments@federalreserve.gov.* Include docket number in the subject line of the message.
- FAX: (202) 452–3819 or (202) 452–3102.
- Mail: Ann Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments will be made available on the Board's website at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm* as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room 146, 1709 New York Avenue NW, Washington, DC 20006, between 9:00 a.m. and 5:00 p.m. on weekdays.

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Systems; or Gavin Smith, Senior Counsel, Legal Division (202 452–3474), Board of Governors of the Federal Reserve System. For users of Telecommunications Device for the Deaf (TDD), contact (202–263–4869.)

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. payment system faces a critical juncture in its evolution. Advances in technology have created an opportunity for significant improvements to the way individuals and businesses make payments in today's economy. Smartphones, high-speed computing and cloud capabilities, extensive communication networks, and other innovations allow individuals and businesses to send and receive messages, post and consume content online, search for and obtain information, and conduct myriad other activities almost immediately and at any time. Similarly, today's technology presents a pivotal opportunity for the Federal Reserve and the payment industry to modernize the nation's payment system to establish a safe and efficient foundation for the future.

A. Background

Services to conduct ''faster payments'' have begun to emerge to address shortcomings of traditional payment methods. Faster payments allow individuals and businesses to send and receive payments within seconds at any time of the day, on any day of the year, such that the receiver can use the funds almost instantly.[1] Faster payment services are growing in popularity, but typically require users to all participate in the same specific service to exchange payments. However, there is broad consensus within the U.S. payment community that, just as immediate services available around the clock have become standard for other everyday activities, faster payment services have the potential to become widely used, resulting in a significant and positive impact on the U.S. economy.

Faster payments can yield real economic benefits beyond speed and convenience. Through faster payments, individuals and businesses can have more flexibility to manage their money and can make time-sensitive payments whenever needed. For a small business, the ability to receive payments immediately may result in better cash flow management. More broadly, faster payments may provide businesses with considerable opportunity to improve efficiency and reduce costs of payments relative to paper checks and other existing payment methods. For individuals, the ability to both send and receive payments more quickly may help alleviate mismatches between the time that incoming funds are received and the time that spending needs to occur. This improved ability to manage their money can enable some individuals to avoid high-cost borrowing and penalties, such as overdraft or late fees.

In light of these potential benefits, an appropriate foundation is essential to support the development of faster payment services that are safe, efficient, and broadly accessible to the public. This foundation involves creating an infrastructure that connects banks across the country, paving the way for innovative faster payment services.[2] This infrastructure would allow individuals and businesses to exchange funds in their accounts almost instantly to make payments for goods, services, or other purposes. A key function of this infrastructure is the movement of information and funds between banks, also known as interbank clearing and settlement.[3]

Since its founding, the Federal Reserve has played a key operational role in the nation's payment system by providing such infrastructure.[4] The importance of this role has been broadly recognized, with independent reviewers concluding that the payment system and its users have benefited over the long run from the Federal Reserve's operational involvement.[5] This key role, given by Congress, stems from the Federal Reserve's unique ability, as the nation's central bank, to provide interbank settlement without introducing liquidity or credit risks.[6] In fulfilling this role, the Reserve Banks operate services, including check, automated clearinghouse (ACH), and funds transfer services, that provide core infrastructure for financial transactions.[7] Throughout its history, the Federal Reserve has provided these services alongside, and in support of, similar services offered by the private sector.

In the past, the Federal Reserve's provision of payment and settlement services has helped to advance fundamental improvements in the nation's payment system.[8] The potential exists today to achieve once again such improvements through upgrades to the payment capabilities of both the Federal Reserve and the private sector. In terms of current Federal Reserve services supporting the U.S. payment system, those services have served the nation's economy well but were not designed to support 24x7x365 real-time retail payments.[9] Advances in technology

[1] Consistent with the concept of a faster payment in this notice, and reflecting improvements to retail payment systems around the world, the Committee on Payments and Market Infrastructures (CPMI) has defined a ''fast payment'' as ''a payment in which the transmission of the payment message and the availability of 'final' funds to the payee occur in real time or near-real time on as near to a 24-hour and seven-day (24/7) basis as possible.'' Final funds are funds received such that the receiver has unconditional and irrevocable access to them, meaning that the receiver can use the funds without the risk that they will be recalled. *See* Committee on Payments and Market Infrastructures, Bank for International Settlements, ''Fast payments—Enhancing the speed and availability of retail payments,'' (November 2016). Available at *https://www.bis.org/cpmi/publ/d154.pdf.*

[2] Throughout this notice, the term ''bank'' will be used to refer to any type of depository institution. Depository institutions include commercial banks, savings banks, savings and loan associations, and credit unions.

[3] Three types of services are typically required to complete a payment between two individual or business bank accounts: End-user services, clearing services, and interbank settlement services. End-user services support the exchange of information between a bank and its customer (that is, an individual or business). Clearing services directly or indirectly support the exchange of payment information between banks. Interbank settlement services discharge financial obligations between and among banks arising from payments by adjusting balances in settlement accounts. Depending on the arrangement, some or all of these levels can be provided by distinct entities or integrated in a single entity.

[4] Additional information about the Federal Reserve's role in the payment system is available in ''The Federal Reserve System Purposes & Functions: 6. Fostering Payment and Settlement System Safety and Efficiency,'' (October 2016). Available at *https://www.federalreserve.gov/aboutthefed/pf.htm.*

[5] *See e.g.,* U.S. Gov't Accountability Off., GAO–16–614, ''Federal Reserve's Competition with Other Providers Benefits Customers, but Additional Reviews Could Increase Assurance of Cost Accuracy'' (2016). Available at *https://www.gao.gov/products/GAO-16-614.*

[6] In particular, settlement through the Federal Reserve does not involve liquidity or credit risk with respect to the Federal Reserve as the settlement institution. *See* Committee on Payment and Settlement Systems, Bank for International Settlements, ''The Role of Central Bank Money in Payment Systems'' (August 2003). Available at *https://www.bis.org/cpmi/publ/d55.pdf.*

[7] As authorized by the Federal Reserve Act, these payment and settlement services involve transferring funds between and among accounts held at the Reserve Banks. Specific services offered by the Reserve Banks include the Fedwire Funds Service, the National Settlement Service, and FedACH® services. Throughout this notice, these services operated by the Reserve Banks will generally be referred to as Federal Reserve services.

[8] Improvements achieved through these operational roles include facilitating efficient nationwide clearing of checks, supporting the development of the ACH system, encouraging the nation's transition to a virtually all-electronic check-processing environment, and establishing a real-time interbank funds transfer system for wholesale payments.

[9] Retail payments typically involve lower-value transfers, such as those among individuals or between an individual and a business, that yield a large number of payments. *See* Committee on

provide the ability to develop Federal Reserve services with the operating hours, processing capacity, and overall functionality needed to support 24x7x365 real-time capabilities for the payment system. Similar considerations have led central banks in various countries to develop improved infrastructure to support faster payments.[10]

The Board views support for faster payments as requiring modernization of, and upgrades to, Federal Reserve services alongside broader modernization of the payment industry as a whole. Beginning in 2013, the Federal Reserve launched the Strategies for Improving the U.S. Payment System (SIPS) initiative, a collaborative effort with stakeholders to foster improvements to the nation's payment system. As part of the SIPS initiative, the Federal Reserve convened the Faster Payments Task Force (FPTF), comprising a wide range of industry stakeholders, to identify and evaluate alternative approaches for implementing safe and ubiquitous faster payment capabilities in the United States.

The FPTF published in 2017 a set of consensus recommendations focused on actions to support improvements to the nation's payment system.[11] These recommendations were intended to help achieve the FPTF's vision of ubiquitous faster payment capabilities in the United States that would allow any end user (that is, an individual or business) to safely, efficiently, and seamlessly send a faster payment to any other end user, no matter which banks or payment services they use. Among the FPTF's consensus recommendations were requests for the Federal Reserve (i) to develop a 24x7x365 settlement service to support faster payments and (ii) to explore and assess the need for other Federal Reserve operational role(s) in faster payments. The U.S. Treasury subsequently recommended that ''the Federal Reserve move quickly to facilitate a faster retail payments system, such as through the development of a real-time settlement service, that would also allow for more efficient and ubiquitous access to innovative payment capabilities.''[12]

Following publication of the FPTF's final report, the Federal Reserve began to pursue the FPTF's recommendations in considering settlement and broader operational support to facilitate the advancement of faster payments in the United States.[13] In addition, the Board approved in 2017 final guidelines for evaluating requests for joint accounts at the Reserve Banks intended to facilitate settlement between and among banks participating in private-sector payment systems for faster payments.[14] The impetus for allowing broader use of joint accounts was to facilitate private-sector developments in faster payments. In an arrangement using a joint account, real-time settlement occurs on an internal ledger maintained by a private-sector operator, supported by funds that are held in an account at a Reserve Bank for the joint benefit of the service's participants. To support settlement through such a service, each participant bank ensures sufficient funding in the joint account to cover its payment obligations on a 24x7x365 basis. Without the Federal Reserve's actions related to joint accounts, other providers alone would be unable to provide real-time interbank settlement services for faster payments supported by a joint account at a Reserve Bank.

B. 2018 Federal Register Notice on Potential Federal Reserve Actions

In November 2018, the Board published a **Federal Register** notice (2018 Notice) seeking public comment on potential actions that the Federal Reserve could take to advance the development of faster payments and support the modernization of payment services in the United States.[15] In considering the goal of ubiquitous, safe, and efficient faster payments, the Board proposed that a real-time gross settlement (RTGS) infrastructure would provide the safest and most efficient method for interbank settlement of faster payments and, therefore, would be the most appropriate strategic foundation for faster payments in the United States.[16] Further, the Board expressed the view that the private sector alone may face significant challenges in providing equitable access to an RTGS infrastructure with nationwide reach, which in turn would jeopardize the development of ubiquitous, safe, and efficient end-user faster payment services.[17]

The Board specifically discussed two potential services that could be developed by the Reserve Banks: (i) An interbank 24x7x365 RTGS service with integrated clearing functionality to support faster payments and (ii) a liquidity management tool that would enable transfers between accounts held at the Reserve Banks on a 24x7x365 basis to support services for real-time interbank settlement of faster payments.

Payments and Market Infrastructures, Bank for International Settlements, ''A Glossary of Terms Used in Payments and Settlement Systems,'' (October 2016). Available at *https://www.bis.org/cpmi/publ/d00b.htm.*

[10] For a discussion of global developments related to faster payments, see ''Fast payments—Enhancing the speed and availability of retail payments,'' *supra* note 1.

[11] *See* Faster Payments Task Force, ''Final Report Part Two: A Call to Action,'' (July 2017). Available at *https://fedpaymentsimprovement.org/wp-content/uploads/faster-payments-task-force-final-report-part-two.pdf.*

[12] The U.S. Treasury also noted that ''[i]n particular, smaller financial institutions, like community banks and credit unions, should also have the ability to access the most-innovative technologies and payment services. While Treasury believes that a payment system led by the private sector has the potential to be at the forefront of innovation and allow for the most advanced payments system in the world, back-end Federal Reserve payment services must also be appropriately enhanced to enable innovations.'' U.S. Treasury, ''A Financial System That Creates Economic Opportunity: Nonbank Financials, Fintech, and Innovation,'' (July 2018) at 156. Available at *https://home.treasury.gov/sites/default/files/2018–07/A-Financial-System-that-Creates-Economic-Opportunities-Nonbank-Financi.pdf.*

[13] *See* The Federal Reserve System, ''Federal Reserve Next Steps in the Payments Improvement Journey,'' (September 6, 2017). Available at *https://fedpaymentsimprovement.org/wp-content/uploads/next-step-payments-journey.pdf.*

[14] Board of Governors of the Federal Reserve System, ''Guidelines for Evaluating Joint Account Requests,'' (Issued 2017). Available at *https://www.federalreserve.gov/paymentsystems/joint_requests.htm.* In 2016, Federal Reserve staff received a request from a private-sector service provider to open a new joint account for that organization's proposed faster payment system. The use of a joint account at a Reserve Bank to support settlement mitigates certain risks by reproducing, as closely as possible, the risk-free nature of settlement in central bank money.

[15] ''Potential Federal Reserve Actions To Support Interbank Settlement of Faster Payments, Request for Comments,'' 83 FR 57351 (Nov. 15, 2018). Available at *https://www.federalregister.gov/d/2018-24667.* The comment period ended on December 14, 2018.

[16] RTGS involves interbank settlement occurring in real time on a payment-by-payment basis. As described in the 2018 Notice, RTGS for faster payments implies that settlement occurs prior to the provision of final funds to the receiver with settlement of individual payments possible at any time, on any day. In the 2018 Notice, the Board noted that certain end-user services currently rely on deferred interbank settlement to complete a payment. In deferred settlement arrangements, interbank settlement information is collected, stored, and sometimes netted before interbank settlement occurs. Because faster payments involve the immediate provision of final funds to the receiver, deferred interbank settlement of faster payments inherently involves interbank settlement risk. Although faster payment systems that rely on deferred settlement can incorporate certain measures to mitigate this risk, those measures may be complex and costly to implement. By contrast, RTGS structurally removes interbank settlement risk because the receiver only receives final funds after interbank settlement has occurred.

[17] Throughout this notice, the terms ''nationwide reach'' and ''nationwide scope'' will be used to refer to a payment service or infrastructure that is accessible to virtually all banks nationwide. In this context, the term ''nationwide'' reflects various dimensions of accessibility, including geography and institution size and type.

At present, one RTGS service for faster payments, operated since November 2017 by a private-sector entity, exists in the United States. Section III presents a full analysis of the landscape of RTGS services for faster payments in the United States.

The Board explained that a Federal Reserve RTGS service for faster payments, alongside private-sector RTGS services, would provide the infrastructure needed to achieve ubiquitous, safe, and efficient faster payments in the United States. Other parties, such as banks, payment processors, and providers of payment services, could develop end-user and auxiliary services that build upon the core functionality of an interbank settlement service provided by the Federal Reserve. The Board further explained that a liquidity management tool, in turn, could help alleviate liquidity management issues for banks engaged in RTGS-based faster payments. In particular, such a tool would enable movement of funds between accounts at the Reserve Banks during hours when traditional payment and settlement services are currently not open to allow liquidity to be moved, when needed, to an account or accounts used to support real-time settlement of faster payments. The 2018 Notice proposed that the tool could be provided by expanding operating hours of current Federal Reserve services or through a new service.

In the 2018 Notice, the Board requested comment on the appropriateness of real-time gross settlement as the strategic foundation for faster payments in the United States and the public benefits, implications, and challenges of the Federal Reserve taking either, both, or neither of the potential actions. The Board also sought feedback on other specific topics to inform these potential actions, such as potential demand for faster payment services and adjustments that the payment industry would need to make in a 24x7x365 real-time settlement environment.

C. Planned Actions

1. The FedNow℠ Service

After considering the comments received in response to the 2018 Notice and analyzing the implications of the potential actions, the Board has determined that the Reserve Banks should develop a new interbank 24x7x365 real-time gross settlement service with integrated clearing functionality, called the FedNow Service, to support faster payments. The Board's determination is based on the public benefits that the service would provide and the Board's assessment that such a service would meet the requirements of the Depository Institutions Deregulation and Monetary Control Act of 1980 (MCA), as well as the Board's criteria for new or enhanced Federal Reserve payment services.[18]

The planned service would conduct real-time, payment-by-payment, final settlement of interbank obligations through debits and credits to banks' balances in accounts at the Reserve Banks. The service would incorporate clearing functionality, allowing banks, in the process of settling each payment, to exchange information needed to make debits and credits to the accounts of their customers. The service's functionality would support banks' (or their agents') provision of end-to-end faster payments to their customers.

The Federal Reserve's provision of the FedNow Service would provide core infrastructure to promote ubiquitous, safe, and efficient faster payments in the United States. Historical experience with the development of other payment systems in the United States indicates that other providers alone will face significant challenges establishing such infrastructure, in part because of the complexity of the nation's banking system.[19] A landscape where the Federal Reserve operates a 24x7x365 RTGS service alongside private-sector services, which aligns with most payment systems in the United States, is most likely to create an RTGS infrastructure with nationwide reach for faster payment services.

Significantly, the Board expects that the recently established private-sector RTGS service is likely to remain the sole private-sector provider of RTGS services for faster payments in the United States. Such an outcome would have significant implications for the Board's policy objectives regarding the accessibility, safety, and efficiency of the nation's payment system.

Based on its analysis and comments received in response to the 2018 Notice, the Board expects that a single private-sector provider of such services is unlikely to connect to the thousands of small and midsize banks necessary to yield nationwide reach, even in the long term. No traditional payment system, including checks, ACH, funds transfers, or payment cards, has ever achieved nationwide reach through a single private-sector provider. The Federal Reserve, however, has long-standing relationships with, and has built a nationwide infrastructure to provide service to, more than 10,000 depository institutions (or their agents) across the country, which would provide a key channel to reach thousands of smaller institutions in the United States that might otherwise not have access to an RTGS infrastructure for faster payments.

Additionally, a single provider of RTGS services for faster payments without competition is likely to create undesirable outcomes for pricing, innovation, service quality, and reach. Conversely, provision of the FedNow Service alongside private-sector RTGS service would give banks the option of choosing a service or connecting to more than one service, a choice they have today for all existing payment services. Indeed, Federal Reserve and private-sector payment services operating alongside one another would be consistent with the structure of other existing payment systems. The presence of multiple RTGS services for faster payments could yield efficiency benefits such as lower prices, higher service quality, and increased innovation.

A market outcome with a single RTGS service for faster payments would also create a single point of failure. An additional RTGS service for faster payments would promote resiliency through redundancy, a common solution in many retail payment systems. Serving an operational role in the payment system also allows the Federal Reserve to provide stability and support to the banking system and the broader economy in normal times and in times of stress.

Finally, the Federal Reserve does not have plenary regulatory or supervisory authority over the U.S. payment system and instead has traditionally influenced retail payment markets through its role as an operator.[20] Therefore, as has been the case with other retail payment systems, the Federal Reserve's operational role as a provider of interbank settlement is the most effective approach to improve the

[18] ''Depository Institutions Deregulation and Monetary Control Act of 1980,'' Public Law 96–221 (Mar. 31, 1980), available at *https://fraser.stlouisfed.org/title/1032;* Board of Governors of the Federal Reserve System, ''The Federal Reserve in the Payments System,'' (Issued 1984; revised 1990). Available at *https://www.federalreserve.gov/paymentsystems/pfs_frpaysys.htm.*

[19] The United States has more than 10,000 depository institutions that vary greatly in terms of size, level of technical capabilities, operational practices, and customers and communities served.

[20] To the extent that the current private-sector RTGS service for faster payments could be considered subject to the Bank Service Company Act (BSCA) by providing services to federally supervised depository institutions, the Board and other federal banking agencies would have authority to examine the performance of those services as if the depository institution were performing the service itself on its own premises. 12 U.S.C. 1867. The BSCA, however, does not grant enforcement authority to the Board or other federal banking agencies over the third party service providers. In addition, that authority does not appear applicable to public benefit, competitive equity, effectiveness, or scope—key criteria that the Board considers with regard to Federal Reserve payment services.

prospects of ubiquitous, safe, and efficient faster payments in the United States. Serving such an operational role would be consistent with the Federal Reserve's historical role as a provider of payment services alongside the private sector.

Recognizing that time-to-market is an important consideration for industry participants related to faster payment services, the Federal Reserve is committed to launching the FedNow Service as soon as practicably possible. Pending engagement with the industry, the Board anticipates the FedNow Service will be available in 2023 or 2024. However, the Board believes that achievement of true nationwide reach, as opposed to initial availability of a service, is a critical measure of success for faster payments. The Board expects that it will take longer for any service, including the FedNow Service or a private-sector service, to achieve nationwide reach regardless of when the service is initially available. The Federal Reserve will engage quickly with industry participants to gather input for finalizing the initial design and features of the service. Once specific design and features of the FedNow Service have been finalized, the Board will publish a final service description in a subsequent **Federal Register** notice, with additional information provided through existing Reserve Bank communication channels.

2. Expanded Operating Hours for Current Services

The Board has further determined that the Federal Reserve should explore the expansion of hours for the Fedwire Funds Service and the National Settlement Service (NSS), up to 24x7x365, subject to additional analysis of relevant operational, risk, and policy considerations. The Board believes that expanded hours for the Fedwire Funds Service and NSS would be the most effective way to provide the liquidity management functionality described in the 2018 Notice and could provide additional benefits to financial markets broadly, beyond support for faster payments. Subject to the outcome of analyzing the relevant operational, risk, and policy considerations, the Board will seek public comment separately on plans to expand hours for the Fedwire Funds Service and NSS.

D. Organization of This Notice

This notice is organized in two parts. Part One contains a high-level discussion of the comments received by the Board in response to the 2018 Notice (Section II), an assessment of the planned FedNow Service pursuant to the requirements of the MCA and the Board's criteria for new services and major service enhancements (Section III), and a discussion of potential benefits of expanded service hours for the Fedwire Funds Service and NSS (Section IV).

Part Two contains a service description of the planned FedNow Service, outlining the proposed features and functionality (Section V) and the Board's initial competitive impact analysis of the service (Section VI). The Board is seeking public comment on all aspects of this service.

Part One

II. Summary of Comments

The Board received 405 comment letters in response to the 2018 Notice.[21] Several comment letters were signed by multiple parties, bringing the total number of entities responding to the 2018 Notice to 812.[22] Comments were submitted by a wide variety of stakeholders in the U.S. payment system corresponding to the following segments: small and midsize banks, large banks, individuals, consumer organizations, merchants, service providers, private-sector operators, fintech companies, trade organizations, and other interested parties.[23] Overall, banks were the largest group of respondents, with small and midsize banks comprising approximately 60 percent of the total comments—the largest individual segment—and representing institutions from 34 states. Trade organizations submitted letters representing several commenter segments, including small and midsize banks, large banks, merchants, fintech companies, and service providers. Trade organization comments often aligned with those submitted individually by their members. However, some trade organization comments presented varied opinions based on disparate views within their membership, such as contrasting views among banks of different sizes.

The following subsections provide a summary of general themes from comments received in response to the 2018 Notice. A detailed discussion of specific themes raised by the commenters can be found in Sections III, IV, and V.[24]

A. Faster Payments

Commenters provided feedback on topics broadly related to faster payments, in addition to the specific questions posed by the Board. A number of commenters noted that faster payments are likely to become a significant part of the nation's payment system in the future. Some commenters argued that the United States is lagging behind other nations with respect to payment innovation, noting that several countries have already implemented faster payment services. Other commenters, particularly small and midsize banks, noted that customer expectations are shifting towards the real-time capabilities of faster payments and that the ability to implement faster payment services for customers will affect the long-term viability of small and midsize banks. Several commenters also argued that widespread adoption of faster payments could improve financial inclusion, in addition to helping reduce fees that lower income households often face, such as overdraft and late fees.

Approximately 90 commenters, from most commenter segments, addressed topics related to demand for faster payments in the United States, often focusing on whether demand would be sufficient to support the Federal Reserve's development of a 24x7x365 RTGS service.[25] More than 70 of these commenters identified potential sources for such demand, with most expecting the greatest initial demand to come from low-dollar person-to-person payments

[21] The Board also received over 150 additional comment letters that suggested the Board should select a specific service or business as the provider of Federal Reserve services. The Board considered these comments to be outside the scope of its request for comment.

[22] Many of the comment letters signed by multiple parties represented small and midsize banks. The Board considered comment letters signed by multiple parties as a single response for the purposes of this notice, but the additional signatures are noteworthy in evaluating the commenters' perspectives and overall industry engagement on the Board's request for comment.

[23] ''Banks'' include any type of depository institution, such as commercial banks, savings banks, savings and loan associations, and credit unions. ''Service providers'' are entities, such as core payment processors, that provide payment services, processing, or operational and technical support to financial institutions. ''Private-sector operators'' are entities that operate payment systems, such as the operator of the current private-sector RTGS service for faster payments and payment card networks. ''Other interested parties'' include payment standards organizations, a congressional member organization, research and academic groups, and a foreign central bank. For the purposes of this notice, a ''small bank'' is defined as having assets of less than $10 billion and a ''large bank'' is defined as having assets of more than $50 billion, while a ''midsize bank'' is defined as having assets between $10 billion and $50 billion.

[24] In addition to addressing the potential actions raised by the Board, commenters addressed a number of other topics, for example, encouraging the Federal Reserve to review the applicability of existing regulations to faster payments and to continue serving as a leader for industry collaboration.

[25] These commenters included small and midsize banks, large banks, individuals, consumer organizations, merchants, service providers, fintech companies, trade organizations, and other interested parties.

or consumer-to-business payments. Some of these commenters also noted the possibility of demand related to business payments, such as payroll, vendor payments, or benefit disbursement, with some noting that demand could vary across businesses of different sizes or types.

B. Real-Time Gross Settlement of Interbank Obligations

Nearly 150 commenters addressed whether RTGS is the appropriate strategic foundation for interbank settlement of faster payments.[26] Of these, approximately 140 commenters from all segments agreed that RTGS is the appropriate strategic foundation for interbank settlement of faster payments. Approximately 10 commenters, from a number of segments, did not support RTGS as the strategic foundation for interbank settlement of faster payments.[27]

Of those commenters supporting RTGS as the appropriate strategic foundation, many echoed the considerations outlined in the 2018 Notice. Most notably, many of these commenters stated that, by matching the speed of settlement with the speed of payment, RTGS better mitigates interbank settlement risk compared with other settlement arrangements. A number of commenters further stated that the use of RTGS for interbank settlement of faster payments is consistent with industry expectations and aligns with the FPTF's criteria for an effective faster payment solution.[28] Some commenters also noted that RTGS is the approach taken by other countries for interbank settlement of faster payments.

Commenters not supporting RTGS as the appropriate strategic foundation for faster payments argued that deferred settlement can similarly serve as an appropriate foundation for such payments. These commenters stated that, compared with an RTGS arrangement for faster payments, a deferred settlement arrangement has lower costs, is less complex for participating banks, and requires less liquidity.

A few commenters, although supportive of RTGS as the appropriate strategic foundation for faster payments, expressed concern about the need for increased liquidity to conduct immediate settlement and avoid payments failing because of insufficient liquidity. Some commenters also stressed the importance of resiliency to mitigate RTGS service disruptions.

C. Federal Reserve RTGS Service and Liquidity Management Tool

More than 350 commenters addressed whether the Federal Reserve should develop an RTGS service for faster payments.[29] Approximately 320 commenters, from all segments, supported the Federal Reserve developing an RTGS service for faster payments. Approximately 30 commenters, mostly comprising large banks and private-sector operators, including many that have been involved in the recent development of a private-sector RTGS service for faster payments, were not supportive of the Federal Reserve's development of such a service.

Commenters that supported the Federal Reserve's provision of an RTGS service for faster payments pointed to a number of factors underlying their support. Many commenters argued that the Federal Reserve would provide equitable access to banks of all sizes and facilitate nationwide reach for faster payments. Many commenters also discussed the importance of safety for faster payments, stating that the Federal Reserve is a trusted entity with a record of stability during periods of crisis and that a Federal Reserve RTGS service for faster payments could enhance resiliency and reduce risks in the payment system. Some commenters discussed the potential efficiency benefits of such a service, including increased competition, decreased market concentration, lower costs, and greater innovation.

Commenters not supportive of the Federal Reserve developing an RTGS service for faster payments argued that such a service was unnecessary given actions taken by the private sector, including the recent development of a private-sector RTGS service for faster payments. Several of these commenters specifically questioned whether the Federal Reserve could meet the Board's criteria for the provision of new services.[30] Other commenters argued that the Federal Reserve's decision to consider an RTGS service for faster payments is slowing the adoption of faster payments. These commenters argued that some industry participants may decide not to offer faster payments until after a final decision from the Federal Reserve or may further wait until after implementation of a Federal Reserve service, in the event of such a decision.

Approximately 230 commenters addressed whether the Federal Reserve should develop a liquidity management tool.[31] Approximately 225 commenters, from all segments, supported the Federal Reserve developing such a tool. Fewer than 5 commenters were not supportive of the Federal Reserve developing a liquidity management tool.[32]

Commenters that supported development of a liquidity management tool discussed the importance of liquidity management in RTGS services for faster payments. Several commenters indicated that such a tool could help with managing liquidity in the recently introduced private-sector RTGS service. Commenters that did not support the Federal Reserve developing a liquidity management tool indicated that the private sector could develop methods on its own to manage liquidity for faster payments.

III. Assessment of the FedNow Service

In 1984, the Board established criteria for the consideration of new or enhanced Federal Reserve payment services in its policy ''The Federal Reserve in the Payments System.'' [33] The policy incorporates the cost recovery requirements of the MCA and the MCA's objective of achieving an adequate level of service nationwide. In expressing the Board's overall

[26] Some commenters addressed RTGS as the appropriate strategic foundation for interbank settlement of faster payments without taking a position, typically citing a lack of consensus among their membership.

[27] These commenters were from the following segments: small and midsize banks, large banks, individuals, service providers, private-sector operators, and trade organizations.

[28] In order to evaluate possible faster payment services, the FPTF developed a set of effectiveness criteria that addressed various features of a faster payment service. With respect to interbank settlement, the FPTF considered a faster payment service to be ''very effective'' if, among other things, interbank settlement occurs within 30 minutes of the completion of a faster payment for end users. *See* Faster Payments Task Force, ''Faster Payments Effectiveness Criteria,'' (January 26, 2016). Available at *https://fedpaymentsimprovement.org/wp-content/uploads/fptf-payment-criteria.pdf*.

[29] Approximately 50 additional commenters raised issues related to the Federal Reserve's development of an RTGS service for faster payments but did not take a position on whether the Federal Reserve should offer such a service. Many of these commenters cited a lack of consensus among their membership, while others advocated for enhancement of current Federal Reserve payment services but did not take a position on the provision of an RTGS service for faster payments.

[30] *See* ''The Federal Reserve in the Payments System,'' *supra* note 18. The Board's criteria for new services and related comments are discussed in Section III.

[31] At least one additional commenter raised issues related to a liquidity management tool but did not express a view about whether the Federal Reserve should offer such a tool.

[32] These commenters were from the following segments: private-sector operators, fintech companies, and other interested parties.

[33] *See* ''The Federal Reserve in the Payments System,'' *supra* note 18. As stated in the policy, the Board, in its sole discretion, determines when the process outlined in the policy is applicable and makes all decisions related to the process.

expectations for the Federal Reserve's provision of payment services, the policy takes into account longstanding public policy objectives to promote the safety and efficiency of the payment system and to ensure the provision of payment services to banks nationwide on an equitable basis, and the importance of achieving these objectives in an atmosphere of competitive fairness.

The policy specifically addresses the introduction of new services or major service enhancements in light of the Board's overall expectations and requires all of the following criteria to be met:

- The service should be one that other providers alone cannot be expected to provide with reasonable effectiveness, scope, and equity. For example, it may be necessary for the Federal Reserve to provide a payment service to ensure that an adequate level of service is provided nationwide or to avoid undue delay in the development and implementation of the service. (*Other Providers Criterion*)
- The Federal Reserve must expect that its providing the service will yield a clear public benefit, including, for example, promoting the integrity of the payments system, improving the effectiveness of financial markets, reducing the risk associated with payments and securities-transfer services, or improving the efficiency of the payments system. (*Public Benefits Criterion*)
- The Federal Reserve must expect to achieve full recovery of costs over the long run. (*Cost Recovery Criterion*)

The following sections provide a detailed assessment of the FedNow Service under these three criteria. The assessment uses a similar set of measures to evaluate each criterion. In particular, the *Other Providers Criterion* and the *Public Benefits Criterion* both consider measures related to the Federal Reserve's broader objectives of promoting the accessibility, safety, and efficiency of the nation's payment system. However, the Board's policy requires considering whether public policy goals would be achieved according to these measures in two different situations: one where a service may be provided by other providers alone (*Other Providers Criterion*), and a second where the Federal Reserve develops a new service or major service enhancement (*Public Benefits Criterion*).

In the assessment that follows, the Board applies the common set of measures first in evaluating the *Other Providers Criterion* and then again in evaluating the *Public Benefits Criterion.* Such an approach creates overlap and some repetition in the analysis of each criterion. The Board believes that this approach is necessary to ensure a comprehensive assessment. Specifically, this approach allows a more systematic assessment of whether, relative to other providers, the Federal Reserve's provision of a service can be expected to advance desirable outcomes in the payment system that are consistent with public policy goals and might otherwise not be achieved by other providers alone.

The Board's policy also requires a forward-looking evaluation of the probable or likely future state of the payment system over the long run, with or without Federal Reserve action.[34] Therefore, when assessing new services or major service enhancements, the Board focuses on expected long-term outcomes and does not require a determination that each of the criteria is satisfied at present or will be with certainty in the future. Requiring such certainty would prevent the Federal Reserve from acting until after negative consequences occur, making any detrimental effects more difficult, if not impossible, to remedy. For example, as noted in the Board's policy, it may be necessary for the Federal Reserve to provide a payment service to avoid an undue delay in the development and implementation of the service. Waiting until undue delay had already occurred, however, would render ineffective the Federal Reserve's objective of providing such a service to facilitate its timely development and implementation.

A. Other Providers Criterion: The service should be one that other providers alone cannot be expected to provide with reasonable effectiveness, scope, and equity. For example, it may be necessary for the Federal Reserve to provide a payment service to ensure that an adequate level of service is provided nationwide or to avoid undue delay in the development and implementation of the service.

The Board's *Other Providers Criterion* balances the important role that the private sector plays in providing payment services to the public with the Federal Reserve's overall mission to promote the accessibility, safety, and efficiency of the nation's payment system. Therefore, the Board first considers whether the payment services that other providers alone can be expected to offer sufficiently advance the Federal Reserve's overall objectives in the payment system absent any Federal Reserve action.[35] In the context of the FedNow Service, the Board's assessment of this criterion involves consideration of whether other providers alone can be expected to offer RTGS services for faster payments that advance the Federal Reserve's objectives according to the measures outlined below.

1. Relevant Measures

The Board's policy for assessing new services or major service enhancements considers three measures to evaluate expected outcomes under the *Other Providers Criterion:* Scope, equity, and effectiveness.

a. Scope and Equity

The measures of scope and equity in the Board's *Other Providers Criterion* reflect the Federal Reserve's objective of ensuring the adequate provision of payment services nationwide on an equitable basis. Taken together, these measures reflect the Federal Reserve's broader mission of promoting accessibility in the nation's payment system, as also considered in the *Public Benefits Criterion.*

The measure of scope takes into account the Federal Reserve's policy goal, and an objective of the MCA, to achieve an adequate level of payment services nationwide. Providing payment services that are accessible to virtually all U.S. banks benefits all payment system participants by facilitating ubiquitous payment services and allowing the full realization of network effects.[36] Therefore, the *Other Providers Criterion* includes consideration of whether other providers alone can be expected to provide a service that is accessible to banks nationwide and on

[34] The Board's focus on expected long-term outcomes predates both the MCA and the Board's policy for assessing new services or major service enhancements. For example, the Federal Reserve undertook efforts to pilot ACH services in the late 1960's because of the expected long-term potential of those services for improving the payment system. These services were fully operational in the early 1970s and were intended, in part, to address growing paper check volumes, which the Board expected would eventually exceed 50 billion items 15 years later, in the mid-1980s.

[35] As noted previously, the Federal Reserve has already taken actions to support the ability of other providers to offer RTGS services for faster payments. In particular, the Board approved in 2017 guidelines for evaluating requests for joint accounts at the Reserve Banks intended to facilitate settlement between and among banks participating in private-sector payment systems for faster payments. One such account has been provided to a private-sector operator. Without these actions, other providers alone would be unable to provide RTGS services for faster payments, supported by a joint account at a Reserve Bank, that reproduce, as closely as possible, the risk-free nature of settlement in central bank money.

[36] When network effects are present, the value of a service to each user increases as the total number of users grows.

terms that are equitable and facilitate broad participation.

The measure of equity reflects the Federal Reserve's objective to ensure the provision of payment services to banks on an equitable basis. The availability of payment services to banks on an equitable basis promotes competition and a level playing field in the payment industry overall. Equity comprises a number of elements, including whether a service is broadly accessible to banks on reasonable terms and in comparable quality, whether a service is provided in a transparent manner, and whether a service has adequate measures in place to take into account the interests and needs of virtually all industry stakeholders. Moreover, equity considerations can affect banks' decisions to join a payment service, which can feed back into the measure of scope.

b. Effectiveness

The measure of effectiveness addresses the extent to which other providers alone can be expected to advance desirable outcomes in the U.S. payment system. In the context of the *Other Providers Criterion,* effectiveness can be viewed through the elements of safety and efficiency, key objectives that the Federal Reserve seeks to promote in the U.S. payment system.

The element of safety reflects the Federal Reserve's objective to promote the safe functioning of the U.S. payment system.[37] The safety of a payment system depends on many factors, including the security of individual transactions, the general resiliency of end-user services, and resiliency mechanisms for addressing specific events, such as bank failures, operational outages, or natural disasters and other systemic events. A safe payment system is crucial to economic growth and financial stability because the effective operation of markets for virtually every good and service is dependent on the smooth functioning of the nation's banking and payment systems.

The element of efficiency reflects the Federal Reserve's objective to promote the efficient functioning of the U.S. payment system.[38] Efficiency encompasses a number of factors, including whether a service is provided in a cost-efficient manner, whether it results in efficiency gains brought about by competition and innovation, and whether it achieves sufficient scope to realize the efficiency benefits of network effects. An efficient payment system facilitates and encourages economic activity, whereas an inefficient payment system can result in frictions and costs that could hinder economic activity and dampen growth.

2. Public Comments

a. Scope and Equity

More than 200 commenters expressed views on whether other providers alone will provide RTGS services for faster payments with reasonable scope and equity.[39] Approximately 175 commenters, representing a wide variety of distinct interests, raised concerns that other providers alone will not be able to implement services that can achieve nationwide scope or to provide broadly accessible RTGS services for faster payments on an equitable basis.[40] In contrast, approximately 30 commenters, mostly comprising large banks and private-sector operators, expressed views indicating that the private sector can provide RTGS services for faster payments built for banks of all sizes in the United States with reasonable scope and equity.

Many commenters focused on the private-sector RTGS service for faster payments, established in November 2017 and owned by the largest banks in the United States. Commenters that expressed a critical view of this service argued that a private-sector operator without the experience or infrastructure necessary for working with the majority of banks in the United States would face substantial challenges in establishing new connections and relationships with such banks. Some of these commenters argued that the process of doing so could take many years, with a few commenters suggesting it could take at least a decade or more, and others questioning whether such connections and relationships would ever be possible. These commenters frequently argued that a private-sector service, particularly one provided by an operator that they believe has been historically focused on serving large banks, will not adequately account for the unique challenges facing smaller banks and may struggle to scale its services to allow access for the nation's more than 10,000 banks. Some commenters also expressed doubt that use of service providers, acting as agents for banks that do not wish to connect to the service directly, will allow private-sector services to achieve nationwide reach.

Some commenters also indicated that perceived equity concerns may further affect the ability of private-sector RTGS services to achieve reasonable scope. In particular, as described later, approximately 100 commenters, mostly from small and midsize banks and trade organizations, raised equity concerns related to private-sector RTGS services, indicating they may avoid joining such services in light of those concerns.

Other commenters, comprising private-sector operators and large banks, argued that the existing private-sector RTGS service for faster payments was on course to reach almost half of U.S. deposit accounts by the end of 2018. These commenters further stated that the service has a credible plan for reaching near ubiquity at the end of 2020 by, among other things, using service providers to facilitate participation of small and midsize banks. These commenters also argued that the service should have time to demonstrate its ability to achieve nationwide scope. These commenters further argued that, by publicly announcing the possibility of developing an RTGS service for faster payments, the Federal Reserve has stalled progress that the service could otherwise make towards achieving ubiquity.

Finally, some commenters expressed the view that, if a single private-sector operator were the only provider of a nationwide RTGS service in the United States, this outcome could adversely affect the environment for private-sector innovation and the development of new use cases. These commenters argued that an RTGS operator with a dominant market position would have substantial impact on the emergence of potentially innovative uses of faster payments through its policies and prices, such that it could limit uses of faster payments that were not in its business interest or the interest of its owners. In contrast, other commenters argued that the existing private-sector RTGS service for faster payments has the ability to support a wide variety of use cases and can serve as a platform for innovation in end-user payment services.

With respect to equity, many small and midsize banks, as well as commenters that would be end users of

[37] The element of safety may be referred to as integrity in other contexts.

[38] Improvements in the efficiency of the payment system were a central motivation when Congress originally established an operational role in the payment system for the Federal Reserve. Congress's decision to make the Federal Reserve an active participant in the payment system when it passed the Federal Reserve Act in 1913 was, in part, a response to inefficiencies that resulted from the circuitous routing of checks in the early 1900s to avoid presentment fees.

[39] Approximately 35 additional commenters raised issues related to scope and equity but did not express a view about whether the other providers alone will be able to achieve nationwide scope or provide services with reasonable equity.

[40] These commenters included small and midsize banks, individuals, consumer organizations, merchants, fintech companies, service providers, and trade organizations.

faster payment services settled via RTGS, such as individuals and merchants, expressed concern that the private-sector RTGS service is unlikely to be delivered in an equitable manner. Small and midsize banks in particular argued that it is likely that smaller banks, which are not owners of the private-sector service, will be unable to gain access to the service on reasonable terms and in a transparent manner over the long run. Some commenters noted the stated commitment of the service's operator to address equity concerns through its pricing and access policies but questioned whether it will maintain these commitments in the future, arguing that doing so may not be in the long-term business interest of the operator's owner banks. In particular, commenters questioned whether the operator would maintain a uniform pricing structure, especially if it achieves a dominant market position.

Several small and midsize banks expressed further concerns, unrelated to pricing, that an RTGS service for faster payments established by competitors with a business profile different than their own will not provide them with equitable service. Many smaller banks argued that the service's operator will not understand their business needs and will be unlikely to take into account their interests, particularly if they are excluded from its governance processes. For example, some commenters argued that non-owner banks have no meaningful role in the service's rulemaking or pricing decisions compared with the service's owner banks. In addition, several commenters expressed concerns that joining the service could grant their competitors a competitive advantage by allowing them access to detailed information about their payment operations and customer base.

Other commenters, mostly private-sector operators and large banks, argued that the operator of the private-sector RTGS service for faster payments has demonstrated its willingness to accommodate the interests and needs of a wide variety of prospective participants and has taken concrete steps to facilitate near-universal access on equitable terms. In particular, these commenters emphasized that the service's pricing terms, including a uniform pricing structure without minimum volume requirements or volume discounts common in other payment systems, do not favor any particular type of bank and demonstrate the equitable and impartial provision of the service. These commenters also argued that the service's use of service providers facilitates access for banks of all sizes and promotes equitable access to the service. Several of these commenters also stated that the service operates in a transparent manner, for example, by making its rules publicly available. Finally, these commenters noted that the service's operator plans to incorporate input from small and midsize banks, as well as other stakeholders, through advisory panels and other types of engagement, and argued that such measures should be sufficient to assure non-owner banks that they will receive access to the service on an equitable basis, today and in the future.[41]

b. Effectiveness

Overall, more than 200 commenters raised issues related to the safety and efficiency of settlement arrangements for faster payments. Approximately 180 commenters, representing a wide variety of distinct interests, raised topics that indicate safety or efficiency concerns may result from other providers alone providing settlement arrangements for faster payments.[42] In contrast, around 30 commenters, comprising large banks, trade organizations, and private-sector operators, indicated that the provision of such services by other providers alone would promote a safe and efficient payment system.

Whether RTGS services for faster payments offered by other providers alone will be reasonably effective in promoting the efficiency of the U.S. payment system depends in large part on whether such services achieve nationwide reach. As discussed in the context of scope, many commenters expressed concerns about the ability of private-sector RTGS services for faster payments to achieve nationwide reach, which commenters suggested would prevent an RTGS infrastructure from fully realizing potential efficiency benefits.[43]

Many commenters also addressed potential efficiency concerns if an RTGS infrastructure for faster payments attains nationwide reach but is provided by a single dominant private-sector operator. In particular, approximately 120 commenters, representing a wide variety of distinct interests, noted various ways in which a dominant private-sector RTGS operator could use its market power to harm efficiency.[44] Many commenters noted that payment markets with either limited competition or a dominant private-sector operator often exhibit monopolistic pricing. Other commenters expressed concerns that, in the long term, evolution of such a service could be driven primarily by the desire of the dominant operator to retain its position in the market and forestall entry of other potential providers, to the detriment of competition and efficiency gains that might result from competition. Some commenters, particularly individuals and merchants, specifically pointed to issues with payment cards as examples of challenges that the market may face with a dominant operator. For example, these commenters raised concerns about high prices and impediments to competition and innovation that they believe occur in the payment card market.

Approximately 30 commenters, mostly large banks and private-sector operators, argued that a single provider of RTGS services for faster payments would be able to serve the market adequately and that the presence of multiple RTGS services could lead to market inefficiencies such as fragmentation and increased connection costs. As discussed in the context of scope, these commenters argued that the private-sector RTGS service for faster payments is on course to achieve nationwide reach, which would allow it to realize efficiency gains through participants' ability to exchange payments with a wide range of counterparties. A few of these commenters argued that, should the service achieve nationwide reach, additional entrants would not be able to generate incremental benefits to justify their setup and operational costs from an efficiency perspective. Many of these commenters further expressed concerns that should multiple RTGS services for faster payments enter the market, but not be able to interoperate, banks would either need to incur high costs of connecting to multiple RTGS services or would need to choose to connect to just one of multiple RTGS services, resulting in an inefficient, fragmented faster payment market. These commenters argued that, as a result, a single provider is the most efficient way to provide RTGS services for faster payments.

With respect to innovation in a market with a single dominant private-

[41] As discussed in detail later, the service's operator announced changes in early 2019 intended to reinforce its intention to be inclusive and equitable.

[42] These commenters included small and midsize banks, individuals, consumer organizations, merchants, fintech companies, service providers, trade organizations, and other interested parties.

[43] Such benefits would stem primarily from the full realization of network effects with virtually all banks participating in the RTGS infrastructure for faster payments.

[44] These commenters included small and midsize banks, individuals, consumer organizations, merchants, fintech companies, service providers, and trade organizations.

sector RTGS service for faster payments, some commenters argued that a lack of competition would curtail innovation in the nascent market for faster payments, resulting in higher costs and an inferior product. These commenters expressed the view that the provider would innovate to meet the needs of a narrow group of banks at the expense of smaller banks or certain end users. In contrast, other commenters expressed the view that the private sector is best positioned to foster innovation in faster payments, arguing that the private sector can quickly respond to market demand, in contrast to public-sector entities that need to follow a formal process to propose and implement certain types of operational changes. These commenters pointed to the clearing capabilities of the private-sector RTGS service for faster payments and its ability to support a variety of payment types, such as business-to-business or consumer-to-business payments, arguing that the service is a platform for innovation.

Many commenters expressed safety and resiliency concerns about the potential outcome of a nationwide RTGS infrastructure for faster payments being provided by just one private-sector operator, particularly as the prominence of faster payments grows over the long term. Many commenters specifically expressed concerns about the market being served by a single private-sector provider in the event of a systemic event or natural disaster. Several commenters argued that such an operator would be ineffective at providing resiliency and stability to the faster payment ecosystem in times of crisis, particularly if the operator did not have previous experience managing disruptions that may occur across a wide range of banks or geographic areas. Some commenters expressed concern that a single private-sector operator would serve as a single point of failure in the faster payment market. Finally, some commenters expressed concerns that, if private-sector RTGS services for faster payments are unable to achieve nationwide reach, some banks may be unable to offer faster payment services to their customers altogether. The commenters further expressed concern that such a result would lead customers to adopt services provided outside of the banking industry, involving institutions that the commenters viewed as insufficiently regulated and potentially unsafe.

A few commenters, mostly from large banks and private-sector operators, noted that the operator of the private-sector RTGS service provides other payment services that have proven to be resilient in times of stress, including the financial crisis and natural disasters. These commenters stated that the operator has similarly designed its RTGS service for faster payments to be highly resilient.

3. Board Analysis

The Board finds that substantial uncertainty exists about the long-term success of RTGS services for faster payments, despite actions already taken by the private sector. As articulated in the 2018 Notice, the Board continues to believe that RTGS is the appropriate strategic foundation for interbank settlement of faster payments. However, certain challenges may prevent other providers alone from implementing a nationwide RTGS infrastructure for faster payments that provides a basis for ubiquitous, safe, and efficient faster payments in the United States.

The magnitude of the task involved in achieving any large-scale improvement in the U.S. payment system, such as establishing a new foundational infrastructure for faster payments, is significant. The banking industry plays a key role in the U.S. payment system, which necessitates the industry's involvement in payment system improvements.[45] However, the United States has a highly complex banking system with more than 10,000 depository institutions, including commercial banks, savings banks, savings and loan associations, and credit unions.[46] As a result, the U.S. banking system (and, by extension, the payment ecosystem) is extremely diverse, with a wide variety of market participants and stakeholders that have heterogeneous circumstances, interests, and needs.

This diversity inherently creates significant coordination challenges that, along with the high fixed costs necessary to develop RTGS services for faster payments, are likely to limit the number and type of entrants in the market.[47] Indeed, only one private-sector RTGS service for faster payments has been established in the nearly six years since the Federal Reserve launched the SIPS initiative and articulated the goal of a ubiquitous, safe, and efficient faster payment system.[48] Comments received by the Board support the expectation that this service is likely to remain the sole private-sector provider of RTGS services for faster payments in the United States.

Given this likely outcome, and in light of the comments received, historical context, and economic analysis, the Board does not expect that other providers alone will provide an RTGS infrastructure for faster payments with reasonable effectiveness, scope, and equity. Two issues in particular present significant obstacles: Achieving nationwide scope on an equitable basis, and efficiency and safety issues likely to arise in a single-provider market.

a. Scope and Equity

Achieving nationwide scope has been a recurring challenge for the U.S. payment system, and, to date, no single private-sector payment service provider of traditional payment services, such as check, ACH, funds transfer, or payment card services, has done so alone. Although the importance of network effects may give operators an incentive to pursue broad reach for new payment services, the cost and difficulty of reaching virtually all banks in an environment as complex as the U.S. banking industry means that many operators are unlikely to invest the resources and effort necessary to achieve true nationwide scope. Extending access to a few thousand

[45] In the United States, deposits in accounts with banks comprise the monetary asset that is most widely held by the public to conduct payments. As of June 2019, the value of transferable deposits held by the public, including demand deposits and other checkable deposits, was $2.17 trillion, while the value of currency in circulation outside banks was $1.66 trillion. *See* Board of Governors of the Federal Reserve System, ''Money Stock and Debt Measures—H.6 Release, Table 5,'' (July 11, 2019). Available at *https://www.federalreserve.gov/releases/h6/current/default.htm.*

[46] As noted previously, these institutions vary greatly in terms of size, level of technical sophistication, and operational practices, as well as the customers and communities served. Institutions also vary with respect to the connections and relationships that they have with payment operators, service providers, and other intermediaries, such as bankers' banks and corporate credit unions.

[47] Specifically, with respect to coordination challenges, the diverse nature of the nation's banking system results in disparate operational and use-case needs, which can be difficult to accommodate. These disparate views and the large number of parties holding them make coordination challenging for any single entity attempting to establish a service that represents the interests and needs of diverse institutions. As a result, new services are likely to be developed by small groups of institutions with closely aligned interests, which may make such services less attractive to other types of institutions. Coordination between numerous institutions is also necessary to obtain funding because of the high fixed costs typically involved in the development of a new payment service. Such coordination is especially challenging when numerous institutions with limited resources try to assemble sufficient funds to develop their own services. As a result, new services are likely to be developed by small groups of institutions with significant resources.

[48] Faster payment services were established even earlier in some jurisdictions internationally. For example, the Faster Payment Service in the United Kingdom began operating in 2008, nearly 10 years before the U.S. payment industry began attempting to establish broadly accessible faster payment services. *See* ''Fast payments—Enhancing the speed and availability of retail payments,'' *supra* note 1.

banks, let alone the more than 10,000 diverse depository institutions necessary to achieve true nationwide scope, is especially costly and time-consuming for operators with limited relationships with and connections to these institutions. For this reason, private-sector operators have historically tended to concentrate on providing payment services to a subset of institutions, and existing payment systems, such as those for checks, ACH payments, funds transfers, and payment cards, all achieved nationwide reach with multiple providers of payment and settlement services.

A single operator of a new service aiming to achieve nationwide reach is likely to find that establishing costly new connections and providing adequate support to the significant number of smaller banks in the U.S. market is much harder than doing so for the few hundred largest banks or even a few thousand institutions. The benefit to a private-sector operator of ensuring access to the ''long tail'' of small banks in the United States is unlikely to outweigh the cost that it would incur to reach them. Given the small number of deposit accounts that each additional small bank would bring to the service, the diminishing returns generated by onboarding and supporting these banks are unlikely to offset the cost of doing so. Ultimately, the cost-benefit calculation of a single private-sector operator could lead it to forgo pursuing true nationwide scope, particularly if establishing new relationships with and connections to the large number of small banks proves more challenging or costly than anticipated.

The recently established private-sector RTGS service endeavors to achieve nationwide reach by extending access to banks of all sizes. Although the service can attain substantial reach across deposit accounts simply through connections with all of its large owner banks, measuring reach in terms of deposit accounts does not accurately reflect true reach across the nation's substantial number of smaller banks. Attaining such reach across deposit accounts through a small number of large banks would still leave the vast majority of the nation's 10,000 banks without access to the service. In fact, by the middle of 2019, banks that had joined the service represented less than one percent of the institutions in U.S. banking system.

For a number of reasons, it is unlikely that the private-sector RTGS service for faster payments alone will reach the thousands of small banks necessary to yield nationwide scope, even in the long term. Given its traditional focus on providing services primarily to a small number of large banks in the United States, the operator of the private-sector RTGS service would need to develop significant expertise to handle the large number and substantial diversity of U.S. banks. It would further need to expand and adapt its logistical support, currently geared towards its existing bank customers, for smaller and more diverse banks. Although the service plans to use service providers to extend reach to small and midsize banks, many commenters expressed concerns that building such connections to the service will nevertheless take many years. This problem may be exacerbated by the fact that many small and midsize banks do not currently have relationships with the service providers that work with the private-sector RTGS service or any relevant service provider.

The challenge of achieving nationwide scope for an RTGS infrastructure is likely to be further exacerbated by concerns of numerous commenters, representing large segments of the U.S. payment market, about whether access extended by the private-sector RTGS service for faster payments will be equitable. The operator of the service has looked to address these concerns by taking concrete steps to assure market participants of equitable treatment, now and in the future. In particular, it has publicly stated its commitment to a transparent and uniform pricing regime. In addition, the private-sector operator has taken measures to incorporate perspectives from non-owner stakeholders in its governance processes, including recent measures that involved adding seats for community banks and credit unions to the service's business committee and announcing business principles intended to guide the operation and maintenance of the service.[49]

Despite these steps, equity concerns may persist for a number of reasons. First, although the operator has stated its commitment to equitable pricing, nonprice measures can be equally important in determining whether services are provided equitably. For instance, an RTGS service for faster payments designed with a focus on large, technologically sophisticated banks may not be easily adopted by smaller banks, regardless of pricing structure.[50] Second, a service owned by a small group of institutions with closely aligned interests will confront persistent concerns from other market participants that the service will not equitably represent the interests and needs of the broader payment industry. In particular, potential participants in the service may have concerns, as expressed by commenters, that its operator will have incentives to take actions that favor its owner banks at the expense of non-owner banks.[51]

Concerns about future treatment may be particularly pronounced if it is perceived that the operator could alter its current commitments to equitable access in response to changing market conditions, such as the operator achieving a dominant position in the market for RTGS services for faster payments or, alternatively, facing the increased prospect of competition from other parties. These concerns may be especially persistent if such commitments can be changed unilaterally and are not subject to a public and transparent process whereby all interested parties have the opportunity to provide input.

Ultimately, these concerns about the ability to access the private-sector RTGS service for faster payments on an equitable basis over the long run are likely to cause significant uncertainty among small and midsize banks about the value of connecting to the service. This uncertainty may cause small and midsize banks to choose not to join the

[49] On March 28, 2019, the service's operator announced that it had added four seats for community banks and credit unions to the service's business committee in an effort to expand the type and number of banks providing input to the service. At the same time, the service's operator also announced a set of business principles intended to guide the operation and maintenance of the service as long as the service remains the nation's sole provider of faster real-time interbank clearing and settlement.

The principles include, for example, making rules publicly available, periodically soliciting input on rules, disclosing major decisions to relevant stakeholders, maintaining flat fees that do not include volume discounts, and making the service available to all institutions that meet the service's eligibility requirements. Available at *https://www.theclearinghouse.org/payment-systems/articles/2019/03/-/media/080a875636784eec87bfc13ddf0ef6a4.ashx.*

[50] Examples of RTGS design features that could disadvantage smaller, less sophisticated banks with standard operating hours include the need to prefund separate settlement accounts on a 24x7x365 basis, as well as reliance on 24x7x365 computer-to-computer connections that are commonly used by larger banks with significant payment volume.

[51] Such a possibility could reflect what is known as ''vertical foreclosure.'' Under vertical foreclosure, the operator of an RTGS service for faster payments, as the provider of a key input into banks' provision of payment services to their customers, may have an incentive to limit access to non-owner banks in order to allow its owner banks to attract customers and gain market share. Although such an operator has countervailing incentives, particularly early on, to allow broad access to the service in order to increase its value through network size, a more established service may be more likely to limit equitable access to non-owner banks, especially if the service does not face direct competition from other service providers.

service and to consider instead alternative non-RTGS-based arrangements for faster payments. The result would only further complicate the challenges that the private-sector RTGS service will face in achieving nationwide reach.

b. Effectiveness

Economic analysis, historical context, and the comments received all identify market structure, the number of providers in the market, and the nature of competition between those providers as key drivers of effectiveness, as viewed through the lens of safety and efficiency. Competition generates incentives for firms to offer products that broadly appeal to customers, at prices close to the cost of making those products, and to continually innovate and improve their products in the hope of attracting customers from their competitors. Compared with firms facing competition, a monopoly firm can charge higher prices, causing customers to pay more than the actual cost and to buy less than is socially desirable. Without competitors, a monopoly firm can also limit supply to certain segments of the market. Finally, customers who can only buy a product from one firm may have no choice but to accept products, even if they are lower quality. Economic theory and real-world experience both demonstrate that, although setting up and operating additional firms is often costly, the resulting competition leads to societal efficiency gains that outweigh such costs, generating outcomes that are better for the public than if a single firm serves a market.[52]

These considerations are important in the context of the market for RTGS services for faster payments, which is likely to involve a single private-sector provider, for reasons discussed previously. Although a single-provider market structure avoids duplicating the substantial development and operating costs of additional RTGS services, it is likely to have a detrimental effect on the efficiency and safety of the faster payment market. As described earlier, a likely market outcome is that only a portion of banks in the United States would actually connect to the sole private-sector RTGS service. In such a scenario, the remaining, likely smaller, banks would either not join any faster payment services or would explore alternative arrangements, such as services based on a deferred settlement model.[53] The resulting fragmentation of the end-user faster payment market between those end users with access to RTGS-based faster payment services, those with access to faster payment services based on deferred settlement, and those without any access to faster payment services through their banks could prevent end users and the U.S. payment industry as a whole from realizing fully the benefits associated with nationwide RTGS-based faster payments.

Furthermore, a single provider of RTGS services for faster payments may not advance other desirable outcomes in the U.S. payment system with respect to competition, innovation, and efficiency. As described earlier, a single service provider without competition can yield undesirable outcomes for faster payments, such as lower service quality or higher prices, which may result in reduced adoption rates of RTGS services for faster payments by banks. Such undesirable outcomes could limit adoption of faster payments by end users, which could in turn curtail efficiency benefits to the broader economy.

Notably, a single provider of RTGS services for faster payments may not provide a neutral foundation for innovative, competitive end-user faster payment services. Instead, a single provider may focus on specific use cases that do not promote the potential for faster payments to be used in a wide variety of ways. For example, an RTGS service could eschew innovation in use cases that undermine its owners' existing interests and profits from traditional payment methods. Moreover, the RTGS service's owners could favor their end-user products at the expense of other competing products by inhibiting the ability of competing products to use the RTGS service. Such limitations on access to the RTGS service could further reduce potential competition and innovation for end-user services.

With respect to payment system safety, a market outcome with a single RTGS service for faster payments would make it difficult and costly for faster payment services to achieve resiliency through redundancy. Such redundant connections have been a common solution in many retail payment markets, suggesting that many banks find the resiliency benefits outweigh the cost of connecting to multiple services. For example, a number of banks connect to two ACH services in pursuit of resiliency, despite the fact that achieving nationwide reach requires connecting to just a single ACH service. In a market without redundancy, a sole provider may serve as a single point of failure for RTGS-based faster payments.

There exist alternative retail payment methods with nationwide reach, such as the ACH or payment card systems. However, those payment methods differ from RTGS-based faster payments in important ways, such as speed, message types, and technology. As a result, substitution between those payment methods and RTGS-based faster payments could create significant operational, technical, cost, and timing challenges for banks seeking to use such substitutes as a backup for faster payments. These challenges may make such alternative payment methods inadequate for resiliency purposes related to faster payments.

All of the challenges described above regarding scope, equity, and effectiveness are likely to pose significant obstacles to other providers that might attempt to implement an RTGS infrastructure that would provide the foundation for ubiquitous, safe, and efficient faster payments in the United States. Therefore, the Board believes that, on balance, other providers alone cannot be expected to provide the service with reasonable effectiveness, scope, and equity.

Furthermore, as described previously, the Federal Reserve does not have plenary regulatory or supervisory authority over the U.S. payment system and instead has traditionally influenced retail payment markets through its role as an operator. As a result, the Federal Reserve having an operational role in the settlement of faster payments would

[52] For example, in its 2016 report, the GAO found that competition by the Federal Reserve in payment markets has generally had a positive impact, with benefits that include lowered cost of processing payments for end users. *See* ''Federal Reserve's Competition with Other Providers Benefits Customers, but Additional Reviews Could Increase Assurance of Cost Accuracy,'' *supra* note 5.

From an economic perspective, an exception to the efficiency-through-competition argument is a ''natural monopoly.'' In this situation, the cost of setting up and operating a firm is so high that it can be more efficient for a single firm to supply the whole market, although achieving efficiency usually requires that the natural monopolist be regulated. With respect to such regulation of payment systems, as described previously, the Federal Reserve does not have plenary regulatory or supervisory authority over the U.S. payment system.

[53] The widespread availability of traditional payment systems, which can enable deferred settlement for faster payments, may make faster payment services based on deferred settlement an appealing alternative to RTGS-based services. A number of commenters, mostly small banks, voiced concerns that if they were unable to meet customer demand for faster payment services, they would be placed at a significant competitive disadvantage, which could eventually jeopardize their continued operation. Should such banks expect that they would not be able to gain equitable access to private-sector RTGS services, they could instead adopt faster payment services based on deferred settlement in an effort to remain competitive, undermining an RTGS infrastructure's ability to reach nationwide scope and potentially increasing risk in the payment system.

be the most effective approach to address the challenges faced by other providers alone and would yield a clear public benefit.

B. Public Benefits Criterion: The Federal Reserve must expect that its providing the service will yield a clear public benefit, including, for example, promoting the integrity of the payments system, improving the effectiveness of financial markets, reducing the risk associated with payments and securities-transfer services, or improving the efficiency of the payments system.

The Board's *Public Benefits Criterion* requires that a new service yield long-term benefits to the public and the economy as a whole. Therefore, in determining whether the Federal Reserve should develop the FedNow Service, the Board has considered the expected public benefits and potential offsetting costs of the service.

1. Relevant Measures

The *Public Benefits Criterion* focuses on whether the service is expected to provide a clear public benefit. In the context of payments, public benefits result from a payment system that is accessible, safe, and efficient. Such a payment system is a key component of commerce and economic activity. The criterion also provides specific examples of potential public benefits related to safety (promoting the integrity of the payment system, reducing the risk associated with payments and securities-transfer services) and efficiency (improving the efficiency of the payment system).

Therefore, in evaluating a new service under the *Public Benefits Criterion,* the Board considers three measures consistent with the Federal Reserve's longstanding public policy objectives: accessibility, safety, and efficiency. The measure of accessibility is closely related to those of scope and equity, as considered in the context of the *Other Providers Criterion.* In particular, a payment service is generally more accessible if it is available to banks on equitable terms. Moreover, a service that is broadly accessible should more easily achieve nationwide scope in the long term. The measures of safety and efficiency are identical to those considered in the context of the effectiveness measure in the Board's *Other Providers Criterion.*

2. Public Comments

a. Accessibility

Approximately 130 commenters addressed whether a Federal Reserve RTGS service would affect accessibility in the faster payment market.[54] Approximately 110 commenters, from most commenter segments, expressed the view that the Federal Reserve developing an RTGS service for faster payments would help ensure equal access for banks nationwide.[55] In contrast, around 20 commenters, comprising large banks and private-sector operators, expressed the view that the Federal Reserve's involvement would hinder development of faster payments in the United States in the short term.

Many commenters, in particular small and midsize banks, stated that a Federal Reserve RTGS service would provide banks of all sizes the ability to access an RTGS infrastructure for faster payments. Some of these commenters noted that most banks already have relationships with the Federal Reserve, including access to Federal Reserve accounts, either directly or through a correspondent banking relationship, that could be used for faster payments and would lower barriers to participation compared to other services without such existing relationships. Commenters, comprising small and midsize banks, merchants, service providers, fintech companies, and trade organizations, noted that the Federal Reserve's history of providing services to banks on fair and equitable terms would facilitate similar access to RTGS services for faster payments. Many of these commenters argued that, unlike the private sector, the Federal Reserve has a unique mission and demonstrated history of providing nationwide access to payment services, noting the Federal Reserve's check and ACH services as specific examples.

Other commenters, comprising private-sector operators and large banks, argued that a Federal Reserve RTGS service is unnecessary to ensure access for all banks because industry participants are already in the process of implementing the private-sector RTGS service for faster payments. These commenters argued that the private-sector RTGS service has mechanisms in place to allow all banks to access the service and that the service's operator has already committed to providing access on equitable and impartial terms.

Commenters also argued that the Federal Reserve's existing connections and relationship would not necessarily facilitate accessibility of RTGS services for faster payments, noting that such connections are not easily extended to handle faster payments, as they are not equipped to support the volumes, speeds, and redundancies required for an RTGS service. In addition, many of these commenters expressed concern that a Federal Reserve RTGS service could be detrimental to achieving nationwide reach of an RTGS infrastructure. Several commenters argued it would take the Federal Reserve too long to build such a service. Other commenters stated that a market with multiple RTGS services may require banks to connect to multiple services to achieve nationwide reach and that only the largest banks would do so because of the significant costs of additional connections.

Finally, more than 130 commenters, from all commenter segments, discussed the importance of interoperability for achieving nationwide access to an RTGS infrastructure for faster payments.[56]

b. Safety

More than 80 commenters expressed views on whether a Federal Reserve RTGS service would promote the safety of faster payments.[57] Nearly all of these commenters argued that the Federal Reserve would improve the safety of faster payment through the development of an RTGS service for faster payments.[58] A few commenters expressed doubt that a Federal Reserve RTGS service would have any significant impact on the safety of faster payments.[59]

Commenters that expressed views on safety emphasized the importance of resiliency for RTGS services. Many of these commenters, especially small and midsize banks, argued that development of a Federal Reserve RTGS service for faster payments would be consistent with the Federal Reserve's role in promoting the safety of the payment system. Commenters argued that because of this role, the Federal Reserve would be committed to a higher level of safety than private-sector service providers. A few commenters specifically argued that, unlike private-

[54] Approximately 15 additional commenters raised issues related to accessibility but did not express a view about whether a Federal Reserve RTGS service would affect accessibility in the faster payment market.

[55] These commenters included small and midsize banks, individuals, merchants, service providers, fintech companies, and trade organizations.

[56] Topics related to interoperability are further discussed in the Board's analysis of accessibility.

[57] Approximately 60 additional commenters raised issues related to safety but did not express a view about whether a Federal Reserve RTGS service would promote the safety of faster payments.

[58] These commenters included small and midsize banks, individuals, consumer organizations, merchants, service providers, fintech companies, trade organizations, and other interested parties.

[59] Commenters expressing this view included those from the following segments: Large banks, private-sector operators, and individuals.

sector service providers, the Federal Reserve would focus on broader public policy objectives rather than returns on investment when considering the safety of faster payments. Many small and midsize banks argued that the Federal Reserve's operational role provides stability in the financial system during a time of crisis, citing the Federal Reserve's role following the terrorist attack on September 11, 2001, as an example. Some commenters also suggested that having multiple RTGS services for faster payments in the market could increase faster payment resiliency through redundancy, similar to other retail payment systems for which there are multiple operators.

A few commenters expressed doubts about whether a Federal Reserve RTGS service for faster payments would improve safety and resiliency. Large banks in particular argued that, although integration with a second RTGS service may bring marginal improvements to the safety of faster payments, these improvements would come at a high cost. Finally, at least one commenter expressed concerns that adopting a second RTGS service would divert bank resources, which could instead be used to improve resiliency and security of the private-sector RTGS service.

c. Efficiency

Approximately 120 commenters expressed views about whether a Federal Reserve RTGS service would promote efficiency in the faster payment market.[60] Approximately 100 commenters, from nearly all segments, argued that a Federal Reserve RTGS service would promote efficiency in the faster payment market.[61] In contrast, approximately 20 commenters, mostly comprising large banks and private-sector operators, argued that such a service would not improve efficiency and could create additional burdens for banks with limited resources.

Commenters that argued a Federal Reserve RTGS service for faster payments would promote efficiency generally discussed how such a service would enhance competition, promote innovation, or reduce costs. These commenters, comprising merchants and small and midsize banks, argued that historically, the Federal Reserve's presence as an operator has improved competition and efficiency, leading to lower prices and accelerated payment system improvements, such as the shift from paper to electronic payments. Some commenters further cited the payment card market as an example where concentration of market power in the absence of the Federal Reserve having an operational role led to inefficiencies in the market, such as high fees and restrictive rules that limit competition and innovation. At least one commenter argued that by the time such inefficiencies began to emerge in the early 2000s, it was too late for the Federal Reserve to provide a service to the market as an operator. Many small and midsize banks also stated that a Federal Reserve RTGS service would enhance competition in the broader banking market by allowing small and midsize banks to remain competitive with large banks and new entrants like fintech companies.

Other commenters argued that a Federal Reserve RTGS service for faster payments would not offer any measurable efficiency benefits over the current private-sector service and could distort the market. Many of these commenters argued that a Federal Reserve RTGS service would be costly to develop and that banks would need to expend additional resources to connect to multiple RTGS services for faster payments. A few of these commenters also suggested that the Federal Reserve's long-run cost recovery mandate is less demanding than the challenges facing the private sector, including scrutiny from shareholders and auditors, and may discourage private-sector entities from developing competing services. Finally, a few commenters also argued that cost-based pricing could stifle innovation by forcing RTGS service providers to divert resources away from developing new features.

3. Board Analysis

The Board expects that the Reserve Banks providing the FedNow Service would yield a clear public benefit. In particular, the Board's analysis suggests that, by serving an operational role, the Federal Reserve can help to create an accessible, safe, and efficient RTGS infrastructure for faster payments. This role would align with the Federal Reserve's history of providing services for most other payment systems alongside, and in support of, similar services offered by the private sector. The expected public benefit stems in large part from contributions the FedNow Service would make towards achieving nationwide reach of an RTGS infrastructure for faster payments, promoting the safety and resiliency of that infrastructure, and encouraging competition between payment services.

a. Accessibility

Enabling virtually all banks to gain access to a nationwide RTGS infrastructure for faster payments would support the core objective of ubiquitous faster payment services for individuals and businesses in the United States. However, as discussed with respect to the Board's *Other Providers Criterion,* the breadth and diversity of the U.S. banking system makes it difficult to implement an RTGS infrastructure that connects virtually all banks in the United States. The Board expects that the Federal Reserve's provision of the FedNow Service would help address this challenge in a number of ways, enhancing the accessibility of an RTGS infrastructure for faster payments and allowing that infrastructure to achieve nationwide reach.

In light of the significant heterogeneity in the nation's banking system, achieving nationwide reach will inevitably be challenging for any provider of RTGS services for faster payments, including the Federal Reserve. However, since its inception, an underlying public policy rationale for the Federal Reserve's involvement in the payment system has been to provide services in a safe and efficient manner to banks nationwide. Because of this long-standing policy commitment to promoting nationwide access, the Federal Reserve has historically extended access to banks of all sizes, including smaller banks in rural and remote areas of the country. Applied to the FedNow Service, this longstanding policy commitment would result in a service that is similarly accessible to banks of all sizes, ultimately increasing the long-term likelihood of such banks both accessing an RTGS infrastructure and implementing faster payment services.

As a provider of payment services to thousands of banks today, the Federal Reserve is in a unique strategic position to promote accessibility of an RTGS infrastructure for faster payments.[62] For small and midsize banks seeking to implement faster payment services, an RTGS service provided by the Federal Reserve is likely to be particularly important. The relatively high cost and difficulty of onboarding such institutions to an RTGS service is likely to constitute a significant obstacle for

[60] Approximately 20 additional commenters raised issues related to efficiency but did not express a view on whether a Federal Reserve RTGS service would promote efficiency.

[61] These commenters included small and midsize banks, individuals, consumer organizations, merchants, service providers, fintech companies, trade organizations, and other interested parties.

[62] The payment services that the Federal Reserve provides to banks today allow for settlement directly in banks' accounts held at the Reserve Banks or in settlement accounts held by other banks through a correspondent relationship.

private-sector operators. Regardless of any investments in developing clearing and settlement technology, a private-sector operator without existing relationships would nevertheless have to incur substantial costs to build connections and customer service capabilities before it could onboard the significant number of smaller banks needed to achieve true nationwide reach.[63] The Federal Reserve, however, has already made substantial investments in such capabilities, including connections and customer support systems, and have significant experience and expertise in providing services to smaller banks. The associated long-standing relationships with and connections to thousands of banks across the country provide a solid foundation for the FedNow Service to facilitate those banks gaining access to an RTGS infrastructure for faster payments. The FedNow Service therefore can reasonably be expected to reach thousands of smaller banks in the United States that might otherwise not have access to an RTGS infrastructure. The resulting widespread access to an RTGS infrastructure for faster payments would benefit small and midsize banks and the communities they serve.

Furthermore, the FedNow Service may serve as an impetus for many small and midsize banks to implement faster payment services. Although small and midsize banks responding to the 2018 Notice generally indicated an interest in adopting faster payment services, thousands of other banks may face significant uncertainty about the overall benefits of offering such services and the appropriateness of RTGS-based settlement arrangements for smaller institutions. The Federal Reserve's commitment to promoting payment system improvements through its provision of modernized infrastructure may decrease such uncertainty for those banks. With more certainty about the benefits of joining an RTGS infrastructure for faster payments, small and midsize banks may be more likely than they otherwise would have been to upgrade their capabilities and offer RTGS-based faster payment services to their customers.

Finally, the Board has also considered as part of its analysis the possible relationships between the FedNow Service and the private-sector RTGS service, and the resulting effect on nationwide reach. In a payment system with multiple operators, banks would have a choice whether to join a single service or multiple services such that an RTGS infrastructure for faster payments could achieve nationwide reach in two main ways.

First, interoperability via direct exchange of payments between RTGS infrastructure operators could allow payments originated by a participant of one service to be received by a participant of another service. If multiple services are interoperable in such a way, no single service needs to achieve nationwide reach on its own. This situation exists today with the nation's ACH system.

Second, banks could participate in multiple services that are not interoperable, but nationwide reach could still be achieved through at least one service achieving nationwide reach on its own. This situation exists today with large-value funds transfer systems. In this environment, banks could benefit from the existence of multiple services despite the lack of interoperability. A bank that participates in multiple services could choose which service to use for transactions, depending on any number of factors, such as fees, functionality, and the counterparties that a particular service can reach.

Many commenters described interoperability as important in the case of RTGS services for faster payments, with some commenters noting that interoperability could be developed in incremental steps. Commenters also expressed the view that the Federal Reserve would be well positioned to facilitate interoperability between RTGS services for faster payments. Commenters comprising large banks and private-sector operators, however, expressed significant concerns that interoperability poses potentially insurmountable technical and operational challenges.

The Board agrees with commenters that interoperability between RTGS services for faster payment services is a desirable outcome but also recognizes that it may be difficult to achieve, especially early on. As opposed to interoperability in and of itself, the Board views nationwide reach as a key objective for an RTGS infrastructure. Such reach does not inherently depend on interoperability between RTGS services, because there are other paths to achieving this objective.

During its engagement with the industry, the Federal Reserve intends to explore both interoperability and other paths to achieving nationwide reach. Although direct exchange of payments between RTGS infrastructure operators may not be an initial element of the FedNow Service, as standards, technology, and industry practices change over time and the relationship between RTGS services for faster payments evolves, interoperability will continue to be a desirable outcome that the Board pursues.

b. Safety

As the use of faster payment services increases in the future, the safety of such services will be crucial to the long-term safety of the overall payment system. The Federal Reserve has a long-standing focus on promoting the safety of the U.S. payment system. Recognizing that a safe payment system is crucial to the nation's economic growth and financial stability, the Federal Reserve has historically played an important role in promoting the safety of the U.S. payment system by providing liquidity and operational continuity in times of crisis. Serving an operational role in the payment system has allowed the Federal Reserve to take action in response to financial turmoil, terrorist attacks, natural disasters, and other crises. Indeed, comments in response to the 2018 Notice indicate that industry stakeholders and the public look to the Federal Reserve to use the tools at its disposal to provide support when needed, actions that might not be possible if the Federal Reserve were not in an operational role. As the prominence of faster payments in the United States grows, the development of the FedNow Service would allow the Federal Reserve to retain its ability to provide stability and support to the banking system and the broader economy in times of crisis.

Providing the FedNow Service would also allow the Federal Reserve to facilitate the safety of faster payments in the United States. Because of their irrevocable, real-time nature, the overall safety of faster payments depends in part on how well fraud can be detected and prevented. As the operator of the FedNow Service, the Federal Reserve would be in a position to promote the development and implementation of industry-wide standards, as has been the case in other payment systems where the Federal Reserve has played an operational role.[64] This ability to

[63] The use of service providers is unlikely to resolve this obstacle fully because some banks may prefer to use a direct connection or may already have relationships with service providers that are not connected to a private-sector RTGS service.

[64] For example, in the early 2000s, using its operational role in the check system, the Federal Reserve was able to support and encourage the industry's transition from paper to more efficient electronic check processing. Similarly, the Federal Reserve was able to improve speed and reduce risks associated with ACH payments in the early 1990s by facilitating electronic origination and receipt of ACH transactions processed by the Federal Reserve. *See* Federal Reserve Bank of New York, ''All-Electronic ACH Proposal,'' (Jan. 9, 1991). Available at *https://fraser.stlouisfed.org/files/docs/historical/*

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promote industry-wide standards would be particularly important in the development and adoption of standards to mitigate fraud. Moreover, if the Federal Reserve were to play an operational role, competition among RTGS services for faster payments may increase innovation related to fraud prevention, contributing to a safer faster payment environment.

Finally, the development of the FedNow Service could also enhance the safety of the U.S. payment system by promoting resiliency through redundancy. In particular, the availability of multiple RTGS services for faster payments would allow banks to connect to more than one such service, as a number do today for wire, ACH, and check services. Although connecting to multiple services could result in additional costs and operational complexity, the choice to connect would lie with the banks, many of which have expressed a desire historically to connect to multiple services for contingency purposes. These banks may instead look to achieve resiliency by using existing retail payment methods, for example ACH or payment cards. Over time, however, such alternatives will likely not provide adequate substitutes for RTGS-based faster payments from a cost, technological, operational, or end-user perspective.

c. Efficiency

The efficiency benefits associated with the FedNow Service are likely to come from two sources. First, by providing banks with an alternative RTGS service with integrated clearing functionality and by improving the prospect of banks' gaining access to a nationwide RTGS infrastructure for faster payments, the FedNow Service could allow more banks and their customers to reach one another. Such enhanced ability to reach one another would increase the benefits to each bank participating in the RTGS infrastructure, with the resulting network effects leading to improved efficiency in the faster payment market. Even banks that would already have joined the private-sector RTGS service could benefit from the broader reach that would result from the FedNow Service, because they would be able to join a service that provides access to counterparty banks that they would otherwise be unable to reach. Furthermore, as discussed in the context of the Board's *Other Providers Criterion* for evaluating new services, competition among RTGS services for faster payments could yield efficiency benefits by leading to lower prices and higher service quality.

Second, the development of the FedNow Service could indirectly generate efficiency benefits at the level of end-user faster payment services. A nationwide RTGS infrastructure would make the development of new faster payment services based on real-time settlement more attractive, increasing innovation and competition in the market for end-user faster payment services. Because the Federal Reserve seeks to encourage payment system improvements, the FedNow Service could serve as a neutral platform for private-sector entities to offer competitive and innovative faster payment services to end users based on transfers between banks.

Finally, the Board recognizes that the FedNow Service would generate societal costs that may reduce the net efficiency benefit of the service. In particular, the FedNow Service would require societal resources to develop in the short term and to operate in the long term. Further, banks that choose to connect to multiple RTGS services for faster payments in pursuit of broader reach or resiliency through redundancy may incur additional connection costs.[65] However, the Board expects that the benefits of the FedNow Service, as discussed earlier, would ultimately outweigh these additional costs. Therefore, the Board expects that overall the FedNow Service will yield a clear public benefit in the areas of accessibility, safety, and efficiency.

C. Cost Recovery Criterion: The Federal Reserve Must Expect to Achieve Full Recovery of Costs Over the Long Run

The Board's *Cost Recovery Criterion* accounts for the requirements in the MCA. In evaluating whether a new service or major service enhancement can be expected to achieve full cost recovery, the Board further considers its policy, ''Principles for the Pricing of Federal Reserve Bank Services'' (pricing principles), and its previous application of those principles to existing services.[66]

1. Relevant Measures

a. The MCA

The MCA required the Board to adopt a set of pricing principles for Federal Reserve services and a schedule of fees pursuant to those principles. The MCA specified certain principles on which fees must be based, including the principle that ''(o)ver the long run, fees shall be established on the basis of all direct and indirect costs actually incurred in providing the Federal Reserve services.'' [67] In addition, the MCA provided that the pricing principles ''shall give due regard to competitive factors and the provision of an adequate level of such services nationwide.'' [68]

b. The Pricing Principles

The pricing principles incorporate the statutory requirements of the MCA and include additional provisions consistent with the purposes of the MCA.[69] Although Congress intended the MCA to stimulate competition to promote the provision of services at the lowest cost to society, Congress was also concerned about achieving an adequate level of services nationwide and avoiding the reemergence of undesirable banking practices—such as nonpar banking or circuitous routing of checks—that the Federal Reserve's operational role in the payment system was intended to eliminate.[70] Therefore, like the Board's policy for evaluating new services, the pricing principles balance the importance of competitive fairness in the Federal Reserve's provision of services with the Federal Reserve's objectives to promote the accessibility, safety, and efficiency of the payment

ny%20circulars/nycirc_1991_10424.pdf#pdfjs.action=download.

[65] The need to connect to multiple RTGS services in pursuit of broader reach would occur if the FedNow Service and private-sector RTGS services were not interoperable.

[66] Board of Governors of the Federal Reserve System, ''Principles for the Pricing of Federal Reserve Bank Services,'' (Issued 1980). Available at *https://www.federalreserve.gov/paymentsystems/pfs_principles.htm.*

[67] These costs include imputed costs that a private-sector firm would incur if it were to provide the services. *See* Public Law 96–221, *supra* note 18. This imputed cost is referred to as the private-sector adjustment factor.

[68] *See* Public Law 96–221, *supra* note 18.

[69] For example, the Board's principles 1 and 2 mirror the MCA's statutory requirements that all covered Federal Reserve services must be explicitly priced and available to nonmember banks at the same price as member banks. In adopting the pricing principles, however, the Board noted that ''the Monetary Control Act and its legislative history recognize the importance of the Federal Reserve maintaining an operational presence in the nation's payments mechanism, providing an adequate level of service nationwide and encouraging competition.'' The Board explained that ''in the light of these considerations, the Federal Reserve has developed additional pricing principles that build on those of the Act.'' Therefore, other pricing principles reflect policy determinations by the Board intended to provide guidance on the pricing policies and strategies the Federal Reserve will follow, such as principle 6's expectation that the Federal Reserve should be sensitive to the changing needs for services in particular markets. *See* Board of Governors of the Federal Reserve System, ''Federal Reserve Bank Services; Proposed Fee Schedules and Pricing Principles,'' 45 FR 58689, 58690–58692 (Sep. 4, 1980). Available at *https://cdn.loc.gov/service/ll/fedreg/fr045/fr045173/fr045173.pdf.*

[70] *See* ''Principles for the Pricing of Federal Reserve Bank Services,'' *supra* note 66.

system.[71] Three pricing principles are relevant in considering this balance.

First, pricing principle 3 directly incorporates relevant provisions from the MCA requiring that over the long run, fees shall be established on the basis of all direct and indirect costs actually incurred in providing the services priced. In doing so, principle 3 includes the MCA's requirement to give due regard to competitive factors and the provision of an adequate level of such services nationwide.

Second, although the MCA mandates cost recovery for Federal Reserve services as a whole, pricing principle 5 specifies that the Board further intends fees to be set so that revenues for major service categories match costs, including a private-sector adjustment factor. However, principle 5 also notes that, during an initial start-up period, new operational requirements and variation in volume may temporarily change unit costs for some service categories. Principle 5 states that, in such a situation, the Federal Reserve intends to match revenues and costs as soon as possible.[72]

Finally, pricing principle 7 states that fee structures may be designed to reflect desirable long-run improvements in the nation's payment system. Principle 7 also states that the Board will seek public comment when changes in fees and service arrangements are proposed that would have significant long-run effects on the nation's payment system.

2. Public Comments

Approximately 20 commenters addressed cost recovery in response to the 2018 Notice.[73] Approximately 15 commenters believed the Federal Reserve would be able to recover the costs of developing and operating an RTGS service for faster payments, pointing to the Federal Reserve's ability to achieve cost recovery goals in the past for other services.[74] Fewer than 10 commenters argued that the Federal Reserve may not be able to recover costs for a new RTGS service, generally noting the significant cost of developing and operating such a service.[75]

3. Board Analysis

The Board believes that the provision of the FedNow Service would satisfy the *Cost Recovery Criterion*. In particular, the Board expects that the FedNow Service would achieve full recovery of costs over the long run, although the first instance of long-run cost recovery is expected to occur outside the 10-year period that the Board typically applies to existing, mature services. The Board's view that the service would satisfy the *Cost Recovery Criterion* is based on its consideration of the MCA's requirements regarding long-run cost recovery, the Board's pricing principles as they relate to new services compared with mature services, the Federal Reserve's public policy objectives, including the provision of an adequate level of service nationwide, and the previous application of these considerations to other Federal Reserve services.

The MCA does not specify the ''long-run'' period over which Federal Reserve services must recover costs, nor does the legislative history of the MCA indicate that Congress intended a specific length of time for the cost recovery period. The Board has typically used a rolling ten-year period when assessing long-run cost recovery of existing services (10-year cost recovery).[76] The Board views this standard 10-year cost recovery expectation as appropriate for assessing the long-run cost recovery of mature services, which generally have stable and predictable volumes, costs, and revenues.

However, a new service, such as the FedNow Service, differs from mature services in a number of important ways. By its nature, a new service generally involves high development costs. Moreover, unlike mature services, a new service may not initially have a critical mass of customer participation and, as a result, is likely to have low and unpredictable initial volumes. Certain specific circumstances—such as the length of time to develop the service, the use of the service by certain customer segments, or changes to the market landscape—may affect volumes and, thus, the costs and revenues of a new service. Taken together, these factors imply that, unlike mature services, a new service is unlikely to have stable costs and revenues when it is first deployed, making cost recovery challenging in the time frame that the Board has typically applied to mature services.

Given these considerations, the Board believes that the 10-year period used to evaluate cost recovery for mature services is an inappropriate standard for evaluating the long-run cost recovery of a new service similar to the FedNow Service. Applying such a standard could limit the Federal Reserve's ability to develop new services or undertake major service enhancements that support the provision of an adequate level of services nationwide or induce desirable long-term changes in the payment system.

The Federal Reserve's ACH service, the last new retail payment service developed by the Federal Reserve, provides an illustrative historical example of the importance of these considerations for cost recovery of new services. In evaluating the expected cost recovery of the FedACH service, the Board determined that, compared with the time frame for existing services, an extended cost recovery time frame was appropriate. It did so to encourage the development of an electronic funds transfer system for retail payments and to foster the development of efficient new technologies that would benefit the public in the long run.[77] Based on the

[71] Specifically, in preparing the pricing principles, the Board stated that the principles and future fee schedules take into account ''the objectives of fostering competition, improving the efficiency of the payment mechanism, and lowering costs of these services to society at large. At the same time, the Board is cognizant of, and concerned with, the Federal Reserve's continuing responsibility for maintaining the integrity and reliability of the payment mechanism and providing an adequate level of service nationwide.'' ''Principles for the Pricing of Federal Reserve Bank Services,'' *supra* note 66.

[72] Principle 5 explains that the Board will monitor progress in meeting this goal by reviewing regular reports submitted by the Reserve Banks. In the event that the Board authorizes a fee schedule for a service below cost in the interest of providing an adequate level of services nationwide, principle 5 states that the Board will announce its decision. *See* ''Principles for the Pricing of Federal Reserve Bank Services,'' *supra* note 66.

[73] Approximately 15 additional commenters raised issues related to cost recovery but did not express a view about whether a Federal Reserve RTGS service could recover its costs.

[74] These commenters included small and midsize banks, individuals, consumer organizations, and trade organizations.

[75] These commenters included large banks, trade organizations, and other interested parties.

[76] Notwithstanding the Board's standard 10-year long-run cost recovery period for existing services, the Board has previously needed to balance competing considerations in determining long-run cost recovery for those services. For example, efforts to modernize Federal Reserve check services in the early 2000s resulted in intermittent under-recovery of the service's costs during certain 10-year cost recovery periods.

[77] In partnership with the private sector, the Federal Reserve began piloting ACH services in the late 1960s. The Federal Reserve determined that ACH services had the potential to yield long-term improvements to the payment system because of concerns related to rapidly growing paper check volumes. For example, in 1971, the Federal Reserve's ''Statement of Policy on the Payments Mechanism'' explained that ''(i)ncreasing the speed and efficiency with which the rapidly mounting volume of checks is handled is becoming a matter of urgency. Until electronic facilities begin to replace check transfer in substantial volume, the present system is vulnerable to serious transportation delays and manpower shortages.'' Board of Governors of the Federal Reserve System, ''Statement of Policy on the Payments Mechanism,'' (June 18, 1971). Available at *https://fraser.stlouisfed.org/files/docs/publications/frbrichreview/rev_frbrich197107.pdf.* The first ACH pilot service became fully operational in the early 1970s. The Federal Reserve worked with the industry and the U.S. Treasury to expand the service during the 1970s and 1980s.

service's anticipated long-term benefits, the Board determined, both before and after passage of the MCA, that the nascent service's fees should be based on the costs associated with mature volume estimates.[78] As volume grew, the service first achieved annual cost recovery nearly 15 years after launching a pilot in 1972, and achieved 10-year cost recovery after more than 20 years of operation.[79]

Like the Federal Reserve's ACH service, the Board expects that the FedNow Service will take significant time to mature, as the industry takes steps to adopt the service. Ultimately, although the Board expects the service's first instance of long-run cost recovery to occur outside the 10-year cost recovery period typically applied to mature services, the service is nevertheless expected to achieve full recovery of costs over the long run in compliance with the Board's *Cost Recovery Criterion.* This expectation is based on certain conditions related to demand for faster payments, overall expansion of the market over the long term, time to market for the service, and direct or indirect participation in the service by banks of all sizes.

Expected long-run cost recovery for the FedNow Service outside the traditional 10-year cost recovery period for mature services may also affect aggregate cost recovery of Federal Reserve priced services, which would comprise the new FedNow Service and existing mature services. As noted above, although the Board's pricing principles impose an objective of full cost recovery for each service line, the cost recovery objective specified in the MCA only requires overall cost recovery of Federal Reserve services as a whole. Combining the revenues and costs of the FedNow Service with those of mature services may create the appearance of under-recovery for Federal Reserve services overall. Therefore, the Board believes it would be most appropriate to report the FedNow Service's cost recovery independently of mature Federal Reserve services until the FedNow Service reaches maturity.

The Board believes that an approach to cost recovery for the FedNow Service, as a new service, that does not rely on the standard applied to mature services is consistent with the language and purpose of the MCA and the Board's pricing principles for a number of reasons.

First, this approach is consistent with the MCA's requirement, incorporated in pricing principle 3, for the Federal Reserve to give due regard to the provision of an adequate level of service nationwide. As described above with respect to the Board's *Other Providers Criterion* and *Public Benefits Criterion,* in the absence of the FedNow Service, the objective of achieving an adequate level of service nationwide to support the development of ubiquitous RTGS-based faster payments in the United States is unlikely to be realized.

Second, this approach is consistent with pricing principle 5 as it relates to the start-up period for a service. In explaining its adoption of principle 5, the Board specifically noted the need for pricing flexibility during an initial start-up period when low and potentially variable volumes and high fixed costs could result in prohibitively high service fees, negatively affecting service usage and policy goals.[80] Such issues could arise for the FedNow Service if the Board required cost recovery over the same period as mature services.

Finally, this approach is consistent with pricing principle 7. Specifically, in adopting principle 7, the Board explained that pricing flexibility may be necessary to induce desirable long-run changes in the payment system and to foster development of services that will ultimately benefit the public.[81] Given that a nationwide RTGS infrastructure for new faster payments is a desirable long-run improvement, and in light of the benefits that would be likely to occur with the FedNow Service, as discussed under the *Public Benefits Criterion,* the Board believes that an expected cost recovery period of longer than 10 years is appropriate.

As part of this approach to cost recovery, the Board will regularly disclose the service's cost recovery beginning the year the service is available to participating banks and will monitor progress toward matching revenues and costs.[82] The Board will regularly confirm the expectation that the service will meet cost recovery objectives over the long run. As would be applicable to any Federal Reserve service, if it becomes clear that the FedNow Service is no longer expected to achieve long-run cost recovery or that the service will challenge the cost recovery of Federal Reserve priced services overall, the Board would reassess whether to continue providing the service. Such a reassessment would only occur after giving time for market development and adoption and would take into account other objectives, including the provision of equitable access to payment services and an adequate level of services nationwide.[83] Further information on expected service pricing is found in Part Two, including areas where comment is requested.

IV. Assessment of Expanded Operating Hours for the Fedwire Funds Service and the National Settlement Service To Support Liquidity Management for Faster Payments and For Other Purposes

The second potential action in the 2018 Notice was the development of a liquidity management tool to support RTGS services for faster payments. RTGS-based faster payment services require banks to have sufficient liquidity to perform interbank settlement at any time, on any day.[84] Without sufficient liquidity to conduct

[78] In establishing fees for the Federal Reserve's ACH service, the Board allowed fees to be set based on costs of operating a mature service instead of current costs. *See* Board of Governors of the Federal Reserve System, ''Adoption of Fee Schedules and Pricing Principles for Federal Reserve Bank Services,'' 46 FR 1338, 1343 (Jan. 6, 1981). Available at *https://cdn.loc.gov/service/ll/fedreg/fr046/fr046003/fr046003.pdf.*

After passage of the MCA, the Board approved a fee schedule that recovered 40 percent of the service's current costs and required the service to increase its cost recovery targets 20 percent each year thereafter until the service achieved 100 percent cost recovery. *See* Board of Governors of the Federal Reserve System, ''Fee Schedules for Federal Reserve Bank Services,'' 47 FR 53500 (Nov. 26, 1982) available at *https://cdn.loc.gov/service/ll/fedreg/fr047/fr047228/fr047228.pdf;* Board of Governors of the Federal Reserve System, ''Fee Schedules for Federal Reserve Bank Services,'' 50 FR 47624, 47625 (Nov. 19, 1985) available at *https://cdn.loc.gov/service/ll/fedreg/fr050/fr050223/fr050223.pdf.* The Board does not believe it is appropriate at this time to similarly set a specific year in which the new FedNow Service would recover costs, as was done for the ACH service. This is largely because the ACH service was not an entirely new service at the time the principles were adopted and, for a new service in a dynamic market, the likelihood of accurately forecasting when cost recovery will occur is low. The Board will annually review the appropriateness of setting such an expectation for the FedNow Service.

[79] The ACH service became fully operational in 1974. *See* ''The Federal Reserve System Purposes & Functions,'' *supra* note 4.

[80] *See* ''Adoption of Fee Schedules and Pricing Principles for Federal Reserve Bank Services,'' *supra* note 78.

[81] *See id.*

[82] Costs would include those related to development of the service and ongoing operations.

[83] As stated in the Board's policy ''The Federal Reserve in the Payments System,'' ''a decision to continue to provide a service that could not reasonably be expected to meet cost-recovery objectives would be made by the Federal Reserve Board only after seeking public comment and only where there were clear public benefits to such a course of action. Similarly, any decision to withdraw from the service would be undertaken in an orderly way, giving due regard to the transition problems associated with the discontinuation of a service.'' ''The Federal Reserve in the Payments System,'' *supra* note 18.

[84] Liquidity can take various forms, including funds in an account at a settlement institution or extensions of credit that allow payments to be completed when funds in an account are not sufficient to cover outgoing payments.

settlement, a faster payment cannot be completed in an RTGS-based service where, by design, interbank settlement occurs before final funds can be made available to the receiver. This risk of payments not being completed highlights the need for banks to be able to manage their liquidity on a 24x7x365 basis in accounts that support settlement of faster payments.

At present, the Federal Reserve does not offer a service that would allow banks to move liquidity as needed, in particular on weekends and holidays, to support real-time settlement of faster payments.[85] To reduce the risk of insufficient liquidity during those periods, banks can increase the funds in accounts that support settlement of faster payments to provide additional prefunding for future transactions. This additional prefunding, however, could be costly for banks because it prevents those funds from being used for other purposes. Prefunding also requires predicting the number and aggregate value of future customer payments, which has a degree of uncertainty. In consideration of the risk of failed transactions because of insufficient liquidity, the Board proposed developing a tool that would enable movement of funds between accounts at the Reserve Banks on a 24x7x365 basis, either by expanding the hours of current Federal Reserve services or through a new service.

A liquidity management tool could support private-sector RTGS arrangements for faster payments that are based on a joint account at a Reserve Bank.[86] Such a tool, as described in the 2018 Notice, could enable movement of funds between a joint account and banks' master accounts at any time of the day, any day of the year.[87] This tool would allow funds to be transferred, as needed, to support the payment activity of participants in private-sector RTGS services using a joint account.[88]

In the 2018 Notice, the Board requested feedback on whether the Federal Reserve should provide such a liquidity management tool and, if so, the desirable functionality of such a tool. The Board further requested comment on whether such a tool could be used for purposes other than supporting real-time settlement of faster payments.

A. Public Comments

Approximately 230 commenters expressed views about whether the Federal Reserve should develop a liquidity management tool to support RTGS services.[89] Approximately 225 commenters, from all segments, supported the Federal Reserve developing such a tool. Fewer than five commenters were not supportive of the Federal Reserve developing a liquidity management tool to support RTGS services.[90]

Several large banks and other commenters indicated that the proposed tool could help with managing liquidity in the existing private-sector RTGS service for faster payments. Other commenters more generally discussed the importance of liquidity management in RTGS services for faster payments and noted the challenge of managing the timing of payment inflows and outflows on a 24x7x365 basis. Many commenters emphasized the importance of automated features for a liquidity management tool, such that liquidity transfers could occur outside standard business hours without the need for operational staff at participating banks during those hours. At least one commenter noted that functionality provided through a liquidity management tool should be available to all systems that could benefit from it. This comment was consistent with those from other commenters that emphasized the Federal Reserve should more generally enhance its current services to support a variety of payment activities.

Most of the commenters that addressed how the Federal Reserve should provide a liquidity management tool expressed the view that it should do so through expansion of operating hours for the Fedwire Funds Service. Commenters noted the potential for a variety of payment activities to benefit from expanded operating hours for the Fedwire Funds Service. A few commenters stated that the Federal Reserve should expand operating hours for NSS. No commenters suggested that the Federal Reserve should develop a new service to support liquidity management in RTGS services for faster payments.

The commenters that did not support the Federal Reserve developing a liquidity management tool indicated that liquidity management could be accomplished through software developed by the private sector that would alert a bank about balance levels in their account at the Reserve Banks.

B. Board Analysis

The Board believes that expanding the operating hours of the Fedwire Funds Service and NSS, potentially up to 24x7x365, would be the most effective way to provide the liquidity management functionality described in the 2018 Notice and could provide additional benefits to financial markets broadly.

The ability to transfer funds from master accounts to a joint account during nonstandard business hours would allow participants in a private-sector RTGS service to manage liquidity on a ''just-in-time'' basis. Just-in-time liquidity management would remove the need to increase funding in a joint account ahead of weekends, holidays, and other times when liquidity transfers are not currently possible. Just-in-time liquidity management would also decrease the likelihood that a bank would have insufficient liquidity to settle a payment. As a result, the system would have less risk that an individual or business would experience an incomplete payment because its bank does not have the requisite funds available in a joint account to support settlement. These benefits might broaden the appeal of a private-sector RTGS service using a joint account, thereby potentially expanding the use of RTGS services for settlement of faster payments.

Expanded hours for the Fedwire Funds Service and NSS could also benefit other retail payment services. For retail services that conduct interbank settlement on a deferred basis, including certain faster payment services and traditional payment card services, expanded hours could enable these services to settle net interbank

[85] The Fedwire Funds Service operating hours for each business day begin at 9:00 p.m. eastern time (ET) on the preceding calendar day and end at 6:30 p.m. ET, Monday through Friday, excluding designated holidays. Current operating hours for NSS are 7:30 a.m. ET to 5:30 p.m. ET, Monday through Friday, excluding designated holidays.

[86] In such an arrangement, real-time settlement occurs on an internal ledger maintained by a private-sector operator of an RTGS service for faster payments, supported by funds that are held in an account at a Reserve Bank for the joint benefit of the service's participants. To support settlement through such a service, each participant bank ensures sufficient funding in the joint account to cover its payment obligations on a 24x7x365 basis.

[87] A master account is the record of financial rights and obligations between an account-holding bank and a Reserve Bank. The account is where opening, intraday, and closing balances are determined.

[88] The private sector could develop alternative mechanisms to enable liquidity management for participants in a private-sector RTGS service for faster payments based on a joint account. For example, to address liquidity needs over the weekend, a private-sector operator could allow participants with excess funds on its ledger to transfer those funds within the service to those with a shortage.

[89] At least one additional commenter raised issues related to a liquidity management tool but did not express a view about whether the Federal Reserve should offer such a tool.

[90] Commenters expressing this view included those from the following segments: Private-sector operators and fintech companies.

obligations at times not currently possible, including weekends and holidays. Expanded Fedwire Funds Service and NSS hours could also benefit ACH payments by enabling additional settlement windows.[91]

In addition, expanded Fedwire Funds Service hours would increase the overlap between the hours of the Fedwire Funds Service and those of large-value payment systems in other countries, thereby supporting wholesale payment activity in multiple markets. For example, expanded hours could allow U.S. banks that provide clearing services to global correspondents and multinational corporations to meet client needs outside standard business hours. Expanded hours could support a broad range of domestic wholesale payment activity as well, such as margin payments related to trading conducted on 24-hour platforms or payments related to mergers and acquisitions that close on a weekend.

In light of these potential benefits, the Board has determined that the Federal Reserve should explore the expansion of Fedwire Funds Service and NSS hours. However, because of the systemic importance of the Fedwire Funds Service and the Board's risk management expectations for the service, additional analysis is needed to evaluate fully the relevant operational, risk, and policy considerations for both the Reserve Banks and participants. The Federal Reserve plans to engage with the industry on issues related to expanded Fedwire Funds Service and NSS operating hours, as well as potential approaches for expanding those hours. Implementation approaches could range from limited availability on weekends and holidays to full 24x7x365 availability. Through this engagement, the Federal Reserve intends to solicit additional information about the industry's specific needs and readiness related to these options. The Board will announce any decision regarding the expansion of hours for the Fedwire Funds Service and NSS, including issuing a request for comment if necessary, after further analysis is completed.

Part Two

V. FedNow Service Description

In what follows, the Board has outlined a general description of the planned FedNow Service and provided additional details on the service's potential features and functionality. The features and functionality, along with related implementation considerations, incorporate feedback from comments received in response to the 2018 Notice.

The Board is seeking comment on all aspects of the FedNow Service. The Federal Reserve also intends to convene industry groups and facilitate other outreach forums to gather input on the service.[92] The Federal Reserve will use the feedback gained through written comments and other channels to finalize the design and features of the FedNow Service. Once these details have been finalized, a final service description will be published in a subsequent **Federal Register** notice with additional information provided through existing Reserve Bank communication channels.

A. Public Comments

In the 2018 Notice, the Board sought input on certain issues related to the design and implementation of a potential RTGS service for faster payments. First, the Board sought comment on the ideal timeline for implementing such a service. Second, the Board requested comment on the adjustments that banks and their customers would need to make under an accounting regime in which the Reserve Banks would record and report end-of-day balances for each calendar day, including weekends and holidays (a seven-day accounting regime).[93] Third, the Board sought input on the operational burden that banks would face if an RTGS service for faster payments were designed to use accounts separate from banks' master accounts.[94] Fourth, the Board sought feedback on the need for auxiliary services, such as fraud prevention services that provide tools to detect fraudulent payments or a directory that allows faster payment services to route end-user payments using the receiver's public identifier, such as a phone number or email address, rather than bank routing and account information.[95] For each question, commenters from nearly every segment provided input.

More than 140 commenters, from all segments, addressed the ideal timeline for implementing a Federal Reserve RTGS service for faster payments. The majority of these commenters encouraged the Federal Reserve to implement such a service as quickly as possible. These commenters noted that the market for faster payments is rapidly evolving and that, if the Federal Reserve were unable to provide a service in the near future, it would face difficulty achieving widespread adoption. A few commenters cautioned that, while acting quickly may be ideal, the timing of a new service should take into consideration the adjustments that banks and service providers would need to make to implement the service.

Approximately 40 commenters addressed operational adjustments that would be required if an RTGS service for faster payments used a seven-day accounting regime.[96] Some of these commenters noted that, although certain banks may have already adopted 24x7x365 accounting for services such as ATM and debit card transactions, some banks and their business customers may need to make substantial back-office adjustments to implement a seven-day accounting regime. These adjustments included system upgrades, operational changes, and staffing outside of standard business hours. Approximately 10 commenters stated that the option to defer receipt of transaction reporting during

[91] In a separate notice, the Board has requested comment on potential modifications to Federal Reserve payment services to facilitate adoption of a later same-day ACH processing and settlement window. Under the proposal in that notice, the Federal Reserve would extend the daily operating hours of the Fedwire Funds Service and NSS by 30 and 60 minutes, respectively, to accommodate a third same-day ACH settlement window at 6:00 p.m. ET. *See* Board of Governors of the Federal Reserve System, ''Potential Modifications to the Federal Reserve Banks' National Settlement Service and Fedwire Funds Service To Support Enhancements to the Same-Day ACH Service and Corresponding Changes to the Federal Reserve Policy on Payment System Risk, Request for Comments,'' 84 FR 22123, 22129 (May 16, 2019). Available at *https://www.federalregister.gov/d/2019-09949*.

[92] The Reserve Banks will communicate information about industry groups and forums through established channels. Industry engagement is expected to be a continual process as part of ongoing service and product development.

[93] At present, end-of-day balances are recorded and reported for each banking day that Federal Reserve services operate. Normal banking days are Mondays through Fridays. Because Federal Reserve services do not currently operate over the weekend (or on holidays), this current practice corresponds to a five-day accounting regime.

[94] As described previously, a master account is the record of financial rights and obligations between account-holding banks and a Reserve Bank. The Reserve Banks typically permit a single master account per eligible institution, and the settlement activity for most Federal Reserve payment services occurs in master accounts.

[95] The receiver's bank routing and account information is generally required to deliver payments between end-user bank accounts. This information can be difficult for the sender of a payment to obtain. As a result, some payment services allow the sender to direct a payment using a public identifier of the intended receiver. For such a public identifier to be used in a payment, the sender's bank must be able to link the public identifier to the intended receiver's banking information. A directory allows a bank to obtain this information through a database that connects public identifiers with the receiver's banking information, without requiring the sender to have that information or the receiver to reveal it to the sender.

[96] These commenters included small and midsize banks, large banks, individuals, consumer organizations, service providers, fintech companies, trade organizations, and other interested parties.

nonstandard business hours might be useful until banks are able to support 24x7x365 back-office operations.

Approximately 50 commenters expressed views on the incremental operational burden if an RTGS service were to settle faster payments in dedicated Federal Reserve accounts, separate from banks' master accounts.[97] The majority of these commenters indicated that, if necessary, banks would likely be able to manage separate settlement accounts. Some of these commenters further stated that if separate accounts were used, the benefits of such a structure would need to outweigh the burden for banks of managing separate accounts. Commenters also noted that a liquidity management tool would be needed to move funds during nonstandard business hours between master accounts and separate accounts for settlement of faster payments. Most commenters that addressed the use of separate accounts stated that, if separate Federal Reserve accounts were used for settlement of faster payments, balances in those accounts should earn interest and count towards reserve requirements.

More than 100 commenters, from all segments, discussed whether a directory service is needed for an RTGS service for faster payments. Many of these commenters stated that directories are an important driver for adoption of faster payments because individuals and businesses value the ability to make payments based on public identifiers. These commenters often indicated that the Federal Reserve should support development of a directory service for faster payments, citing their views of the Federal Reserve as a trusted service provider with broad reach. Some of these commenters suggested the Federal Reserve could build and operate its own directory service whereas others suggested that it could serve as a centralized link to existing directories. A few commenters did not support the Federal Reserve developing its own directory service because private-sector directories are already available.

More than 90 commenters addressed the importance of fraud prevention services.[98] Many of these commenters suggested that an RTGS service for faster payments should include fraud prevention services, with some noting that such services could be more efficient and less susceptible to vulnerabilities if they were an integral part of an RTGS service for faster payments. Some commenters noted that fraud prevention services could include a database of known fraudulent accounts or automated fraud detection tools to identify unusual payment activity. Some commenters noted that a potential Federal Reserve RTGS service for faster payments would not require fraud prevention services because the private sector already offers such services. In the context of discussing fraud prevention services, some commenters also highlighted the need for tools that would assist in compliance with regulations to prevent money laundering and terrorist financing.

B. General Description of the FedNow Service

The FedNow Service would process individual payments within seconds, 24 hours a day, 7 days a week, 365 days a year. The service would be designed to support credit transfers, where a sender initiates a payment to an intended receiver for a variety of use cases, such as person-to-person payments, bill payments, and smaller-value business-to-business payments.[99] The service would settle interbank obligations through debit and credit entries to balances in banks' master accounts at the Reserve Banks. All settlement entries for transactions through the FedNow Service would be final, meaning that settlement cannot be cancelled or revoked once a transaction is processed by the service. Consistent with the goal of supporting faster payments, use of the service would require participating banks to make the funds associated with individual payments available to their end-user customers immediately after receiving notification of settlement from the service. The service would support values initially limited to $25,000.[100] The service would have the ability to process a large volume of payments rapidly, including volumes that may be unusually large at certain times of the day or days of the year.

The FedNow Service would incorporate clearing functionality with messages containing information required to complete end-to-end payments, such as account information for the sender and receiver, in addition to interbank settlement information. The service would also support the inclusion of additional descriptive information related to a payment, such as remittance or invoice information, and may further allow for nonvalue message types.[101] Payment message format would be based on the ISO 20022 standard.[102]

In its simplest form, a completed payment through the FedNow Service involving two participating banks would have the following steps.[103] To start, a sender would initiate a payment through its bank, by submitting instructions to it using an end-user interface outside the FedNow Service. After the sender's bank authenticates the sender and validates the payment, it would submit a payment message to a Reserve Bank using the FedNow Service. The FedNow Service would authenticate the sender's bank and validate the payment message, for example, by verifying that the message meets the FedNow format specifications. Before the Reserve Bank executes the payment message, the service would place a provisional hold on funds in the master account of the sender's bank and would then send an inquiry message to the receiver's bank seeking confirmation that the receiver's bank, among other things, maintains a valid account for the receiver included in the payment message received by the Reserve Bank. If the receiver's bank sends a positive response to the inquiry, the FedNow Service would execute the payment for the Reserve Banks by sending a payment message forward with an advice of credit to the receiver's bank and nearly simultaneously processing a final debits and final credit to the master accounts of the sender's bank and receiver's bank,

[97] These commenters included small and midsize banks, large banks, individuals, service providers, fintech companies, and trade organizations.

[98] These commenters included small and midsize banks, individuals, merchants, service providers, and trade organizations.

[99] Some traditional payments, such as card payments and certain ACH payments, are conducted as debit transfers. In a debit transfer, the party that wishes to be paid provides instructions that allow its bank to pull funds from the account of the party that needs to pay for a good or service, subject to the approval of that party and its bank. Because credit transfers require the sender to authorize and initiate each individual payment, services based on such transfers can decrease the risk of fraudulent or otherwise unauthorized payments. This and other considerations have led credit transfers to be the basis of faster payment systems in other countries.

[100] The initial $25,000 value limit would be intended to restrict the size of potential fraudulent transactions, while also supporting payments associated with a variety of use cases. Like other aspects of the service, this value limit could change after experience with the service provides additional information about whether a change would be appropriate. Banks would also be able to establish value limits for their customers below the $25,000 limit.

[101] For example, one possible message type is a ''request for payment'' in which the intended receiver submits a request for the sender to initiate a payment. A request-for-payment message type is addressed in the discussion of specific service features.

[102] Additional information about the ISO 20022 standard is provided in the discussion of specific service features.

[103] Other steps could occur, for example, if either bank were to use an agent, service provider, or correspondent or if a directory service were used.

respectively.[104] The banks are responsible for debiting and crediting their customers' accounts and providing further notification to their customers that the payment has been completed. The entire process would take place within seconds.

Like current Federal Reserve services, the FedNow Service would be available to banks eligible to hold accounts at the Reserve Banks under applicable federal statutes and Federal Reserve rules, policies, and procedures.[105] Participating banks would be able to designate a service provider or agent to submit or receive payment instructions on their behalf. Participating banks could also choose to settle payments in the account of a correspondent bank.[106]

The service would establish a ''business day'' by setting opening (beginning-of-day) and closing (end-of-day) times (in eastern time). This business day would be used to determine end-of-day balances and conduct associated reserve and interest calculations, as well as for transaction reporting and account reconciliation purposes. The existence of these opening and closing times would not affect the service's 24x7x365 continuous processing of payments. End-of-day balances would be calculated for master accounts on each calendar day, including weekends and holidays, as part of a seven-day accounting regime. Banks would be expected to manage their accounts to have a positive end-of-day account balance each day and avoid overnight overdrafts.

The Board recognizes that, in a market structure with multiple operators of RTGS services for faster payments, the ability to achieve ubiquity in faster payments is advanced when customers of a bank participating in one RTGS service are able to reach the customers of a bank participating in another RTGS service. This type of reach can be achieved in multiple ways, such as by banks participating in multiple services, or through interoperability where direct exchange of payments across services is possible. Each of these requires some degree of cooperation among private-sector operators, banks, and service providers. During its engagement with the industry, the Federal Reserve intends to explore both interoperability and other paths to achieving nationwide reach in support of ubiquitous faster payments, recognizing that these approaches may change over time.

C. Discussion of Specific Features and Functionality

The Board has considered the specific features and functionality of the planned FedNow Service. These features and functionality, as well as whether they would be part of the service initially, offered incrementally after the service is operational, or offered at all, may need to be adjusted based on the Federal Reserve's industry engagement efforts. In addition, industry engagement may identify other features and functionality not described here that may be addressed in the subsequent **Federal Register** notice as part of the final service description or through existing Reserve Bank customer communication channels.

1. Message Standard

Payment message formats in the FedNow Service would be based on the ISO 20022 standard and its implementation with respect to faster payments in the United States.[107] The service would support various message types, including payment instructions, confirmations, and request for payment. As part of a payment, the service would also support the exchange of remittance or other information related to a specific payment or invoice. Message specifications for the service, including specific message types and interpretation of ISO formats, would be provided to the industry prior to the initial launch of the service through established Reserve Bank communication channels.

2. Settlement Account

Like other Federal Reserve payment and settlement services, the FedNow Service would settle payments in master accounts.[108] Depending on the services used by a participating bank, transactions from multiple Federal Reserve services would settle in a master account at any given time during standard business hours.[109] Banks would need to monitor their master accounts and possibly adjust practices in managing those accounts because of the real-time settlement activity associated with the FedNow Service (see also the *Liquidity and Credit* discussion).

3. Seven-Day Accounting Regime

After considering Financial Accounting Standards Board (FASB) principles, the Board believes that a seven-day accounting regime is appropriate for the FedNow Service.[110] Funds associated with a payment made using the FedNow Service would be transferred between the sender's bank and the receiver's bank upon final settlement. Therefore, in light of the FASB principles' guidance on when transferred assets should be recognized on each parties' financial records, the Reserve Banks would record and report transactions for accounting purposes as they occur, each day of the week, including weekends and holidays.[111]

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[104] The receiver's bank would need to respond to the message sent to it by the service within a certain amount of time. In the event that the response process is not completed within the expected time, the transaction would not be completed. Instead, the payment would be rejected, with the provisional hold on funds removed from the master account of the sender's bank and the banks being notified of the rejection. A payment could also be rejected, with associated notifications of payment rejection, if any of the necessary steps were not completed. For example, a payment could be rejected because of invalid account information for the receiver, which would cause the receiver's bank to reject the payment.

[105] Section 13(1) of the Federal Reserve Act permits Reserve Banks to receive deposits from member banks or other depository institutions. 12 U.S.C. 342. Section 19(b)(1)(A) of the act includes as depository institutions any federally insured bank, mutual savings bank, savings bank, savings association, or credit union. 12 U.S.C. 461(b). The Reserve Banks may maintain accounts for additional institutions under other statutory authority.

[106] A correspondent bank is a bank that has authorized a Reserve Bank to settle debit and credit transaction activity to its master account for a respondent bank. Correspondent/respondent relationships are established under Federal Reserve Operating Circular 1.

[107] The ISO 20022 standard is a message format standard for payments, securities, trade services, payment cards, and foreign exchange. For more information, see *https://www.iso20022.org/*. The standard is published by the International Organization for Standardization (ISO), an independent, non-governmental organization comprised of 161 national standards bodies. For more information, see *http://www.iso.org.* The ISO 20022 standard is increasingly being adopted around the world as part of efforts to modernize payment services, including those that are used for faster payments.

[108] As discussed in the 2018 Notice, the Board contemplated a two-account structure, with a separate account dedicated to settlement of faster payments to possibly reduce the technical complexity of an RTGS service and reduce time-to-market. However, this structure would introduce significant operational complexity for both the Federal Reserve and participating banks. For example, a separate account for settlement of faster payments would require new balance reconciliation procedures and introduce the need for participating banks to make transfers between the two accounts.

[109] These other services are check services, the Fedwire Funds Service, NSS, the Fedwire Securities Service, and FedACH services.

[110] FASB accounting principles are developed under the FASB Statements of Financial Accounting Concepts, which the FASB states are ''intended to serve the public interest by setting the objectives, qualitative characteristics, and other concepts that guide . . . financial reporting.'' More information on the FASB Statements of Financial Accounting Concepts is available at *https://www.fasb.org/cs/ContentServer?c=Page&cid=1176156317989&d=&pagename=FASB%2FPage%2FPreCodSectionPage.*

[111] The Board considered a five-day accounting regime for the service, which would be consistent with the Federal Reserve's current approach and that of many banks, but determined that, under the FASB principles, a seven-day regime is most appropriate for the FedNow Service. Specifically, the FASB principles outline that once control of an

Similarly, an end-of-day balance would also be calculated for each participating bank at the FedNow Service's designated closing time each day of the week, including weekends and holidays (see also the *Business Day* discussion).

A seven-day accounting regime adopted by the Federal Reserve for the FedNow Service does not dictate or preclude use of specific other accounting regimes by participating banks. Based on their interpretation of accounting principles, participating banks may choose to use other accounting approaches internally; for example, banks may use five-day accounting in which they record and report weekend transactions on their financial records as occurring on Monday.[112] The service would provide queries, confirmations, and reports to support transaction monitoring, reporting, and reconciliation by participating banks under their chosen internal accounting approach. Banks could elect either to receive daily accounting reports at the end of each business day to allow management of reserve balances or to receive reports for weekends and holidays on the next business day.

4. Business Day

In considering the implications of a business day for the FedNow Service in light of business day practices for current Federal Reserve services, the Board has determined that the business day of the FedNow Service should align with the business day of the Fedwire Funds Service.[113] Given the 24x7x365 nature of the FedNow Service, the opening time would be designated to occur immediately after the closing time, with the intention that transitions between closing and opening for the next business day would not disrupt continuous processing. Transactions completed after the FedNow Service's closing but before midnight each calendar day would be recorded on Federal Reserve accounting records as transactions occurring on the next business day.

A business day for the FedNow Service that aligns with the Fedwire Funds Service, however, does not dictate that participating banks adopt the same convention, or preclude other conventions, for recording transactions in their customers' accounts. For example, banks could post faster payment transactions occurring after the close of the FedNow business day to customers' accounts in real time based on the calendar day in which they are received.[114]

5. Liquidity and Credit

Comments in response to the 2018 Notice indicated concerns about adequate liquidity being available to support faster payments, particularly on weekends and holidays. To support their current payment services, the Reserve Banks provide liquidity in the form of intraday credit, also known as daylight overdrafts, to eligible banks and subject to the Federal Reserve's Policy on Payment System Risk (PSR Policy).[115] Intraday credit supports the smooth functioning of the payment system by supplying temporary liquidity to cover shortages that can result when the timing of payment inflows and outflows are not balanced.

Like current services, access to intraday credit for FedNow transactions could support the smooth functioning of payments through the service. The Board is considering the impact of providing intraday credit on a 24x7x365 basis under the same terms and conditions as for current Federal Reserve services. As is the case today, participating banks would be expected to manage their master accounts in compliance with Federal Reserve policies, including avoiding overnight overdrafts.[116] These expectations would apply over weekends and holidays given that the FedNow Service would operate 24x7x365.

Account balance management would become more complex in a 24x7x365 environment where payments settle continuously in master accounts. Given the retail nature of payments through the FedNow Service, transaction values are expected to be relatively small compared with other activity in master accounts, such as Fedwire Funds transfers. Nevertheless, participating banks may need to adjust internal account monitoring practices to manage intraday liquidity. Liquidity management would be particularly important to avoid a negative balance at the service's closing time. Specifically, banks would need to carefully monitor transactions in real time or ensure that sufficient funding is available in their master accounts to cover payments that may arise shortly before the service's closing.

The Federal Reserve is conducting analysis of when it may be beneficial to extend discount window operations to include weekends or holidays.[117] At least initially, however, discount window loan originations would likely not be available on weekends and holidays. The discount window would continue to be available until the close of the Fedwire Funds Service on Fridays under the same or similar terms as today.

The Board will engage with the industry to consider features and tools to assist institutions with the effective management of intraday and end-of-day account balances.[118] The Board may

asset, such as balances in a Federal Reserve account, is transferred to a new owner, the asset should be removed from the original owner's financial records and recognized on the new owner's financial records.

[112] Over time, participating banks could alternatively choose to adopt a seven-day accounting approach.

[113] Today, the Fedwire Funds Service closes at 6:30 p.m. ET and re-opens for the next business day at 9:00 p.m. ET on the same calendar day. The Board recently requested comment on moving the close of the Fedwire Funds Service to 7:00 p.m. ET to accommodate later settlement for ACH transactions. *See* ''Potential Modifications to the Federal Reserve Banks' National Settlement Service and Fedwire Funds Service,'' *supra* note 91.

Fedwire Funds transactions between 9:00 p.m. ET and midnight ET are recorded as occurring on the next business day and typically support international markets and settlement of other domestic and global payment systems. The Board considered setting a midnight ET closing time for the FedNow Service to align across business and calendar days. However, such an approach would not allow balance calculations performed by the Federal Reserve to be measured on the same business day for the Fedwire Funds service and the FedNow Service, making calculation of balances problematic. Such a misalignment could have consequences for the current activity occurring over the Fedwire Funds Service.

[114] This practice would be akin to banks' common practice of ''memo posting'' for ATM withdrawals and certain other transaction activity. Under this practice, transactions are provisionally posted to customers' accounts on the date they are made but are reported on a later date for the purposes of monthly account statements.

[115] Intraday credit is generally available to banks that are financially healthy and have regular access to the discount window (the Federal Reserve's program for overnight lending to banks). *See* Board of Governors of the Federal Reserve System, ''The Federal Reserve Policy on Payment System Risk,'' (As amended effective September 15, 2017). Available at *https://www.federalreserve.gov/paymentsystems/psr_about.htm.*

[116] To minimize Reserve Bank exposure to overnight overdrafts, policy established by the Board discourages institutions from incurring overnight overdrafts by charging a penalty fee. *See* Board of Governors of the Federal Reserve System, ''Policy on Overnight Overdrafts,'' (Effective July 12, 2012). Available at *https://www.federalreserve.gov/paymentsystems/oo_policy.htm.*

[117] The discount window is a Federal Reserve lending facility that helps to relieve liquidity strains for individual banks and for the banking system as a whole by providing a reliable backup source of funding. Additional information on the discount window is available at *https://www.federalreserve.gov/regreform/discount-window.htm.*

[118] Today, banks use the Reserve Bank's Account Management Information services for a near real-time view of account balances. At least initially, the Federal Reserve expects that banks would need to monitor account balances outside standard business hours by reconciling payment activity against the last available closing balance. However, the Federal Reserve expects that the Reserve Bank's Account Management Information services would be

Continued

apply additional controls, initially or over time, in the PSR Policy as necessary to mitigate the credit risk incurred by the Reserve Banks in providing access to liquidity and credit.

6. Network Access

Participating banks would access the FedNow Service through the FedLine® network, which would be enhanced to support the service's 24x7x365 processing.[119] Participating banks would need to deploy and test enhanced or upgraded FedLine components to enable the FedNow Service. Depending on their electronic connection with the FedLine network, banks also would need to maintain adequate telecommunications services to support the expected end-to-end speed of payments through the FedNow Service.

7. Service Pricing

Before the FedNow Service is launched, the Board will announce the service's fee structure and fee schedule.[120] Based on prevailing market practices, the Board expects that the fee structure would include a combination of per-item fees, charged to sending and potentially to receiving banks, and fixed participation fees.[121] Separate per-item fees could also be charged for other message types that may be offered in the future.

As discussed in Section III under the *Cost Recovery Criterion,* the Board expects that the FedNow Service will take significant time to mature, as the industry takes steps to adopt the service. The Board expects the service's first instance of long-run cost recovery to occur outside the 10-year cost recovery period typically applied to mature services. The Board anticipates that, until the FedNow Service reaches maturity with relatively stable costs and revenues and a critical mass of bank participation, fees would be based on costs associated with mature volume estimates.[122] The Board believes that this approach to cost recovery for the FedNow Service, as a new service, which would not rely on the standard applied to mature services, is consistent with the language and purpose of the MCA and the Board's pricing principles. The Board is requesting comment on factors that may be relevant to consider in evaluating the long-run cost recovery of new Federal Reserve services compared with mature services.

8. Request for Payment

In the FedNow Service, a request for payment would be a separate nonvalue message type that, when received through an end-user service, would prompt a sender to initiate a payment to the receiver who is requesting funds. The request for payment functionality allows a sender to authorize a credit transfer in real time, based on the receiver's request message. This functionality may increase the use of faster payments by allowing end users to more easily conduct certain types of transactions, such as bill payments. This functionality allows a sender to retain control of the authorization in sending a payment in real time, helps avoid mistakes of sending payments to the wrong party, and reduces the fraud risk relative to that of debit transfers.[123] The Board is seeking input on the incremental value and ideal implementation timing of such functionality to advance broad adoption of faster payments in the United States.

9. Directory Service

Comments received in response to the 2018 Notice indicated the ability to originate payments using a receiver's public identifier, such as an email address or cell phone number, would be beneficial to help drive adoption of faster payments. To send a valid payment message in the FedNow Service, however, the sender's bank must have the banking information of the receiver. Therefore, if a sender wanted to originate a payment using a public identifier, the sender's bank would need to be able to find the banking information of the intended receiver using the public identifier. The availability of a directory that connects public identifiers with receivers' banking information would provide the sender's bank with the needed information, without ever revealing that information to the sender.

Access to a directory for purposes of payments made using the FedNow Service could be accomplished in multiple ways. Individually, banks could establish connections to existing private-sector directories and develop an automated mechanism for populating payment messages with information provided by these external directories. Alternatively, the Reserve Banks could establish a centralized link with private-sector directories on behalf of participating banks, rather than each participating bank needing to do so individually. A further option would be for the Reserve Banks to build their own directory, enabling a message type that would allow banks to query the directory as part of the FedNow Service. The Federal Reserve intends to engage with industry stakeholders to understand more fully the benefits and drawbacks of these potential approaches and to assess possible paths forward to advance broad adoption of faster payments in the United States.

10. Fraud Prevention Services

Comments received in response to the 2018 Notice emphasized the heightened risk of fraud with real-time transactions and noted the importance of fraud-monitoring solutions to aid in mitigating fraud risk. The Board agrees that strong security mechanisms are necessary to support the overall safety of the nation's payment system. Across the payment system, payment security at the end-user level rests between end users and their banks, while at the payment system level, service operators may have additional layers of security.

For the FedNow Service, participating banks would continue to serve as a primary line of defense against fraudulent transactions, as they do today, with solutions to mitigate fraud enabled as part of the end-user services banks offer their customers. At the payment system level, the FedNow Service could offer additional fraud mitigation features, such as payment monitoring to alert participating banks of unusual transactions. In addition, the Federal Reserve remains committed to working with the industry on best practices and standards for mitigating fraud across these levels. The Federal Reserve intends to engage with industry stakeholders to better assess FedNow Service features that could help mitigate fraud risk and advance the safety of faster payments in the United States.

available during the same hours as the FedNow Service shortly after the service becomes available.

[119] FedLine Solutions is a set of electronic connection products that over 10,000 banks (or their agents) use to access Federal Reserve payment and information services. More information is available at *https://frbservices.org/fedline-solutions/index.html.*

While not envisioned at this time, the Board may consider in the future whether enabling access to the FedNow Service through alternate messaging networks would enhance resiliency or interoperability for faster payments.

[120] After announcing the initial fee schedule, consistent with existing practice, the Board would include the FedNow Service with its annual service-pricing process for all priced services.

[121] The ultimate fee structure and schedule would be informed by the Board's assessment of market practices at the time of implementation, which could evolve from today's practices.

[122] This approach is consistent with that used for the Federal Reserve's ACH service before it became a mature service.

[123] Many payments in the United States, such as electronic bill payments and card payments have traditionally been accomplished as debit transfers, in which the sender provides the receiver with information and authorization to debit the sender's bank account.

D. Implementation

The Board acknowledges the time-to-market pressure for industry participants related to faster payment services and is committed to launching the FedNow Service as soon as practicably possible. The Federal Reserve will engage quickly with industry participants to gather input for finalizing the initial design and features of the service. Pending engagement with the industry, the Board anticipates the FedNow Service will be available in 2023 or 2024.

VI. Competitive Impact Analysis

The Board conducts a competitive impact analysis when considering an operational or legal change to a new or existing service, such as the planned FedNow Service. The Board has considered whether the FedNow Service as described in Section V would have a direct and material adverse effect on the ability of other service providers to compete effectively with the Federal Reserve in providing similar services due to differing legal powers or constraints or due to a dominant market position of the Federal Reserve deriving from such legal differences.[124]

In conducting a competitive impact analysis, the Board first determines whether the proposal has a direct and material adverse effect on the ability of other service providers to compete effectively with the Federal Reserve in providing similar services. In instances where such direct and material adverse effects on the ability of the private-sector provider to compete are identified, the Board then considers whether such effects were due to either legal differences or a dominant market position deriving from such legal differences. If the Board determines that the material adverse effects were the result of legal differences or the Federal Reserve's dominant market position, the Board then evaluates the potential public benefits of the new service in order to determine whether those benefits could be reasonably achieved with a lesser or no adverse competitive impact. Based on these considerations, the Board then either modifies the proposal to lessen or eliminate the adverse impact on competitors' ability to compete or determines that the payment system objectives may not be reasonably achieved if the proposal is modified. If reasonable modifications would not mitigate the material adverse effect, the Board then determines whether the anticipated benefits of the new service are significant enough to proceed with the service even though it may adversely affect the ability of other service providers to compete with the Federal Reserve in that service.

The Board has conducted an initial competitive impact analysis for the FedNow Service. However, the Board will conduct a final competitive impact analysis after considering the comments received during the public comment period.

A. Relevant Private-Sector Providers of Similar Services

In conducting its initial competitive impact analysis, the Board first identified relevant private-sector providers of similar services. At present, there is one private-sector RTGS service for faster payments in the United States, which has been operational since November 2017.[125] Like the planned FedNow Service, the private-sector RTGS service conducts real-time payment-by-payment final settlement of interbank obligations on a 24x7x365 basis. Unlike the FedNow Service, which would settle in central bank money using master accounts, the private-sector RTGS service relies on an internal ledger kept by its operator to conduct settlement, which is supported by funds held in a joint account at a Reserve Bank.[126]

B. Material Adverse Effects on the Ability of Relevant Service Providers To Compete Effectively

After identifying relevant private-sector providers of similar services, the Board then compared those providers' services with the FedNow Service. The purpose of this comparison is to identify differences between private-sector and Federal Reserve services. Such differences could create a direct and material adverse effect on the ability of the private-sector services to compete effectively with the Federal Reserve. Ultimately, it would be difficult to create total parity between the Federal Reserve and private-sector providers in their provision of payment services. Certain differences may provide advantages in the Federal Reserve's provision of priced services, while other differences may provide competitive advantages to private-sector entities.[127]

In this regard, certain specific differences between the FedNow Service and the private-sector RTGS provider are relevant. For example, the eligibility of funds held in master accounts to earn interest and count toward reserve requirements is a particularly notable difference between the two services. However, whether these and other differences between the two services will, on net, have a direct and material adverse effect on the ability of the private-sector RTGS service to compete effectively with the Federal Reserve is unclear.

First, the FedNow Service would allow participants to use their master accounts at the Reserve Banks, whereas the private-sector RTGS provider uses a separate non-interest-bearing joint account that each participant must prefund. Use of master accounts may provide an advantage to the FedNow Service because funds remain in participants' Federal Reserve accounts, earning interest and counting towards reserve requirements, and can be used for other purposes. Unlike funds held in a master account, funds held in the private-sector service's joint account do not earn interest or count towards reserve requirements and are not available for other purposes that may arise, such as satisfying payment or liquidity needs outside the private-sector service.[128]

Second, if the Board confirms that the FedNow Service would provide access to intraday credit under the same terms and conditions as for current Federal Reserve services, such intraday credit would lower the risk that payments will be rejected because of lack of funds. In such a scenario, the Federal Reserve would expect banks to manage their

[124] "The Federal Reserve in the Payments System," *supra* note 18.

[125] The Board recognizes that the FedNow Service may affect additional private-sector entities that may be indirect competitors to or users of the FedNow Service. However, because these entities do not provide RTGS services for faster payments, the Board does not view them as private-sector providers of similar services and, therefore, has not considered them as part of this analysis.

[126] A joint account enables settlement for participants in a private-sector arrangement to be supported by funds held for the joint benefit of the service's participants. Accordingly, the operator of a private-sector arrangement that relies on a joint account can perform real-time, payment-by-payment settlement by adjusting participant positions on its own ledger, which, in the aggregate, will be equal to or less than the amount held in the joint account. Settlement supported by a joint account can occur at any time or on any day at the settlement-arrangement operator's discretion because settlement takes place on the ledger of the settlement-arrangement operator.

[127] For example, although private-sector providers generally do not need to publish their fees, the Federal Reserve publishes fees for their priced services in a manner that is transparent to competitors and customers alike.

[128] In adopting guidelines for evaluating joint account requests, the Board explained that the treatment of joint account balances depends on the nature of the private-sector arrangement, including the rights and obligations of the parties involved. Therefore, determining whether balances held in a joint account can be used to meet reserve requirements or are eligible for interest is assessed for each request individually. *See* Board of Governors of the Federal Reserve System, "Final Guidelines for Evaluating Joint Account Requests," 82 FR 41951, 41956 (Sept. 5, 2017). Available at *https://www.federalregister.gov/d/2017-18705.*

master accounts at all times in compliance with Federal Reserve policies. Further, because the Board does not expect that the discount window would be available initially on weekends and holidays, participants in the FedNow Service would need to manage their master accounts more actively during those times to avoid overnight overdrafts.

In the private-sector service, participants are able to use intraday credit available to them under the Federal Reserve's PSR Policy to fund the joint account. Access to intraday credit in funding the joint account mitigates the risk of private-sector RTGS faster payment transactions being rejected. However, access would be limited to the current operating hours of the Fedwire Funds Service, resulting in continued risk of rejected payments because of lack of prefunding outside those hours. Participants in the private-sector service, however, can manage this risk by establishing credit arrangements outside of Federal Reserve services, making the materiality of this possible difference unclear.

The Board identified additional differences between the two services that may provide advantages or disadvantages to either service. The FedNow Service and the private-sector service require participants to manage their account positions in different ways, presenting different challenges for some institutions. The FedNow Service's use of master accounts requires consideration of the defined closing and opening of other Federal Reserve payment services also settling in the same account. Further, use of master accounts for a service operating 24x7x365, such as the FedNow Service, adds a layer of complexity to banks' management of their positions to meet reserve requirements and avoid overnight overdrafts and associated penalties. At the same time, use of a joint account requires participants to prefund that account, removing liquidity from their master accounts, and to manage their contributions to the joint account to ensure sufficient liquidity to avoid rejected payments.

The Board is requesting comment on whether the differences identified above would have a direct and material adverse effect on the ability of other service providers to compete effectively with the Federal Reserve and whether additional differences are also relevant. The Board will conduct a final assessment of these differences and others that may be identified in light of comments received.

C. Legal Differences Between the FedNow Service and the Private-Sector Service

The Board has considered whether the differences between the FedNow Service and the private-sector service that have potential direct and material adverse effects are due to legal differences or due to a dominant market position deriving from such legal differences. The Board invites comment on the following initial analysis.

Several of the differences identified above as potentially advantageous to the FedNow Service would be available to a private-sector service if it were to use an operating model other than one based on a joint account at a Reserve Bank. For example, the service could use a commercial bank to hold the prefunding that backs the service's internal ledger. The funds in an account at a commercial bank could potentially earn interest. A commercial bank may also allow overdrafts and extensions of credit, thereby reducing the risk of rejected payments. Depending on the arrangement, balances held at a commercial bank to settle faster payments may count towards reserve requirements.

Choice of a different operating model, however, would have potentially negative implications for other aspects of a private-sector RTGS service for faster payments. Most significantly, if a commercial bank were used, balances would be subject to risk of loss if the commercial bank holding the account were to fail. The use of a joint account at a Reserve Bank to support settlement mitigates this risk by reproducing, as closely as possible, the risk-free nature of settlement in central bank money.

The Board believes that the inherently risk-free nature of deposits at a central bank relative to deposits at a commercial bank is a unique legal difference between the Federal Reserve and other possible institutions, such as a commercial bank, that may result in a competitive advantage for the FedNow Service. This advantage may have a direct and material effect in light of the private-sector operator's use of a joint account.

D. Achieving Potential Benefits With a Lesser, or No, Adverse Competitive Impact

As described in Section III, the Board believes the FedNow Service would offer clear public benefits. Specifically, the service would promote the Federal Reserve's objective of an accessible, safe, and efficient payment system by helping ensure nationwide access to an RTGS infrastructure for faster payments, promoting the safety of the payment system and reducing risks associated with faster payments, and having positive effects on competition and innovation in the payment industry.

If the differences between the FedNow Service and the private-sector service discussed above are determined to have a material adverse effect on the ability of the private-sector provider to compete effectively with the Federal Reserve as part of the Board's final competitive impact analysis, certain actions may help to lessen those effects while still advancing the Federal Reserve's objectives. Specifically, if the Federal Reserve were to offer expanded Fedwire Funds Service or NSS hours, those services could enable access to liquidity during nonstandard business hours, when such access is currently not available. With expanded Fedwire Funds Service or NSS hours, direct participants in the private-sector RTGS service may be able to reduce the amount of prefunding, in particular, on weekends and holidays. This reduction in prefunding could then reduce the amount of liquidity committed to the joint account and allow more funds to remain in participants' master accounts, where those funds could accrue interest, count towards reserve requirements, and be used for purposes other than faster payments. Further, an expansion of Fedwire Funds Service or NSS hours could eventually allow participants in the private-sector RTGS service to have access to intraday credit during times that Fedwire Funds Service and NSS are currently closed.

The expanded functionality provided by these actions, if implemented, may help reduce, if not fully eliminate, the potentially adverse effects described earlier. The Board is requesting comment on modifications to the FedNow Service or other actions that would further reduce or eliminate potentially adverse effects without significantly compromising the anticipated public benefit associated with the service. The Board will conduct and publish its final competitive impact analysis of the FedNow Service as part of the subsequent **Federal Register** notice presenting the final FedNow Service description.

By order of the Board of Governors of the Federal Reserve System August 2, 2019.

Ann Misback,

Secretary of the Board.

[FR Doc. 2019–17027 Filed 8–8–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Solicitation of Nominations for Appointment to the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHACHSPT)

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) is seeking nominations for membership on the CHACHSPT. The CHACHSPT consists of 18 experts in fields associated with public health; epidemiology; laboratory practice; immunology; infectious diseases; drug abuse; behavioral science; health education; healthcare delivery; state health programs; clinical care; preventive health; medical education; health services and clinical research; and healthcare financing, who are selected by the Secretary of the U.S. Department of Health and Human Services (HHS).

DATES: Nominations for membership on the CHACHSPT must be received no later than August 31, 2019. Packages received after this time will not be considered for the current membership cycle.

ADDRESSES: All nominations should be mailed to 1600 Clifton Road NE, Mailstop: E07, Atlanta, GA 30329–4027, emailed (recommended) to *zkr7@cdc.gov,* or faxed to (404) 639–8317.

FOR FURTHER INFORMATION CONTACT: Margie Scott-Cseh, Committee Management Specialist, CDC, 1600 Clifton Road NE, Mailstop: E07, Atlanta, GA 30329–4027, (404) 639–8317, *zkr7@cdc.gov.*

SUPPLEMENTARY INFORMATION: The CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment shall advise the Director, CDC, and the Administrator and Associate Administrator for HIV/AIDS, HRSA, regarding objectives, strategies, policies, and priorities for HIV and STD prevention and treatment efforts including surveillance of HIV infection, AIDS, STDs, and related behaviors; epidemiologic, behavioral, health services, and laboratory research on HIV/AIDS and STD; identification of policy issues related to HIV/STD professional education, patient healthcare delivery, and prevention services; agency policies about prevention of HIV/AIDS and other STDs, treatment, healthcare delivery, and research and training; strategic issues influencing the ability of CDC and HRSA to fulfill their missions of providing prevention and treatment services; programmatic efforts to prevent and treat HIV and STDs; and support to the agencies in their development of responses to emerging health needs related to HIV and other STDs.

Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishments of the committee's objectives. Nominees will be selected based on expertise in the fields of HIV/AIDS, Viral Hepatitis and STD prevention, control and treatment. Experts in the disciplines of public health; epidemiology; laboratory practice; immunology; infectious diseases; drug abuse; behavioral science; health education; healthcare delivery; state health programs; clinical care; preventive health; medical education; health services and clinical research; and healthcare financing. Federal employees will not be considered for membership. Members may be invited to serve for up to four-year terms.

Selection of members is based on candidates' qualifications to contribute to the accomplishment of CHACHSPT objectives. The U.S. Department of Health and Human Services policy stipulates that committee membership be balanced in terms of points of view represented, and the committee's function. Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, gender identity, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens, and cannot be full-time employees of the U.S. Government. Current participation on federal workgroups or prior experience serving on a federal advisory committee does not disqualify a candidate; however, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships. Committee members are Special Government Employees (SGEs), requiring the filing of financial disclosure reports at the beginning and annually during their terms. CDC reviews potential candidates for CHACHSPT membership each year, and provides a slate of nominees for consideration to the Secretary of HHS for final selection. HHS notifies selected candidates of their appointment near the start of the term in December 1, 2020, or as soon as the HHS selection process is completed. Note that the need for different expertise varies from year to year and a candidate who is not selected in one year may be reconsidered in a subsequent year. SGE Nominees must be U.S. citizens, and cannot be full-time employees of the U.S. Government. Candidates should submit the following items:

- Current curriculum vitae, including complete contact information (telephone numbers, mailing address, email address)
- At least one letter of recommendation from person(s) not employed by the U.S. Department of Health and Human Services. (Candidates may submit letter(s) from current HHS employees if they wish, but at least one letter must be submitted by a person not employed by an HHS agency (*e.g.,* CDC, NIH, FDA, etc.).

Nominations may be submitted by the candidate him- or herself, or by the person/organization recommending the candidate. The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019–17064 Filed 8–8–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9117–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—April Through June 2019

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

ACTION: Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from April through June 2019, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need.

Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone Number
I CMS Manual Instructions	Ismael Torres	(410) 786-1864
II Regulation Documents Published in the **Federal Register**	Terri Plumb	(410) 786-4481
III CMS Rulings	Tiffany Lafferty	(410)786-7548
IV Medicare National Coverage Determinations	Wanda Belle, MPA	(410) 786-7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786-6877
VI Collections of Information	William Parham	(410) 786-4669
VII Medicare –Approved Carotid Stent Facilities	Sarah Fulton, MHS	(410) 786-2749
VIII American College of Cardiology-National Cardiovascular Data Registry Sites	Sarah Fulton, MHS	(410) 786-2749
IX Medicare's Active Coverage-Related Guidance Documents	JoAnna Baldwin, MS	(410) 786-7205
X One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin, MS	(410) 786-7205
XI National Oncologic Positron Emission Tomography Registry Sites	Stuart Caplan, RN, MAS	(410) 786-8564
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	David Dolan	(410) 786-3365
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	Sarah Fulton, MHS	(410) 786-2749
XIV Medicare-Approved Bariatric Surgery Facilities	Sarah Fulton, MHS	(410) 786-2749
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	Stuart Caplan, RN, MAS	(410) 786-8564
All Other Information	Annette Brewer	(410) 786-6580

I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) Furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS website or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and ''real time'' accessibility. In addition, many of the websites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the website. These listservs avoid the need to check the website, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a website proves to be difficult, the contact person listed can provide information.

III. How To Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at *http://www.cms.gov/manuals.*

Dated: July 26, 2019.

Kathleen Cantwell,

Director, Office of Strategic Operations and Regulatory Affairs.

BILLING CODE 4120–01–P

Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: August 13, 2018 (83 FR 40043), November 2, 2018 (83 FR 55174) February 19, 2019 (84 FR 4805) and April 29, 2019 (84 FR 18040). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (April through June 2019)

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

How to Obtain Manuals

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: http://cms.gov/manuals.

How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at http://www.gpo.gov/libraries/

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the manual for Updates to Publication (Pub.) 100-01, Medicare General Information, Eligibility, and Entitlement, Chapter 6, Disclosure of Information Disclosure of Information, use (CMS-Pub. 100-01) Transmittal No. 123.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual. For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at www.cms.gov/Manuals.

Transmittal Number	Manual/Subject/Publication Number
Medicare General Information (CMS-Pub. 100-01)	
123	Updates to Publication (Pub.) 100-01, Medicare General Information, Eligibility, and Entitlement, Chapter 6, Disclosure of Information Disclosure of Information
Medicare Benefit Policy (CMS-Pub. 100-02)	
	None
Medicare National Coverage Determination (CMS-Pub. 100-03)	
214	National Coverage Determination (NCD90.2): Next Generation Sequencing (NGS)
215	National Coverage Determination (NCD90.2): Next Generation Sequencing (NGS)
216	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions

Medicare Claims Processing (CMS-Pub. 100-04)	
4273	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4274	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4275	Quarterly Update for the Temporary Gap Period of the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) - July 2019
4276	Indian Health Services (IHS) Hospital Payment Rates for Calendar Year 2019
4277	New Waived Tests
4278	Pub. 100-04, Chapter 29 – Appeals of Claims Decisions – Revisions CMS Decisions Subject to the Administrative Appeals Process Who May Appeal Steps in the Appeals Process: Overview Where to Appeal Time Limits for Filing Appeals & Good Cause for Extension of the Time Limit for Filing Appeals Good Cause Conditions and Examples That May Establish Good Cause for Late Filing by Beneficiaries Conditions and Examples That May Establish Good Cause for Late Filing by Providers, Physicians, or Other Suppliers Good Cause - Administrative Relief Following a Disaster Procedures to Follow When a Party Fails to Establish Good Cause Amount in Controversy General Requirements Principles for Determining Amount in Controversy Aggregation of Claims to Meet the Amount in Controversy Who May Be an Appointed or Authorized Representative How to Make and Revoke an Appointment When and Where to Submit the Appointment Rights and Responsibilities of a Representative Curing a Defective Appointment of Representative Incapacitation or Death of Beneficiary How to Make and Revoke a Transfer of Appeal Rights Where to Submit the Transfer of Appeal Rights Rights of the Assignee of Appeal Rights Curing a Defective Transfer of Appeal Rights Medicare Secondary Payer (MSP) Specific Limitations or Additional Requirements with Respect to the Appointment of Representatives Inclusion and Consideration of Evidence of Fraud and/or Abuse Claims Where There is Evidence That Items or Services Were Not Furnished or Were Not Furnished as Billed Responsibilities of Adjudicators Letter Format Fraud and Abuse Investigations Appeal Decision Involving Multiple Beneficiaries Filing a Request for Redetermination Time Limit for Filing a Request for Redetermination The Redetermination Dismissals Dismissal Letters Model Dismissal Notices Processing Requests to Vacate Dismissals Medicare Redetermination Notice (For Partly or Fully Unfavorable Redeterminations Effect of the Redetermination Effectuation of the Redetermination Decision Reconsideration - The Second Level of Appeal Filing a Request for a Reconsideration MAC Responsibilities – General QIC Case File Preparation QIC Jurisdictions Effectuation of Reconsiderations Administrative Law Judge (ALJ) Hearing or Attorney Adjudicator Review at Office of Medicare Hearings and Appeals (OMHA) - The Third Level of Appeal Requests for an ALJ Hearing Forwarding Requests to OMHA Review and Effectuation of OMHA Decisions Effectuation Time Limits & Responsibilities Duplicate OMHA Decisions Payment of Interest on OMHA Decisions Departmental Appeals Board - Appeals Council - The Fourth Level of Appeal Recommending Agency Referral of OMHA Decisions or Dismissals Requests for Case Files District Court Review - The Fifth Level of Appeal Requests for U.S. District Court Review by a Party Workload Data Analysis Execution of Workload Prioritization Workload Priorities
4279	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4280	Update to Pub. 100-04, Chapter 11 Hospice Election Periods and Benefit Periods in Medicare Systems Data Required on the Institutional Claim to A/B MAC (HHH Administrative Activities Hospice Attending Physician Services Independent Attending Physician Services Care Plan Oversight Processing Professional Claims for Hospice Beneficiaries Billing and Payment for Services Unrelated to Terminal Illness Coinsurance on Inpatient Respite Care
4281	Update to Chapter 28 in Publication (Pub.) 100-04 to Provide Language-Only Changes for the New Medicare Card Project Beneficiary Insurance Assignment Selection Consolidation of the Claims Crossover Process Coordination of Benefits Agreement (COBA) Detailed Error Report Notification Process Coordination of Benefits Agreement (COBA) ASC X12 837 Coordination of

	Benefits (COB) Mapping Requirements as of July 2012 National Council for Prescription Drug Programs (NCPDP) Version D.0 Coordination of Benefits (COB) Requirements
4282	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
4283	Documentation of Evaluation and Management Services of Teaching Physicians Evaluation and Management (E/M) Services
4284	File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions
4285	Quarterly Update to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)
4286	Update to Chapter 21 in Publication (Pub.) 100-04 to Provide Language-Only Changes for the New Medicare Card Project Specifications for Section 1: Summary (Page 1) Specifications for Content Variations of Spanish MSNs
4287	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4288	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4289	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4290	Medicare Summary Notice (MSN) Changes to Assist Beneficiaries Enrolled in the Qualified Medicare Beneficiary (QMB) Program Qualified Medicare Beneficiary (QMB) Program
4291	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4292	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4293	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4294	Home Health (HH) Patient-Driven Groupings Model (PDGM) - Additional Manual Instructions Home Health Prospective Payment System (HH PPS) Consolidated Billing Responsibilities of Home Health Agencies Responsibilities of Providers/Suppliers of Services Subject to Consolidated Billing Home health Consolidated Billing Edits in Medicare Systems Therapy Editing Other Editing Related to Home Health Consolidated Billing Only Request for Anticipated Payment (RAP) Received and Services Fall Within 60 Days after RAP Start Date No RAP Received and Therapy Services Rendered in the Home Eligibility Query to Determine Status CWF Response to Inquiry Timeliness and Limitations of CWF Responses National Home Health Prospective Payment Episode History File Opening and Length of HH PPS Episodes/Periods of Care Closing, Adjusting and Prioritizing HH PPS Episodes/Periods of Care Based on RAPs and HHA Claim Activity Other Editing for HH PPS Episodes
	Coordination of HH PPS Claims With Inpatient Claim Types Exhibit: Chart Summarizing the Effects of RAP/Claim Actions on the HH PPS Episode File Request for Anticipated Payment (RAP HH PPS Claims IIII PPS Claims When No RAP is Submitted - "No-RAP" LUPAs Input/Output Record Layout Decision Logic Used by the Pricer on RAPs Decision Logic Used by the Pricer on Claims Annual Updates to the HH Pricer
4295	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 4 Payment for CRNA Pass-Through Services
4296	Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
4297	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4298	Medicare Physician Fee Schedule Database (MPFSDB) File Record Layout MPFSDB Record Layout MPFSDB File Record Layout and Field Descriptions
4299	Re-implementation of the AMCC Lab Panel Claims Payment System Logic Automated Test Listing Organ or Disease Oriented Panels Claims Processing Requirements for Panel and Profile Tests Laboratory Tests Utilizing Automated Equipment History Display Special Processing Considerations
4300	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4301	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4302	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4303	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code
4304	Claim Status Category and Claim Status Codes Update
4305	Annual Updates to the Prior Authorization/Pre-Claim Review Federal Holiday Schedule Tables for Generating Reports
4306	Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - July 2019 Update
4307	Instructions for Downloading the Medicare ZIP Code Files for October 2019
4308	Implementation of the Medicare Performance Adjustment (MPA) for the Maryland Total Cost of Care (MD TCOC) Model
4309	Documentation of Medical Necessity of the Home Visit; and Physician Management Associated with Superficial Radiation Treatment
4310	Home Services (Codes 99341 - 99350) Physician Management Associated with Superficial Radiation Treatment
4311	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
4312	Home Health (HH) Patient-Driven Groupings Model (PDGM) - Additional

	Manual Instructions Adjustments of Episode Payment – Validation of HIPPS Home Health Prospective Payment System (HH PPS) Consolidated Billing Responsibilities of Home Health Agencies Responsibilities of Providers/Suppliers of Services Subject to Consolidated Billing Home health Consolidated Billing Edits in Medicare Systems Therapy Editing Other Editing Related to Home Health Consolidated Billing Only Request for Anticipated Payment (RAP) Received and Services Fall Within 60 Days after RAP Start Date No RAP Received and Therapy Services Rendered in the Home Eligibility Query to Determine Status CWF Response to Inquiry Timeliness and Limitations of CWF Responses National Home Health Prospective Payment Episode History File Opening and Length of HH PPS Episodes/Periods of Care Closing, Adjusting and Prioritizing HH PPS Episodes/Periods of Care Based on RAPs and HHA Claim Activity Other Editing for HH PPS Episodes Coordination of HH PPS Claims With Inpatient Claim Types Medicare Secondary Payment (MSP) and the HH PPS Episodes File Exhibit: Chart Summarizing the Effects of RAP/Claim Actions on the HH PPS Episode File Request for Anticipated Payment (RAP) HH PPS Claims HH PPS Claims When No RAP is Submitted - "No-RAP" LUPAs Billing for Nonvisit Charges Input/Output Record Layout Decision Logic Used by the Pricer on RAPs Decision Logic Used by the Pricer on Claims Annual Updates to the HH Pricer
4313	July 2019 Update of the Hospital Outpatient Prospective Payment System (OPPS)
4314	July 2019 Integrated Outpatient Code Editor (I/OCE) Specifications Version 20.2
4315	Annual (2020) Update of the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)
4316	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
4317	Implement Operating Rules - Phase III Electronic Remittance Advice (ERA) Electronic Funds Transfer (EFT): Committee on Operating Rules for Information Exchange (CORE) 360 Uniform Use of Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and Claim Adjustment Group Code (CAGC) Rule - Update from Council for Affordable Quality Healthcare (CAQH) CORE
4318	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4319	July 2019 Update of the Ambulatory Surgical Center (ASC) Payment System
4320	Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - July 2019 Update
4321	July Quarterly Update for 2019 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
4322	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4323	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4324	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
4325	Medicare Part A Skilled Nursing Facility (SNF) Prospective Payment System (PPS) Pricer Update FY 2020
4326	Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
4327	July 2019 Integrated Outpatient Code Editor (I/OCE) Specifications Version 20.2
	Medicare Secondary Payer (CMS-Pub. 100-05)
	None
	Medicare Financial Management (CMS-Pub. 100-06)
312	Updates to Medicare Financial Management Manual Chapter 4, Section 50-50.6 Extended Repayment Schedules Establishing an Extended Repayment Schedule (ERS) - (formerly known as an Extended Repayment Plan (ERP)) ERS Required Documentation --Physician is a Sole Proprietor ERS Required Documentation– Provider is an Entity Other Than a Sole Proprietor ERS Approval Process Sending the ERS Request to the Regional Office (RO) Monitoring an Approved Extended Repayment Schedule (ERS) and Reporting Requirements Requests from Terminated Providers or Debts that are Pending Referral to Department of Treasury
313	Notice of New Interest Rate for Medicare Overpayments and Underpayments -3rd Qtr Notification for FY 2019
314	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
315	Update to Publication (Pub.) 100-06 to Provide Language-Only Changes for the New Medicare Card Project Demand Letter Contents Recovery From the Beneficiary Beneficiary Wishes to Refund in Installments Bankruptcy Forms Termination of Collection Action – Beneficiary Overpayments Collection of Fee-for-Service Payments Made During Periods of Medicare Advantage (MA) Enrollment Treasury Cross-Servicing Dispute Resolution Exhibit 20 - Procedures for Reporting Currently Not Collectible (CNC) Debt Receiving and Processing Unsolicited/Voluntary Refund Checks When Identifying Information is Provided Receiving and Processing Unsolicited/Voluntary Refund Checks When Identifying Information is not Provided

	Overpayment Refund Form Recording Savings Section B - Cause of Overpayments Recording Savings Body of Report Section I – Redeterminations Processing CMS-838 Claims Adjustments Completing the CMS-838 Exhibit II: Medicare Credit Balance Report Detail Page
316	Updates to Medicare Financial Management Manual Chapter 4, Section 20 and 20.1 Demand Letters Demand Letters Number of Demand Letters INITIAL DEMAND LETTER - NON-935 INITIAL DEMAND LETTER - 935 Initial Demand Letter- Cost Reports Filed Initial Demand Letter- Unfiled Cost Report Intent to Refer Letter- Non 935 Intent to Refer Letter- 935 Unfiled Cost Reports Only
317	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
Medicare State Operations Manual (CMS-Pub. 100-07)	
188	Revisions to the State Operations Manual (SOM 100-07) Chapter 2, The Certification Process, Chapter 3, Additional Program Activities, and Chapter 4, Program Administration and Fiscal Management Outcome and Assessment Information Set (Oasis) Requirements/2202.9B - Right to See, Review, and Request Changes Documentation Guide List - Termination for Noncompliance With §§1866(b)(2)(A) and (C)/3028B - Additional Documentation - Charging for Covered Services and/or Refusing to Refund Incorrect Collections Budget and Financial Report Files – Records to be Retained/4802K. Supplementary Medical Insurance (SMI) General Enrollment Period (GEP) Records (N1-440-95-1, Item 10)
189	Budget and Financial Report Files – Records to be Retained/4802K. Supplementary Medical Insurance (SMI) General Enrollment Period (GEP) Records (N1-440-95-1, Item 10)
190	Updates to the State Operations Manual (SOM) Chapters 2, 3 and 9 to add Instructions for Organ Transplant Programs. Organ Transplant Programs Definitions Regulatory Background Request for Medicare Approval of an Organ Transplant Program Survey and Approval Procedures for Organ Transplant Programs Types of Surveys and Related Guidance Determining Level of Deficiency for Clinical Experience (Volume) and Outcome Requirements Standards: Post-Survey Activities Transmission of Program Approval Information Mitigating Factors
	Relationship Between the Transplant CoPs and Hospital CoPs Termination of Organ Transplant Programs Options letter for transplant program inactive at 12 months
Medicare Program Integrity (CMS-Pub. 100-08)	
872	Updates to Immunosuppressive Guidance
873	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
874	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
875	Updates to Immunosuppressive Guidance--Exceptions
876	Update to Publication (Pub.) 100-08 to Provide Language-Only Changes for the New Medicare Card Project Sources of Data for ZPICs Overview of Prepayment and Postpayment Reviews Maintaining Provider Information Denial Types Prior Authorization Procedural Requirements Program Integrity Security Requirements Medical Review for Program Integrity Purposes Contact Center Operations MAC Complaint Screening Referrals to the UPIC Guidelines for Incentive Reward Program Complaint Tracking Documentation of Identity Theft and Compromised Medicare beneficiary Identifiers in the FID Worksheets Providing Sample Information to the CERT Review Contractor Medicare Diabetes Prevention Program (MDPP) Suppliers Independent Diagnostic Testing Facility (IDTF) Standards Claims against Surety Bonds Reactivations – Miscellaneous Policies
877	Update to Publication (Pub.) 100-08 to Provide Language-Only Changes for the New Medicare Card Project Sources of Data for ZPICs Overview of Prepayment and Postpayment Reviews Maintaining Provider Information Denial Types Prior Authorization Procedural Requirements Program Integrity Security Requirements Review for Program Integrity Purposes Contact Center Operations MAC Complaint Screening Referrals to the UPIC Guidelines for Incentive Reward Program Complaint Tracking Worksheets Providing Sample Information to the CERT Review Contractor Medicare Diabetes Prevention Program (MDPP) Suppliers Independent Diagnostic Testing Facility (IDTF) Standards Claims against Surety Bonds

	Reactivations – Miscellaneous Policies
878	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
879	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
880	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
881	Update to Chapter 15 of Publication (Pub.) 100-08
882	Local Coverage Determinations (LCDs)
883	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
884	Update to Exhibit 46.2, 46.3, 46.4, and 46.5 in Publication (Pub.) 100-08 DME MAC Unified Post-payment ADR Sample Letter Recovery Audit Contractor (RAC) Unified Postpayment ADR Sample Letter CERT Unified Post-payment ADR Sample Letter SMRC Postpayment ADR Sample Letter
885	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
886	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
887	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
888	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
889	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
30	QIO Manual Chapter 16 – "Healthcare Quality Improvement Program" Quality Improvement Interventions Developing and Spreading Successful Interventions Documenting and Disseminating Results
31	Update to Publication (Pub.) 100-10 to Provide Language-Only Changes for The New Medicare Card Project
Medicare Quality Improvement Organization (CMS- Pub. 100-10)	
32	Update to Publication (Pub.) 100-10 to Provide Language-Only Changes for the New Medicare Card Project
Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)	
10	Update to Publication (Pub.) 100-14 to Provide Language-Only Change for the New Medicare Card Project CMS-Directed Changes (Notifications) to the Network Patient Database Processing Form CMS-2728-U3 CMS ESRD Forms Data Discrepancies and Data Corrections Coordination of Additional Renal Related Information Additional Considerations Acronyms/Medicare ESRD Network Organizations List of Commonly Used Acronyms
Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)	
	None
Medicare Managed Care (CMS-Pub. 100-16)	
	None
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
	None
Medicare Prescription Drug Benefit (CMS-Pub. 100-18)	
19	Update to Publication (Pub.) 100-18 to Provide Language-Only Changes and URL Location Updates for the New Medicare Card Project
Demonstrations (CMS-Pub. 100-19)	
224	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
225	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
226	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
227	Next Generation ACO Model - Demo Code Placement
One Time Notification (CMS-Pub. 100-20)	
2275	User CR: MCS - Add Date to NU Screen for Health Insurance Claim Number (HICN) Changes
2276	Update to Claim Processing Logic to Allow 53 Automated Development System (ADS) Messages (Three Header and 50 Claim Lines)
2277	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instructions
2278	Implementation of the Skilled Nursing Facility (SNF) Patient Driven Payment Model (PDPM)
2279	Direct Mailing Notification to the Medicare Administrative Contractors (MACs) Regarding Clinical Laboratory Fee Schedule (CLFS)
2280	MAC Reporting of Issuance of Compliance Letters to Specific Providers and Suppliers Regarding Inappropriate Billing of Qualified Medicare Beneficiaries (QMBs) for Medicare Cost-Sharing
2281	Implementation to Exchange the list of Electronic Medical Documentation Requests (eMDR) for Registered Providers via the Electronic Submission of Medical Documentation (esMD) System
2282	Direct Mailing Notification to the Medicare Administrative Contractors (MACs) Regarding Clinical Laboratory Fee Schedule (CLFS)
2283	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instructions
2284	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
2285	Common Working File (CWF) to Medicare Beneficiary Database (MBD) Extract File Changes to send all Hospice periods to Support HIPAA Eligibility Transaction System (HETS)
2286	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
2287	Health Insurance Portability and Accountability Act (HIPAA) Electronic Data Interchange (EDI) Front End Updates for October 2019
2288	User CR: FISS - Develop Enhanced Claims Search Reporting in FISS - Phase
2289	User CR: FISS Update RPTMEDR1 to Provide Medical Policy Parameters (MPP) Status
2290	User CR: ViPS Medicare System (VMS) - New Standard Paper Remittance (SPR) Files for Use on Durable Medical Equipment Medicare Administrative

	Contractors (DME MAC) Web Portals
2291	User CR: FISS - Expand Number of Archived Claims That May Be Retrieved per Cycle
2292	User CR: FISS - Analysis Only - Enhancement to Allow MACs to Copy VSAM Files from One Region to Another to Reduce File Maintenance
2293	Systems Changes to Allow IPPS-Excluded IIospitals to Operate IPPS-Excluded Units
2294	FISS Integrated Outpatient Code Editor (IOCE) Claim Return Buffer Interface Changes Related to New Return Code Field Updates
2295	Archiving and Retrieving of the Integrated Outpatient Code Editor (I/OCE) for Processing Claims
2296	Updating Fiscal Intermediary Shared System (FISS) for Pricing Drugs at Different Rates Depending on Provider Type
2297	Modifications to the National Coordination of Benefits Agreement (COBA) Crossover Process
2298	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)
2299	Implementation of the Skilled Nursing Facility (SNF) Patient Driven Payment Model (PDPM)
2300	Reporting the Patient Relationship Categories and Codes
2301	User CR: MCS - Update the RB55 Job to Include Processing of Additional Fields on the Procedure Code File
2302	Implementation to Send Pre-Pay Electronic Medical Documentation Requests (eMDR) to Participating Providers via the Electronic Submission of Medical Documentation (esMD) System
2303	Shared System Enhancement 2018: Rewrite Fiscal Intermediary Shared System (FISS) module FSSB6001, Common Working File (CWF) Unsolicited Response Function
2304	Automatic Transmission of the Prepayment File to the Recovery Audit Contractor (RAC) Data Warehouse (DW)
2305	Implementation to Send Post-Pay Electronic Medical Documentation Requests (eMDR) to Participating Providers via the Electronic Submission of Medical Documentation (esMD) System
2306	Analysis for First Coast Service Options (FCSO) and Novitas for the CMS Enterprise Identity Management OKTA/Saviynt Migration
2307	Additional Processing Instructions to Update the Standard Paper Remit (SPR)
2308	New CWF Edit for Part A Outpatient Medicare Advantage (MA), Health Maintenance Organization (HMO)
2309	New Overpayment Field Established within the ViPS Medicare System (VMS) for Healthcare Integrated General Ledger Accounting System (HIGLAS) Reporting
2310	Viable Information Processing Systems (ViPS) Medicare Systems (VMS) Changes to Accommodate National Provider Identifier Associations Analysis and Development
2311	Bills Pending Reports to Assist Medicare Administrative Contractors (MACs) with Monthly Status Report (MSR)
2312	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instructions
2313	FISS Integrated Outpatient Code Editor (IOCE) Claim Return Buffer Interface Changes Related to New Return Code Field Updates
2314	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
2315	Mobile Personal Identity Verification (PIV) Station Pilot Project
2316	Fiscal Intermediary Shared System (FISS) Enhancement of PC Print Billing Software
2317	Mobile Personal Identity Verification (PIV) Station Pilot Project
Medicare Quality Reporting Incentive Programs (CMS-Pub. 100-22)	
	None
Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)	
	None

Addendum II: Regulation Documents Published in the Federal Register (April through June 2019)

Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register,** contact GPO at www.gpo.gov/fdsys. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is available as an online database through GPO Access. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at http://www.gpoaccess.gov/fr/index.html. The following website http://www.archives.gov/federal-register/ provides information on how to access electronic editions, printed editions, and reference copies.

This information is available on our website at: http://www.cms.gov/quarterlyproviderupdates/downloads/Regs-2Q19QPU.pdf

For questions or additional information, contact Terri Plumb (410-786-4481).

Addendum III: CMS Rulings (April through June 2019)

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

The rulings can be accessed at http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

Addendum IV: Medicare National Coverage Determinations (April through June 2019)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS website. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. For the purposes of this quarterly notice, we are providing only the specific updates to national coverage determinations (NCDs), or reconsiderations of completed NCDs published in the 3-month period. This information is available at: www.cms.gov/medicare-coverage-database/. For questions or additional information, contact Wanda Belle, MPA (410-786-7491).

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer	NCD 90.2	215	04/10/2019	02/15/2018

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (April through June 2019)

(Inclusion of this addenda is under discussion internally.)

Addendum VI: Approval Numbers for Collections of Information (April through June 2019)

All approval numbers are available to the public at Reginfo.gov. Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at www.reginfo.gov/public/do/PRAMain. For questions or additional information, contact William Parham (410-786-4669).

Addendum VII: Medicare-Approved Carotid Stent Facilities, (April through June 2019)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: http://www.cms.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	Provider Number	Effective Date	State
The following facilities are new listings for this quarter.			
Adventist Health White Memorial 11720 Cesar E. Chavez Avenue Los Angeles, CA 90033	050103	04/09/2019	CA
Sentara Rockingham Medical Center 12010 Health Campus Drive Harrisonburg, VA 22801	1780694372	04/23/2019	VA
Clinch Valley Medical Center 6801 Gov. G.C. Peery Highway Richlands, VA 24641	1871534297	05/14/2019	VA
Catholic Medical Center 100 McGregor Street Manchester, NH 03102	1528150273	05/14/2019	NH

Facility	Provider Number	Effective Date	State
Brookdale University Hospital Medical Center One Brookdale Plaza Brooklyn NY 11212	330233	05/14/2019	NY
Deaconess Hospital Inc. -The Heart Hospital at Deaconess Gateway 4007 Gateway Boulevard Newburg, IN 47630	150082	05/14/2019	IN
The following facilities have editorial changes (in bold).			
FROM: Florida Hospital Heart Heartland Medical Center Sebring **TO: AdventHealth Sebring** 4200 Sun 'n Lake Boulevard Sebring, FL 33872	100109	04/30/2012	FL
FROM: Florida Hospital Memorial Medical Center **TO: AdventHealth Daytona Beach** 301 Memorial Medical Parkway Daytona Beach, FL 32117	100068	07/20/2005	FL
FROM: Florida Hospital Wesley Chapel **TO: AdventHealth Wesley Chapel** 2600 Bruce B. Downs Boulevard Wesley Chapel, FL 33544	100319	07/18/2013	FL
FROM: Florida Hospital Zephyrhills **TO: AdventHealth Zephyrhills** 7050 Gall Boulevard Zephyrhills, FL 33541-1399	100046	07/07/2005	FL
FROM: Florida Hospital Orlando **TO: AdventHealth Orlando** 601 East Rollins Street Orlando, FL 32803	100007	06/07/2005	FL
FROM: Scott & White Healthcare - Round Rock **TO: Scott & White Hospital – Round Rock** 302 University Boulevard Round Rock, TX 78665	670034	06/04/2010	TX
FROM: Borgess Medical Center **TO: Ascension Borgess Hospital** 1521 Gull Road Kalamazoo, MI 49048	230117	04/12/2005	MI
FROM: Eliza Coffee Memorial Hospital **TO: North Alabama Medical Center** P.O. Box 818 Florence, AL 35630	010006	05/05/2005	AL
FROM: MedCentral Health System **TO: OhioHealth Mansfield Hospital** 335 Glessner Avenue Mansfield, OH 44903	360118	11/29/2005	OH
FROM: Riverside Methodist Hospital **TO: OhioHealth Riverside Methodist Hospital** 3535 Olentangy River Road Columbus, OH 43214	360006	04/20/2005	OH
FROM: Grant Medical Center **TO: OhioHealth Grant Medical Center** 111 S. Grant Avenue Columbus, OH 43215	360017	01/04/2006	OH
FROM: Central Baptist Hospital **TO: Baptist Health Lexington** 1740 Nicholasville Road Lexington, KY 40503	180103	04/27/2005	KY
FROM: St. Joseph's Mercy Health Center **TO: CHI St. Vincent Hospital Hot Springs** 300 Werner Street Hot Springs, AR 71903	040026	05/26/2005	AR
FROM: Mercy Medical Center **TO: Mercy Hospital of Northwest Arkansas** 2710 Rife Medical Lane Rogers, AR 72758	040010	01/07/2011	AR

Addendum VIII:
American College of Cardiology's National Cardiovascular Data Registry Sites (April through June 2019)

The initial data collection requirement through the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) has served to develop and improve the evidence base for the use of ICDs in certain Medicare beneficiaries. The data collection requirement ended with the posting of the final decision memo for Implantable Cardioverter Defibrillators on February 15, 2018.

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum IX: Active CMS Coverage-Related Guidance Documents (April through June 2019)

CMS issued a guidance document on November 20, 2014 titled "Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document". Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS's implementation of coverage with evidence development (CED) through the national coverage determination process. The document is available at http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27. There are no additional Active CMS Coverage-Related Guidance Documents for the 3-month period. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

Addendum X: List of Special One-Time Notices Regarding National Coverage Provisions (April through June 2019)

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is available at www.cms.hhs.gov/coverage. For questions or additional information, contact JoAnna Baldwin, MS (410-786 7205).

Addendum XI: National Oncologic PET Registry (NOPR) (April through June 2019)

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on **positron emission tomography** (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. This information is available at http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (April through June 2019)

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy.

For the purposes of this quarterly notice, we are providing only the specific updates to the list of Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is available at http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage. For questions or additional information, contact David Dolan, JD, (410-786-3365).

Facility	Provider Number	Date of Initial Certification	Date of Recertification	State
The following facilities are new listings for this quarter.				
St. Joseph's Hospital 3001 W Dr. Martin Luther King Jr Boulevard Tampa, FL 33614 Other information: DNV GL Certificate #: 285554-2019-VAD	100075	02/28/2019		FL
UMass Memorial Medical Center 55 Lake Avenue North Worcester, MA 01655	220163	02/06/2019		MA

Facility	Provider Number	Date of Initial Certification	Date of Recertification	State
Other information: Joint Commission ID # 5640				
Largo Medical Center 201 14th Street SW Largo, FL 33770 Other information: DNV GL Certificate #: 595753-2019-VAD	100248	04/04/2019		FL
OHSU 3181 SW Sam Jackson Park Road Portland, OR 97239 Other information: DNV GL Certificate #: 575469-2019-VAD	380009	05/17/2019		OR
Dignity Health 350 West Thomas Rd. Phoenix, AZ 85013 Other information: Joint Commission ID # 9494	030024	05/08/2019		AZ
The following facilities have editorial changes (in bold).				
Brigham and Women's Hospital **75 Francis Street** Boston, MA 02115 Other information: Joint Commission ID #: 5503 VAD Previous Re-certification Dates: 2008-11-04; 2010-12-09; 2012-12-07; 2014-11-07; 2016-12-13	220110	01/09/2004	**02/27/2019**	MA
Florida Hospital 601 East Rollins Street Orlando, FL 32803 Other information: Joint Commission ID #: 6873 VAD Previous Re-certification Dates: 2014-10-07; 2016-11-15	100007	11/09/2016	**01/30/2019**	FL
UCSF Medical Center 505 Parnassus Avenue San Francisco, CA 94143 Other Information: Joint Commission ID #: 10095	050454	10/16/2012	**01/30/2019**	CA
VAD Previous Re-certification Dates: 2014-11-04; 2016-12-06				
FROM: Tacoma General – Allenmore Hospital **TO: Multicare Tacoma General Hospital** 315 Martin Luther King Jr. Way Tacoma, WA 98405 Other information: Joint Commission ID #: 9649 VAD Previous Re-certification Dates: 2012-11-14; 2014-11-18; 2016-12-06	500129	11/04/2010	**02/06/2019**	WA
Fresno Community Hospital and Medical Center 2823 Fresno Street Fresno, CA 93721 Other information: Joint Commission ID #: 9832	050060	12/14/2016	**02/13/2019**	CA
Abbott Northwestern Hospital **800 East 38th Street** **Minneapolis, MN 55407** Other information: Joint Commission ID #: 8149 VAD Previous Re-certification Dates: 2012-11-29; 2014-11-18; 2016-12-06	240057	11/17/2010	**02/13/2019**	MN
JFK Medical Center 5301 South Congress Avenue Atlantis, FL 33462 Other information: Joint Commission ID #: 6836	100080	01/25/2017	**03/06/2019**	FL
Mercy Medical Center 1111 6th Avenue Des Moines, IA 50314 Other information: Joint Commission ID #: 8248 VAD Previous Re-certification Dates: 2017-02-14	160083	01/15/2015	**03/27/2019**	IA

Facility	Provider Number	Date of Initial Certification	Date of Recertification	State
St. Luke's Hospital 801 Ostrum Street Bethlehem, PA 18015 Other information: Joint Commission ID #: 6024 VAD Previous Re-certification Dates: 2017-01-24	390049	12/18/2014	**03/06/2019**	PA
Henry Ford Hospital 2799 W Grand Boulevard Detroit, MI 48202 Other information: Joint Commission ID #: 7485 VAD Previous Re-certification Dates: 2008-10-30; 2010-10-21; 2012-11-06; 2014-10-28; 2016-12-20	230053	01/06/2004	**03/13/2019**	MI
Intermountain Medical Center 5121 South Cottonwood Street Murry, UT 84157 Other information: Joint Commission ID #: 9540 VAD Previous Re-certification Dates: 2008-10-31; 2010-12-07; 2012-12-11; 2014-12-16; 2017-01-24	460010	10/23/2003	**03/13/2019**	UT
Yale - New Haven Hospital 20 York Street New Haven, CT 06510 Other information: Joint Commission ID #: 5677 VAD Previous Re-certification Dates: 2013-01-15; 2014-12-16; 2017-02-28	070022	02/04/2011	**05/22/2019**	CT
FROM: Loma Linda University Medical Center and Children's Hospital **TO: Loma Linda University Medical Center** 11234 Anderson Street Loma Linda, CA 92354 Other information: Joint Commission ID # 9898 Previous Re-certification Dates: 2014-01-23; 2016-02-24	050327	02/17/2012	**04/11/2018**	CA
University of Colorado Hospital Authority **12605 E 16th Avenue** **Aurora, CO 80045-2545** Other information: Joint Commission ID # 9384 Previous Re-certification Dates: 2008-07-23; 2010-08-17; 2012-08-10; 2014-07-22; 2016-07-26	060024	11/06/2003	**07/17/2018**	CO
Beth Israel Deaconess Medical Center 330 Brookline Avenue Boston, MA 02215 Other information: Joint Commission ID # 5501	220086	06/23/2017	**05/22/2019**	PA
Presbyterian Medical Center of the UPHS **51 North 39th Street** **Philadelphia, PA 19104** Other information: Joint Commission ID # 6145 Previous Re-certification Dates: 2012-11-07; 2014-12-09; 2017-03-21	390223	10/11/2011	**04/17/2019**	PA

Facility	Provider Number	Date of Initial Certification	Date of Recertification	State
FROM: Shands at the University of Florida **TO: Shands Teaching Hospitals & Clinics, Inc.** 1600 SW Archer Rd. Gainesville, FL 32608 Other information: Joint Commission ID # 6804 Previous Re-certification Dates: 2008-11-18; 2011-02-08; 2013-02-12; 2015-01-27; 2017-02-14	10113	11/26/2003	**04/24/2019**	FL
Nebraska Medical Center 4350 Dewey Avenue Omaha, NE 68198-7400 Other information: Joint Commission ID # 186313 Previous Re-certification Dates: 2013-01-29; 2015-02-24; 2017-02-14	280013	02/02/2011	**04/17/2019**	NE
University of Colorado Hospital Authority **12605 E 16th Ave.** **Aurora, CO 80045-2545** Other information: Joint Commission ID # 9384 Previous Re-certification Dates: 2008-07-23; 2010-08-17; 2012-08-10; 2014-07-22; 2016-07-26	060024	11/06/2003	07/18/2018	CO

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (April through June 2019)

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commision on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.

Only the first two types are in the list. For the purposes of this quarterly notice, there are no specific updates to the listing of facilities for lung volume reduction surgery published in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (April through June 2019)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS' minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

This information is available on our website at www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (April through June 2019)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

[FR Doc. 2019–17025 Filed 8–8–19; 8:45 am]

BILLING CODE 4120–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Comment Request; Older Americans Act, Title VI Grant Application

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 30 days for public comment in response to the notice.

This notice solicits comments on the Proposed New Collection and solicits comments on the information collection requirements related to the Application for Older Americans Act, Title VI Parts A/B and C Grants.

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by September 9, 2019.

ADDRESSES: Submit written comments on the collection of information by:

(a) Email to: *OIRA_submission@omb.eop.gov,* Attn: OMB Desk Officer for ACL;

(b) fax to 202.395.5806, Attn: OMB Desk Officer for ACL; or

(c) by mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Rhonda Schwartz, Administration for Community Living, Washington, DC 20201, Rhonda Schwartz, *Rhonda.Schwartz@acl.hhs.gov,* (617) 565–1165.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance.

ACL is responsible for administering the Title VI A/B (Nutrition and Supportive Service) and C (Caregiver) grants. The purpose of this data collection is to improve and standardize the format of the application. The instrument will collect data as prescribed by the Older Americans Act Section 612(a), 614(a) and 45 CFR 1326.19 related to the eligibility of Federally-recognized Tribes and Native Hawaiian organizations for grant funds under this program and their capacity to deliver services to elders.

The Application for Older Americans Act, Title VI A/B and C Grants collects information on the ability of federally-recognized American Indian, Alaskan Native and Native Hawaiian organizations to provide nutrition, supportive, and caregiver services to elders within their service area. Applicants are required to provide a description of their organization's service area, the number of eligible elders in their service area, and their ability to deliver services and sign assurances that the organization will comply with all applicable laws and regulations.

This is a new data collection. In prior grant cycles, AoA used ACL's generic clearance for the funding opportunity announcement (FOA) information collection currently approved under OMB control number 0985–0018. The proposed data collection materials have been updated to better align with the requirements of the Older Americans Act and Federal regulations, as well as to improve data quality and grantee accountability. Furthermore, this grantee application will better line up with the revised Title VI Program Performance Report under 0985–0059 and will eliminate duplicate reporting requirements for grantees. This data collection will also support ACL in tracking performance outcomes and efficiency measures with respect to the annual and long-term performance targets established in compliance with the Government Performance Results Modernization Act (GPRMA).

A notice was published in the **Federal Register** on June 3, 2019, Vol. 84, No. 106, pp. 25546–25547.

The proposed data collection tools may be found on the ACL website for review at *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden

Title VI grant applications are required once every three (3) years, so an annual response is not required for this instrument (the annual burden below reflects this calculation). Additionally, Title VI funding is broken into three categories.

Parts A and B are for nutritional and supportive programming, with Part A being restricted to American Indian and Alaska Native grantees, and Part B restricted to Native Hawaiian grantees. Part C is for caregiver programming. All Part C grantees must have Part A/B funding, but not all Part A/B grantees will have Part C programs. Therefore, there are likely to be 295 unique respondents, but only 250 will have to complete all three portions of the application. This application covers all three parts of Title VI.

ACL estimates the burden associated with this collection of information as follows:

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Title VI Application Part A/B	295	1	2.75	270.4
Title VI Application Part C	250	1	1.5	125
Total			4.25	395.4

The number of burden hours associated with the Title VI, Part C, data collection was calculated as 811.25. However, since this instrument is used only once every 3 years, this number was annualized by dividing it into thirds. This resulted in an annualized number of 270.4 hours. Similarly, the total hours associated with the Title VI, Part C, application is 375. This number was annualized by dividing it by three, resulting in an annual burden hours of 125.

Dated: August 5, 2019.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2019–17072 Filed 8–8–19; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3019]

Transit Times to Slaughter Facilities, Milking Frequency, and Interpretation of Zero-Day Withdrawal Periods and Zero-Day Milk Discard Times Assigned to New Animal Drugs; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is soliciting comments on transit times to slaughter, milking frequency, and how end users interpret zero-day withdrawal period or zero-day milk discard time statements found on new animal drug labeling.

DATES: Submit either electronic or written comments by October 8, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 8, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 8, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–3019 for ''Transit Times to Slaughter Facilities, Milking Frequency, and Interpretation of Zero-Day Withdrawal Periods and Zero-Day Milk Discard Times Assigned to New Animal Drugs.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Charli M. Long-Medrano, Center for Veterinary Medicine (HFV–150), Food and Drug Administration, 7500 Standish Place, Rm. E340, Rockville, MD 20855, 240–402–0850, *Charli.Long-Medrano@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

New animal drugs are assigned withdrawal periods and milk discard times when approved for use in food-producing animals. The withdrawal period or milk discard time is the interval between the time of the last administration of a new animal drug and the time when the animal can be slaughtered safely for human food or the milk can be consumed safely by humans, respectively.[1] Zero-day withdrawal periods and zero-day milk discard times are assigned to new animal drugs when the labeling indications and directions (*i.e.,* the approved conditions of use) allow entry of edible tissues, including milk, into the human food supply without regard to the elapsed time following the last drug administration.[2] In most instances, we assign a zero-day withdrawal period or zero-day milk discard time to new animal drugs when data or information demonstrate that edible tissues or milk can be consumed safely at timepoints known as practical zero withdrawal or practical zero-milk discard time, respectively. Practical zero withdrawal [3] and practical zero-milk discard time are

[1] Guidance for Industry #3, ''General Principles for Evaluating the Human Food Safety of New Animal Drugs Used in Food-Producing Animals'' (*https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052180.pdf*).

[2] Guidance for Industry #207 (VICH GL48), ''Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Marker Residue Depletion Studies to Establish Product Withdrawal Periods'' (*https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM207941.pdf*).

[3] Ibid.

the shortest time intervals, including transit time to a slaughter facility, between administration of the last dose of the drug and slaughter or collection of milk for human consumption, respectively.

Since the 1980s, the Agency has assumed that poultry spent at least 6 hours in transit to a slaughter facility, cattle and pigs spent at least 12 hours in transit to a slaughter facility, and dairy cows were milked at 12-hour intervals. These assumptions led the Agency to define practical zero withdrawal as 6 hours for poultry and 12 hours for cattle and pigs and practical zero-milk discard time as 12 hours for lactating dairy cows. Accordingly, we currently assign a zero-day withdrawal period or zero-day milk discard time to new animal drugs if data from scientific studies or other available information confirm that residue concentrations in edible tissues or milk from treated animals are safe for human consumption after 6 hours withdrawn from drug for poultry or after 12 hours withdrawn from drug for cattle, pigs, sheep, goats, and lactating dairy animals (*i.e.,* practical zero withdrawal and practical zero-milk discard time). A zero-day withdrawal period or zero-day milk discard time is often communicated to the end user by a labeling statement (*e.g.,* ''zero-day withdrawal period,'' ''zero-day milk discard time,'' or ''no withdrawal period or milk discard time is required'').

The concept of practical zero withdrawal does not apply to drugs administered to laying hens (eggs only), food-producing aquatic animals, or honey bees. In these situations, we apply an ''absolute zero withdrawal approach,'' meaning that collection time or transit time is not considered and drug residues in eggs from treated hens, edible tissues from treated food-producing aquatic animals, and honey from treated honey bees must be below the assigned tolerance at all times during and after administration of a drug that has been assigned a zero-day withdrawal. Samples intended to support a zero-day withdrawal in these species are collected while animals are on the drug or immediately following the final drug administration.

II. Issues for Consideration

We recognize that the animal agriculture industry has undergone significant changes since the 1980s, when the current assumptions about transit time to slaughter and milking frequency were formulated. An accurate understanding of current industry practices and the end user's interpretation of labeling statements is necessary to approve labeling that ensures the safe and effective use of new animal drugs, which is central to our mission to protect and promote public health. Therefore, we are requesting comments on current industry practices regarding transit times to slaughter for food-producing animals, milking frequency, and how end users interpret a zero-day withdrawal period or zero-day milk discard time. We welcome comments on these topics for all food-producing animals except laying hens, honey bees, and food-producing aquatic animals because, as noted earlier, the concept of practical zero withdrawal does not apply to these classes of food-producing animals.

We invite comments on any or all the questions from individuals with direct knowledge of current industry practices. Please include the sector within the industry from where this information is derived (*e.g.,* a veterinarian, cooperative, individual producer, hauler, trade organization, packers and processors, etc.), as well as the source of the information (*e.g.,* survey, farm practices, published information, etc.) We specifically request comment on the following:

1. What is the minimum amount of time that food-producing animals spend in transit to a slaughter facility in the United States (*i.e.,* minimum transit time)? Please include the animal species and animal class(es) for each time provided.

2. What is the minimum amount of time that food-producing animals spend at slaughter facilities in the United States prior to being slaughtered for human consumption (*i.e.,* minimum holding time)? Please include the animal species and animal class(es) for each time provided.

3. What milking frequencies do United States commercial dairy operations commonly use (*e.g.,* two times per day, three times per day, greater than three times per day)? To what extent is each milking frequency used nationally, regionally, or within a particular sector (*e.g.,* 25 percent of dairies nationally, 30 percent of dairies in the Midwest, 50 percent of dairies serviced by a veterinary practice, etc.)?

4. How do end users of new animal drugs interpret labeling that has a ''zero-day withdrawal period'' or ''zero-day milk discard time,'' or that states ''no withdrawal period or milk discard time is required''?

We will consider the submitted comments to evaluate if our current approach to assigning zero-day withdrawal periods and zero-day milk discard times to new animal drugs is appropriate.

Dated: August 5, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17053 Filed 8–8–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Tribal Self-Governance; Negotiation Cooperative Agreement

Announcement Type: New.

Funding Announcement Number: HHS–2019–IHS–TSGN–0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.444.

Key Dates

Application Deadline Date: October 23, 2019.

Earliest Anticipated Start Date: November 22, 2019.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Tribal Self-Governance (OTSG) is accepting applications for Negotiation Cooperative Agreements for the Tribal Self-Governance Program (TSGP). This program is authorized under Title V of the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. 5383(e). This program is described in the Assistance Listings located at *https://beta.sam.gov* (formerly known as Catalog of Federal Domestic Assistance) under 93.444.

Background

The TSGP is more than an IHS program; it is an expression of the Government-to-Government relationship between the United States (U.S.) and Indian Tribes. Through the TSGP, Tribes negotiate with the IHS to assume Programs, Services, Functions, and Activities (PSFAs), or portions thereof, which gives Tribes the authority to manage and tailor health care programs in a manner that best fits the needs of their communities.

Participation in the TSGP affords Tribes the most flexibility to tailor health care PSFAs and is one of three ways that Tribes can choose to obtain health care from the Federal Government for their citizens. Specifically, Tribes can choose to: (1) Receive health care services directly from the IHS; (2) contract with the IHS to administer individual programs and services the IHS would otherwise provide (referred to as Title I Self-

Determination Contracting; and (3) compact with the IHS to assume control over health care programs the IHS would otherwise provide (referred to as Title V Self-Governance Compacting or the TSGP). These options are not exclusive and Tribes may choose to combine options based on their individual needs and circumstances.

The TSGP is a tribally-driven initiative and strong Federal-Tribal partnerships are essential to the program's success. The IHS established the OTSG to implement the Tribal Self-Governance authorities under the ISDEAA. The primary OTSG functions are to: (1) Serve as the primary liaison and advocate for Tribes participating in the TSGP; (2) develop, direct, and implement TSGP policies and procedures; (3) provide information and technical assistance to Self-Governance Tribes; and (4) advise the IHS Director on compliance with TSGP policies, regulations, and guidelines. Each IHS Area has an Agency Lead Negotiator (ALN), designated by the IHS Director to act on his or her behalf, who has authority to negotiate Self-Governance Compacts and Funding Agreements (FA). Prospective Tribes interested in participating in the TSGP should contact their respective ALN to begin the Self-Governance planning process. Also, Tribes currently participating in the TSGP, who are interested in expanding existing or adding new PSFAs, should also contact their respective ALN to discuss the best methods for expanding or adding new PSFAs.

Purpose

The purpose of this Negotiation Cooperative Agreement is to provide Tribes with resources to help defray the costs associated with preparing for and engaging in TSGP negotiations. TSGP negotiations are a dynamic, evolving, and tribally-driven process that requires careful planning, preparation and sharing of precise, up-to-date information by both Tribal and Federal parties. Because each Tribal situation is unique, a Tribe's successful transition into the TSGP, or expansion of their current program, requires focused discussions between the Federal and Tribal negotiation teams about the Tribe's specific health care concerns and plans. One of the hallmarks of the TSGP is the collaborative nature of the negotiations process, which is designed to: (1) Enable a Tribe to set its own priorities when assuming responsibility for IHS PSFAs; (2) observe and respect the Government-to-Government relationship between the U.S. and each Tribe; and (3) involve the active participation of both Tribal and IHS representatives, including the OTSG. Negotiations are a method of determining and agreeing upon the terms and provisions of a Tribe's Compact and FA, the implementation documents required for the Tribe to enter into the TSGP. The Compact sets forth the general terms of the Government-to-Government relationship between the Tribe and the Secretary of the U.S. Department of Health and Human Services (HHS). The FA: (1) Describes the length of the agreement (whether it will be annual or multi-year); (2) identifies the PSFAs, or portions thereof, the Tribe will assume; (3) specifies the amount of funding associated with the Tribal assumption; and (4) includes terms required by Federal statute and other terms agreed to by the parties. Both documents are required to participate in the TSGP and they are mutually negotiated agreements that become legally binding and mutually enforceable after both parties sign the documents. Either document can be renegotiated at the request of the Tribe.

The negotiations process has four major stages, including: (1) Planning; (2) pre-negotiations; (3) negotiations; and (4) post-negotiations. Title V of the ISDEAA requires that a Tribe or Tribal organization complete a planning phase to the satisfaction of the Tribe. The planning phase must include legal and budgetary research and internal Tribal Government planning and organizational preparation relating to the administration of health care programs. *See* 25 U.S.C. 5383(d). The planning phase is critical to negotiations and helps Tribes make informed decisions about which PSFAs to assume and what organizational changes or modifications are necessary to support those PSFAs. A thorough planning phase improves timeliness and efficient negotiations and ensures that the Tribe is fully prepared to assume the transfer of IHS PSFAs to the Tribal health program.

During pre-negotiations, the Tribal and Federal negotiation teams review and discuss issues identified during the planning phase. Pre-negotiations provide an opportunity for the Tribe and the IHS to identify and discuss issues directly related to the Tribe's Compact, FA and Tribal shares. They may take the form of a formal meeting or a series of informal meetings or conference calls.

In advance of final negotiations, the Tribe should work with the IHS to secure the following: (1) Program titles and descriptions; (2) financial tables and information; (3) information related to the identification and justification of residuals; and (4) the basis for determining Tribal shares (distribution formula). The Tribe may also wish to discuss financial materials that show estimated funding for next year, and the increases or decreases in funding it may receive in the current year, as well as the basis for those changes.

Having reviewed the draft documents and funding tables, at final negotiations both negotiation teams work together in good faith to determine and agree upon the terms and provisions of the Tribe's Compact and FA. Negotiations are not an allocation process; they provide an opportunity to mutually review and discuss budget and program issues. As issues arise, both negotiations teams work through the issues to reach agreement on the final documents.

There are various entities involved throughout the negotiations process. For example, a Tribal government selects its representative(s) for negotiations and the Tribal negotiations team, which may include a Tribal leader from the governing body, a Tribal health director, technical and program staff, legal counsel, and other consultants. Regardless of the composition of the Tribal team, Tribal representatives must have decision making authority from the Tribal governing body to successfully negotiate and agree to the provisions within the agreements. The Federal negotiations team is led by the ALN and may include area and headquarters staff, including staff from the OTSG, the Office of Finance and Accounting, and the Office of the General Counsel. The ALN is the only member of the Federal negotiations team with delegated authority to negotiate on behalf of the IHS Director. The ALN is the designated official that provides Tribes with Self-Governance information, assists Tribes in planning, organizes meetings between the Tribe and the IHS, and coordinates the Agency's response to Tribal questions during the negotiations process. The ALN role requires detailed knowledge of the IHS, awareness of current policy and practice, and understanding of the rights and authorities available to a Tribe under Title V of the ISDEAA.

In post-negotiations, after the Compact, FA and all negotiations are complete, the documents are signed by the authorizing Tribal official and submitted to the ALN who reviews the final package to ensure each document accurately reflects what was negotiated. Once the ALN completes this review, then the final package is submitted to the OTSG to be prepared for the IHS Director's signature, provided that no outstanding issues delay or prevent

signature. After the Compact and FA have been signed by both parties, they become legally binding and enforceable agreements. A signed Compact and FA are necessary for the payment process to begin. The negotiating Tribe then becomes a ''Self-Governance Tribe'' and a participant in the TSGP.

Acquiring a Negotiation Cooperative Agreement is not a prerequisite to enter the TSGP. A Tribe may use other resources to develop and negotiate its Compact and FA. *See* 42 CFR 137.26. Tribes that receive a Negotiation Cooperative Agreement are not obligated to participate in Title V and may choose to delay or decline participation or expansion in the TSGP.

II. Award Information

Type of Award

Cooperative Agreement.

Estimated Funds Available

The total funding identified for fiscal year (FY) 2019 is approximately $240,000. Individual award amounts are anticipated to be $48,000. The funding available for competing and subsequent continuation awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately five awards will be issued under this program announcement.

Period of Performance

The period of performance is for one year.

Cooperative Agreement

Cooperative agreements awarded by the HHS are administered under the same policies as a grant. However, the funding agency (IHS) is anticipated to have substantial programmatic involvement in the project during the entire award segment. Below is a detailed description of the level of involvement required for IHS.

Substantial IHS Involvement Description for Cooperative Agreement

A. Provide descriptions of PSFAs and associated funding at all organizational levels (Service Unit, Area, and Headquarters), including funding formulas and methodologies related to determining Tribal shares.

B. Meet with Negotiation Cooperative Agreement recipients to provide program information and discuss methods currently used to manage and deliver health care.

C. Identify and provide statutes, regulations, and policies that provide authority for administering IHS programs.

D. Provide technical assistance on the IHS budget, Tribal shares, and other topics as needed.

III. Eligibility Information

1. Eligibility

To be eligible for the New Negotiation Cooperative Agreement under this announcement, an applicant must:

(A) Be an ''Indian Tribe'' as defined in 25 U.S.C. 5304(e); a ''Tribal Organization'' as defined in 25 U.S.C. 5304(l); or an ''Inter-Tribal Consortium: as defined at 42 CFR 137.10. However, Alaska Native Villages or Alaska Native Village Corporations are not eligible if they are located within the area served by an Alaska Native regional health entity. See Consolidated Appropriations Act, 2014, Public Law 113–76 and Consolidated Appropriations Act, 2018, Public Law 115–141. By statute, the Native Village of Eyak, Eastern Aleutian Tribes, and the Council for Athabascan Tribal Governments have also been deemed Alaska Native regional health entities and therefore are eligible to apply. Those Alaska Tribes not represented by a Self-Governance Tribal consortium FA within their area may still be considered to participate in the TSGP.

(B) Applicant must request participation in self-governance by resolution or other official action by the governing body of each Indian tribe to be served. Please see IV. Application and Submission Information, 2. Content and Form Application Submission, Additional Required Documentation, Tribal Resolution(s) for details.

(C) Demonstrate for three fiscal years, financial stability and financial management capability. The Indian Tribe must provide evidence that, for the three fiscal years prior to requesting participation in the TSGP, the Indian Tribe has had no uncorrected significant and material audit exceptions in the required annual audit of the Indian Tribe's Self-Determination Contracts or Self-Governance FAs with any Federal Agency. *See* 25 U.S.C. 5383; 42 CFR 137.15–23.

For Tribes or Tribal organizations (T/TO) that expended $750,000 or more ($500,000 for fiscal years ending after December 31, 2003) in Federal awards, the OTSG shall retrieve the audits directly from the Federal Audit Clearinghouse.

For T/TO that expended less than $750,000 ($500,000 for fiscal years ending after December 31, 2003) in Federal awards, the T/TO must provide evidence of the program review correspondence from IHS or Bureau of Indian Affairs officials. *See* 42 CFR 137.21–23

Meeting the eligibility criteria for a Negotiation Cooperative Agreement does not mean that a T/TO is eligible for participation in the IHS TSGP under Title V of the ISDEAA. *See* 25 U.S.C. 5383; 42 CFR 137.15–23. For additional information on the eligibility for the IHS TSGP, please visit the ''Eligibility and Funding'' page on the OTSG website located at: *http://www.ihs.gov/SelfGovernance.*

Note: Please refer to Section IV.2 (Application and Submission Information/Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required, such as Tribal resolutions, proof of non-profit status, etc.

2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

Applications with budget requests that exceed the highest dollar amount outlined under the Award Information, Estimated Funds Available section, or exceed the Period of Performance outlined under the Award Information, Period of Performance section will be considered not responsive and will not be reviewed. The Division of Grants Management (DGM) will notify the applicant.

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement is hosted on *https://www.Grants.gov.*

Please direct questions regarding the application process to Mr. Paul Gettys at (301) 443–2114 or (301) 443–5204.

2. Content and Form Application Submission

The applicant must include the project narrative as an attachment to the application package. Mandatory documents for all applicants include:

- Abstract (one page) summarizing the project.
- Application forms:
  - SF–424, Application for Federal Assistance.
  - SF–424A, Budget Information—Non-Construction Programs.
  - SF–424B, Assurances—Non-Construction Programs.

- Project Narrative (not to exceed 10 pages). See IV.2.A Project Narrative for instructions.
  - Background information on the organization.
  - Proposed scope of work, objectives, and activities that provide a description of what the applicant plans to accomplish.
- Budget Justification and Narrative (not to exceed 5 pages). See IV.2.B Budget Narrative for instructions.
- One-page Timeframe Chart.
- Tribal Resolution(s) (please see additional information below).
- Letters of Support from organization's Board of Directors.
- Biographical sketches for all Key Personnel.
- Contractor/Consultant resumes or qualifications and scope of work.
- Disclosure of Lobbying Activities (SF–LLL).
- Certification Regarding Lobbying (GG-Lobbying Form).
- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required in order to receive IDC).
- Organizational Chart (optional).
- Documentation of current Office of Management and Budget (OMB) Financial Audit (if applicable).

Acceptable forms of documentation include:

- Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or

Face sheets from audit reports. Applicants can find these on the FAC website: *https://harvester.census.gov/facdissem/Main.aspx.*

Additional Required Documentation

Tribal Resolution(s)

Submit Tribal resolution(s) from the appropriate governing body of the Indian Tribe to be served by the ISDEAA Compact authorizing the submission of a Negotiation Cooperative Agreement application. Tribal consortia applying for a TSGP Negotiation Cooperative Agreement shall submit Tribal Council resolutions from each Tribe in the consortium. Tribal resolutions can be attached to the electronic online application.

The DGM must receive an official, signed Tribal resolution prior to issuing a Notice of Award (NoA) to any applicant selected for funding. An Indian Tribe or Tribal organization that is proposing a project affecting another Indian Tribe must include resolutions from all affected Tribes to be served. However, if an official, signed Tribal resolution cannot be submitted with the application prior to the application deadline date, a draft Tribal resolution must be submitted with the application by the deadline date in order for the application to be considered complete and eligible for review. The draft Tribal resolution is not in lieu of the required signed resolution, but is acceptable until a signed resolution is received. If an official signed Tribal resolution is not received by DGM when funding decisions are made, then a NoA will not be issued to that applicant and it will not receive IHS funds until it has submitted a signed resolution to the Grants Management Specialist listed in this Funding Announcement.

Public Policy Requirements

All Federal public policies apply to IHS grants and cooperative agreements with the exception of the Discrimination Policy.

Requirements for Project and Budget Narratives

A. Project Narrative: This narrative should be a separate document that is no more than 10 pages and must: (1) Have consecutively numbered pages; (2) use black font 12 points or larger; (3) be single-spaced; (4) and be formatted to fit standard letter paper (8-1/2 x 11 inches).

Be sure to succinctly answer all questions listed under the evaluation criteria (refer to Section V.1, Evaluation Criteria) and place all responses and required information in the correct section noted below or they will not be considered or scored. If the narrative exceeds the page limit, the application will be considered not responsive and not be reviewed. The 10-page limit for the narrative does not include the work plan, standard forms, Tribal resolutions, budget, budget justifications, narratives, and/or other appendix items.

There are three parts to the narrative: Part 1—Program Information; Part 2—Program Planning and Evaluation; and Part 3—Program Report. See below for additional details about what must be included in the narrative.

The page limits below are for each narrative and budget submitted.

Part 1: Program Information (Limit—4 Pages)

Section 1: Needs

Introduction and Need for Assistance

Demonstrate that the Tribe has conducted previous Self-Governance planning activities by clearly stating the results of what was learned during the planning process. Explain how the Tribe has determined it has the: (1) Knowledge and expertise to assume or expand PSFAs; and (2) the administrative infrastructure to support the assumption of PSFAs. Identify the need for assistance and how the Negotiation Cooperative Agreement would benefit the health activities the Tribe is preparing to assume or expand.

Part 2: Program Planning and Evaluation (Limit—4 Pages)

Section 1: Program Plans

Project Objective(s), Work Plan and Approach

State in measureable terms the objectives and appropriate activities to achieve the following Negotiation Cooperative Agreement recipient award activities:

(A) Determine the PSFAs that will be negotiated into the Tribe's Compact and FA. Prepare and discuss each Program, Service, Function, and Activity in comparison to the current level of services provided so that an informed decision can be made on new or expanded program assumption.

(B) Identify Tribal shares associated with the PSFAs that will be included in the FA.

(C) Develop the terms and conditions that will be set forth in both the Compact and FA to submit to the ALN prior to negotiations.

(D) Describe fully and clearly how the Tribe's proposal will result in an improved approach to managing the PSFAs to be assumed or expanded. Include how the Tribe plans to demonstrate improved health services to the community and incorporate the proposed timelines for negotiations.

Organizational Capabilities, Key Personnel, and Qualifications

Describe the organizational structure of the Tribe and its ability to manage the proposed project. Include resumes or position descriptions of key staff showing requisite experience and expertise. If applicable, include resumes and scope of work for consultants that demonstrate experience and expertise relevant to the project.

Section 2: Program Evaluation

Describe fully and clearly how the improvements that will be made by the Tribe to manage the health care system and identify the anticipated or expected benefits for the Tribe. Define the criteria to be used to evaluate objectives associated with the project.

Part 3: Program Report (Limit—2 Pages)

Section 1: Describe major accomplishments over the last 24 months associated with the goals of this announcement. Please identify and describe significant health related program accomplishments associated with the delivery of quality health

services. This section should highlight major program achievements over the last 24 months.

Section 2: Describe major activities over the last 24 months. Please provide an overview of significant program activities associated with the delivery of quality health services over the last 24 months. This section should address significant program activities and include those related to the accomplishments listed in the previous section.

B. Budget Narrative (Limit—5 Pages)

Provide a budget narrative that explains the amounts requested for each line of the budget. The budget narrative should specifically describe how each item will support the achievement of proposed objectives. Be very careful about showing how each item in the ''other'' category is justified. Do NOT use the budget narrative to expand the project narrative.

3. Submission Dates and Times

Applications must be submitted through *Grants.gov* by 11:59 p.m. Eastern Daylight Time (EDT) on the Application Deadline Date. Any application received after the application deadline will not be accepted for review. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the application process, contact *Grants.gov* Customer Support (see contact information at *https://www.grants.gov*). If problems persist, contact Mr. Paul Gettys (*Paul.Gettys@ihs.gov*), DGM Grant Systems Coordinator, by telephone at (301) 443–2114 or (301) 443–5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a *Grants.gov* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

The IHS will not acknowledge receipt of applications.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are not allowable.
- The available funds are inclusive of direct and appropriate indirect costs.
- Tribes can apply for a Planning Cooperative Agreement and a Negotiation Cooperative Agreement in the same cycle, so long as the project proposals are different for each application. Tribes cannot apply for both the Planning Cooperative Agreement and the Negotiation Cooperative Agreement within the same grant cycle with the same proposed project.
- Only one Negotiation grant/cooperative agreement will be awarded per applicant per grant cycle under this announcement.

6. Electronic Submission Requirements

All applications must be submitted via *Grants.gov*. Please use the *https://www.Grants.gov* website to submit an application. Find the application by selecting the ''Search Grants'' link on the homepage. Follow the instructions for submitting an application under the Package tab. No other method of application submission is acceptable.

If the applicant cannot submit an application through *Grants.gov*, a waiver must be requested. Prior approval must be requested and obtained from Mr. Robert Tarwater, Director, DGM. A written waiver request must be sent to *GrantsPolicy@ihs.gov* with a copy to *Robert.Tarwater@ihs.gov.* The waiver must: (1) Be documented in writing (emails are acceptable), before submitting an application by some other method; and (2) include clear justification for the need to deviate from the required application submission process.

Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions. A copy of the written approval must be included with the application that is submitted to DGM. Applications that are submitted without a copy of the signed waiver from the Director of the DGM will not be reviewed. The Grants Management Officer of the DGM will notify the applicant via email of this decision. Applications submitted under waiver must be received by the DGM no later than 5:00 p.m., EDT, on the Application Deadline Date. Late applications will not be accepted for processing. Applicants that do not register for both the System for Award Management (SAM) and *Grants.gov* and/or fail to request timely assistance with technical issues will not be considered for a waiver to submit an application via alternative method.

Please be aware of the following:

- Please search for the application package in *https://www.Grants.gov* by entering the CFDA number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application, please contact *Grants.gov* Customer Support (see contact information at *https://www.grants.gov*).
- Upon contacting *Grants.gov*, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for SAM and *Grants.gov* could take up to twenty working days.
- Please follow the instructions on *Grants.gov* to include additional documentation that may be requested by the NOFO.
- Applicants must comply with any page limits described in this funding announcement.
- After submitting the application, the applicant will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The IHS will not notify the applicant that the application has been received.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

Applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B, which uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, please access the request service through *https://fedgov.dnb.com/webform,* or call (866) 705–5711.

The Federal Funding Accountability and Transparency Act of 2006, as amended (''Transparency Act''), requires all HHS recipients to report information on sub-awards. Accordingly, all IHS grantees must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that are not registered with SAM will need to obtain a DUNS number first and then access the SAM online registration through the SAM

home page at *https://www.sam.gov* (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Please see *SAM.gov* for details on the registration process and timeline. Registration with the SAM is free of charge, but can take several weeks to process. Applicants may register online at *https://www.sam.gov.*

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, are available on the IHS Grants Management, Policy Topics web page: *https://www.ihs.gov/dgm/policytopics/.*

V. Application Review Information

Weights assigned to each section are noted in parentheses. The 10-page narrative should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully. Points will be assigned to each evaluation criteria adding up to a total of 100 possible points. Points are assigned as follows:

1. Criteria

A. Introduction and Need for Assistance (25 Points)

Demonstrate that the Tribe has conducted previous Self-Governance planning activities by clearly stating the results of what was learned during the planning process. Explain how the Tribe has determined it has the: (1) Knowledge and expertise to assume or expand PSFAs; and (2) the administrative infrastructure to support the assumption of PSFAs. Identify the need for assistance and how the Negotiation Cooperative Agreement would benefit the health activities the Tribe is preparing to assume or expand.

B. Project Objective(s), Work Plan and Approach (25 Points)

State in measurable terms the objectives and appropriate activities to achieve the following Negotiation Cooperative Agreement recipient award activities:

(1) Determine the PSFAs that will be negotiated into the Tribe's Compact and FA. Prepare and discuss each Program, Service, Function and Activity in comparison to the level of services provided so that an informed decision can be made on new or expanded program assumption.

(2) Identify Tribal shares associated with the PSFAs that will be included in the FA.

(3) Develop the terms and conditions that will be set forth in both the Compact and FA to submit to the ALN prior to negotiations. Clearly describe how the Tribe's proposal will result in an improved approach to managing the PSFAs to be assumed or expanded. Include how the Tribe plans to demonstrate improved health care services to the community and incorporate the proposed timelines for negotiations.

C. Program Evaluation (25 Points)

Describe fully the improvements that will be made by the Tribe to manage the health care system and identify the anticipated or expected benefits for the Tribe. Define the criteria to be used to evaluate objectives associated with the project.

D. Organizational Capabilities, Key Personnel and Qualifications (15 Points)

Describe the organizational structure of the Tribe and its ability to manage the proposed project. Include resumes or position descriptions of key staff showing requisite experience and expertise. If applicable, include resumes and scope of work for consultants that demonstrate experience and expertise relevant to the project.

E. Categorical Budget and Budget Justification (10 Points)

Submit a budget with a narrative describing the budget request and matching the scope of work described in the project narrative. Justify all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the project narrative.

Additional Documents Can Be Uploaded as Appendix Items in Grants.gov

- Work plan, logic model and/or time line for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff that reflect current duties.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (*i.e.,* data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the Objective Review Committee (ORC) based on evaluation criteria. Incomplete applications and applications that are not responsive to the administrative thresholds will not be referred to the ORC and will not be funded. The applicant will be notified of this determination.

Applicants must address all program requirements and provide all required documentation.

3. Notifications of Disposition

All applicants will receive an Executive Summary Statement from the IHS OTSG within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application. The summary statement will be sent to the Authorizing Official identified on the face page (SF–424) of the application.

A. Award Notices for Funded Applications

The Notice of Award (NoA) is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period. Each entity approved for funding must have a user account in GrantSolutions in order to retrieve the NoA. Please see the Agency Contacts list in Section VII for the systems contact information.

B. Approved but Unfunded Applications

Approved applications not funded due to lack of available funds will be held for one year. If funding becomes available during the course of the year, the application may be reconsidered.

Note: Any correspondence other than the official NoA executed by an IHS grants management official announcing to the project director that an award has been made to their organization is not an authorization to implement their program on behalf of the IHS.

VI. Award Administration Information

1. Administrative Requirements

Cooperative agreements are administered in accordance with the following regulations and policies:

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Grants:

- Uniform Administrative Requirements for HHS Awards, located at 45 CFR part 75.

C. Grants Policy:

• HHS Grants Policy Statement, Revised 01/07.

D. Cost Principles:

• Uniform Administrative Requirements for HHS Awards, ''Cost Principles,'' located at 45 CFR part 75, subpart E.

E. Audit Requirements:

• Uniform Administrative Requirements for HHS Awards, ''Audit Requirements,'' located at 45 CFR part 75, subpart F.

2. Indirect Costs

This section applies to all recipients that request reimbursement of indirect costs (IDC) in their application budget. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to obtain a current IDC rate agreement prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award's budget period. If the current rate is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate agreement is provided to the DGM.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) *https://rates.psc.gov/* and the Department of Interior (Interior Business Center) *https://www.doi.gov/ibc/services/finance/indirect-Cost-Services/indian-tribes.* For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under ''Agency Contacts'' or the main DGM office at (301) 443–5204.

3. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports are required to be submitted electronically by attaching them as a ''Grant Note'' in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required semi-annually, within 30 days after the budget period ends. These reports must include a brief comparison of actual accomplishments to the goals established for the period, a summary of progress to date or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within 90 days of expiration of the period of performance.

B. Financial Reports

Federal Financial Report (FFR or SF–425), Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services, HHS at *https://pms.psc.gov.* The applicant is also requested to upload a copy of the FFR (SF–425) report into our grants management system, GrantSolutions. Failure to submit timely reports may result in adverse award actions blocking access to funds.

Grantees are responsible and accountable for accurate information being reported on all required reports: the Progress Reports and Federal Financial Report.

C. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards.

The IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a $25,000 sub-award obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the period of performance is made up of more than one budget period) and where: (1) The period of performance start date was October 1, 2010 or after, and (2) the primary awardee will have a $25,000 sub-award obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting.

For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Policy website at *https://www.ihs.gov/dgm/policytopics/.*

D. Compliance With Executive Order 13166 Implementation of Services

Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. The HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see *https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-VI/.*

The HHS Office for Civil Rights (OCR) also provides guidance on complying with civil rights laws enforced by HHS. Please see *https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html;* and *https://www.hhs.gov/civil-rights/index.html.* Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see *https://www.hhs.gov/civil-rights/for-individuals/disability/index.html.* Please contact the HHS OCR for more information about obligations and prohibitions under federal civil rights laws at *https://www.hhs.gov/ocr/about-us/contact-us/index.html* or call (800) 368–1019 or TDD (800) 537–7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically

appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.*

Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of his/her exclusion from benefits limited by federal law to individuals eligible for benefits and services from the IHS.

Recipients will be required to sign the HHS–690 Assurance of Compliance form which can be obtained from the following website: *https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf,* and send it directly to the: U.S. Department of Health and Human Services, Office of Civil Rights, 200 Independence Ave. SW, Washington, DC 20201.

E. Federal Awardee Performance and Integrity Information System (FAPIIS)

The IHS is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information System (FAPIIS), at *http://www.fapiis.gov,* before making any award in excess of the simplified acquisition threshold (currently $150,000) over the period of performance. An applicant may review and comment on any information about itself that a federal awarding agency previously entered. The IHS will consider any comments by the applicant, in addition to other information in FAPIIS in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed by applicants as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, non-federal entities (NFEs) are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than $10,000,000 for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, effective January 1, 2016, the IHS must require a non-federal entity or an applicant for a federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award.

Submission is required for all applicants and recipients, in writing, to the IHS and to the HHS Office of Inspector General all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. 45 CFR 75.113.

Disclosures must be sent in writing to:

U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Robert Tarwater, Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, (Include ''Mandatory Grant Disclosures'' in subject line), Office: (301) 443–5204, Fax: (301) 594–0899, Email: *Robert.Tarwater@ihs.gov*.

AND

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW, Cohen Building, Room 5527, Washington, DC 20201, URL: *https://oig.hhs.gov/fraud/report-fraud/*, (Include ''Mandatory Grant Disclosures'' in subject line), Fax: (202) 205–0604 (Include ''Mandatory Grant Disclosures'' in subject line) or Email: *MandatoryGranteeDisclosures@oig.hhs.gov*.

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance, including suspension or debarment (See 2 CFR parts 180 & 376 and 31 U.S.C. 3321).

VII. Agency Contacts

1. *Questions on the programmatic issues may be directed to:* Roxanne Houston, Program Officer, Office of Tribal Self-Governance, 5600 Fishers Lane, Mail Stop: 08E05, Rockville, MD 20857, Phone: (301) 443–7821, Email: *Roxanne.Houston@ihs.gov*, Website: *http://www.ihs.gov/self-governance*.

2. *Questions on grants management and fiscal matters may be directed to:* Vanietta Armstrong, Grants Management Specialist, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443–4792, Fax: (301) 594–0899, Email: *Vanietta.Armstrong@ihs.gov*.

3. *Questions on systems matters may be directed to:* Paul Gettys, Grant Systems Coordinator, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443–2114; or the DGM main line (301) 443–5204, Fax: (301) 594–0899, E-Mail: *Paul.Gettys@ihs.gov*.

VIII. Other Information

The Public Health Service strongly encourages all grant, cooperative agreement and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Chris B. Buchanan,

Assistant Surgeon General, RADM, U.S. Public Health Service Deputy Director, Indian Health Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Tribal Self-Governance Planning Cooperative Agreement

Announcement Type: New.

Funding Announcement Number: HHS–2019–IHS–TSGP–0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.444.

Key Dates

Application Deadline Date: October 23, 2019.

Earliest Anticipated Start Date: November 22, 2019.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Tribal Self Governance (OTSG) is accepting applications for Planning Cooperative Agreements for Tribal Self-Governance Program (TSGP). This program is authorized under Title V of the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. 5383(e). This program is described in the Assistance Listings located at *https://beta.sam.gov* (formerly known as Catalog of Federal Domestic Assistance) under 93.444.

Background

The TSGP is more than an IHS program; it is an expression of the Government-to-Government relationship between the United States (U.S.) and Indian Tribes. Through the TSGP, Tribes negotiate with the IHS to assume Programs, Services, Functions, and Activities (PSFAs), or portions thereof, which gives Tribes the authority to manage and tailor health care programs in a manner that best fits the needs of their communities.

Participation in the TSGP affords Tribes the most flexibility to tailor health care PSFAs and is one of three ways that Tribes can choose to obtain health care from the Federal Government for their citizens. Specifically, Tribes can choose to: (1) Receive health care services directly from the IHS; (2) contract with the IHS to administer individual programs and services the IHS would otherwise provide (referred to as Title I Self-Determination Contracting; and (3) compact with the IHS to assume control over health care programs the IHS would otherwise provide (referred to as Title V Self-Governance Compacting or the TSGP). These options are not exclusive and Tribes may choose to combine options based on their individual needs and circumstances.

The TSGP is a tribally-driven initiative, and strong Federal-Tribal partnerships are essential to the program's success. The IHS established the OTSG to implement the self-governance authorities under the ISDEAA. The primary OTSG functions are to: (1) Serve as the primary liaison and advocate for Tribes participating in the TSGP; (2) develop, direct, and implement TSGP policies and procedures; (3) provide information and technical assistance to Self-Governance Tribes; and (4) advise the IHS Director on compliance with TSGP policies, regulations, and guidelines. Each IHS Area has an Agency Lead Negotiator (ALN), designated by the IHS Director to act on his or her behalf, who has authority to negotiate Self-Governance Compacts and Funding Agreements. Prospective Tribes interested in participating in the TSGP should contact their respective ALN to begin the Self-Governance planning process. Also, Tribes currently participating in the TSGP, who are interested in expanding existing or adding new PSFAs should also contact their respective ALN to discuss the best methods for expanding or adding new PSFAs.

Purpose

The purpose of this Planning Cooperative Agreement is to provide resources to Tribes interested in entering the TSGP and to existing Self-Governance Tribes interested in assuming new or expanded PSFAs. Title V of the ISDEAA requires a Tribe or Tribal organization to complete a planning phase to the satisfaction of the Tribe. The planning phase must include legal and budgetary research and internal Tribal government planning and organizational preparation relating to the administration of health care programs. See 25 U.S.C. 5383(d).

The planning phase is critical to negotiations and helps Tribes make informed decisions about which PSFAs to assume and what organizational changes or modifications are necessary to successfully support those PSFAs. A thorough planning phase improves timeliness and efficient negotiations and ensures that the Tribe is fully prepared to assume the transfer of IHS PSFAs to the Tribal health program.

A Planning Cooperative Agreement is not a prerequisite to enter the TSGP and a Tribe may use other resources to meet the planning requirement. Tribes that receive Planning Cooperative Agreements are not obligated to participate in the TSGP and may choose to delay or decline participation based on the outcome of their planning activities. This also applies to existing Self-Governance Tribes exploring the option to expand their current PSFAs or assume additional PSFAs.

II. Award Information

Funding Instrument

Cooperative Agreement.

Estimated Funds Available

The total funding identified for fiscal year (FY) 2019 is approximately $600,000. Individual award amounts are anticipated to be $120,000. The funding available for competing and subsequent continuation awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately five awards will be issued under this program announcement.

Period of Performance

The period of performance is for one year.

Cooperative Agreement

Cooperative agreements awarded by the Department of Health and Human Services (HHS) are administered under the same policies as a grant. However, the funding agency (IHS) is anticipated to have substantial programmatic involvement in the project during the entire award segment. Below is a detailed description of the level of involvement required for the IHS.

Substantial IHS Involvement Description for Cooperative Agreement

A. Provide descriptions of PSFAs and associated funding at all organizational levels (service unit, area, and headquarters), including funding formulas and methodologies related to determining Tribal shares.

B. Meet with Planning Cooperative Agreement recipients to provide program information and discuss methods currently used to manage and deliver health care.

C. Identify and provide statutes, regulations, and policies that provide authority for administering IHS programs.

D. Provide technical assistance on the IHS budget, Tribal shares, and other topics as needed.

III. Eligibility Information

1. Eligibility

To be eligible for the New Planning Cooperative Agreement under this announcement, an applicant must:

(A) Be an ''Indian Tribe'' as defined in 25 U. S. C. 5304(e); a ''Tribal Organization'' as defined in 25 U.S.C. 5304(l); or an ''Inter-Tribal Consortium: as defined at 42 CFR 137.10. However, Alaska Native Villages or Alaska Native Village Corporations are not eligible if they are located within the area served by an Alaska Native regional health entity. See Consolidated Appropriations Act, 2014, Public Law 113–76 and Consolidated Appropriations Act, 2018, Public Law 115–141. By statute, the Native Village of Eyak, Eastern Aleutian Tribes, and the Council for Athabascan Tribal Governments have also been deemed Alaska Native regional health entities and therefore are eligible to apply. Those Alaska Tribes not represented by a Self-Governance Tribal consortium Funding Agreement within their area may still be considered to participate in the TSGP.

(B) Applicant must request participation in self-governance by resolution or other official action by the governing body of each Indian tribe to be served. Please see IV. Application and Submission Information, 2. Content and Form Application Submission,

Additional Required Documentation, Tribal Resolution(s) for details.

(C) Demonstrate for three fiscal years, financial stability and financial management capability. The Indian Tribe must provide evidence that, for the three fiscal years prior to requesting participation in the TSGP, the Indian Tribe has had no uncorrected significant and material audit exceptions in the required annual audit of the Indian Tribe's Self-Determination Contracts or Self-Governance Funding Agreements with any Federal Agency. See 25 U.S.C. 5383; 42 CFR 137.15–23.

For Tribes or Tribal organizations (T/TO) that expended $750,000 or more ($500,000 for fiscal years ending after December 31, 2003) in Federal awards, the OTSG shall retrieve the audits directly from the Federal Audit Clearinghouse.

For T/TO that expended less than $750,000 ($500,000 for fiscal years ending after December 31, 2003) in Federal awards, the T/TO must provide evidence of the program review correspondence from IHS or Bureau of Indian Affairs officials. *See* 42 CFR 137.21–23.

Meeting the eligibility criteria for a Planning Cooperative Agreement does not mean that a Tribe/Tribal Organization is eligible for participation in the IHS TSGP under Title V of the ISDEAA. *See* 25 U.S.C. 5383; 42 CFR 137.15–23. For additional information on the eligibility for the IHS TSGP, please visit the ''Eligibility and Funding'' page on the OTSG website located at: *http://www.ihs.gov/SelfGovernance.*

Note: Please refer to Section IV.2 (Application and Submission Information/Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required, such as Tribal resolutions, proof of non-profit status, etc.

2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

Applications with budget requests that exceed the highest dollar amount outlined under the Award Information, Estimated Funds Available section, or exceed the Period of Performance outlined under the Award Information, Period of Performance section will be considered not responsive and will not be reviewed. The Division of Grants Management (DGM) will notify the applicant.

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement is hosted on *https://www.Grants.gov*.

Please direct questions regarding the application process to Mr. Paul Gettys at (301) 443–2114 or (301) 443–5204.

2. Content and Form Application Submission

The applicant must include the project narrative as an attachment to the application package. Mandatory documents for all applicants include:

- Abstract (one page) summarizing the project.
- Application forms:
  - SF–424, Application for Federal Assistance.
  - SF–424A, Budget Information—Non-Construction Programs.
  - SF–424B, Assurances—Non-Construction Programs.
- Project Narrative (not to exceed 10 pages). See IV.2.A Project Narrative for instructions.
  - Background information on the organization.
  - Proposed scope of work, objectives, and activities that provide a description of what the applicant plans to accomplish.
- Budget Justification and Narrative (not to exceed 5 pages). See IV.2.B Budget Narrative for instructions.
- One-page Timeframe Chart.
- Tribal Resolution(s) (please see additional information below).
- Letters of Support from organization's Board of Directors.
- Biographical sketches for all Key Personnel.
- Contractor/Consultant resumes or qualifications and scope of work.
- Disclosure of Lobbying Activities (SF–LLL).
- Certification Regarding Lobbying (GG–Lobbying Form).
- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required in order to receive IDC).
- Organizational Chart (optional).
- Documentation of current Office of Management and Budget (OMB) Financial Audit (if applicable).

Acceptable forms of documentation include:

- Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or Face sheets from audit reports. Applicants can find these on the FAC website: *https://harvester.census.gov/facdissem/Main.aspx*.

Additional Required Documentation

Tribal Resolution(s)

Submit Tribal resolution(s) from the appropriate governing body of the Indian Tribe to be served by the ISDEAA Compact authorizing the submission of a Planning Cooperative Agreement application. Tribal consortia applying for a TSGP Planning Cooperative Agreement shall submit Tribal Council resolutions from each Tribe in the consortium. Tribal resolutions can be attached to the electronic online application.

The DGM must receive an official, signed Tribal resolution prior to issuing a Notice of Award (NoA) to any applicant selected for funding. An Indian Tribe or Tribal organization that is proposing a project affecting another Indian Tribe must include resolutions from all affected Tribes to be served. However, if an official, signed Tribal resolution cannot be submitted with the application prior to the application deadline date, a draft Tribal resolution must be submitted with the application by the deadline date in order for the application to be considered complete and eligible for review. The draft Tribal resolution is not in lieu of the required signed resolution, but is acceptable until a signed resolution is received. If an official signed Tribal resolution is not received by DGM when funding decisions are made, then a NoA will not be issued to that applicant and it will not receive IHS funds until it has submitted a signed resolution to the Grants Management Specialist listed in this Funding Announcement.

Public Policy Requirements

All Federal public policies apply to IHS grants and cooperative agreements with the exception of the Discrimination Policy.

Requirements for Project and Budget Narratives

A. Project Narrative: This narrative should be a separate document that is no more than 10 pages and must: (1) Have consecutively numbered pages; (2) use black font 12 points or larger; (3) be single-spaced; (4) and be formatted to fit standard letter paper (8-1/2 x 11 inches).

Be sure to succinctly answer all questions listed under the evaluation criteria (refer to Section V.1, Evaluation Criteria) and place all responses and required information in the correct section noted below or they will not be considered or scored. If the narrative exceeds the page limit, the application will be considered not responsive and not be reviewed. The 10-page limit for the narrative does not include the work

plan, standard forms, Tribal resolutions, budget, budget justifications, narratives, and/or other appendix items.

There are three parts to the narrative: Part 1—Program Information; Part 2—Program Planning and Evaluation; and Part 3—Program Report. See below for additional details about what must be included in the narrative.

The page limits below are for each narrative and budget submitted.

Part 1: Program Information (Limit—4 Pages)

Section 1: Needs

Describe the Tribe's current health program activities, including: How long it has been operating, what programs or services are currently being provided, and if the applicant is currently administering any ISDEAA Title I Self-Determination Contracts or Title V Self-Governance Compacts. Identify the need for assistance and how the Planning Cooperative Agreement would benefit the health activities the Tribe is currently administering or looking to expand.

Part 2: Program Planning and Evaluation (Limit—4 Pages)

Section 1: Program Plans

Project Objective(s), Work Plan and Approach

State in measureable terms the objectives and appropriate activities to achieve the following Planning Cooperative Agreement recipient award activities:

(A) Research and analyze the complex IHS budget to gain a thorough understanding of funding distribution at all organizational levels and determine which PSFAs the Tribe may elect to assume or expand.

(B) Establish a process to identify PSFAs and associated funding that may be incorporated into current programs.

(C) Determine the Tribe's share of each PSFA and evaluate the current level of health care services being provided to make an informed decision on new or expanded program assumption.

(D) Describe how the objectives are consistent with the purpose of the program, the needs of the people to be served, and how they will be achieved within the proposed time frame. Identify the expected results, benefits, and outcomes or products to be derived from each objective of the project.

Organizational Capabilities, Key Personnel, and Qualifications

Describe the organizational structure of the Tribe and its ability to manage the proposed project. Include resumes or position descriptions of key staff showing requisite experience and expertise. If applicable, include resumes and scope of work for consultants that demonstrate experience and expertise relevant to the project.

Section 2: Program Evaluation

Define the criteria to be used to evaluate planning activities. Describe fully and clearly the methodology that will be used to determine if the needs identified are being met and if the outcomes are being achieved. This section must address the following questions:

(A) Are the goals and objectives measurable and consistent with the purpose of the program and the needs of the people to be served?

(B) Are they achievable within the proposed time frame?

Part 3: Program Report (Limit—2 Pages)

Section 1: Describe major accomplishments over the last 24 months associated with the goals of this announcement. Please identify and describe significant health related program activities and achievements associated with the delivery of quality health services. Provide a comparison of the actual accomplishments to the goals established for the period of performance, or if applicable, provide justification for the lack of progress. This section should highlight major program achievements over the last 24 months.

Section 2: Describe major activities over the last 24 months. Please provide an overview of significant program activities associated with the delivery of quality health services over the last 24 months. This section should address significant program activities and include those related to the accomplishments listed in the previous section.

B. Budget Narrative (Limit—5 Pages)

Provide a budget narrative that explains the amounts requested for each line of the budget. The budget narrative should specifically describe how each item will support the achievement of proposed objectives. Be very careful about showing how each item in the ''other'' category is justified. Do NOT use the budget narrative to expand the project narrative.

3. Submission Dates and Times

Applications must be submitted through *Grants.gov* by 11:59 p.m. Eastern Daylight Time (EDT) on the Application Deadline Date. Any application received after the application deadline will not be accepted for review. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the application process, contact *Grants.gov* Customer Support (see contact information at *https://www.grants.gov*). If problems persist, contact Mr. Paul Gettys (*Paul.Gettys@ihs.gov*), DGM Grant Systems Coordinator, by telephone at (301) 443–2114 or (301) 443–5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a *Grants.gov* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

The IHS will not acknowledge receipt of applications.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are not allowable.
- The available funds are inclusive of direct and appropriate indirect costs.
- Tribes can apply and be awarded both a Planning Cooperative Agreement and a Negotiation Cooperative Agreement in the same cycle, so long as the project proposals are different for each application. Tribes cannot apply for both the Planning Cooperative Agreement and the Negotiation Cooperative Agreement within the same grant cycle with the same proposed project.
- Only one Planning grant/cooperative agreement will be awarded per applicant per grant cycle under this announcement.

6. Electronic Submission Requirements

All applications must be submitted via *Grants.gov*. Please use the *https://www.Grants.gov* website to submit an application. Find the application by selecting the ''Search Grants'' link on the homepage. Follow the instructions for submitting an application under the Package tab. No other method of application submission is acceptable.

If the applicant cannot submit an application through *Grants.gov*, a waiver must be requested. Prior approval must be requested and obtained from Mr. Robert Tarwater, Director, DGM. A written waiver request must be sent to *GrantsPolicy@ihs.gov* with a copy to *Robert.Tarwater@ihs.gov*. The waiver must: (1) Be documented in writing (emails are acceptable), before submitting an application by some other

method, and (2) include clear justification for the need to deviate from the required application submission process.

Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions. A copy of the written approval must be included with the application that is submitted to DGM. Applications that are submitted without a copy of the signed waiver from the Director of the DGM will not be reviewed. The Grants Management Officer of the DGM will notify the applicant via email of this decision. Applications submitted under waiver must be received by the DGM no later than 5:00 p.m., EDT, on the Application Deadline Date. Late applications will not be accepted for processing. Applicants that do not register for both the System for Award Management (SAM) and *Grants.gov* and/or fail to request timely assistance with technical issues will not be considered for a waiver to submit an application via alternative method.

Please be aware of the following:

- Please search for the application package in *https://www.Grants.gov* by entering the CFDA number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application, please contact *Grants.gov* Customer Support (see contact information at *https://www.grants.gov*).
- Upon contacting *Grants.gov,* obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for SAM and *Grants.gov* could take up to twenty working days.
- Please follow the instructions on *Grants.gov* to include additional documentation that may be requested by the NOFO.
- Applicants must comply with any page limits described in this funding announcement.
- After submitting the application, the applicant will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The IHS will not notify the applicant that the application has been received.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

Applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B, which uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, please access the request service through *https://fedgov.dnb.com/webform,* or call (866) 705–5711.

The Federal Funding Accountability and Transparency Act of 2006, as amended (''Transparency Act''), requires all HHS recipients to report information on sub-awards. Accordingly, all IHS grantees must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that are not registered with SAM will need to obtain a DUNS number first and then access the SAM online registration through the SAM home page at *https://www.sam.gov* (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Please see *SAM.gov* for details on the registration process and timeline. Registration with the SAM is free of charge, but can take several weeks to process. Applicants may register online at *https://www.sam.gov.*

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, are available on the IHS Grants Management, Policy Topics web page: *https://www.ihs.gov/dgm/policytopics/.*

V. Application Review Information

Weights assigned to each section are noted in parentheses. The 10-page narrative should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully. Points will be assigned to each evaluation criteria adding up to a total of 100 possible points. Points are assigned as follows:

1. Criteria

A. Introduction and Need for Assistance (25 Points)

Describe the Tribe's current health program activities, including: How long it has been operating, what programs or services are currently being provided, and if the applicant is currently administering any ISDEAA Title I Self-Determination Contracts or Title V Self-Governance Compacts. Identify the need for assistance and how the Planning Cooperative Agreement would benefit the health activities the Tribe is currently administering and/or looking to expand.

B. Project Objective(s), Work Plan and Approach (25 Points)

State in measurable terms the objectives and appropriate activities to achieve the following Planning Cooperative Agreement recipient award activities:

(1) Research and analyze the complex IHS budget to gain a thorough understanding of funding distribution at all organizational levels and determine which PSFAs the Tribe may elect to assume or expand.

(2) Establish a process to identify PSFAs and associated funding that may be incorporated into current programs.

(3) Determine the Tribe's share of each PSFA and evaluate the current level of health care services being provided to make an informed decision on new or expanded program assumption.

(4) Describe how the objectives are consistent with the purpose of the program, the needs of the people to be served, and how they will be achieved within the proposed time frame. Identify the expected results, benefits, and outcomes or products to be derived from each objective of the project.

C. Program Evaluation (25 Points)

Define the criteria to be used to evaluate planning activities. Clearly describe the methodologies and parameters that will be used to determine if the needs identified are being met and if the outcomes identified are being achieved. Are the goals and objectives measurable and consistent with the purpose of the program and meet the needs of the people to be served? Are they achievable within the proposed time frame? Describe how the assumption of PSFAs enhances sustainable health delivery. Ensure the measurement includes activities that will lead to sustainability.

D. Organizational Capabilities, Key Personnel and Qualifications (15 Points)

Describe the organizational structure of the Tribe and its ability to manage the proposed project. Include resumes or position descriptions of key staff showing requisite experience and expertise. If applicable, include resumes and scope of work for consultants that demonstrate experience and expertise relevant to the project.

E. Categorical Budget and Budget Justification (10 Points)

Submit a budget with a narrative describing the budget request and matching the scope of work described in the project narrative. Justify all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the project narrative.

Additional Documents Can Be Uploaded as Appendix Items in Grants.gov

- Work plan, logic model and/or time line for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff that reflect current duties.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (*i.e.,* data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the Objective Review Committee (ORC) based on evaluation criteria. Incomplete applications and applications that are not responsive to the administrative thresholds will not be referred to the ORC and will not be funded. The applicant will be notified of this determination.

Applicants must address all program requirements and provide all required documentation.

3. Notifications of Disposition

All applicants will receive an Executive Summary Statement from the IHS OTSG within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application. The summary statement will be sent to the Authorizing Official identified on the face page (SF–424) of the application.

A. Award Notices for Funded Applications

The Notice of Award (NoA) is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period. Each entity approved for funding must have a user account in GrantSolutions in order to retrieve the NoA. Please see the Agency Contacts list in Section VII for the systems contact information.

B. Approved but Unfunded Applications

Approved applications not funded due to lack of available funds will be held for one year. If funding becomes available during the course of the year, the application may be reconsidered.

Note: Any correspondence other than the official NoA executed by an IHS grants management official announcing to the project director that an award has been made to their organization is not an authorization to implement their program on behalf of the IHS.

VI. Award Administration Information

1. Administrative Requirements

Cooperative agreements are administered in accordance with the following regulations and policies:

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Grants:

- Uniform Administrative Requirements for HHS Awards, located at 45 CFR part 75.

C. Grants Policy:

- HHS Grants Policy Statement, Revised 01/07.

D. Cost Principles:

- Uniform Administrative Requirements for HHS Awards, ''Cost Principles,'' located at 45 CFR part 75, subpart E.

E. Audit Requirements:

- Uniform Administrative Requirements for HHS Awards, ''Audit Requirements,'' located at 45 CFR part 75, subpart F.

2. Indirect Costs

This section applies to all recipients that request reimbursement of indirect costs (IDC) in their application budget. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to obtain a current IDC rate agreement prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award's budget period. If the current rate is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate agreement is provided to the DGM.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) *https://rates.psc.gov/* and the Department of Interior (Interior Business Center) *https://www.doi.gov/ibc/services/finance/indirect-Cost-Services/indian-tribes.* For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under ''Agency Contacts'' or the main DGM office at (301) 443–5204.

3. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports are required to be submitted electronically by attaching them as a ''Grant Note'' in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required semi-annually at the 6 month from start date and then the final report within 30 days after the budget period ends. These reports must include a brief comparison of actual accomplishments to the goals established for the period, a summary of progress to date or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report

must be submitted within 90 days of expiration of the period of performance.

B. Financial Reports

Federal Financial Report (FFR or SF–425), Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services, HHS at *https://pms.psc.gov.* The applicant is also requested to upload a copy of the FFR (SF–425) report into our grants management system, GrantSolutions. Failure to submit timely reports may result in adverse award actions blocking access to funds.

Grantees are responsible and accountable for accurate information being reported on all required reports: The Progress Reports and Federal Financial Report.

C. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards.

The IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a $25,000 sub-award obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the period of performance is made up of more than one budget period) and where: (1) The period of performance start date was October 1, 2010 or after, and (2) the primary awardee will have a $25,000 sub-award obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting.

For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Policy website at *https://www.ihs.gov/dgm/policytopics/.*

D. Compliance With Executive Order 13166 Implementation of Services Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. The HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see *https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-VI/.*

The HHS Office for Civil Rights (OCR) also provides guidance on complying with civil rights laws enforced by HHS. Please see *https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html;* and *https://www.hhs.gov/civil-rights/index.html.* Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see *https://www.hhs.gov/civil-rights/for-individuals/disability/index.html.* Please contact the HHS OCR for more information about obligations and prohibitions under federal civil rights laws at *https://www.hhs.gov/ocr/about-us/contact-us/index.html* or call (800) 368–1019 or TDD (800) 537–7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.*

Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of his/her exclusion from benefits limited by federal law to individuals eligible for benefits and services from the IHS.

Recipients will be required to sign the HHS–690 Assurance of Compliance form which can be obtained from the following website: *https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf,* and send it directly to the: U.S. Department of Health and Human Services, Office of Civil Rights, 200 Independence Ave. SW, Washington, DC 20201.

E. Federal Awardee Performance and Integrity Information System (FAPIIS)

The IHS is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information System (FAPIIS), at *https://www.fapiis.gov,* before making any award in excess of the simplified acquisition threshold (currently $150,000) over the period of performance. An applicant may review and comment on any information about itself that a federal awarding agency previously entered. The IHS will consider any comments by the applicant, in addition to other information in FAPIIS in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed by applicants as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, non-federal entities (NFEs) are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than $10,000,000 for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, effective January 1, 2016, the IHS must require a non-federal entity or an applicant for a federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award.

Submission is required for all applicants and recipients, in writing, to the IHS and to the HHS Office of Inspector General all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. 45 CFR 75.113.

Disclosures must be sent in writing to:

U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management,

ATTN: Robert Tarwater, Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857. (Include ''Mandatory Grant Disclosures'' in subject line). Office: (301) 443–5204, Fax: (301) 594–0899, Email: *Robert.Tarwater@ihs.gov*.

AND

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW, Cohen Building, Room 5527, Washington, DC 20201, URL: *https://oig.hhs.gov/fraud/report-fraud/*. (Include ''Mandatory Grant Disclosures'' in subject line). Fax: (202) 205–0604 (Include ''Mandatory Grant Disclosures'' in subject line) or Email: *MandatoryGranteeDisclosures@oig.hhs.gov*.

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance, including suspension or debarment (See 2 CFR parts 180 & 376 and 31 U.S.C. 3321).

VII. Agency Contacts

1. *Questions on the programmatic issues may be directed to:* Roxanne Houston, Program Officer, Office of Tribal Self-Governance, 5600 Fishers Lane, Mail Stop: 08E05, Rockville, MD 20857, Phone: (301) 443–7821, Email: *Roxanne.Houston@ihs.gov*, Website: *https://www.ihs.gov/self-governance*.

2. *Questions on grants management and fiscal matters may be directed to:* Vanietta Armstrong, Grants Management Specialist, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443–4792, Fax: (301) 594–0899, Email: *Vanietta.Armstrong@ihs.gov*.

3. *Questions on systems matters may be directed to:* Paul Gettys, Grant Systems Coordinator, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443–2114; or the DGM main line (301) 443–5204, Fax: (301) 594–0899, E-Mail: *Paul.Gettys@ihs.gov*.

VIII. Other Information

The Public Health Service strongly encourages all grant, cooperative agreement and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

RADM Chris B. Buchanan,

Assistant Surgeon General, U.S. Public Health Service, Deputy Director, Indian Health Service.

[FR Doc. 2019–17137 Filed 8–8–19; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 Neurological Disorders and Stroke Special Emphasis Panel; Comparative Effectiveness Research.

Date: August 12, 2019.

Time: 6:00 p.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center Building (NSC), 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Shanta Rajaram, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, NSC, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892, (301) 435–6033, *rajarams@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: August 5, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–17034 Filed 8–8–19; 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 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 Child Health and Human Development Initial Review Group; Reproduction, Andrology, and Gynecology Subcommittee.

Date: October 25, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Helen Huang, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, Bethesda, MD 20817, 301–435–8380, *helen.huang@nih.gov.*

(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: August 5, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–17033 Filed 8–8–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2018–0006; OMB No. 1660–0103]

Agency Information Collection Activities: Proposed Collection; Comment Request; Property Acquisition and Relocation for Open Space

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a reinstatement, with change, of a previously approved information collection for which approval has expired. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the property acquisition and relocation for open space process as part of the administration of FEMA's mitigation grant programs, and the withdrawal of three previously proposed forms (FEMA Form 086–0–31a, FEMA Form 086–0–31b, and FEMA Form 086–0–31c) from the Information Collection included in the initial 60-day public comment period regarding the Severe Risk Property Acquisition (SRPA) direct grant to property owners for acquisition and demolition of severe repetitive loss structures. After reviewing all the comments submitted, FEMA has determined there is no need for SRPA direct grant-related forms at this time. At this time, FEMA has decided not to implement the SRPA direct to property owners grant.

DATES: Comments must be submitted on or before October 8, 2019.

ADDRESSES: To avoid duplicate submissions to the docket, please use only one of the following means to submit comments:

(1) *Online.* Submit comments at *www.regulations.gov* under Docket ID FEMA–2018–0006. Follow the instructions for submitting comments.

(2) *Mail.* Submit written comments to Docket Manager, Office of Chief Counsel, DHS/FEMA, 500 C Street SW, 8NE, Washington, DC 20472–3100.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available via the link in the footer of *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jennie Orenstein, Grants Policy Branch Chief, FIMA, FEMA, (202) 212–4071. You may contact the Records Management Division for copies of the proposed collection of information at email address: *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: Regulations at 44 CFR part 80 govern property acquisitions for the creation of open space under FEMA's three hazard mitigation assistance (HMA) grant programs: The Pre-Disaster Mitigation program (PDM) and Hazard Mitigation Grant Program (HMGP), authorized under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended, 42 U.S.C. 5121–5207; and the Flood Mitigation Assistance Program (FMA) authorized under the National Flood Insurance Act (NFIA) of 1968, as amended, 42 U.S.C. 4001 *et seq.* Acquisition and relocation of property for open space use is a popular mitigation activity eligible under PDM, HMGP, and FMA. These programs require any property acquired with FEMA funds to be deed restricted and maintained as open space in perpetuity to ensure against future risk from hazards to life and property, and to reduce the need for disaster assistance or insurance payments for damages to property. This proposed information collection previously published in the **Federal Register** on February 27, 2018 at 83 FR 8493 with a 60-day public comment period. The comment period closed on April 30, 2018. FEMA received ninety-two comments in response to Information Collection 1660–0103, including comments that express both support and opposition to different parts of the Collection. Many comments were similar, but they will be recorded as 102 distinct comments since they addressed multiple parts of the Collection. Of the 102 comments received, 67 comments were opposed to language in the three new forms pertaining to the Severe Risk Property Acquisition (SRPA) direct grants to property owners that included an option identified as ''Pathway 2: Demolition of Structure(s) Only, Property Owner(s) Retains Ownership.'' The Pathway allowed property owners to build new structures on the land after the existing structures were acquired and demolished by FEMA. A commitment to use the property as open space in perpetuity was not required. The new structures were required to meet current community flood management building codes, which presumably would be to a higher standard than the damaged structure was built to. Mitigation would thus be accomplished by reducing the long-term risk to a natural hazard. In comparison, the other Pathway SRPA offered was that the subrecipient (local community) could acquire the property and commit the property to open space use in perpetuity. With either Pathway, the choice was up to the property owner, assuming the community was interested in acquisition if the property owner chose that option. A SRPA grant would only be offered under FEMA's Flood Mitigation Assistance (FMA) program.

Eleven (11) comments were supportive of SRPA and the three new related forms. 3 comments were neutral and recommended changes to provide support to SRPA. 3 comments opposed using the public comment period for discussing the feasibility of SRPA. 6 comments were beyond the scope of the Information Collection and 12 comments were not germane.

The 67 comments submitted in opposition to SRPA's Pathway 2: Demolition of Structure(s) Only, Property Owner(s) Retains Ownership option came from a variety of sources, including State and local government, non-profit organizations, individuals, and anonymous sources. Commenters listed primary reasons for opposition such as:

- Inconsistency under the National Flood Insurance Act (NFIA) of 1968 42 U.S.C. 4104c since the forms only offered property owners one mitigation option, acquisition, and no other mitigation activities such as relocation, structure elevation, or mitigation reconstruction
- Inconsistency under 44 CFR part 80 Property Acquisition and Relocation for Open Space, which restricts post-acquisition land use to outdoor recreational activities, wetlands management, nature reserves, farming (*i.e.,* cultivation, grazing), camping and other uses FEMA determines are compatible with open space and limits the type of new structures that can be built on the property
- Inconsistency with current Hazard Mitigation Assistance (HMA) Guidance for acquisition of properties, and inconsistency with the way FEMA has implemented acquisition projects for the past 30 years, which require the

acquired property to be dedicated and maintained in perpetuity as open space for the conservation of natural floodplain functions

Several comments cited additional reasons for opposition to the SRPA forms for Pathway 2: Demolition of Structure(s) Only, Property Owner(s) Retains Ownership, including:

- New structures would endanger first responders in the flood prone area
- Direct grants discourage conversion of developed land to open space
- Direct grants fail to reduce the risk posed to property and human lives
- Lack of robust codes in many communities would not guarantee a rebuild to a higher standard
- Lack of information justifying how Pathway 2 would be cost-effective (an eligibility requirement for all HMA projects), and demonstrate savings over alternative mitigation options
- Propose limitation to ensure direct grants would not be abused to spur coastal development

Commenters also noted that the new forms were not clear on who would be responsible for monitoring these properties post-acquisition to ensure that new structures and improvements conform to grant requirements. Without clear identification of responsibilities, there was concern that new structures would not be constructed to meet community flood building standards.

The 11 comments in support of SRPA also came from a variety of sources, including local government, a non-profit organization and individuals. Commenters in support of SRPA provided the following reasons:

- Expedited access to funding that will help survivors recover more quickly
- Reduced risk of experiencing another flood at the same property in the short-term
- Increase in or maintenance of a community's tax base
- SRPA would result in reconstruction to a higher building code
- Provides a good alternative when a state does not prioritize substantially damaged homes, or does not expedite an acquisition project

Of the comments that expressed support, several of them had reservations. For example, one commenter expressed strong support for the property owner to retain land after a demolition but expressed concern regarding what would happen if the local government did not want the property owner to do this. Additionally, the commenter was unsure how the property would be maintained in perpetuity and reported every three years. The comment reflects a misconception about a SRPA direct grant as the property owner who retains ownership would not be required to commit the property to open space in perpetuity. Another commenter supported SRPA but opined that a property owner should only be eligible when neither the local jurisdiction nor state have a flood mitigation plan in place. One association supported SRPA but only if elevation is included in the eligible project list.

Three (3) comments neutral to SRPA came from individuals. The commenters offered recommendations that if followed would make SRPA acceptable to them. One commenter wanted the added option of elevation, in addition to the demolition and property owner retention option. According to the commenter, elevations would address the removal of tax bases and provide more flexibility in areas impacted by flooding.

One individual recommended that to make NFIP more fiscally secure, individuals should be denied NFIP insurance if they reject the options for a buyout, elevation, and mitigation reconstruction project after flooding multiple times in a set number of years and once flood insurance payments total the value of the house. While FEMA recognizes that denying flood insurance to property owners who reject the option to mitigate may incentivize mitigation, FEMA does not have statutory authority to implement such a measure.

Another commenter indicated a spelling error in the header of a form, recommended language change in the Statement of Voluntary Participation form to align more with what is written in the FEMA FORM 086–0–31C and inquired about why the acquisition and demolition process must be done by FEMA and not by the local community. The form with the spelling error is no longer an instrument of this Information Collection.

Three (3) comments opposed using the public comment period for discussing the feasibility of SRPA. One commenter expressed concern about making a fundamental change to buyout programs through ''the obscure context and mechanism of reinstating and changing a series of federal forms.'' The comment reflects a misconception that adding the forms to the Information Collection alone would be enough to implement this new type of grant. Adding the forms was a means of FEMA preparing to implement the SRPA grant if FEMA received an appropriation for it. However, FEMA did not receive an appropriation to implement a SRPA grant and has no plans to implement a SRPA grant currently.

Another commenter felt the Information Collection lacked ''explanatory material for the assumptions and procedures in which the proposed forms are expected to be used . . .'' Specifically, the commenter wanted access to the proposed forms. FEMA is not able to publicly post the forms because they have not yet been approved by OMB. However, if the commenter reaches out to HMA's Point of Contact for this Information Collection (Jennie Orenstein), they will be provided access to the forms.

Lastly, one commentator wanted to ''extend and expand the public comment period to allow more knowledgeable evaluation.'' A standard Paperwork Reduction Act Information Collection requires both a 60-day public comment period, followed by a 30-day public comment period. The program office is responsible for responding to all comments during these two comment periods. The commenter's remark was part of the 60-day comment period and, thus, there will be another 30-day comment period following adjudication of responses and potential changes to forms.

Six (6) comments were beyond the scope of the Information Collection and involved the following topics:

- Inquire into specific mechanisms used to compel local governments to participate in SRPA grants
- Inquire about funding streams, which do not currently exist for SRPA grants
- Inquire about how to determine if a State and/or community would not have the capacity to manage direct grants
- Inquire about addressing urban flooding by redefining flood zones and providing a socially equitable solution to low to middle income communities when experiencing flooding
- Express a belief that current floodplains are based on best guesses and anecdotal evidence, which leads to inaccuracies

Following Hurricane Harvey, to address the dire circumstances of property owners with substantially damaged homes, FEMA explored implementing a statutory provision in the National Flood Insurance Act, 42 U.S.C. 4104c(a)(3), which authorizes FEMA to provide direct grants to property owners with severe repetitive loss (SRL) properties under FMA. After considering the 102 comments submitted mostly in opposition to SRPA but also supporting it, in some cases with reservations, FEMA has decided

not to implement SRPA and to withdraw the three forms related to the SRPA grant, consisting of FEMA Form 086–0–31a, FEMA Form 086–0–31b, and FEMA Form 086–0–31c from the Information Collection.

FEMA appreciated the input provided, and felt the commenters raised many worthy issues for discussion concerning a direct grant to property owners. Consequently, FEMA intends to pursue an ongoing dialogue with stakeholders, non-governmental organizations, and other entities or individuals, as appropriate, to address the merits and problems with implementing this type of grant.

In response to comments, FEMA has withdrawn three previously proposed forms (FEMA Form 086–0–31a, FEMA Form 086–0–31b, and FEMA Form 086–0–31c) from the Information Collection included in the initial 60-day public comment period regarding the Severe Risk Property Acquisition (SRPA) direct grant to property owners for acquisition and demolition of severe repetitive loss structures. After reviewing all the comments submitted, FEMA has determined there is no need for SRPA direct grant-related forms at this time. At this time, FEMA has decided not to implement the SRPA direct to property owners grant.

With the withdrawal of the three SRPA-related forms, the Information Collection contains only three new forms necessary to obtain information for HMA's usual grants: Real Property Status Report, SF–429, Declaration and Release (Declaracion Y Autorizacion) (FEMA Form 009–0–3 or 009–0–4 (Spanish)), and FEMA Form 086–035a (Pages 9–10) NFIP Repetitive Loss Update Worksheet. The fourth form, the Property Owners' Voluntary Participation Statement (FEMA Form 86–0–31) is necessary for FEMA to ensure compliance with regulatory requirements that the property owner's participation in an acquisition is voluntary. See 44 CFR 80.13. This form was published in previous information collections.

The Real Property Status Report, SF–429 is a standard, OMB-approved form under OMB Collection 4040–0016, with a current expiration date of 02/28/2022. It is used to certify that the subrecipient has inspected properties to ensure consistency with the terms of the deed restrictions committing the properties to open space in perpetuity. The SF–429 is an addition to this collection as part of the 2 CFR 200.311 requirements for property management and disposition. While FEMA has always collected property management reports every three years for acquired properties, the SF–429 form was not included in previous collections. Historically, some recipients and subrecipients used the SF–429 forms, and others used their own formats. FEMA is now proposing to use the SF–429 to have a uniform and consistent format.

FEMA collects Declaration and Release, FEMA Form 009–0–3 or Declaracion Y Autorizacion FEMA Form 009–0–4 (Spanish) (OMB No. 1660–0002), to certify an individual's information and eligibility. FEMA will be adding this form to this information collection to obtain necessary information for its eligibility determinations. This form is already approved under OMB Collection 1660–0002, Disaster Assistance Registration which expires on July 31, 2019 and is currently pending OMB's approval.

FEMA Form 086–0–35a (Pages 9–10) NFIP Repetitive Loss Update Worksheet, is a form used by the State, Tribe or local community when acquiring a property to update the status of properties classified as NFIP repetitive loss to indicate if they have been previously acquired, retrofitted or mitigated through a different eligible project type. These pages are included in an already approved OMB Collection No.1660–0022, Community Rating System (CRS) Program—Application Letter and CRS Quick Check, Community Annual Recertification and Environmental and Historic Preservation Certifications, which expires on March 31, 2020. This form is necessary to keep records for flood insurance purposes, which allows the NFIP to modify their flood insurance policies.

This information collection, OMB No. 1660–0103, expired on January 31, 2018. FEMA is requesting a reinstatement, with change, of a previously approved information collection for which approval has expired. The purpose of this 60-day notice is to notify the public of the changes FEMA has made to the originally proposed Information Collection in the previous 60-day notice and allow for a new 60-day period for comments on the updated Information Collection.

Collection of Information

Title: Property Acquisition and Relocation for Open Space.

Type of Information Collection: Reinstatement, with change, of a previously approved information collection for which approval has expired.

OMB Number: 1660–0103.

Form Titles and Numbers: FEMA Form 086–0–31, Statement of Voluntary Participation for Acquisition of Property for Purpose of Open Space, (OMB No.1660–0103); 009–0–3 (English) and 009–0–4 (Spanish), Declaration and Release, (OMB No. 1660–0002); 086–0–35a (Pages 9–10), NFIP Repetitive Loss Update Worksheet (OMB No. 1660–0022); SF–429, Real Property Status Report (OMB No. 4040–0016).

Abstract: FEMA and State, Tribal and local recipients of FEMA mitigation grant programs will use the information collected to meet the Property Acquisition requirements to implement acquisition activities under the terms of grant agreements for acquisition and relocation activities. FEMA and State/local grant recipients will also use the information to monitor and enforce the open space requirements for all properties acquired with FEMA mitigation grants.

Affected Public: State, local or Tribal Government; Individuals or Households.

Estimated Number of Respondents: 2,773.

Estimated Total Annual Burden Hours: 11,528.

Estimated Cost: The estimated annual cost to respondents for the hour burden is $520,710.

Estimated Respondents' Operation and Maintenance Costs: There are no annual costs to respondents' operations and maintenance costs for technical services.

Estimated Respondents' Capital and Start-Up Costs: There is no annual start-up or capital costs.

Estimated Total Annual Cost to the Federal Government: The cost to the Federal Government is $687,687.

Comments: Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) 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; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) 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.

Maile Arthur,

Acting Records Management Branch Chief, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2019–17102 Filed 8–8–19; 8:45 am]

BILLING CODE 9111–47–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0095]

Agency Information Collection Activities; Revision of a Currently Approved Collection: Notice of Appeal or Motion

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration (USCIS) invites the general public and other Federal agencies to comment upon this proposed revision of a currently approved collection of information or new collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until October 8, 2019.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0095 in the body of the letter, the agency name and Docket ID USCIS–2008–0027. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Online.* Submit comments via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2008–0027;

(2) *Mail.* Submit written comments to DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW, Washington, DC 20529–2140.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, 20 Massachusetts Avenue NW, Washington, DC 20529–2140, telephone number 202–272–8377 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *http://www.uscis.gov,* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2008–0027 in the search box. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Notice of Appeal or Motion.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–290B; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. Form I–290B standardizes requests for appeals and motions and ensures that the basic information required to adjudicate appeals and motions is provided by applicants and petitioners, or their attorneys or representatives. USCIS uses the data collected on Form I–290B to determine whether an applicant or petitioner is eligible to file an appeal or motion, whether the requirements of an appeal or motion have been met, and whether the applicant or petitioner is eligible for the requested immigration benefit. Form I–290B can also be filed with ICE by schools appealing decisions on Form I–17 filings for certification to ICE's Student and Exchange Visitor Program (SEVP).

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–290B is 28,000 and the estimated hour burden per response is 1.5 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 42,000 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $8,652,000.

Dated: August 5, 2019.

Jerry L. Rigdon,

Deputy Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2019–17031 Filed 8–8–19; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7011–N–31]

30-Day Notice of Proposed Information Collection: Pay for Success Pilot Applicant Requirements

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD has submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date:* September 9, 2019.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD has submitted to OMB a request for approval of the information collection described in Section A. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on May 8, 2018 at 84 FR 20157.

A. Overview of Information Collection

Title of Information Collection: Pay for Success Pilot Application Requirements.

OMB Approval Number: 2502–0613.

Type of Request: This is a revision of a currently approve collection.

Form Number: HUD–2530, SF 424 family of forms, HUD–2880, HUD–424–CBW, HUD- 9250, Certification of Owner Eligibility, Cooperative Agreement, Site-Specific Environmental Review (Part 1 of 2), and Office of Multifamily Housing Pay for Success Program Narrative Template.

- Form HUD–2530, Previous Participation Certification, is completed by the Intermediary. The Intermediary submits the form to HUD via grants.gov as part of the application package for the PFS pilot. The type of information collected includes the Intermediary's (principals) Name, Address, Social Number/IRS Employee Number, Signature, etc. The form is required to provide HUD with a certified report of all previous participation in HUD multifamily housing projects by those parties making application and is used by HUD to determine eligibility to participate in Multifamily programs.
- ***SF–424 family of forms (SF–424A–D, as applicable), Application for Federal Assistance and Assurances, is completed by the Intermediary. The Intermediary submits this family of forms to HUD via grants.gov as part of the application for the PFS pilot. The type of information collected includes the Intermediary's Name, EIN/TIN, Address, Email address, etc. This family of forms is required for use as a cover sheet for submission of preapplications and applications and related information under discretionary programs. Applicants are required to submit this family of forms to HUD as part of the application package for the PFS pilot.
- Form HUD–2880, Applicant/Recipient Disclosure/Update Report, is completed by the Intermediary. The Intermediary submits the from to HUD via the grants.gov as part of the application package for the PFS pilot. The type of information collected includes the Intermediary's Name, address, phone number, social security number and EIN, etc. The Intermediary is required to submit this form in order to provide accountability and integrity in the provision of assistance that is administered by HUD.
- Form HUD 424–CBW (excel spreadsheet), Detailed Budget Worksheet, is completed by the Intermediary. The Intermediary submits this form to HUD via email or US mail for approval. The type of information collected includes a detailed description of budget as it pertains to each participating property. The Intermediary submits this form to HUD in program phases for completion of the retrofits in all participating properties in the PFS program.
- Form HUD–9250, Funds Authorization, is completed by the Owner. The Owner submits this form by email or by US mail to HUD for approval. The type of information collected includes Owner's name, address, mortgagee, etc. Owners are required to submit this form to HUD to request withdrawal from the Reserve for Replacements or Residual Receipts Funds.
- Certification of Owner Eligibility, Owner must complete this form to be eligible to participate in the Pay for Success pilot. Owner submits certification to HUD for approval via email or by US mail. The type of information collected includes Owner's name, iREMS number, address, signature, etc. Owners must provide a certification to HUD that they and the property meet HUD eligibility requirements in order to be able to participate in the Pilot.
- Cooperative Agreement is administered by HUD's Office of Multifamily Housing Programs, which will have oversight of the Intermediaries, ensuring compliance with all included provisions and authorizing payments when and if required conditions are met. The type of information collected includes Date agreement was entered with Intermediary, total of units HUD awarded intermediary, signature and HUD official. The form is submitted to HUD/Intermediary via email or by US mail.
- Site-Specific Environment Review (Part 1 of 2), this form should be used only to initiate site-specific reviews for individual HUD-assisted properties undertaking energy and water conservation retrofits under the Multifamily Energy and Water Conservation Pay for Success Pilot. Intermediary completes the form and any relevant documents for each site identified to participate in the PFS Pilot and submits it to HUD to upload in the HUD Environmental Review Online System (HEROS).
- Office of Multifamily Housing Pay for Success Program Narrative Template is completed by the Intermediary and is submitted to HUD via *grants.gov*. The type of information collected includes the Intermediary's name, EIN, organization name, etc. The narrative template is provided to Applicants under the Pay for Success Pilot program and will be evaluated by HUD.

Description of the need for the information and proposed use: Title LXXXI of the Fixing America's Surface Transportation Act (Pub. L. 114–94) authorizes the Department of Housing and Urban Development (HUD) to establish a demonstration program under which the Secretary may execute budget-neutral, performance-based agreements in fiscal years 2016 through 2019 that result in a reduction in energy

or water costs. The legislation authorizes HUD to implement this pilot in up to 20,000 units of multifamily buildings participating in the project-based rental assistance (PBRA) program under section 8 of the United States Housing Act of 1937; supportive housing for the elderly program operating under section 202 of the Housing Act of 1959; and supportive housing for persons with disabilities under section 811(d)(2) of the Cranston-Gonzalez National Affordable Housing Act. The Statute authorizes HUD to execute performance-based agreements in fiscal years 2016 through 2019 covering up to 20,000 units in eligible properties. HUD is responsible for submitting annual program evaluation reports to Congress for the duration of the Pilot.

HUD is authorized under this legislation to establish a competitive process for selecting one or more qualified applicants to serve as Intermediaries who will, per agreements with HUD, be responsible for initiating and managing an energy and water conservation retrofit program at eligible properties. For the purpose of this program, applicants are defined as entities applying to participate. The documents that are the subject of this notice are those used by applicants applying to participate in this program. This information will allow applicants to submit their proposal and for the government to evaluate this information.

I. ****Application.* The applicants responding to the NOFA will need to submit the before the prescribed deadline all standard forms including Previous Participation Certification (Form 2530), SF–424 family of forms, and Form HUD–2880; responses to the NOFA's rating factors describing the applicant's qualifications and proposed approach to all aspects of program implementation; and an Executive Summary of no more than four pages.

II. *Project Initiation.* Once selected, Intermediaries will enter into a Cooperative Agreement with HUD for each property they will be retrofitting under the program which will provide for performance-based payments by HUD based on the savings realized by HUD after the retrofit has been completed. Intermediaries will also be required to submit a copy of an executed PFS Contracts with each property owner that will be attached to the Cooperative and serve to identify the specific units being affected by the retrofit. Within 30 days of entering into each Cooperative Agreement, an Intermediary will submit to HUD a Work Plan consisting of a description of all documentary deliverables and due dates related to that Agreement and a proposed approach to periodic consultation with HUD for the purposes of oversight. The Intermediary will also submit a request for approval for the Independent Evaluator that will be validating key information submitted to HUD by the Intermediary over the course of the Cooperative Agreement. Each participating property owner will submit to HUD a Certification of Eligibility and a written agreement to replace equipment installed under the PFS Pilot only with equipment of like or better efficiency.

III. *Retrofit implementation.* Before a retrofit is implemented, the Intermediary will to develop and submit (with support from the property owner) a Site-specific Environmental Review form with the following information: High-level description of the project's scope of work; whether the property lies within a Coastal Barrier Resource unit; whether the property lies within a floodplain and proof of any required flood insurance policies; whether the project will destroy or modify a wetland; previous uses of the site and other evidence of contamination on or near the site; and whether any historic preservation policies apply to the site or the building(s). Intermediaries intending to use property-level reserve funds to pay for no more than half of the hard costs associated with the retrofit must submit a Scope of Work for the retrofit and a Reserve Analysis demonstrating that the retrofit will leave the property in as good or better financial shape as it would otherwise have been. The property owner must submit a Funds Authorization Form (HUD–9250) to request HUD's approval to use funds for this purpose.

IV. *Retrofit completion.* When the retrofit is completed, the Intermediary will submit a Certification of Retrofit Completion with the following information: A list of installed measures with cost information; weather- and occupancy-normalized pre-retrofit consumption baselines for each affected tenant- and owner-paid utility, and all component data used to calculate those baselines, including utility consumption, rates, utility allowances, and climatic and occupancy data, and the calculation methodology used; weather- and occupancy-normalized post-retrofit consumption projections for each affected tenant- and owner-paid utility, and all component data used to calculate those baselines, including utility consumption, rates, utility allowances, and climatic and occupancy data, and the calculation methodology used; recalculated pre-retrofit baseline utility allowances and post-retrofit utility allowances for each unit size/type; recalculated pre-retrofit baseline owner rental subsidy and post-retrofit owner renter for each unit size/type; and post-retrofit per-unit annual savings to HUD relative to pre-retrofit baseline.

V. *Performance payments.* Intermediaries will submit Invoices for Performance Payments concurrent with each property's annual rent adjustment cycle for the remainder of the period of performance of the Cooperative Agreement pertaining to that property. Invoices will include thorough documentation of all calculations contributing to the calculation of the amount being invoiced (as provided in the work plan) as well as a written certification by the Independent Evaluator that the performance payment has been calculated according to the methodology contained in the Cooperative Agreement; no adverse changes to the qualifications of the Independent Evaluator have occurred since the last submission from the Independent Evaluator; and no conflict of interest or apparent conflict of interest exists with the Intermediary or with respect to any property or Owner which would preclude the Independent Evaluator from performing its obligations in a truly independent manner. In the event of a change in the physical structure of a property during the period of performance which materially impacts utility usage, the Owner and the Intermediary will mutually agree upon an equitable modification of the pre-retrofit baseline for Owner-paid utility and/or of the pre-retrofit baseline of tenant utility allowances to reflect the impact of the change on utility usage and notify HUD of the change. In the event that the Intermediary wishes to assign performance payments to a third party, the Intermediary must submit to HUD a written request for approval.

VI. *Other program administration requirements.* Beginning with the execution of their first cooperative agreement with HUD, Intermediaries will submit quarterly reports regarding the status of all properties for which work under the PFS Pilot is unfinished, including the work that has been completed, the work that remains the anticipated projected completion date. If at any point it becomes necessary to replace a partner entity performing one or more core functions program administration functions (project management, capital sources, oversight of SOW development and retrofit implementation, and/or invoicing HUD), the Intermediary must collect and submit evidence from the proposed

replacement partner entity similar to the qualifications detailed for the original partner entity in the Intermediary's initial application. As this is pilot program and HUD is responsible for submitting annual program evaluation reports to Congress, Intermediaries may be required to work with a program evaluation team and provide relevant information, possibly including (but not limited to) information pertaining to retrofit implementation, program administration, post-retrofit behavioral interventions, and certain fees. Intermediaries may be asked to clarify or provide additional context for previously submitted information, including additional details on their sources and uses of funds.

Respondents: Entities applying to be Intermediaries under this program, selected Intermediaries.

Estimated Number of Respondents: 15.

Estimated Number of Responses: 1,000.

Frequency of Response: 66.67.

Average Hours per Response: 4.40.

Total Estimated Burdens: 4,401.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) 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) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(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 collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: July 29, 2019.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2019–17095 Filed 8–8–19; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–ES–2018–N146; FF09E41000 190 FXES111609C0000; OMB Control Number 1018–New]

Agency Information Collection Activities; Policy Regarding Voluntary Prelisting Conservation Actions

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service, we), are proposing a new information collection in use without an OMB Control Number.

DATES: Interested persons are invited to submit comments on or before October 8, 2019.

ADDRESSES: Send your comments on the information collection request (ICR) by mail to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail); or by email to *Info_Coll@fws.gov.* Please reference OMB Control Number 1018–VPCA in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Madonna L. Baucum, Service Information Collection Clearance Officer, by email at *Info_Coll@fws.gov,* or by telephone at (703) 358–2503.

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.

We are 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 Service; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Service enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Service 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. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you 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: The Service is charged with implementing the Endangered Species Act of 1973, as amended (Act; 16 U.S.C. 1531 *et seq.*). The goal of the Act is to provide a means to conserve the ecosystems upon which listed species depend and a program for listed species conservation. Through our Candidate Conservation program, we encourage the public to take conservation actions for species prior to them being listed under the Act. Doing so may result in precluding the need to list a species, may result in listing a species as threatened instead of endangered, or, if a species becomes listed, may provide the basis for its recovery and eventual removal from the protections of the Act.

This policy gives landowners, government agencies, and others incentives to carry out voluntary conservation actions for unlisted species. It allows the use of any benefits to the species from voluntary conservation actions undertaken prior to listing under the Act—by the person who undertook such actions or by third parties—to mitigate or offset the detrimental effects of other actions undertaken after listing. The policy requires participating States to track the voluntary conservation actions and provide this information to us on an annual basis. We require this information in order to provide the entities that have taken the conservation actions with proper credit that can later be used to mitigate for any detrimental actions they take after the species is listed.

We plan to collect the following information:

- Description of the prelisting conservation action being taken.
- Location of the action (does not include a specific address).

• Name of the entity taking the action and their contact information (email address only).

• Frequency of the action (ongoing for X years, or one-time implementation) and an indication if the action is included in a State Wildlife Action Plan.

• Any transfer to a third party of the mitigation or compensatory measure rights.

Each State that chooses to participate will collect this information from landowners, businesses and organizations, and tribal and local governments that wish to receive credit for voluntary prelisting conservation actions. States may collect this information via an Access database, Excel spreadsheet, or other database of their choosing and submit the information to the Fish and Wildlife Service (via email) annually. We will use this information to calculate the number of credits that the entity taking the conservation action will receive. We will keep track of the credits and notify the entity of how much credit they have earned. The entity can then use these credits to mitigate or offset the detrimental effects of other actions they take after the species is listed (assuming it is listed).

Title of Collection: Policy Regarding Voluntary Prelisting Conservation Actions.

OMB Control Number: 1018—New.

Form Number: None.

Type of Review: Existing collection in use without an OMB Control Number.

Respondents/Affected Public: Individuals; businesses and organizations; and State, local, and Tribal governments.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Ongoing for recordkeeping and annually for reporting.

Total Estimated Annual Nonhour Burden Cost: None.

Requirement	Annual number of respondents	Average number of responses each	Annual number of responses	Average completion time per response (hours)	Estimated annual burden hours *
Collect and Report Information on Voluntary Prelisting Conservation Actions:					
Government	1	1	1	20	20
Report Information on Voluntary Prelisting Conservation Actions to States:					
Individuals	1	1	1	.25	.25
Private Sector	1	1	1	.25	.25
Government	1	1	1	.25	.25
Development of Conservation Strategy:					
Government	1	1	1	200	200
States Develop a Voluntary Conservation-Action Program:					
Government	1	1	1	320	320
Site Agreement:					
Individuals	1	1	1	100	100
Private Sector	1	1	1	100	100
Government	1	1	1	100	100
Management Plan:					
Individuals	1	1	1	120	120
Private Sector	1	1	1	120	120
Government	1	1	1	120	120
Credit Agreement:					
Individuals	1	1	1	80	80
Private Sector	1	1	1	80	80
Government	1	1	1	80	80
Total:	*15*	.....	*15*	.....	*1,361*

* Rounded

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: August 6, 2019.

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2019–17057 Filed 8–8–19; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[AAK6006201 190A2100DD AOR3030.999900]

Draft Environmental Impact Statement for the Proposed Eagle Shadow Mountain Solar Project, Clark County, Nevada

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of availability.

SUMMARY: This notice advises the public that the Bureau of Indian Affairs (BIA), as the lead Federal agency, with the Bureau of Land Management (BLM), the Environmental Protection Agency (EPA), U.S. Fish and Wildlife Service (USFWS), Nellis Air Force Base (Nellis AFB) and the Moapa Band of Paiute Indians (Band) as Cooperating Agencies, intends to file a draft environmental impact statement (DEIS) with the EPA for the proposed Eagle Shadow Mountain Solar Project (ESM Solar Project) on the Moapa River Indian Reservation (Reservation) in Clark County, Nevada. This notice also announces that the DEIS is now available for public review and that public meetings will be held to solicit comments on the DEIS.

DATES: The date and locations of the public meetings will be announced at least 15 days in advance through notices in the following local newspapers: Las Vegas Sun, Las Vegas Review Journal and the Moapa Valley Progress and on the following website: *www.esmsolareis.com.* In order to be fully considered, written comments on the DEIS must arrive no later than 45 days after EPA publishes its Notice of Availability in the **Federal Register**.

ADDRESSES: You may mail, email, hand carry or telefax written comments to Mr. Chip Lewis, Regional Environmental Protection Officer, BIA Western Regional Office, Branch of Environmental Quality Services, 2600 North Central Avenue, 4th Floor Mail Room, Phoenix, Arizona 85004–3008; fax (602) 379–3833; email: *chip.lewis@bia.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Chip Lewis, BIA Western Regional Office, Branch of Environmental Quality Services, 2600 North Central Avenue, Phoenix, Arizona 85004–3008, telephone (602) 379–6750; or Mr. Garry Cantley at (602) 379–6750.

SUPPLEMENTARY INFORMATION: The proposed Federal action, taken under 25 U.S.C. 415, is BIA's approval of a 2,200 acre solar energy ground lease and associated agreements entered into by the Band with 326MK 8me LLC (ESM Solar or Applicant), a wholly owned subsidiary of 8Minute Energy, to provide for construction, operation, maintenance, and eventual decommissioning of an up-to 300 megawatt (MW) alternating current solar photovoltaic (PV) electricity generation facility located entirely on the Reservation and specifically on lands held in trust by BIA for the Band. The proposed 230 kilovolt (kV) generation-tie transmission line required for interconnection would be located on Reservation lands, Reservation lands administered and managed by BLM, BLM lands, and private lands owned by NV Energy. The Applicant has accordingly requested that the BIA and BLM additionally approve rights-of-way (ROWs) authorizing the construction and operation of the transmission line. Together, the proposed solar energy facility, transmission line, and other associated facilities make up the proposed ESM Solar Project.

The solar facility would generate electricity using PV panels. Also included would be inverters, a collection system, a potential battery storage system, an on-site substation to step-up the voltage to transmission level voltage at 230 kV, an operations and maintenance building, and other related facilities. A single overhead 230 kV generation-tie transmission line, approximately 12.5 miles long, would connect the solar project to NV Energy's Reid-Gardner 230kV substation.

Construction of the ESM Solar Project is expected to take approximately 16 to 18 months. The Applicant is expected to operate the energy facility for 30 years, with two options to renew the lease for an additional 5 years each, if mutually acceptable to the Band and Applicant. During construction, the PV panels will be placed on top of single-axis tracking mounting systems that are set on steel posts embedded in the ground. Other foundation design techniques may be used depending on the site topography and conditions. No water will be used to generate electricity during operations. Water will be needed during construction for dust control and a minimal amount will be needed during operations for panel washing, administrative, and sanitary water use on site. The water supply required for construction and operation of the Project would be leased from the Band and trucked in from adjacent Band wells. Operational water would be trucked in from adjacent Band wells to the solar site. Access to the ESM Solar Project will be provided via North Las Vegas Boulevard.

The purposes of the ESM Solar Project are to: (1) Help to provide a long-term, diverse, and viable economic revenue base and job opportunities for the Band; (2) help the state of Nevada to meet its renewable energy needs; and (3) allow the Band, in partnership with the Applicant, to optimize the use of the lease site while maximizing the potential economic benefit to the Band.

The BIA and BLM will use the EIS to make decisions on the land lease and ROW applications under their respective jurisdiction; the EPA may use the document to make decisions under its authorities; the Band may use the EIS to make decisions under its Environmental Policy Ordinance; and the USFWS may use the EIS to support its decision under the Endangered Species Act.

Directions for Submitting Comments: Please include your name, return address and the caption: ''DEIS Comments, Proposed Eagle Shadow Mountain Solar Project'' on the first page of your written comments.

Locations Where the DEIS is Available for Review: The DEIS will be available for review at: BIA Western Regional Office, 2600 North Central Avenue, 12th Floor, Suite 210, Phoenix, Arizona; BIA Southern Paiute Agency, 180 North 200 East, Suite 111, St. George, Utah; and the BLM Southern Nevada District Office, 4701 North Torrey Pines Drive, Las Vegas, Nevada. The DEIS is also available on line at: *www.esmsolareis.com.*

To obtain a compact disk copy of the DEIS, please provide your name and address in writing or by voicemail to Mr. Chip Lewis or Mr. Garry Cantley. Their contact information is listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Individual paper copies of the DEIS will be provided only upon request.

Public Comment Availability: Written comments, including names and addresses of respondents will be available for public review at the BIA Western Regional Office, 2600 North Central Avenue, 12th Floor, Suite 210, Phoenix, Arizona during regular business hours, 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. Before including your address, telephone 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: This notice is published in accordance with section 1503.1 of the Council on Environmental Quality regulations (40 CFR 1500 *et seq.*) and the Department of the Interior Regulations (43 CFR part 46) implementing the procedural requirements of the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), and in accordance with the exercise of authority delegated to the Assistant Secretary—Indian Affairs by part 209 of the Department Manual.

Dated: July 29, 2019.

Mark Cruz,

Deputy Assistant Secretary, Policy and Economic Development—Indian Affairs.

[FR Doc. 2019–17109 Filed 8–8–19; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[19XD0120SW/DT20000000/DSW000000.54AB00; OMB Control Number 1035–0003]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Application To Withdraw Tribal Funds From Trust Status

AGENCY: Office of the Special Trustee for American Indians, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of the Special Trustee for American Indians (OST) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before September 9, 2019.

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 John Montel by email at *John_Montel@ost.doi.gov.* Please reference OMB Control Number 1035–0003 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact John Montel by email at *John_Montel@ost.doi.gov,* or by telephone at (202) 208–3939. 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 26, 2018 (83 FR 60444). 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 OST; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the OST enhance the quality, utility, and clarity of the information to be collected; and (5) how might the OST 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: This notice is for renewal of information collection under OMB regulations at 5 CFR part 1320 that implement the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* These regulations require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8 (d)). This notice identifies an information collection activity that the OST is submitting to OMB for renewal.

Public Law 103–412, The American Indian Trust Fund Management Reform Act of 1994, allows Indian tribes on a voluntary basis to take their funds out of trust status within the Department of the Interior (and the Federal Government) in order to manage such funds on their own. 25 CFR part 1200, subpart B, Sec. 1200.13, ''How does a tribe apply to withdraw funds?'' describes the requirements for application for withdrawal. The Act covers all tribal trust funds including judgment funds as well as some settlements funds, but excludes funds held in Individual Indian Money accounts. Both the Act and the regulations state that upon withdrawal of the funds, the Department of the Interior (and the Federal Government) have no further liability for such funds. Accompanying their application for withdrawal of trust funds, tribes are required to submit a Management Plan for managing the funds being withdrawn, to protect the funds once they are out of trust status.

This information collection allows the OST to collect the tribes' applications for withdrawal of funds held in trust by the Department of the Interior. If OST did not collect this information, the OST would not be able to comply with the American Indian Trust Fund Management Reform Act of 1994, and tribes would not be able to withdraw funds held for them in trust by the Department of the Interior.

Title of Collection: Application to Withdraw Tribal Funds from Trust Status, 25 CFR 1200.

OMB Control Number: 1035–0003.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Tribal governments.

Total Estimated Number of Annual Respondents: One respondent, on average, every three years.

Total Estimated Number of Annual Responses: 1.

Estimated Completion Time per Response: 750 hours.

Total Estimated Number of Annual Burden Hours: 750 hours.

Respondent's Obligation: Required to Obtain or Retain a Benefit.

Frequency of Collection: Once per tribe per trust fund withdrawal application.

Total Estimated Annual Nonhour Burden Cost: None.

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: August 5, 2019.

Treci Johnson,

Director, External Affairs, Office of the Special Trustee for American Indians.

[FR Doc. 2019–17110 Filed 8–8–19; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCO922000–L13100000–FI0000–19X]

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease COC70909, Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of reinstatement.

SUMMARY: As authorized in the Mineral Leasing Act of 1920, as amended, the Bureau of Land Management (BLM) received a petition for reinstatement of competitive oil and gas lease COC70909 from Carrizo Oil & Gas for land in Weld County, Colorado. The lessee filed the petition on time, along with all rentals due since the lease terminated. No leases that affect these lands were issued prior to receiving the petition. The BLM proposes to reinstate this lease.

FOR FURTHER INFORMATION CONTACT: Jonathan Fairbairn, Branch Chief, Fluid Minerals, BLM Colorado State Office, 2850 Youngfield Street, Lakewood, CO 80215, telephone: (303) 239–3753, email: *jfairbairn@blm.gov.* Persons who

use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, seven days a week, to leave a message or questions with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The lessee requested reinstatement after the lease automatically terminated for untimely payment of rent. The lessee agrees to the new lease terms for rentals and royalties of $10 per acre, or fraction thereof, per year, and 16 ⅔ percent, respectively. The lessee paid the required $500 administrative fee for lease reinstatement and the $151 cost of publishing this notice. The lessee met the requirements for reinstatement of the lease per Sec. 31(d) and (e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188). The BLM considered the impacts of reinstatement of the lease in Environmental Assessment DOI–BLM–CO–F020–2017–0041, and issued a Finding of No Significant Impact. The BLM proposes to reinstate the lease effective February 1, 2013, under amended lease terms and the increased rental and royalty rates described above.

Authority: 30 U.S.C. 188 and 43 CFR 3108.2–3

Jamie E. Connell,

BLM Colorado State Director.

[FR Doc. 2019–17115 Filed 8–8–19; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCO922000–L13100000–FI0000–19X]

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease COC73427, Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of lease reinstatement.

SUMMARY: As authorized in the Mineral Leasing Act of 1920, as amended, the Bureau of Land Management (BLM) received a petition for reinstatement of competitive oil and gas lease COC73427 from Extraction Oil & Gas, LLC and OOGC America Inc., for land in Weld County, Colorado. The lessees filed the petition on time, along with all rentals due since the lease terminated. No leases that affect these lands were issued prior to receiving the petition. The BLM proposes to reinstate this lease.

FOR FURTHER INFORMATION CONTACT: Jonathan Fairbairn, Branch Chief, Fluid Minerals, BLM Colorado State Office, 2850 Youngfield Street, Lakewood, CO 80215, telephone: (303) 239–3753, email: *jfairbairn@blm.gov*. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact Mr. Fairbairn during normal business hours. The FRS is available 24 hours a day, seven days a week, to leave a message or questions. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The lessees requested reinstatement after the lease automatically terminated for untimely payment of rent. The lessees agree to the new lease terms for rentals and royalties of $10 per acre, or fraction thereof, per year, and 16⅔ percent, respectively. The lessees paid the required $500 administrative fee for lease reinstatement and the $151 cost of publishing this notice. The lessees met the requirements for reinstatement of the lease per Sec. 31(d) and (e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188). The BLM considered the impacts of reinstatement of the lease in Environmental Assessment DOI–BLM–CO–F020–2017–0041–EA and issued a Finding of No Significant Impact. The BLM proposes to reinstate the lease effective December 1, 2014, under amended lease terms and the increased rental and royalty rates described above.

Authority: 30 U.S.C. 188 and 43 CFR 3108.2–3

Jamie E. Connell,

BLM Colorado State Director.

[FR Doc. 2019–17111 Filed 8–8–19; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNMA02000.L51010000.ER0000.17X LVRWG17G1360; NMNM 136976]

Notice of Availability for the Draft Environmental Impact Statement and Land Use Plan Amendment for Borderlands Wind Project in Catron County, New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended (FLPMA), the Bureau of Land Management (BLM) has prepared a Draft Environmental Impact Statement (EIS) for the proposed Borderlands Wind Project (Project) and Proposed Socorro Field Office Resource Management Plan Amendment (RMPA) for the BLM Socorro Field Office, and by this notice is announcing its availability.

DATES: This notice initiates a 90-day public review period of the Draft EIS and RMPA. Comments on the document may be submitted in writing until November 7, 2019. To provide an opportunity to review the Draft EIS and RMPA, the BLM expects to hold one public meeting during the comment period. The BLM will announce the exact date, time, and location for the meetings at least 15 days prior to the event. Announcements will be made by news release to the media and posting on BLM's website listed below.

In order to be included in the Draft EIS and RMPA, comments must be received prior to the close of the 90-day public comment period. The BLM will provide additional opportunities for public participation upon publication of the Final EIS and RMPA.

ADDRESSES: You may submit comments or resource information related to the project by either of the following methods:

- *Electronically: https://www.blm.gov/programs/planning-and-nepa/plans-in-development/new-mexico/proposed-borderlands-wind-project.*
- *By mail:* Jim Stobaugh, National Project Manager, Bureau of Land Management Nevada State Office, Borderlands Wind Project, 1340 Financial Blvd., Reno, NV 89502.

FOR FURTHER INFORMATION CONTACT: For further information and/or to have your name added to our mailing list, contact Virginia Alguire, BLM Socorro Field Office, 901 South Highway 85, Socorro, New Mexico 87801; phone 575–838–1290; or email *valguire@blm.gov.* Any persons wishing to be added to a mailing list of interested parties can call or write to the BLM. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact Ms. Alguire during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: Borderlands Wind, LLC submitted an application to the BLM requesting authorization to construct, operate, maintain, and terminate an up-to 100 megawatt commercial wind energy generation facility —Borderlands Wind

Project (NMNM136976), in Catron County, New Mexico, within a boundary that encompasses land managed by the BLM, the New Mexico State Land Office (SLO), and private landowners. The project would be located south of U.S. Route 60 in Catron County near Quemado, New Mexico, and the Arizona-New Mexico border. Authorization of this proposal requires an amendment to the 2010 Socorro Field Office RMP to modify the visual resource management class in the project area and to modify a right-of-way avoidance area.

The Draft EIS addresses the direct, indirect, and cumulative environmental impacts of the Proposed Action, Alternative 1 (optimize the proposed wind facility components in order to minimize potential environmental impacts), Alternative 2 (change in the turbine generation types), and the No Action Alternative. Alternatives 1 and 2 would be constructed, operated, and maintained within the same project area. The Proposed Action and Alternative 1 would construct 40 turbines. However, because of the difference in type of turbine, Alternative 2 would only construct 34 turbines. The No Action Alternative would be a continuation of existing conditions.

A Notice of Intent to prepare an EIS for the proposed Borderlands Wind Project was published in the **Federal Register** on November 9, 2018 (83 FR 56097). The public scoping period closed on December 10, 2018. The BLM held one public scoping meeting on November 14, 2018. The BLM received 51 public scoping comment submissions during the 45-day scoping period. The scoping comments focused on wildlife, visual and cultural resources, light pollution, human health, local economic benefits, and property values.

The BLM continues to consult with Indian tribes on a government-to-government basis in accordance with Executive Order 13175 and other policies. Tribal concerns, including potential impacts to cultural resources, will be given due consideration.

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.

Timothy R. Spisak,

BLM New Mexico State Director.

[FR Doc. 2019–16912 Filed 8–8–19; 8:45 am]

BILLING CODE 4310–FB–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–28601; 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 27, 2019, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted by August 26, 2019.

ADDRESSES: Comments may be sent via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C St. NW, MS 7228, Washington, DC 20240.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before July 27, 2019. Pursuant to Section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Nominations submitted by State Historic Preservation Officers:

ARIZONA

Maricopa County

Pierson Place, (Residential Subdivisions and Architecture in Central Phoenix, 1870–1963, MPS), Roughly bounded by Central & 7th Aves., Camelback Rd. & Grand Canal, Phoenix, MP100004344

Pima County

Bauder, Jean and Paul, House (Boundary Increase), (Single Family Residential Architecture of Josias Joesler and John and Helen Murphey MPS), 4775 N Camino Antonio, Tucson vicinity, BC100004343

FLORIDA

Duval County

Arpen, Henry C., House, 3318 O'Connor Rd., Jacksonville, SG100004347

Marion County

Silver Springs, 5656 E Silver Springs Blvd., Silver Springs, SG100004353

Pinellas County

Huggins-Stengel Field, 1320 5th St. N, St. Petersburg, SG100004348

Polk County

Craney Spec Houses Historic District, Drexel Ave. NE between 15th St. and 16th St., Winter Haven, SG100004349

Shell Hammock Landing, 3800 Shell Hammock, Lake Wales, SG100004350

Putnam County

Hotel James, 300 St. Johns Ave., Palatka, SG100004351

Sarasota County

Warm Mineral Springs Building Complex, 12220 San Servando Ave., North Port, SG100004352

INDIANA

Allen County

Kensington Boulevard Historic District, Roughly bounded by East State Blvd., North Anthony Blvd., Niagara Dr., and Pemberton Dr., Fort Wayne, SG100004368

Clinton County

TPA Park, 1 Adrian Marks Dr., Frankfort, SG100004364

Delaware County

Muncie Trade School, 1491 West Kilgore Ave., Muncie, SG100004363

La Porte County

Long Beach School, 2501 Oriole Trail, Long Beach, SG100004366

Marion County

Beth-El Zedeck Temple, 3359 Ruckle St., Indianapolis, SG100004362

Marshall County

Sults-Quivey-Hartman Polygonal Barn and Farm, 15605 S Olive Trail, Plymouth, SG100004367

Spencer County

Rockport Historic District, Roughly bounded by First St., Seminary St., a line from north to south following Greenwood St., Lincoln Ave. and Eighth St., and William and Pearl Sts., Rockport, SG100004359

Steuben County

Lime Lake—Lake Gage Channel and Bridge, North Gage Dr., Angola, SG100004361

Washington County

Campbell-Gill House, 8178 S IN 335, New Pekin, SG100004365

MASSACHUSETTS

Suffolk County

Ascension-Caproni Historic District, Roughly bounded by Washington, Newcomb, Thorndike & Reed Sts., Boston, SG100004335

Worcester County

Duprey Building, 16 Norwich St., Worcester, SG100004336

Oakham Center Historic District, Roughly bounded by Coldbrook & Barre Rds., Maple St. & Deacon Allen Dr., Oakham, SG100004337

NEW YORK

Montgomery County

Palatine Bridge Historic District, Carman Ct., Center St., Frey Dr./Ln., Grand (E&W) St., Humbert Ln., Lafeyette St., Spring St., Tilton Rd., Palatine Bridge, SG100004358

OHIO

Butler County

Champion Coated Paper Company, 601 North B St., Hamilton, SG100004357

Defiance County

Defiance High School, 629 Arabella St., Defiance, SG100004356

Montgomery County

Wright Company Factory, 2701 Home Ave., Dayton Heritage National Historical Park, Dayton, SG100004355.

Summit County

Kenmore Boulevard Historic District, Roughly bounded by 872–1030; 873–1017 Kenmore Blvd.; 2181 14th St. SW; 2200 15th St. SW; 940 Florida Ave., Akron, SG100004354

WASHINGTON

Pierce County

Munson, Herbert and Barbara House, 12711 Gravelly Lake Dr. SW, Lakewood, SG100004345

Walla Walla County

Bachtold Building-Interurban Depot, 330 W Main St., Walla Walla, SG100004346

WISCONSIN

Portage County

New Hope Norwegian Evangelical Lutheran Church and Cemetery, 1410 Cty. Rd. T, New Hope, SG100004342

A request for removal has been made for the following resource:

INDIANA

White County

White County Asylum, 5271 Norway Rd., Monticello vicinity, OT10000857

Nomination submitted by Federal Preservation Officers:

The State Historic Preservation Officer reviewed the following nomination and responded to the Federal Preservation Officer within 45 days of receipt of the nomination and supports listing the property in the National Register of Historic Places.

MAINE

York County

Stage Island Monument, NE of Hills Beach on Stage Island, .6 mi. N of mouth of Biddeford Pool, Biddeford, SG100004341.

Authority: Section 60.13 of 36 CFR part 60.

Dated: July 30, 2019.

Paul Lusignan,

Acting Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2019–17065 Filed 8–8–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–28529; 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 20, 2019, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted by August 26, 2019.

ADDRESSES: Comments may be sent via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C St. NW, MS 7228, Washington, DC 20240.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before July 20, 2019. Pursuant to Section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Nominations submitted by State Historic Preservation Officers:

ILLINOIS

Champaign County

Downtown Urbana Historic District, Roughly bounded by Illinois, Walnut, Water, Goose Alley, and Cedar Sts., Urbana, SG100004308

Cook County

First Congregational Church, Des Plaines, 766 Graceland Ave., Des Plaines, SG100004310

De Kalb County

Rollo Congregational United Church of Christ, 2471 Weddell St., Earlville, SG100004311

Madison County

Alton Gas & Electric Power House, 700 W. Broadway, Alton, SG100004309

NEW YORK

Dutchess County, Innisfree, 362 Tyrrel Rd., Millbrook, SG100004333

Herkimer County

Case, James H., III and Laura Rockefeller Case, House, 2333 NY 80, Van Hornesville, SG100004334

New York County

Baldwin, James, House, 137 W. 71st, New York, SG100004332

NORTH CAROLINA

Alexander County

Taylorsville Milling Company Roller Mill, 53 2nd Ave. N., Taylorsville, SG100004324

Cabarrus County

Gem Theatre, 111 W. 1st Street, Kannapolis, SG100004322

Caldwell County

Carolina and Northwestern Railway Freight Station, 1407 College Ave. SW, Lenoir, SG100004319

Davidson County

Finch, T. Austin and Ernestine L., House, 17 E. Main St., Thomasville, SG100004321

Forsyth County

Womble, Bunyan S. and Edith W., House, 200 North Stratford Rd., Winston-Salem, SG100004325

Lee County

Sanford Tobacco Company Redrying Plant and Warehouse, 521 Wicker St., Sanford, SG100004323

Nash County

Caromount Mills, Inc.—Burlington Industries, Inc. Plant, 450 W. Ridge St., 910 Carter St., Rocky Mount, SG100004320

OHIO

Delaware County, Ohio Wesleyan University Fraternity Hill Historic District, 4, 9, 10, 15, 19, 20, 23, 30, and 35 Williams Dr., Delaware, SG100004312

Hamilton County

Mill & Dunn Historic District, 100–139 Williams St., 119 Lock St., 200–328 Dunn St., 100–200 Mill St., and 209–327 Wyoming Ave., Cincinnati, SG100004315

Montgomery County

Downtown Dayton Historic District, Roughly bounded by I 75, St. Clair St., west face of Patterson Blvd., Monument Ave., and Sixth St./Norfolk Southern Railroad line, Dayton, SG100004316

OREGON

Multnomah County

Portland Police Block (Boundary Decrease), 209 SW Oak St., Portland, BC100004313

WASHINGTON

King County

Matzen, George and Irene, House, 320 W. Kinnear Place, Seattle, SG100004329

Baring Bridge, NE Index Creek Rd. off WA 2 over S. Fork of Skykomish River, Baring, SG100004331

Spokane County

McMillen—Dyar House, 526 E. 12th Ave., Spokane, SG100004330

Whitman County

Northern Pacific Railway Depot—Pullman, 330 N. Grand Ave., Pullman, SG100004328

A request for removal has been made for the following resource:

OREGON

Multnomah County

Jefferson Substation, 37 SW Jefferson St., Portland, OT80003368

Nominations submitted by Federal Preservation Officers:

The State Historic Preservation Officer reviewed the following nominations and responded to the Federal Preservation Officer within 45 days of receipt of the nominations and supports listing the properties in the National Register of Historic Places.

ARIZONA

Coconino County

Cliffs Ranger Station, 2 mi. E. of Flagstaff in Walnut Canyon National Monument, Flagstaff vicinity, BC100004317

Cliffs Ranger Station, 2 mi. E. of Flagstaff in Walnut Canyon National Monument, Flagstaff vicinity, AD75000220

OHIO

Medina County

United States Post Office, 143 W. Liberty St., Medina, SG100004307

Authority: Section 60.13 of 36 CFR part 60.

Dated: July 23, 2019.

Lisa Deline,

Acting Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2019–17066 Filed 8–8–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR01313000, 18XR0680A1, RX.00036916.5002000]

Notice of Intent To Prepare an Environmental Impact Statement and Public Scoping Open Houses for the Boise River Basin Feasibility Study, Elmore County, Idaho

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of intent; request for comments.

SUMMARY: The Bureau of Reclamation (Reclamation) intends to prepare an Environmental Impact Statement (EIS) on the Boise River Basin Feasibility Study. Reclamation is requesting public and agency comment to identify significant issues or other alternatives to be addressed in the EIS.

DATES: Submit written comments on the scope of the EIS on or before September 9, 2019.

Three scoping open houses will be held on the following dates and times:

- August 27, 2019, 1:00 p.m. to 3:00 p.m., Pine, ID.
- August 28, 2019, 6:00 p.m. to 8:00 p.m., Boise, ID.
- August 29, 2019, 6:00 p.m. to 8:00 p.m., Mountain Home, ID.

ADDRESSES: Provide written scoping comments, requests to be added to the mailing list, or requests for sign language interpretation for the hearing impaired or other special assistance needs to Ms. Megan Sloan, Project Manager, Bureau of Reclamation, Snake River Area Office, 230 Collins Road, Boise, ID 83702; or email *BOR-SRA-BoiFeasibility@usbr.gov.*

The scoping meetings and open houses will be located at:

- Pine—Boise River Senior Center, 350 North Pine Featherville Road, Pine, Idaho 83647;
- Boise—Wyndham Garden Boise Airport Hotel, 3300 South Vista Avenue, Boise, Idaho 83705; and
- Mountain Home—American Legion, 515 East 2nd South Street, Mountain Home, Idaho 83647.

FOR FURTHER INFORMATION CONTACT: Ms. Megan Sloan, Bureau of Reclamation, Snake River Area Office, 230 Collins Road, Boise, ID 83702; telephone (208) 383–2222; facsimile (208) 383–2210; email *BOR-SRA-BoiFeasibility@usbr.gov.* Persons who use a telecommunications device for the deaf may call the Federal Relay Service (FedRelay) at 1–800–877–8339 TTY/ASCII to contact the above individual during normal business hours or to leave a message or question after hours. You will receive a reply during normal business hours. Information on this project may also be found at: *https://www.usbr.gov/pn/studies/boisefeasibility/index.html.*

SUPPLEMENTARY INFORMATION: Reclamation is issuing this notice pursuant to the National Environmental Policy Act of 1969, as amended (NEPA), 42 U.S.C. 4321 *et seq.;* the Council on Environmental Quality's (CEQ) regulations for implementing NEPA, 43 CFR parts 1500 through 1508; and the Department of the Interior's NEPA regulations, 43 CFR part 46.

Background

Under the Omnibus Public Land Management Act of 2009 (Omnibus Act), Public Law (Pub. L.) 111–11, Section 9001, Congress authorized Reclamation to conduct feasibility studies on projects that address water shortages within the Boise River Basin System and that are considered appropriate for study by Reclamation's 2006 Boise/Payette Water Storage Assessment Report (2006 Assessment Report). The action proposed was identified in the 2006 Assessment Report as appropriate for study and is the subject of an ongoing feasibility study pursuant to the Omnibus Act and the Water Infrastructure Improvements for the Nation (WIIN) Act of 2016. The WIIN Act authorizes Reclamation to enter into agreements with requesting states or subdivisions thereof to design, study, construct, or expand federally owned storage projects, and Congress has specified that this project be studied under WIIN Act authority. Public Law 114–322, Section 4007.

The Bureau of Reclamation, in partnership with the Idaho Water Resource Board (IWRB), proposes to raise Anderson Ranch Dam 6 feet, raising the top of the reservoir pool from the present elevation of 4,196 feet to 4,202 feet, allowing the ability to capture and store approximately 29,000 additional acre-feet of water. This new space would allow Reclamation to capture additional water when available during wet years for supplemental supply and to hold over for use during dry years. Potential spaceholders include existing Reclamation contractors and IWRB, which could in turn contract water to existing Water District 63 water users and/or may offer water through the Idaho water supply bank's Water District 63 rental pool.

Proposed dam structure modifications include:

- Raising the earthen embankment dam crest by 6 feet.

• Demolishing the existing spillway crest structure and bridge.

• Removing, rehabilitating, and re-installing the existing radial gates.

• Constructing a new spillway crest structure and bridge.

• Constructing a new two-lane road across the dam.

The existing road across the dam would be closed during construction. An alternative route has been identified that would provide safe public transport. There would likely be a reservoir restriction of 6–10 feet during spillway construction.

In addition to work on the dam, the project would include modification to structures around the reservoir such as culverts, bridges, and recreation sites.

Reclamation is not presently aware of any known or possible Indian Trust Assets or environmental justice issues associated with the proposed action but requests any information relative to this issue be submitted during the scoping period.

Reclamation intends to complete an EIS for this project pursuant to the National Environmental Policy Act to study the potential environmental effects of the proposal and a reasonable range of alternatives designed to respond to the purpose and need for the project, as well as a no-action alternative. The scoping process and public open houses identified in this notice are intended to inform the public about the project and to request public and agency comment to identify significant issues or alternatives to be addressed in the EIS.

Special Assistance for Public Scoping and Open House Meetings

If special assistance is required to participate in the public scoping and open house meetings, please contact Ms. Megan Sloan, Bureau of Reclamation, Snake River Area Office, 230 Collins Road, Boise, ID 83702; telephone (208) 383–2222; facsimile (208) 383–2210; email *BOR-SRA-BoiFeasibility@usbr.gov.* Persons who use a telecommunications device for the deaf may call the Federal Relay Service (FedRelay) at 1–800–877–8339 TTY/ASCII to contact the above individual during normal business hours or to leave a message or question after hours. You will receive a reply during normal business hours. All meeting facilities are physically accessible to people with disabilities.

Public Disclosure

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Jennifer Carrington,

Acting Regional Director, Pacific Northwest Region.

[FR Doc. 2019–16744 Filed 8–8–19; 8:45 am]

BILLING CODE 4332–90–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1156]

Certain LED Packages Containing PFS Phosphor and Products Containing Same; Commission Determination Not To Review an Initial Determination Granting a Motion To Terminate the Investigation Based on a Stipulated Consent Order and Settlement Agreement; Issuance of Consent Order; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (''ID'') (Order No. 6) issued by the presiding administrative law judge (''ALJ''), granting a joint motion to terminate the investigation based on a stipulated consent order and a settlement agreement. The Commission has also determined to issue a consent order and to terminate the investigation.

FOR FURTHER INFORMATION CONTACT: Robert Needham, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–5468. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on May 16, 2019, based on a complaint filed by Current Lighting Solutions, LLC of East Cleveland, Ohio; General Electric Co. of Boston, Massachusetts; and Consumer Lighting (U.S.), LLC d/b/a GE Lighting of East Cleveland, Ohio (together, ''Complainants''). 84 FR 22164. The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain LED packages containing PFS phosphor and products containing same by reason of infringement of certain claims of U.S. Patent Nos. 7,497,973 and 9,680,067. *Id.* The Commission's notice of investigation named as respondents Cree, Inc. of Durham, North Carolina; Cree Hong Kong Ltd. of Hong Kong; and Cree Huizhou Solid State Lighting Co. Ltd. of Huizhou, China (together, ''Cree''). *Id.* at 22165. The Office of Unfair Import Investigations is not participating in this investigation. *Id.*

On June 20, 2019, Complainants and Cree filed a joint motion to terminate the investigation based on a stipulated consent order and a settlement agreement. No responses to the joint motion were received.

On July 10, 2019, pursuant to Commission Rules 210.21(b) and (c) (19 CFR 210.21(b) and (c)), the ALJ issued the subject ID, granting the motion and terminating the investigation. No petitions for review of the ID were received.

The Commission has determined not to review the subject ID, and has determined to issue a consent order. This investigation is hereby terminated.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: August 6, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–17104 Filed 8–8–19; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–607 and 731–TA–1417 and 1419 (Final)]

Steel Propane Cylinders From China and Thailand; 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 steel propane cylinders from China and Thailand, provided for in subheading 7311.00.00 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 China.[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 May 22, 2018, following receipt of a petition filed with the Commission and Commerce by Worthington Industries Inc. (''Worthington''), Columbus, Ohio, and Manchester Tank and Equipment (''Manchester''), Franklin, Tennessee. The final phase of the investigations was scheduled by the Commission following notification of preliminary determinations by Commerce that imports of steel propane cylinders from China were subsidized within the meaning of section 703(b) of the Act (19 U.S.C. 1671b(b)) and imports from China and Thailand were being 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 March 13, 2019 (84 FR 9135) and revised on April 29, 2019 (84 FR 18084). The hearing was held in Washington, DC, on June 5, 2019, and all persons who requested the opportunity were permitted to appear in person or by counsel.

[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 not participating.

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 August 5, 2019. The views of the Commission are contained in USITC Publication 4938 (August 2019), entitled *Steel Propane Cylinders from China and Thailand: Investigation Nos. 701–TA–607 and 731–TA–1417 and 1419 (Final).*

By order of the Commission.

Issued: August 5, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–17029 Filed 8–8–19; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—UHD Alliance, Inc.

Notice is hereby given that, on July 22, 2019, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), UHD Alliance, Inc. (''UHD Alliance'') filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, CerebrEX, Inc., Osaka, JAPAN; Nanosys, Inc., Milpitas, CA; and Netflix, Inc., Los Gatos, CA, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and UHD Alliance intends to file additional written notifications disclosing all changes in membership.

On June 17, 2015, UHD Alliance filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on July 17, 2015 (80 FR 42537).

The last notification was filed with the Department on May 17, 2019. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on June 17, 2019 (84 FR 28074).

Suzanne Morris,

Chief, Premerger and Division Statistics Unit, Antitrust Division.

[FR Doc. 2019–17119 Filed 8–8–19; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—American Commission of Accreditation for Schools and Universities LLC

Notice is hereby given that, on July 24, 2019, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), American Commission of Accreditation for Schools and Universities LLC (''ACASU'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the name and principal place of business of the standards development organization and (2) the nature and scope of its standards development activities. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to Section 6(b) of the Act, the name and principal place of business of the standards development organization is: American Commission of Accreditation for Schools and Universities LLC, Syracuse, NY. The nature and scope of ACASU's standards development activities are: To develop educational standards and pedagogical tools for international schools and colleges. They will be related to the following categories: School governance structures; educational content and delivery; school operations; school culture; and quality improvement and maintenance plans. Standards will be developed in partnership with various experts in school and college education to promote a broad perspective and ensure applicability to varied international environments. Standards will go through a process of ongoing evaluation and revision based on feedback from our clients and through systematic review processes entailing additional experts. ACASU will also provide evaluation, accreditation, and education training services for educational institutions through the use of pedagogical evaluation tools and

processes for schools and colleges wishing to do so on a voluntary basis. ACASU's mission is to endorse the highest quality education for students to lead to a lifetime of achievement and service to others in a connected world.

Suzanne Morris,

Chief, Premerger and Division Statistics Unit, Antitrust Division.

[FR Doc. 2019–17122 Filed 8–8–19; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Undersea Technology Innovation Consortium

Notice is hereby given that, on July 11, 2019, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Undersea Technology Innovation Consortium (''UTIC'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Advanced Scientific Concepts LLC, Santa Barbara, CA; Analytical Graphics, Inc., Exton, PA; Ardalyst Federal LLC, Annapolis, MD; Azavea Inc., Philadelphia, PA; C–2 Innovations Inc., Stow, MA; Carillon Technologies Management, Arlington, VA; Cisco Systems Inc., San Jose, CA; Contrast Inc., Albuquerque, NM; Decisive Analytics Corporation, Arlington, VA; DRS Laurel Technologies, Johnstown, PA; EDO Western Corporation, Salt Lake City, UT; Electric Boat Corporation, Groton, CT; Falmouth Scientific Inc., Cataumet, MA; G2 Ops Inc., Virginia Beach, VA; Gavial ITC LLC, Santa Barbara, CA; GK Mechanical Systems, Brookfield, CT; GLX Power Systems Inc., Cleveland, Ohio; Hexagon US Federal Inc., Huntsville, AL; ICE ITS Inc., Ashburn, VA; L3 Communication Systems-East | L3 Technologies, Camden, NJ; Linden Photonics Inc., Westford, MA; Lyman Morse Boatbuilding, Thomaston, ME; MACSEA Ltd., Stonington, CT; Moebius Solutions, Inc., San Diego, CA; Montana State University, Bozeman, MT; NAG, LLC dba NAG Marine, Norfolk, VA; NortekUSA Inc., Boston, MA; Pacific Engineering Inc., Roca, NE; Parker Hannifin Corporation, Mayfield Heights, OH; Peregrine Technical Solutions LLC, Yorktown, VA; Prescient Edge Corporation, Mclean, VA; Product Development Associates, Burnsville, MN; Raytheon Missile Systems, Tucson, AZ; Red River Technology LLC, Claremont, NH; RPI Group Inc., Fredericksburg, VA; SeaTrac Systems, Inc., Marblehead, MA; Sonardyne Inc., Houston, TX; TDI Technologies Inc., King of Prussia, PA; The University of Southern Mississippi, Hattiesburg, MS; VACCO Industries, El Monte, CA; and, WWM Solutions LLC, Washington, DC, have been added as parties to this venture.

Also, 6Fathoms Consulting LLC, Austin, TX; Harpon Ventures LLC, Menlo Park, CA; Left of Creative LLC, Wakefield, RI; Pacific Science & Engineering Inc. (PSE), San Diego, CA; and Platron Manufacturing, Pflugerville, TX, have withdrawn as parties from this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and UTIC intends to file additional written notifications disclosing all changes in membership.

On October 9, 2018, UTIC filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on November 2, 2018 (83 FR 55203).

The last notification was filed with the Department on January 28, 2019. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on February 28, 2019 (84 FR 6823).

Suzanne Morris,

Chief, Premerger and Division Statistics Unit, Antitrust Division.

[FR Doc. 2019–17121 Filed 8–8–19; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—ODVA, Inc.

Notice is hereby given that, on August 1, 2019, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), ODVA, Inc. (''ODVA'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Janome Sewing Machine Co., Ltd., Tokyo, JAPAN; Taihan Electric Wire Co., Ltd., Anyang-si, Gyeonggi-do, REPUBLIC OF KOREA; Micro-Epsilon Messtechnik GmbH & Co. KG, Ortenburg, GERMANY; swisca ag, Appenzell, SWITZERLAND; Mitutoyo Corporation, Kawasaki-shi, Kanagawa, JAPAN; and Nippon Gear, Fujisawa-shi, Kanagawa-ken, JAPAN, have been added as parties to this venture.

Also, General Electric Power Conversion, Pittsburgh, PA; Ground Fault Systems bv, Enschede, NETHERLANDS; Monode Marking Products, Inc., Mentor, OH; Beck IPC GmbH, Wetzlar, GERMANY; and Kyland Corporation, San Ramon, CA, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and ODVA intends to file additional written notifications disclosing all changes in membership.

On June 21, 1995, ODVA filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on February 15, 1996 (61 FR 6039).

The last notification was filed with the Department on April 15, 2019. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on April 29, 2019 (84 FR 18087).

Suzanne Morris,

Chief, Premerger and Division Statistics Unit, Antitrust Division.

[FR Doc. 2019–17116 Filed 8–8–19; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—PXI Systems Alliance, Inc.

Notice is hereby given that, on July 23, 2019, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), PXI Systems Alliance, Inc. (''PXI Systems'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions

limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, ALLNET GmbH Computersysteme, Germering, Germany; and Sichuan Jovian Test & Control Technology, Chengdu, People's Republic of China, have been added as parties to this venture.

Also, Beijing Aerospace Measurement & Control Technology, Beijing, People's Republic of China, has withdrawn as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and PXI Systems intends to file additional written notifications disclosing all changes in membership.

On November 22, 2000, PXI Systems filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on March 8, 2001 (66 FR 13971).

The last notification was filed with the Department on May 7, 2019. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on May 20, 2019 (84 FR 22896).

Suzanne Morris,

Chief, Premerger and Division Statistics Unit, Antitrust Division.

[FR Doc. 2019–17126 Filed 8–8–19; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (OJP) Docket No. 1756]

Meeting of the Global Justice Information Sharing Initiative Federal Advisory Committee

AGENCY: Office of Justice Programs (OJP), Justice.

ACTION: Notice of meeting.

SUMMARY: This is an announcement of a meeting of the Global Justice Information Sharing Initiative (Global) Federal Advisory Committee (GAC) to discuss the Global Initiative, as described at *www.it.ojp.gov/global.* This meeting will provide an update on existing projects as well as the status of priorities for the FY19 Fiscal Year.

DATES: The meeting will take place on Tuesday, October 8, 2019, from 9:00 a.m. ET to 4:30 p.m. ET.

ADDRESSES: The meeting will take place at the Office of Justice Programs offices (in the Main Conference Room), 810 7th Street, Washington, DC 20531; Phone: (202) 514–2000 [note: this is not a toll-free number].

FOR FURTHER INFORMATION CONTACT: Tracey Trautman, Global Designated Federal Official (DFO), Bureau of Justice Assistance, Office of Justice Programs, 810 7th Street, Washington, DC 20531; Phone (202) 305–1491 [note: this is not a toll-free number]; Email: *tracey.trautman@ojp.usdoj.gov.*

SUPPLEMENTARY INFORMATION: This meeting is open to the public. Due to security measures, however, members of the public who wish to attend this meeting must register with Ms. Tracey Trautman at the above address at least (7) days in advance of the meeting. Registrations will be accepted on a space available basis. Access to the meeting will not be allowed without registration. All attendees will be required to sign in at the meeting registration desk. Please bring photo identification and allow extra time prior to the meeting.

Anyone requiring special accommodations should notify Ms. Trautman at least seven (7) days in advance of the meeting.

Purpose: The GAC will act as the focal point for justice information systems integration activities in order to facilitate the coordination of technical, funding, and legislative strategies in support of the Administration's justice priorities.

The GAC will guide and monitor the development of the Global information sharing concept. It will advise the Director of the Bureau of Justice Assistance; the Principal Deputy Assistant Attorney General, OJP; the Attorney General; the President (through the Attorney General); and local, state, tribal, and federal policymakers in the executive, legislative, and judicial branches. The GAC will also advocate for strategies for accomplishing a Global information sharing capability.

Interested persons whose registrations have been accepted may be permitted to participate in the discussions at the discretion of the meeting chairman and with approval of the DFO.

Tracey Trautman,

Global DFO, Deputy Director, Bureau of Justice Assistance, Office of Justice Programs, U.S. Department of Justice.

[FR Doc. 2019–17112 Filed 8–8–19; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request; Confidentiality and Disclosure of State Unemployment Compensation Information Final Rule and State Income and Eligibility Verification Provisions of the Deficit Reduction Act of 1984

ACTION: Notice.

SUMMARY: The Department of Labor's (DOL's) Employment and Training Administration (ETA) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, ''Confidentiality and Disclosure of State Unemployment Compensation Information Final Rule and State Income and Eligibility Verification Provisions of the Deficit Reduction Act of 1984.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by October 8, 2019.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained free by contacting John Schuettinger by telephone at 202–693–2680 (this is not a toll-free number), TTY 1–877–889–5627 (this is not a toll-free number), or by email at *Schuettinger.John@dol.gov.*

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration, Office of Unemployment Insurance, 200 Constitution Avenue NW, Washington, DC 20210; by email: *Schuettinger.John@dol.gov;* or by Fax 202–693–3975.

FOR FURTHER INFORMATION CONTACT: Thomas Clendenning by telephone at 202–693–3458 (this is not a toll-free number) or by email at *Clendenning.Thomas.J@dol.gov.*

SUPPLEMENTARY INFORMATION: DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or

continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

The Deficit Reduction Act of 1984 (DEFRA) established an Income and Eligibility Verification System (IEVS) for the exchange of information among state agencies administering specific programs. The programs include Temporary Assistance for Needy Families, Medicaid, Food Stamps, Supplemental Security Income, Unemployment Compensation, and any state program approved under Titles I, X, XIV, or XVI of the Social Security Act. Under the DEFRA, programs participating must exchange information to the extent that it is useful and productive in verifying eligibility and benefit amounts to assist the child support program and the Secretary of Health and Human Services in verifying eligibility and benefit amounts under Titles II and XVI of the Social Security Act.

On September 27, 2006, ETA issued a final rule regarding the Confidentiality and Disclosure of State Unemployment Compensation Information. This rule supports and expands upon the requirements of the DEFRA and subsequent regulatory changes. The DEFRA authorizes this information collection.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1205–0238.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including 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).

Agency: DOL–ETA.

Type of Review: Extension without changes.

Title of Collection: Confidentiality and Disclosure of State Unemployment Compensation Information Final Rule and State Income and Eligibility Verification provisions of the Deficit Reduction Act of 1984.

Form: Not Applicable.

OMB Control Number: 1205–0238.

Affected Public: State Workforce Agencies.

Estimated Number of Respondents: 53.

Frequency: Varied.

Total Estimated Annual Responses: 738,808.

Estimated Average Time per Response: 1 minute.

Estimated Total Annual Burden Hours: 15,917 hours.

Total Estimated Annual Other Cost Burden: $0.

Authority: 44 U.S.C. 3506(c)(2)(A).

John Pallasch,

Assistant Secretary for Employment and Training.

[FR Doc. 2019–17080 Filed 8–8–19; 8:45 am]

BILLING CODE 4510–FW–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request; Student Experiences Assessment of Job Corps Centers

ACTION: Notice.

SUMMARY: The Department of Labor's (DOL's), Employment Training Administration (ETA) is soliciting comments concerning the information collection request (ICR) titled ''Student Experiences Assessment of Job Corps Centers.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by October 8, 2019.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free by contacting Lawrence Lyford by telephone at 202–693–3121 (this is not a toll-free number), TTY 1–877–889–5627 (this is not a toll-free number), or by email at *Lyford.Lawrence@dol.gov.*

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration, Office of Job Corps, 200 Constitution Avenue NW, Room N4507, Washington, DC 20210; by email: *Lyford.Lawrence@dol.gov;* or by Fax 202–693–3113.

FOR FURTHER INFORMATION CONTACT: Lawrence Lyford by telephone at 202–693–3121 (this is not a toll free number) or by email at *Lyford.Lawrence@dol.gov.*

SUPPLEMENTARY INFORMATION: DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

Job Corps is the nation's largest residential, educational, and career technical training program for young Americans. The Economic Opportunity Act established Job Corps in 1964 and it currently operates under the authority of the Workforce Innovation and Opportunity Act (WIOA) of 2014. For over 55 years, Job Corps has helped prepare more than 3 million at-risk young people between the ages of 16 and 24 for success in our nation's workforce. With 123 centers in 50 states, Puerto Rico, and the District of Columbia, Job Corps assists students across the nation in attaining academic credentials, including High School Diplomas (HSD) and/or High School Equivalency (HSE), and career technical training credentials, including industry-recognized certifications, state licensures, and pre-apprenticeship credentials. Job Corps also provides placement services to qualified students after separation.

Job Corps is a national program administered by DOL through the Office of Job Corps and six regional offices. DOL awards and administers contracts for the recruiting and screening of new students, center operations, and the placement and transitional support of graduates and former enrollees. Large and small corporations and nonprofit organizations manage and operate 98 Job Corps centers under contractual agreements with DOL. These contract center operators are selected through a competitive procurement process that evaluates potential operators' technical expertise, proposed costs, past performance, and other factors, in accordance with the Competition in Contracting Act and the Federal Acquisition Regulations. The U.S. Department of Agriculture Forest Service (USDA FS) operates the remaining 25 Job Corps centers; called Civilian Conservation Centers, via an interagency agreement with DOL. DOL has a direct role in the operation of Job Corps, and does not serve as a pass-through agency for this program. The Workforce Innovation Opportunity Act (WIOA), Section 116(b)(2)(A)(i), Section 159(c)(4) and Section 156(a) authorizes this information collection.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB control number 1205–0NEW.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including 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).

Agency: DOL–ETA.

Type of Review: New information collection request.

Title of Collection: Student Experiences Assessment of Job Corps Centers.

Form: N/A.

OMB Control Number: 1205–0NEW.

Affected Public: Active Job Corps students.

Estimated Number of Respondents Annually: 89,776.

Frequency: Quarterly.

Total Estimated Annual Responses: 89,776.

Estimated Average Time per Response: 0.3 hours.

Estimated Total Annual Burden Hours: 26,933 hours.

Total Estimated Annual Other Cost Burden: $0.

Authority: 44 U.S.C. 3506(c)(2)(A).

John Pallasch,

Assistant Secretary for Employment and Training.

[FR Doc. 2019–17079 Filed 8–8–19; 8:45 am]

BILLING CODE 4510–FT–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Benefits Rights and Experience Report

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting the Employment and Training Administration (ETA) sponsored information collection request (ICR) titled, ''Benefits Rights and Experience Report'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before September 9, 2019.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* website at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201905-1205-006.* (This link will only become active on the day following publication of this notice) or by contacting Frederick Licari by telephone at 202–693–8073, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–ETA, Office of Management and Budget, Room 10235, 725 17th Street, NW, Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor–OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW,

Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Frederick Licari by telephone at 202–693–8073, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Benefits Rights and Experience Report information collection. The data in the ETA 218, Benefit Rights and Experience Report, includes numbers of individuals who were and were not monetarily eligible, those eligible for the maximum benefits, those eligible based on classification by potential duration categories, and those exhausting their full entitlement as classified by actual duration categories. This data is collected as part of the initial claim process. It is transmitted electronically to the National Office on a quarterly basis. This data is used by the National Office in solvency studies, cost estimating and modeling, and to assess State benefit formulas. If this data were not available, cost estimating and modeling would be less accurate. Social Security Act 303(a)(6*)* authorizes this information collection. *See* 42 U.S.C. 503(a)(6).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1205–0177.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on August 31, 2019. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on February 7, 2019.

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1205–0177. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including 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.

Agency: DOL–ETA.

Title of Collection: Benefits Rights and Experience Report.

OMB Control Number: 1205–0177.

Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Respondents: 53.

Total Estimated Number of Responses: 216.

Total Estimated Annual Time Burden: 108 hours.

Total Estimated Annual Other Costs Burden: $ 0.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: August 5, 2019.

Frederick Licari,

Departmental Clearance Officer.

[FR Doc. 2019–17085 Filed 8–8–19; 8:45 am]

BILLING CODE 4510–FW–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (19–043)]

Centennial Challenges Space Robotics Challenge Phase 2

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice.

SUMMARY: Phase 2 of the Space Robotics Challenge is open, and teams that wish to compete may now register. Centennial Challenges is a program of prize competitions to stimulate innovation in technologies of interest and value to NASA and the nation. Phase 2 of the Space Robotics Challenge is a prize competition with a $1,000,000 USD total prize purse available for development of software to enable long-term autonomous robotic surface mobility for a notional lunar In-Situ Resource Utilization (ISRU) mission. NASA is providing the prize purse, and the Manned Space Flight Education Foundation, Inc. (*i.e.,* Space Center Houston) will be conducting the Challenge on behalf of NASA.

DATES: Challenge registration for Phase 2 opens August 12, 2019, and will remain open until 5:00PM Central Time on December 20, 2019. No further requests for registration will be accepted after this date.

Other important dates:

January 15, 2020 Packet of Robot Information Delivered to Competitors
March 16, 2020 Qualifying Round opens
August 19, 2020 Qualification Round closes
November 9, 2020 Finalists Announced
December 7, 2020 Final Competition Begins
June 30, 2021 Competition Round Closes
September 2021 Winner(s) Announced

ADDRESSES: The Space Robotics Challenge is a virtual competition. The Challenge competitors will complete their development and practice rounds at their own labs. Final software solutions will be submitted to Space Center Houston for evaluation and testing.

FOR FURTHER INFORMATION CONTACT: To register for or get additional information regarding the Space Robotics Challenge, please visit: *www.spaceroboticschallenge.com.*

For general information on the NASA Centennial Challenges Program please visit: *http://www.nasa.gov/challenges.* General questions and comments regarding the program should be addressed to Monsi Roman, Centennial Challenges Program, NASA Marshall Space Flight Center, Huntsville, AL 35812. Email address: *hq-stmd-centennialchallenges@mail.nasa.gov.*

SUPPLEMENTARY INFORMATION:

Summary

Phase 2 of the Space Robotics Challenge seeks to foster the creation of new or advance existing autonomous capabilities of lunar surface robots. Future ISRU missions may occur on

surfaces such as Earth's moon and Mars, and will likely need to operate autonomously for long periods of time before, during, and after the presence of astronauts. Robots that can successfully perform ISRU tasks with little to no human intervention are valuable due to both the communication latencies and limited bandwidth between these destinations and Earth. Additionally, NASA has unique constraints for robotic systems in space compared to terrestrial applications, namely the radiation and thermal environments encountered, which affect the processing and sensing capabilities available for robotic systems. It is also recognized that many of the robotic capabilities needed for future exploration missions could translate into highly valuable functionality for terrestrial robotic applications, such as disaster relief, exploration of difficult and/or dangerous terrains, and industrial plant maintenance and servicing.

The challenge will consist of a qualification round and a competition round. Both rounds will require fully autonomous operations, such that competitors will not be able to interact with their virtual robotic teams during a challenge run. The qualification round will consist of three tasks, each to be completed individually, and the virtual robotic systems needed to complete these tasks will be provided to competitors. Successful completion of these tasks will provide confidence that competitors can attempt, or possibly complete, the competition round. The tasks will consist of autonomously locating resources in a lunar simulation world, extracting these resources, and navigating about the lunar simulation surface. The top 25 scoring teams will move on to the competition round. For the competition round, competitors will select their own robotic team from a compiled list of different robot archetypes, while meeting a specified mass constraint for the overall team. During this round, competitors' virtual robot teams will locate various resources within the lunar regolith, excavate and collect resources, transport them and deposit them into a processing plant. Constraints will be introduced randomly, including maintenance issues, degradation of systems and recharging needs. The top 10 scoring teams will win prizes.

I. Prize Amounts

The Space Robotics Challenge total prize purse is up to $1,000,000 USD (one million dollars) to be awarded across two (2) rounds of competition. The top 25 scoring competitors in the Qualification Round that meet or exceed a given threshold score, will be awarded prizes from a prize purse of $375,000 USD. Competitors will be able to win a maximum of $15,000 USD. Should a competitor not complete all required tasks, but still be in the Top 25 scoring competitors, a percentage of the $15,000 will be awarded based on the percentage of the trial that was completed. Only the top 25 scoring competitors will be invited to compete in the Competition Round.

The top ten (10) scoring competitors in the Competition Round that meet or exceed a given threshold will be awarded prizes from a purse of $625,000 USD.

First Place: $185,000 USD
Second Place: $125,000 USD
Third Place: $75,000 USD
Fourth Place: $50,000 USD
Fifth Place: $40,000 USD
Sixth through Tenth Place: $30,000 USD

II. Eligibility To Participate and Win Prize Money

To be eligible to win a prize, competitors must:

(1) Register and comply with all requirements in the Official Rules and Team Agreement;

(2) In the case of a private entity, be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, be a citizen or permanent resident of the United States; and

(3) Not be a U.S. Government entity or U.S. Government employee acting within the scope of their employment.

The eligibility requirements (including requirements for foreign participation) can be found on the official challenge site: *www.spaceroboticschallenge.com.*

III. Official Rules

The complete official rules for the Space Robotics Challenge can be found at: *www.spaceroboticschallenge.com.*

Cheryl Parker,

NASA Federal Register Liaison Officer.

[FR Doc. 2019–17061 Filed 8–8–19; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Proposed Collection; Comment Request; NCUA Call Report and Profile

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice and request for comment.

SUMMARY: The National Credit Union Administration (NCUA), as part of a continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the following revisions of a currently approved collection, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments should be received on or before October 8, 2019 to be assured consideration.

ADDRESSES: Interested persons are invited to submit written comments on the information collection to Dawn Wolfgang, National Credit Union Administration, 1775 Duke Street, Suite 6018, Alexandria, Virginia 22314; Fax No. 703–519–8579; or Email at *PRAComments@NCUA.gov.*

FOR FURTHER INFORMATION CONTACT: Address requests for additional information to the address above or telephone 703–548–2279.

SUPPLEMENTARY INFORMATION:

OMB Number: 3133–0004.

Title: NCUA Call Report.

Form: NCUA Form 5300.

Type of Review: Revision of a currently approved collection.

Abstract: Sections 106 and 202 of the Federal Credit Union Act require federally insured credit unions to make financial reports to the NCUA. Section 741.6 prescribes the method in which federally insured credit unions must submit this information to NCUA. NCUA Form 5300, Call Report, is used to file quarterly financial and statistical data and are reported through NCUA's online portal, Credit Unions Online.

The financial and statistical information is essential to NCUA in carrying out its responsibility for supervising federal credit unions. The information also enables NCUA to monitor all federally insured credit unions with National Credit Union Share Insurance Fund (NCUSIF) insured share accounts.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated No. of Respondents: 5,335.

Estimated No. of Responses per Respondent: 4.

Estimated Total Annual Responses: 21,340.

Estimated Burden Hours per Response: 4.

Estimated Total Annual Burden Hours: 85,360.

OMB Number: 3133–NEW.

Title: NCUA Profile.

Form: NCUA Form 4501A.

Type of Review: New collection.

Abstract: Sections 106 and 202 of the Federal Credit Union Act require federally insured credit unions to make

financial reports to the NCUA. Section 741.6 prescribes the method in which federally insured credit unions must submit this information to NCUA. NCUA Form 4501A, Credit Union Profile, is used to obtain non-financial data relevant to regulation and supervision such as the names of senior management and volunteer officials, and are reported through NCUA's online portal, Credit Unions Online.

The financial and statistical information is essential to NCUA in carrying out its responsibility for supervising federal credit unions. The information also enables NCUA to monitor all federally insured credit unions with National Credit Union Share Insurance Fund (NCUSIF) insured share accounts.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated No. of Respondents: 5,335.

Estimated No. of Responses per Respondent: 4.

Estimated Total Annual Responses: 21,340.

Estimated Burden Hours per Response: 2.

Estimated Total Annual Burden Hours: 42,480.

Reason for Change: Currently, the NCUA Call Report (Form 5300) and Profile (4501A) are cleared under OMB control number 3133–0004. At this time, NCUA plans to separate the two forms due to technology resources constraints that create different revision cycles. The Call Report will retain OMB control number 3133–0004 and NCUA will request a new control number for the Profile.

Call Report: Revisions are attributed to the issuance of accounting standards codifications (ASC) by the Financial Accounting Standards Board and other revisions needed to clarify the reporting for cash items. These revisions will not alter the estimated burden hours necessary to review the instructions and complete the filing. The amount of data elements removed compared to those added negates the difference in burden.

The burden hours reflect an adjustment to the number of respondents due to the decline in the number of federally insured credit unions, which has averaged approximately one percent per quarter. Specifically, the number of federally insured credit unions completing the Call Report dropped from 5,530 at March 31, 2018 to 5,335 at March 31, 2019. A decrease of 195 credit unions for a total reduction in burden hours of 47,360, partially due to the decline in credit unions (3,120 hours) and partially due to removal of the Profile burden (44,240 hours).

Request for Comments: Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of public record. The public is invited to submit comments concerning: (a) Whether the collection of information is necessary for the proper execution of the function of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (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 the information on the respondents, including the use of automated collection techniques or other forms of information technology.

By Gerard Poliquin, Secretary of the Board, the National Credit Union Administration, on August 5, 2019.

Dated: August 5, 2019.

Dawn D. Wolfgang,

NCUA PRA Clearance Officer.

[FR Doc. 2019–17028 Filed 8–8–19; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Institute of Museum and Library Services

Submission for OMB Review, Comment Request, Proposed Collection Requests: Public Library Survey FY 2019–FY2021

AGENCY: Institute of Museum and Library Services, National Foundation on the Arts and the Humanities.

ACTION: Submission for OMB Review, comment request.

SUMMARY: The Institute of Museum and Library Services announces the following information collection has been submitted to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. By this notice, IMLS is soliciting comments concerning the new three year approval of the IMLS administered Public Library Survey.

A copy of the proposed information collection request can be obtained by contacting the individual listed below in the **ADDRESSES** section of this notice.

DATES: Comments must be submitted to the office listed in the **FOR FURTHER INFORMATION CONTACT** section below on or before September 9, 2019.

OMB is particularly interested in comments that help the agency to:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including 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).

ADDRESSES: Comments should be sent to Office of Information and Regulatory Affairs, *Attn.:* OMB Desk Officer for Education, Office of Management and Budget, Room 10235, Washington, DC 20503, (202) 395–7316.

FOR FURTHER INFORMATION CONTACT: Dr. Sandra Webb, Director of Grant Policy and Management, Institute of Museum and Library Services, 955 L'Enfant Plaza North SW, Suite 4000, Washington, DC 20024–2135. Dr. Webb can be reached by Telephone: 202–653–4718 Fax: 202–653–4608, or by email at *swebb@imls.gov,* or by teletype (TTY/TDD) for persons with hearing difficulty at 202–653–4614.

SUPPLEMENTARY INFORMATION: The Institute of Museum and Library Services is the primary source of federal support for the nation's libraries and museums. We advance, support, and empower America's museums, libraries, and related organizations through grant making, research, and policy development. Our vision is a nation where museums and libraries work together to work together to transform the lives of individuals and communities. To learn more, visit *www.imls.gov.*

Current Actions: Pursuant to Public Law 107–279, this Public Libraries Survey collects annual descriptive data on the universe of public libraries in the

United States and the Outlying Areas. Information such as public service hours per year, circulation of library books, number of librarians, population of legal service area, expenditures for library collection, programs for children and young adults, staff salary data, and access to technology, etc., would be collected. The Public Libraries Survey has been conducted by the Institute of Museum and Library Services under the clearance number 3137–0074, which expires January 31, 2020. This action is to request a new three year approval.

Agency: Institute of Museum and Library Services.

Title: Public Libraries Survey, FY 2019–FY 2021.

OMB Number: 3137–0074.

Agency Number: 3137.

Affected Public: State and local governments, State library administrative agencies, and public libraries.

Number of Respondents: 56.

Frequency: Annually.

Burden Hours per Respondent: 84.9.

Total Burden Hours: 4,585.

Total Annualized Capital/Startup Costs: n/a.

Total Annual Costs: $130,168.

Total Annual Federal Costs: $925,193.00.

Dated: August 5, 2019.

Kim Miller,

Grants Management Specialist, Institute of Museum and Library Services.

[FR Doc. 2019–17036 Filed 8–8–19; 8:45 am]

BILLING CODE 7036–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Humanities

Meeting of Humanities Panel

AGENCY: National Endowment for the Humanities, National Foundation on the Arts and the Humanities.

ACTION: Notice of meeting.

SUMMARY: The National Endowment for the Humanities will hold sixteen meetings of the Humanities Panel, a federal advisory committee, during August and September 2019. The purpose of the meetings is for panel review, discussion, evaluation, and recommendation of applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965.

DATES: See **SUPPLEMENTARY INFORMATION** for meeting dates. The meetings will open at 8:30 a.m. and will adjourn by 5:00 p.m. on the dates specified below.

ADDRESSES: The meetings will be held at Constitution Center, 400 7th Street SW, Washington, DC 20506, unless otherwise indicated.

FOR FURTHER INFORMATION CONTACT: Elizabeth Voyatzis, Committee Management Officer, 400 7th Street SW, Room 4060, Washington, DC 20506; (202) 606–8322; *evoyatzis@neh.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App.), notice is hereby given of the following meetings:

1. Date: August 26, 2019

This meeting will discuss applications for the American History and Civics Education: National Convenings program, submitted to the Division of Education Programs.

2. Date: September 4, 2019

This meeting—the first of two on this date—will discuss applications for the Humanities Initiatives at Community Colleges grant program, submitted to the Division of Education Programs.

3. Date: September 4, 2019

This meeting—the second of two on this date—will discuss applications for the Humanities Initiatives at Community Colleges grant program, submitted to the Division of Education Programs.

4. Date: September 5, 2019

This meeting will discuss applications on the topics of Education and Public Programs, for the Digital Humanities Advancement Grants program, submitted to the Office of Digital Humanities.

5. Date: September 5, 2019

This meeting will discuss applications for the Humanities Initiatives at Community Colleges grant program, submitted to the Division of Education Programs.

6. Date: September 5, 2019

This meeting will discuss applications on the topics of Global Culture and Gaming, for the Digital Projects for the Public grant program, submitted to the Division of Public Programs.

7. Date: September 6, 2019

This meeting will discuss applications on the topics of U.S. History and Culture, for the Digital Projects for the Public grant program, submitted to the Division of Public Programs.

8. Date: September 9, 2019

This meeting will discuss applications on the topic of Arts and Culture, for the Digital Projects for the Public grant program, submitted to the Division of Public Programs.

9. Date: September 9, 2019

This meeting will discuss applications on the topic of Arts and Media Studies, for the Digital Humanities Advancement Grants program, submitted to the Office of Digital Humanities.

10. Date: September 10, 2019

This meeting will discuss applications on the topics of Languages and Linguistics, for the Digital Humanities Advancement Grants program, submitted to the Office of Digital Humanities.

11. Date: September 10, 2019

This meeting will discuss applications on the topic of Democracy and the Arts, for the Digital Projects for the Public grant program, submitted to the Division of Public Programs.

12. Date: September 11, 2019

This meeting will discuss applications on the topics of U.S. History and Culture, for the Digital Projects for the Public grant program, submitted to the Division of Public Programs.

13. Date: September 12, 2019

This meeting will discuss applications on the topic of U.S. Places, for the Digital Projects for the Public grant program, submitted to the Division of Public Programs.

14. Date: September 12, 2019

This meeting will discuss applications on the topics of Geospatial, Visualization, and Modeling, for the Digital Humanities Advancement Grants program, submitted to the Office of Digital Humanities.

15. Date: September 16, 2019

This meeting will discuss applications on the topic of Scholarly Communication, for the Digital Humanities Advancement Grants program, submitted to the Office of Digital Humanities.

16. Date: September 17, 2019

This meeting will discuss applications on the topic of Digital Collections, for the Digital Humanities Advancement Grants program, submitted to the Office of Digital Humanities.

Because these meetings will include review of personal and/or proprietary financial and commercial information given in confidence to the agency by grant applicants, the meetings will be closed to the public pursuant to sections 552b(c)(4) and 552b(c)(6) of Title 5, U.S.C., as amended. I have made this determination pursuant to the authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee Meetings dated April 15, 2016.

Dated: August 5, 2019.

Caitlin Cater,

Attorney-Advisor, National Endowment for the Humanities.

[FR Doc. 2019–17037 Filed 8–8–19; 8:45 am]

BILLING CODE 7536–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–346; NRC–2019–0028]

FirstEnergy Nuclear Operating Company; Davis-Besse Nuclear Power Station, Unit No. 1

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment application; withdrawal by applicant.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has granted the request of FirstEnergy Solutions Corp. (FES) to withdraw the FirstEnergy Nuclear Operating Company (FENOC, the licensee) application dated October 22, 2018, for a proposed amendment to Renewed Facility Operating License No. NPF–3. The proposed amendment would have made changes to the Davis-Besse Nuclear Power Station (DBNPS), Unit No. 1, technical specifications (TS) to permit certain changes in plant operations when the plant is permanently defueled.

DATES: The withdrawal of the proposed amendment takes effect on August 9, 2019.

ADDRESSES: Please refer to Docket ID NRC–2019–0028 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov/* and search for Docket ID NRC–2019–0028. Address questions about NRC docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Blake A. Purnell, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–1380, email: *Blake.Purnell@nrc.gov.*

SUPPLEMENTARY INFORMATION: The NRC has granted the request of FES to withdraw the FENOC application dated October 22, 2018 (ADAMS Accession No. ML18295A289), as supplemented by letter dated February 27, 2019 (ADAMS Accession No. ML19058A328), for a proposed amendment to Renewed Facility Operating License No. NPF–3 for the DBNPS located in Ottawa County, Ohio. FES is the parent company of FirstEnergy Nuclear Generation, LLC, which owns DBNPS. The proposed amendment would have changed the DBNPS TS to permit changes in plant operations when the plant is permanently defueled. Specifically, the licensee proposed to revise the TS to support the implementation of the certified fuel handler and non-certified operator positions. In addition, certain organization, staffing, and training requirements in the TS would have been revised. The proposed amendment would have also made other administrative changes.

The Commission previously issued a proposed finding that the amendment involves no significant hazards consideration published in the **Federal Register** on January 30, 2019 (84 FR 494). However, by letter dated July 26, 2019 (ADAMS Accession No. ML19207A097), FES requested to withdraw the proposed amendment.

Dated at Rockville, Maryland, this 6th day of August, 2019.

For the Nuclear Regulatory Commission.

Blake A. Purnell,

Project Manager, Plant Licensing Branch III, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2019–17067 Filed 8–8–19; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–346; NRC–2019–0065]

FirstEnergy Nuclear Operating Company; Davis-Besse Nuclear Power Station, Unit No. 1

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment application; withdrawal by applicant.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has granted the request of FirstEnergy Solutions Corp. (FES) to withdraw the FirstEnergy Nuclear Operating Company (FENOC, the licensee) application dated February 5, 2019, for a proposed amendment to Renewed Facility Operating License No. NPF–3. The proposed amendment would have revised the Davis-Besse Nuclear Power Station (DBNPS), Unit No. 1, emergency plan following the permanent cessation of power operations to reflect the post-shutdown and permanently defueled condition.

DATES: The withdrawal of the proposed amendment takes effect on August 9, 2019.

ADDRESSES: Please refer to Docket ID NRC–2019–0065 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov/* and search for Docket ID NRC–2019–0065. Address questions about NRC docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–

415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Blake A. Purnell, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–1380, email: *Blake.Purnell@nrc.gov.*

SUPPLEMENTARY INFORMATION: The NRC has granted the request of FES to withdraw the FENOC application dated February 5, 2019 (ADAMS Accession No. ML19036A524), as supplemented by letters dated April 10 and July 8, 2019 (ADAMS Accession Nos. ML19100A000 and ML19189A109, respectively), for a proposed amendment to Renewed Facility Operating License No. NPF–3 for the DBNPS located in Ottawa County, Ohio. FES is the parent company of FirstEnergy Nuclear Generation, LLC, which owns DBNPS. The proposed amendment would have revised the DBNPS emergency plan following the permanent cessation of power operations to reflect the post-shutdown and permanently defueled condition. The proposed changes included revision of the emergency response organization staffing and editorial changes.

The Commission previously issued a proposed finding that the amendment involves no significant hazards consideration published in the **Federal Register** on March 12, 2019 (84 FR 8910). However, by letter dated July 26, 2019 (ADAMS Accession No. ML19207A097), FES requested to withdraw the proposed amendment.

Dated at Rockville, Maryland, this 6th day of August, 2019.

For the Nuclear Regulatory Commission.

Blake A. Purnell,

Project Manager, Plant Licensing Branch III, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2019–17069 Filed 8–8–19; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2019–0080]

Information Collection: Tribal Participation in the Advance Notification Program

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on this proposed collection of information. The information collection is entitled, ''Tribal Participation in the Advance Notification Program.''

DATES: Submit comments by October 8, 2019. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov/* and search for Docket ID NRC–2019–0080. Address questions about NRC docket IDs to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *Mail comments to:* David Cullison, Office of the Chief Information Officer, Mail Stop: T–6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2019–0080 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov/* and search for Docket ID NRC–2019–0080. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2019–0080 on this website.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The supporting statement is available in ADAMS under Accession No. ML19093B836.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

• *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

Please include Docket ID NRC–2019–0080 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov/* as well as enter the comment submissions into ADAMS, and the NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* Tribal Participation in the Advance Notification Program.

2. *OMB approval number:* An OMB control number has not yet been assigned to this proposed information collection.

3. *Type of submission:* New.

4. *The form number, if applicable:* Not Applicable.

5. *How often the collection is required or requested:* Information would be requested (1) every five years, (2) after an Indian Tribe achieves Federal recognition, (3) when a transportation route is approved that is within an Indian Tribe's reservation or that crosses a reservation boundary, and (4) when there are changes. Information is requested from those Indian Tribes seeking to receive advance notifications. Some information is requested one time.

6. *Who will be required or asked to respond:* Federally recognized Indian Tribes. Only those federally recognized Indian Tribes with reservations and either receiving or seeking to receive the advance notifications would be asked to respond to the specific information request.

7. *The estimated number of annual responses:* 22 (7 reporting responses + 15 recordkeepers).

8. *The estimated number of annual respondents:* 15.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 36 (26 hours reporting + 10 hours recordkeeping).

10. *Abstract:* In order to receive notifications when certain shipments of nuclear waste or shipments of irradiated reactor fuel within or across the boundary of an Indian Tribe's reservation, Indian Tribes will submit certifications that Tribal official or their designee(s) has (or have) taken training on the handling of safeguards information (SGI) and the Indian Tribe has the necessary protection measures in place and the Indian Tribe will protect the SGI. If the Tribal official is designating another person to receive the advance notifications, information on the designation will be provided. The Indian Tribe will also provide the contact information for the Tribal official or the Tribal official's designee(s). The Indian Tribe will also provide an affirmation of the boundaries of the Indian Tribe's reservation or the necessary corrections to a map provided by the NRC. The NRC will also collect the name and contact information for the Indian Tribe's emergency response contact(s). NRC licensees will use the information to comply with the NRC's regulations that require them to provide advance notice of certain shipments of radioactive material to participating Indian Tribes.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the estimate of the burden of the information collection accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated at Rockville, Maryland, this 5th day of August, 2019.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2019–17038 Filed 8–8–19; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–346; NRC–2019–0087]

FirstEnergy Nuclear Operating Company; Davis-Besse Nuclear Power Station, Unit No. 1

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment application; withdrawal by applicant.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has granted the request of FirstEnergy Solutions Corp. (FES) to withdraw the FirstEnergy Nuclear Operating Company (FENOC, the licensee) application dated February 5, 2019, for a proposed amendment to Renewed Facility Operating License No. NPF–3. The proposed amendment would have made changes to the Davis-Besse Nuclear Power Station (DBNPS), Unit No. 1, license and technical specifications (TS) to reflect the permanent cessation of reactor operation and permanent defueling of the reactor.

DATES: The withdrawal of the proposed amendment takes effect on August 9, 2019.

ADDRESSES: Please refer to Docket ID NRC–2019–0087 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov/* and search for Docket ID NRC–2019–0087. Address questions about NRC docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Blake A. Purnell, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–1380, email: *Blake.Purnell@nrc.gov.*

SUPPLEMENTARY INFORMATION: The NRC has granted the request of FES to withdraw the FENOC application dated February 5, 2019 (ADAMS Accession No. ML19036A523), as supplemented by letters dated May 16 and June 26, 2019 (ADAMS Accession Nos. ML19136A240 and ML19177A289, respectively), for a proposed amendment to Renewed Facility Operating License No. NPF–3 for the DBNPS located in Ottawa County, Ohio. FES is the parent company of FirstEnergy Nuclear Generation, LLC, which owns DBNPS. The proposed amendment would have revised the DBNPS renewed facility operating license and TS following the permanent cessation of power operations to reflect the post-shutdown and permanently

defueled condition. The proposed amendment would have eliminated TS requirements and license conditions which would not have been applicable once DBNPS ceased power operations and could no longer place fuel in the reactor vessel. The proposed amendment would have also eliminated obsolete license conditions. In addition, the proposed amendment would have revised several license conditions and TS requirements, including limiting conditions for operation, usage rules, definitions, surveillance requirements, and administrative controls. The licensing bases for DBNPS, including the design bases accident analysis, would have also been revised.

The Commission previously issued a proposed finding that the amendment involves no significant hazards consideration published in the **Federal Register** on April 9, 2019 (84 FR 14149). However, by letter dated July 26, 2019 (ADAMS Accession No. ML19207A097), FES requested to withdraw the proposed amendment.

Dated at Rockville, Maryland, this 6th day of August, 2019.

For the Nuclear Regulatory Commission.

Blake A. Purnell,

Project Manager, Plant Licensing Branch III, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2019–17070 Filed 8–8–19; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2019–0154]

Release of Patients Administered Radioactive Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft regulatory guide; extension of comment period.

SUMMARY: On July 29, 2019, the U.S. Nuclear Regulatory Commission (NRC) requested comments on draft regulatory guide (DG), DG–8057, ''Release of Patients Administered Radioactive Material.'' The public comment period was originally scheduled to close on August 26, 2019. The NRC is extending the public comment period to allow more time for members of the public to submit their comments.

DATES: The due date of comments requested in the document published on July 29, 2019 (84 FR 36127) is extended. Comments should be filed no later than September 26, 2019. Comments received after this date will be considered, if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2019–0154. Address questions about NRC dockets IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Vered Shaffer, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 630–829–9862, email: *Vered.Shaffer@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2019–0154 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2019–0154
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The DG–8057 is available in ADAMS under Accession No. ML19108A463.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2019–0154, in your comment submission. The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Discussion

On July 29, 2019, the NRC published a document in the **Federal Register** (84 FR 36127) requesting comments on DG–8057, ''Release of Patients Administered Radioactive Material.'' This draft guide, Revision 1, provides licensees with more detailed instructions to provide to patients before and after they have been administered radioactive material than was in Revision 0. In addition, the guide includes a new section on ''Death of a Patient Following Radiopharmaceutical or Implants Administrations,'' as well as requirements for recordkeeping. Also, Table 3, ''Dosages of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients who are Breastfeeding an Infant or Child,'' has been revised to provide information for the recommended duration of interruption of breastfeeding to ensure that the dose to an infant or child meets the NRC's regulatory requirements. The public comment period was originally scheduled to close on August 26, 2019. The NRC staff has decided to extend the public comment period on this document until September 26, 2019, to allow more time for members of the public to submit their comments.

Dated at Rockville, Maryland, this 6th day of August, 2019.

For the Nuclear Regulatory Commission.

Thomas H. Boyce,

Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2019–17060 Filed 8–8–19; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2019–180 and CP2019–202]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* August 26, 2019.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2019–180 and CP2019–202; *Filing Title:* Request of the United States Postal Service to Add Inbound Competitive Non-Published Rate Agreements with Foreign Postal Operators to the Competitive Products List and Notice of Filing Inbound Competitive NPR–FPO 1 Model Contract and Application for Non-Public Treatment of Materials Filed Under Seal; *Filing Acceptance Date:* August 2, 2019; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Natalie R. Ward; *Comments Due:* August 26, 2019.

This Notice will be published in the **Federal Register**.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2019–17032 Filed 8–8–19; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail and First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 9, 2019.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 6, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & First-Class Package Service Contract 111 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–183, CP2019–205.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–17075 Filed 8–8–19; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 9, 2019.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 6, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & First-Class Package Service Contract 113 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–185, CP2019–207.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–17077 Filed 8–8–19; 8:45 am]

BILLING CODE 7710–12–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

POSTAL SERVICE

Product Change—Priority Mail and First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 9, 2019.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 6, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & First-Class Package Service Contract 112 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–184, CP2019–206.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–17076 Filed 8–8–19; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 9, 2019.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 6, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 545 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–181, CP2019–203.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–17073 Filed 8–8–19; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 9, 2019.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 6, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 546 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–182, CP2019–204.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–17074 Filed 8–8–19; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86567; File No. SR–CboeEDGA–2019–012]

Self-Regulatory Organizations; Cboe EDGA Exchange, Inc.; Notice of Designation of Longer Period for Commission Action on a Proposed Rule Change To Introduce a Liquidity Provider Protection on EDGA

August 5, 2019.

On June 7, 2019, Cboe EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposal to introduce a delay mechanism on EDGA. The proposed rule change was published for comment in the **Federal Register** on June 26, 2019.[3] The Commission has received fourteen comments on the proposed rule change.[4]

Section 19(b)(2) of the Act [5] provides that, within 45 days of the publication of the notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is August 10, 2019.

The Commission is extending the 45-day time period for Commission action on the proposed rule change. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, pursuant to Section 19(b)(2) of the Act,[6] the Commission designates September 24, 2019 as the date by which the Commission shall either approve, disapprove, or institute proceedings to determine whether to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 86168 (June 20, 2019), 84 FR 30282.

[4] *See* Letters from R.T. Leuchtkafer, dated July 12, 2019; Steve Crutchfield, Head of Market Structure, CTC Trading Group, LLC, dated July 15, 2019; Tyler Gellasch, Executive Director, Healthy Markets, dated July 16, 2019; Larry Tabb, Founder and Research Chairman, TABB Group, dated July 16, 2019; Stephen John Berger, Managing Director, Global Head of Government and Regulatory Policy, Citadel Securities, dated July 16, 2019; Mehmet Kinak, Vice President & Global Head of Systematic Trading & Market Structure, and Jonathan D. Siegel, Vice President & Senior Legal Counsel (Legislative & Regulatory Affairs), T. Rowe Price, dated July 16, 2019; Adam Nunes, Head of Business Development, Hudson River Trading LLC, dated July 16, 2019; Joanna Mallers, Secretary, FIA Principal Traders Group, dated July 16, 2019; Ray Ross, Chief Technology Officer, Clearpool, dated July 16, 2019; Eric Swanson, CEO, XTX Markets LLC (Americas), dated July 16, 2019; John Thornton, Co-Chair, Hal S. Scott, President, and R. Glenn Hubbard, Co-Chair, Committee on Capital Markets Regulation, dated July 16, 2019; Kirsten Wegner, Chief Executive Officer, Modern Markets Initiative, dated July 17, 2019; Theodore R. Lazo, Managing Director and Associate General Counsel, SIFMA, dated July 18, 2019; Eric Swanson, CEO, XTX Markets LLC (Americas), dated July 31, 2019, available at *https://www.sec.gov/comments/sr-cboeedga-2019-012/srcboeedga2019012.htm.*

[5] 15 U.S.C. 78s(b)(2).

[6] 15 U.S.C. 78s(b)(2)(A)(ii)(I).

disapprove, the proposed rule change (File No. SR–CboeEDGA–2019–012).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–17046 Filed 8–8–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86576; File No. SR–LCH SA–2019–005]

Self-Regulatory Organizations; LCH SA; Notice of Filing of Proposed Rule Change Relating to Introduction of Clearing of the New Markit iTraxx Subordinated Financials Index CDS and the Related Single Name CDS Constituents and Enhancements to Wrong Way Risk Margin

August 6, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder[2] notice is hereby given that on August 2, 2019, Banque Centrale de Compensation, which conducts business under the name LCH SA (''LCH SA''), filed with the Securities and Exchange Commission (''Commission'') the proposed rule change described in Items I, II and III below, which Items have been prepared primarily by LCH SA. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

Banque Centrale de Compensation, which conducts business under the name LCH SA (''LCH SA''), is proposing to amend its (i) Reference Guide: CDSClear Margin Framework and (ii) CDSClear Default Fund Methodology (together the ''CDSClear Risk Methodology'') and (iii) CDS Clearing Supplement (''Supplement'') and (iv) CDS Clearing Procedures (''Procedures'') to incorporate new terms and to make conforming, clarifying and changes [sic] to allow clearing of the new Markit iTraxx Subordinated Financials Index CDS and the related single name CDS constituents.

LCH SA is also amending its CDSClear Margin Framework to incorporate changes to the Wrong Way Risk margin in order to address some recommendations in respect of the risk model validation.

The text of the proposed rule change has been annexed as Exhibit 5.[3]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, LCH SA 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. LCH SA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of these statements.

A. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

LCH SA is proposing to introduce clearing of the Markit iTraxx Subordinated Financials Index CDS and the related single name CDS constituents (''SubFins'') which is the natural next step following the recent changes in financial entities' issuance patterns that are being rolled out in the wider industry.

In August 2016, IHSMarkit initiated the Markit iTraxx Europe rule review which prescribes how bank entities are included in the Markit iTraxx Europe Indices. At the time, the iTraxx Europe Index Advisory Committee identified that three differing regulatory approaches to TLAC/MREL regulations (Total Loss Absorbing Capacity/ Minimum Requirements and Eligible Liabilities) eligible debt were driving new bank debt issuance patterns:

- Structural Subordination
  - Operating Company versus Holding Company (referred to as OpCoHoldCo)
- Contractual Subordination
  - Senior Non-Preferred Tier 3 Bonds, adopted by Danish, French and Spanish banks, (Seniority tier is SNRLAC: Senior Loss Absorbing Capacity)
- Statutory Subordination
  - All senior unsecured debt made eligible, adopted by German banks

Structural subordination was introduced in September 2017 and Contractual subordination in March 2018.

As a result of these different approaches, LCH SA now manages different levels of debt seniorities in its product scope and risk framework.

The proposed change will naturally extend the product scope eligible for clearing by completing the set of seniority with subordinated debt for financial entities.

For the purpose of introducing clearing of SubFins, LCH SA proposes to modify its CDS Clearing Supplement and Procedures to include the relevant language to allow the clearing of the SubFins.

LCH SA is also taking this opportunity to introduce a few changes to the Wrong Way Risk (''WWR'') margin in order to address some of the open model validation recommendations meant to improve the stability of the WWR margin and to include positions on the iTraxx Main index in the scope of products subject to the WWR margin.

Finally, a clarification to the Default Fund Additional Margin (''DFAM''), independent from the SubFins initiative, is also added to the CDSClear Default Fund Methodology to reflect an adjustment requested by LCH SA's Risk Department for any clearing service in order to cap the DFAM to the Stress Test Loss Over Additional Margin (''STLOAM'').

(1) CDSClear Risk Methodology

The introduction of CDS with subordinated debt as an underlier is akin to introducing Senior Non Preferred debt, therefore the same margins need to be adapted, namely spread margin, wrong way risk, liquidity charge and jump-to-default risk margins (Short Charge and Self-Referencing Margin).

The Senior Non Preferred CDS differ from Subordinated financial CDS with respect to the availability of the historical market data and the recovery rate which for Subordinated debt is conventionally 20% (versus 40% for Senior debt).

The spread margin will use the historical data available for SubFins, and consider Subordinated and Senior debt as different financial instruments with regards to portfolio margining.[4]

Similarly, the WWR margin is extended to cover SubFins in addition to Senior CDS, as if they were different names from an offset perspective, and with shocks defined specifically for SubFins calibrated from the historical data available.

The Liquidity Charge will consider Markit iTraxx Subordinated Financials index to be a new hedging instrument,

[7] 17 CFR 200.30–3(a)(31).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] All capitalized terms not defined herein have the same definition as the Rule Book, Supplement or Procedures, as applicable.

[4] See Article 27 of Commission Delegated Regulation (EU) No 153/2013).

thus extending the existing framework. Then, similarly to the change introduced for Senior Non Preferred CDS, Senior and Subordinated financial CDS will be considered jointly from a concentration perspective. This leads to the need to define a common concentration threshold, linearly interpolated between the thresholds that would be determined by our existing framework for each seniority.

The Short Charge margin is modified in two ways:

(i) The recovery rates used in the calculation of exposures are shocked to capture any adverse move, hence increasing the exposure.

(ii) The number of expected credit events in the 5 days following the default of a member has been decreased from 2 to 1, meaning we only retain the top exposure and no longer consider one of the riskiest entities.

Considering shocks in the recovery rates is necessary to ensure the difference between Senior and Subordinated CDS recovery rates is covered. Doing this without modifying the number of defaults would have led to overly conservative margins, with jump-to-default risk far outweighing the other risks. The second credit event has therefore been reclassified to being under the ''extreme market conditions'' category as opposed to the ''normal market conditions'' category.

In addition to moving from covering the default of two entities to one a floor to the short charge will be introduced. This floor is calculated as the 99.7% quantile of a loss distribution based on a single factor model. In other words, having calculated the exposure the portfolio has to each underlying reference entity, the probability of each combination of defaults is calculated (up to all entities in the portfolio defaulting at the same time) to define the maximum amount that could be lost with a 99.7% confidence due to default events. The greater of this calculated amount and the top exposure with a shifted recovery rate will be retained as being the Short Charge margin.

Consequently, the Stressed Short Charge has been revised with a similar calculation for exposures, with a recovery of 10% for senior debt and 0% for subordinated debt. The global short charge will now consider the top exposure plus the average of the riskiest entities (for an improved stability), while the financial short charge will consider the top two exposures on financial entities. For CDX.HY names specifically, the sum of the top two exposures and the average across the ten riskiest entities will be retained. The Stressed Short Charge would then be the max across those three components.

Separately, the model validation recommendations will lead to two changes to the WWR margin:

(i) The calculation will be done as if the WWR margin was calculated inside the expected shortfall, leading to (a) the starting spread for the WWR P&L reflecting the spread level simulated in the scenarios selected as part of the spread margin and (b) the cap on the offset formula considering the maximum between the portfolio calculation and 20% of the sum of the instrument level calculations will now be applied to the sum of the spread margin and WWR margin (as opposed to the spread margin alone).

(ii) The iTraxx Main index will now be included in the WWR margin calculation, with a dedicated shock defined, separately from the iTraxx Senior Financials and iTraxx Subordinated Financials indices.

Finally, the DFAM is updated and capped to the STLOAM to ensure that the sum of all resources called from a Clearing Member do not exceed the stress tested loss measured for that member. LCH SA's risk framework demands that the stress risk of a given Clearing Member above and beyond a certain threshold (defined as a percentage of the size of the default fund and dependent on the internal credit score (ICS) of such member) be demutualised gradually through the DFAM.

On the other hand, as a CCP, LCH SA doesn't require its Clearing Members to deposit a total amount of resources for a given clearing service higher than their worst stress loss for that service. That is why the DFAM needs to be capped at the STLOAM as it is now defined in the CDSClear Default Fund Methodology.

(2) CDS Clearing Supplement

The Supplement will be amended in order to include the relevant language to allow the clearing of the new Markit iTraxx Subordinated Financials Index CDS and related single name CDS.

In Part A of the Supplement, only Section 8.1. 'Creation of Matched Pairs' will be modified to correct inaccurate references to the CCM Client account structure in the current version of the Supplement. This change is not related to the SubFins initiative.

In Part B of the Supplement, the various references to 'Restructuring Credit Event' will be changed to 'M(M)R Restructuring' or new references to 'M(M)R Restructuring' will be created. Indeed, these provisions apply to transactions for which either 'Mod R' or 'Mod Mod R' is applicable. This change is required as clearing SubFins will introduce transactions for which Restructuring is an applicable Credit Event but where neither 'Mod R' nor 'Mod Mod R' are applicable. This is usually referred to as ''Old R'' (these terms are, for example, applicable to transactions under the Standard Subordinated European Insurance Corporate Transaction Type).

Such change will be reflected in Section 1.2. for the term 'CEN Triggering Period', 'Compression Cut-off Date', 'DC Restructuring Announcement Date', 'DTCC Notice Facility', 'First Novation Date', 'NEMO Triggering Period', 'Novation Cut-off Date', 'Restructuring Matched Pair', 'Spin-off Single Name Cleared Transaction', and also in Section 2.4 'Amendments to 2014 ISDA Credit Derivatives Definitions', Section 4.1 ''Determination of Credit Events and Successions Events', Section 4.3 'Novation and Compression following Credit Events', Section 4.4. 'Re-couponing of Restructuring Cleared Transactions', Section 5.1. 'Creation and Notification of Restructuring Matched Pairs', Section 5.2 'Creation of Restructuring Cleared Transactions', Section 5.3 'Triggering of Restructuring Cleared Transaction', Section 5.5 'Reversal of DC Credit Event Announcements', Section 7.4 'Notification of DTCC Failure and Resolution', Section 7.6 'Clearing Member Communications Failure Event, Section 8.1 'Creation of Matched Pairs', Section 9.1 'Occurrence of Clearing Member Self Referencing Transaction', Section 9.2 'Occurrence of Client Self Referencing Transactions' and Sections 4.4 'Communications Failure Event'; 5 'Determination of Credit Events and Succession Events' and 8.2 'Notification of Self Referencing Transactions' of the 'Appendix XIII: CCM Client Transaction requirements'.

There is also currently a number of provisions which are stated to apply to all Cleared Transactions which reference a Reference Entity. Clearing SubFins will introduce transactions which have the same underlying Reference Entity, but which have different seniorities (*e.g.* Senior Transactions and Subordinated Transactions) and in certain cases different Transactions Types. The treatment of transactions in case of credit event or succession event with respect to the relevant Reference Entity may vary depending upon these terms, as it is possible for certain events only to apply to certain Transaction Types, or only to a certain seniority. Therefore, the current references to Reference Entity will no longer be sufficiently

granular. As a result, we will add wording (predominantly in the relevant defined terms) which will enable a different treatment depending upon the Transaction Type and/or Reference Obligation. It is to be noted that the Reference Obligation is used to determine the seniority of a transaction.

Accordingly, in Section 1.2., the term 'Affected Cleared Transaction' will be amended in order to take into account the case where credit events or succession events apply to a Cleared Transaction (or, in the case of an Index Cleared Transaction, there [sic] relevant portion of such transaction defined as a Component Transaction) based on the Reference Entity but also on the applicable Transaction Type and/or Reference Obligation.

In addition, the term 'Component Transaction' will be created as it is currently mentioned in different Sections of the Supplement. The terms 'Index Cleared Transaction', 'Index CCM Client Transaction', and 'Spin-off Single Name Cleared Transaction' will be modified accordingly.

The terms 'First Novation Date', 'Novation Cut-off Date', and 'Spin-off Single Name Cleared Transaction' will be amended to provide for the correct treatment of transactions based on the combination of the Reference Entity, Transaction Type and Reference Obligation, and not only in respect of a Reference Entity.

Section 2.3. 'Single Name Cleared Transaction Confirmation' will be modified in order to take into account the fact that the form of confirmation for use with the Physical Settlement Matrix that incorporates the 2014 ISDA Credit Derivatives Definitions only requires the election with respect to Restructuring to be included for the North American Corporate and the Standard North American Corporate Transaction Types, and that it be specified as ''Not Applicable''. The proposed changes will simplify the wording and also enable the correct treatment of new Transaction Types introduced by the clearing of SubFins initiative.

Section 2.5. 'Physical Settlement Matrix Updates' will be modified to ensure the assessment of fungibility between terms of a Revised Matrix and an Existing Matrix is conducted for the relevant combination of Reference Entity, Transaction Type and Reference Obligation, and no longer only in respect of a Reference Entity.

In addition, for clarification/consistency purposes, in Section 1.2. the term ''Relevant Physical Settlement Matrix'' has been added, with a reference to Section 4.3 of the Procedures.

Furthermore, in line with the changes proposed under Part A of the Supplement, Section 8.1 'Creation of Matched Pairs' will be modified to correct inaccurate references to the CCM Client account structure in the current version of the Supplement. This change is not related to the SubFins initiative.

In Part C of the Supplement, the term 'M(M)R Restructuring Credit Event' will be changed to 'M(M)R Restructuring' in order to align with the wording mentioned in Part B of the Supplement and with the 2014 ISDA Credit Derivatives Definitions.

Accordingly, in Section 1.2 the term 'CEN Triggering Period', 'Compression Cut-off Date', 'DC Restructuring Announcement Date', 'First Novation Date', 'NEMO Triggering Period', 'Novation Cut-off Date', 'SRMP Triggerable Amount' and Section '2.3 'Amendments to 2014 ISDA Credit Derivatives Definitions', Section 4.1 'Determination of Credit Events and Succession Events', Section 4.2 'M(M)R Restructuring Credit Event Timeline', Section 5.1 'Creation and Notification of Swaption Restructuring Matched Pairs', Section 5.3 'Triggering of Swaption Restructuring Cleared Transactions, Section 5.8 'Effect of Credit Event Notices and Notices to Exercise Movement Option', Section 5.9 'Reversal of DC Credit Event Announcements', Section 5.11 'Expiry of CEN Triggering Period', Section 6.1 'Creation and Notification of Exercise Matched Pairs', Section 7.1 'Creation of Index Cleared Transactions', Section 7.2 'Creation of Initial Single Name Cleared Transactions for Settlement purposes in respect of Credit Events other than M(M)R Restructuring', Section 7.3 'Creation of Restructuring Cleared Transactions for Triggering and/or Settlement purposes', Section 7.4 'Creation of Initial Single Name Cleared Transactions in respect of untriggered M(M)R Restructuring Credit Events', Appendix III 'Form of Credit Event Notice' and Section 8.2 'Creation of Restructuring Single Name Transaction' of Appendix VIII 'CCM Client Transaction Requirements', will be modified.

Further, as mentioned *supra,* additional granularity is required to provide for appropriate treatment in case of a credit or succession event with respect to a Reference Entity, as such treatment will also be dependent upon the applicable Transaction Type and seniority. As a result, we will add wording (predominantly in the relevant defined terms) which will enable a different treatment depending upon the Transaction Type and/or seniority of a transaction. Accordingly, Section 4.2 'M(M)R Restructuring Credit Event Timeline' will be modified in order to take into account the case where a M(M)R Restructuring is applicable to a combination of Reference Entity, Transaction Type and Reference Obligation, and not only in respect of a Reference Entity.

Furthermore, the term 'Component Transaction' will be created for consistency purposes, as it is currently mentioned in different Sections of the Supplement and will be created in Part B of the Supplement. The terms 'First Novation Date', 'Novation Cut-off Date' and Section 4.2 'M(M)R Restructuring Credit Event Timeline, Section 5.1 'Creation and Notification of Swaption Restructuring Matched Pairs', Section 7.2 'Creation of Initial Single Name Cleared Transactions for Settlement purposes in respect of Credit Events other than M(M)R Restructuring', Section 7.3 'Creation of Restructuring Cleared Transactions for Triggering and/or Settlement purposes' and Section 7.4 'Creation of Initial Single Name Cleared Transactions in respect of untriggered M(M)R Restructuring Credit Events' will be modified accordingly.

In addition, the cross-references mentioned in Section 1.2 'Swaption Clearing Member Notice', 'Swaption Clearing Member Notice Deadline', Section 5.1 'Creation and Notification of Swaption Restructuring Matched Pairs', Section 5.3 'Triggering of Swaption Restructuring Cleared Transactions', Section 5.9 (e) 'Reversal of DC Credit Event Announcements', Section 6.1 'Creation and Notification of Exercise Matched Pairs', Section 6.3 'Exercise and Abandonment by way of EEP', Section 6.5 'EEP failure and resolution', Section 6.7 'Termination of Exercise Cleared Transactions', Section 6.8 'Consequences of no Swaption Clearing Member Notice or Swaption CCM Client Notice being received by LCH SA', Section 8.1 'General Rules relating to Notices', Section 8.2 'Failure to notify Matched Pairs', Section 8.4 'Disputes as to Notices', Section 9.1 'Creation of Matched Pairs', Section 9.6 'Clearing Member matched with Itself', Section 12 'Forms of Notices' and Section 5.4 'Consequences of EEP Failure' and 5.8 'Confidentiality Waiver' of, Appendix VIII 'CCM Client Transaction Requirements' will be updated as they are not correct. These corrections are not related to the SubFins initiative but are due to an error in the cross references system.

Finally, in line with the proposed changes under Parts A and B of the Supplement, Section 9.1 'Creation of Matched Pairs' will be modified to correct inaccurate references to the CCM

Client account structure in the current version of the Supplement. This change is not related to the SubFins initiative.

The amendments to the CDS Clearing Supplement also contain typographical amendments and similar technical corrections.

(3) CDS Clearing Procedures

LCH SA also proposes to modify Section 4 of the Procedures in order to take into account the changes to the CDS Clearing Supplement and therefore to enable different treatments depending upon the Transaction Type and/or seniority of a transaction.

In Procedure 4.3. 'Eligible Reference Entities', a reference to the Seniority Level of the Reference Obligation will be added, and the wording will also be modified in order to take into account a combination of Reference Entity, Transaction Type and Reference Obligation.

2. Statutory Basis

LCH SA believes that the proposed rule change in connection with the clearing of SubFins is consistent with the requirements of Section 17A of the Securities Exchange Act of 1934 [5] (the ''Act'') and the regulations thereunder, including the standards under Rule 17Ad–22.[6] In particular, Section 17(A)(b)(3)(F) [7] of the Act requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts, and transactions and to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible.

As noted above, the proposed rule change is designed:

—To manage the risk arising from the clearing of SubFins indices and single name CDS constituents, including collecting and maintaining financial resources intended to cover the risks to which LCH SA is exposed in connection with offering clearing services for SubFins. As such LCH SA will be able to minimize the risk that the losses associated with the default of a participant (or participants) in the clearing service will extend to other participants in the service.

—To streamline the description of the existing margin framework and default fund methodology for CDS to take into account SubFins and improve the organization and clarity of the CDSClear Margin Framework and Default Fund Methodology. The proposed changes to the Methodology guide provide additional clarity regarding LCH SA's risk methodology and enhance readability to further ensure that the documentation remains up-to-date, clear, and transparent. LCH SA believes that having policies and procedures that clearly and accurately document LCH SA's risk methodology and practices are an important component to the effectiveness of LCH SA's risk management systems, which promotes the prompt and accurate clearance and settlement of securities transactions, derivatives agreements, contracts and transactions and contributes to the safeguarding of securities and funds associated with security-based swap transactions in LCH SA's custody or control, or for which LCH SA is responsible.

—To address the independent model validation recommendations on the WWR margin framework which LCH SA believes will enhance the WWR margin model by improving its ability to determine the total amount of margin that should be called and therefore collected to mitigate the spread risk on financial instruments, including on iTraxx Main indices for which circa 24% of the constituents reference Financial single names. This in turn would improve LCH SA's ability to manage financial risk exposures that may arise in the course of its ongoing clearance and settlement activities and thus better allow LCH SA to complete the clearance and settlement process in the event of a member default.

For these reasons, LCH SA believes that the proposed rule change should help promote the prompt and accurate clearance and settlement of securities transactions, derivatives agreements, contracts and transactions. Similarly, it should enhance LCH SA's ability to help assure the safeguarding of securities and funds which are in the custody or control of LCH SA or for which it is responsible.

LCH SA believes that the proposed changes to the CDSClear Margin Framework and the Default Fund Methodology satisfy the requirements of Rule 17Ad–22(e).[8]

Rule 17Ad–22(b)(2) requires a clearing agency to use margin requirements to limit its credit exposures to participants under normal market conditions and to use risk-based models and parameters to set margin requirements.[9] Rule 17Ad–22(b)(3) requires each clearing agency acting as a central counterparty for security-based swaps to maintain sufficient financial resources to withstand, at a minimum, a default by the two participant families to which it has the largest exposure in extreme but plausible market conditions (the ''cover two standard''). Rule 17Ad–22(e)(4) requires a covered clearing agency to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing and settlement processes by maintaining sufficient financial resources,[10] and Rule 17Ad–22(e)(6) requires a covered clearing agency that provides central counterparty services to cover its credit exposures to its participants by establishing a risk-based margin system that meets certain minimum requirements.[11]

As described above, LCH SA proposes to amend its CDSClear Methodology Framework to manage the risks associated with clearing SubFins. Specifically, the proposed rule change amends the Short Charge margin by shocking the recovery rates used in the calculation of the jump to default exposure as a function of the seniority of the underlying single name as well as by only considering the largest exposure and not the largest and the largest amongst the 3 riskiest anymore. It also amends the Liquidity Charge margin by setting the Markit iTraxx Subordinated Financial Index as an additional hedging pillar as well as by commingling exposures on all seniorities of a given single name underlying reference to capture concentration risk appropriately. Finally, it updates all the other margin components of the total initial margin to incorporate SubFins. These changes are designed to use a risk-based model to set margin requirements and use such margin requirements to limit LCH SA's credit exposures to participants in clearing SubFins CDS and/or other CDS and CDS Options under normal market conditions, consistent with Rule 17Ad–22(b)(2). LCH SA also believes that its risk-based margin methodology takes into account, and generates margin levels commensurate with, the risks and particular attributes of each of the SubFins and other CDS as well as CDS Options at the product and portfolio levels, appropriate to the relevant market it serves, consistent with Rule 17Ad–22(e)(6)(i) and (v). In addition, LCH SA believes that the margin

[5] 15 U.S.C. 78q–1.

[6] 17 CFR 240.17Ad–22.

[7] 15 U.S.C. 78q–1(b)(3)(F).

[8] 17 CFR 240.17Ad–22(e).

[9] 17 CFR 240.17Ad–22(b)(22).

[10] 17 CFR 240.17Ad–22(e)(4)(i).

[11] 17 CFR 240.17Ad–22(e)(6)(i).

calculation under the revised CDSClear Margin Framework would sufficiently account for the 5-day liquidation period for house account portfolio and 7-day liquidation period for client portfolio and therefore, is reasonably designed to cover LCH SA's potential future exposure to participants in the interval between the last margin collection and the close out of positions following a participant default, consistent with Rule 17Ad–22(e)(6)(iii). LCH SA also believes that the current pricing methodology with respect to CDS, based on widely accepted ISDA Model with appropriate adjustments for SubFins, as supplemented by methodology for circumstances in which pricing data are not readily available, would generate reliable data set to enable LCH SA to calculate spread margin, consistent with Rule 17Ad–22(e)(6)(iv).

Further, Rule 17Ad–22(b)(3) requires a clearing agency acting as a central counterparty for security-based swaps to establish policies and procedures reasonably designed to maintain the cover two standard.[12] Similarly, Rule 17Ad–22(e)(4)(ii) requires a covered clearing agency that provides central counterparty services for security-based swaps to maintain financial resources additional to margin to enable it to cover a wide range of foreseeable stress scenarios that include, but are not limited to, meeting the cover two standard.[13] LCH SA believes that its Default Fund Methodology, with the modifications described herein, will appropriately incorporate the risk of clearing SubFins CDS, which, together with the proposed changes to the CDSClear Margin Framework, will be reasonably designed to ensure that LCH SA maintains sufficient financial resources to meet the cover two standard, in accordance with Rule 17Ad–22(b)(3) and (e)(4)(ii).[14]

LCH SA also believes that the proposed rule changes are consistent with the requirements of Rule 17Ad–22.[15] Rule 17Ad–22(e)(17) requires a covered clearing agency to manage operational risks by (i) identifying the plausible sources of operational risk, both internal and external, and mitigating their impact through the use of appropriate systems, policies, procedures, and controls; (ii) ensuring that systems have a high degree of security, resiliency, operational reliability, and adequate, scalable capacity; and (iii) establishing and maintaining a business continuity plan that addresses events posing a significant risk of disrupting operations.[16]

As described above, the proposed rule change will enable LCH SA to extend its CDSClear product offering to SubFins as CDSClear has been clearing Senior Financials Indices and Single Names since June 2015. The process and controls already in place to manage Senior Financials will apply to SubFins and no additional operational risk is created in relation to SubFins.

In accordance with the model validation recommendations, the proposed changes on WWR would also improve the stability and accuracy of the WWR margin so that LCH SA can better determine the full margin amount to be collected by the CCP that LCH SA believes is consistent with the relevant requirements of Rule 17Ad–22.[17] Rule 17Ad–22(e)(6)(i)[18] requires LCH SA to establish, implement, maintain and enforce written policies and procedures reasonably designed to result in a margin system that, at a minimum, considers and produces margin levels commensurate with, the risks and particular attributes of each relevant product, portfolio, and market.

Rule 17Ad–22(e)(2)[19] requires LCH SA to have governance arrangements that are clear and transparent to fulfill the public interest requirements in Section 17A of the Act.[20]

LCH SA's governance arrangements clearly assign and document responsibility for risk decisions and require consultation with or approval from the LCH SA Board, Risk committees, or management. CDSClear's proposed rule changes were decided in accordance with the LCH SA governance process, which included review of the changes to the CDSClear Margin Framework and related risk management considerations by the LCH SA Risk Committee and approval by the Board. These governance arrangements continue to be clear and transparent, such that information relating to the assignment of responsibilities for risk decisions and the requisite involvement of the LCH SA Board, committees, and management is clearly documented, consistent with the requirements of Rule 17Ad–22(e)(2).[21]

For the reasons stated above, LCH SA believes that the proposed rule change with respect to the CDSClear Margin Framework, the CDSClear Default Fund Methodology, as well as the Supplement and Procedures in connection with the clearing of SubFins are consistent with the requirements of prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts and transactions, and assuring the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible, in accordance with Section 17(A)(b)(3)(F)[22] of the Act, with the requirements of operational risk management in Rule 17Ad–22(e)(17),[23] and with clear and transparent governance arrangements in Rule 17Ad–22(e)(2).[24]

B. Clearing Agency's Statement on Burden on Competition

Section 17A(b)(3)(I) of the Act requires that the rules of a clearing agency not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[25] LCH SA does not believe that the proposed rule change would impose burdens on competition that are not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the proposed changes to the CDSClear Margin Framework, Default Fund Methodology, Supplement and Procedures would apply equally to all Clearing Members whose portfolios includes SubFins and other CDS and CDS Options. Because the margin methodology and default fund sizing methodology are risk-based, consistent with the requirements in Rule 17Ad–22(b)(2) and (e)(6), depending on a Clearing Member's portfolio, each Clearing Member would be subject to a margin requirement and default fund contribution commensurate with the risk particular to its portfolio. Such margin requirement and default fund contribution impose burdens on a Clearing Member but such burdens would be necessary and appropriate to manage LCH SA's credit exposures to its CDSClear participants and to maintain sufficient financial resources to withstand a default of two participant families to which LCH SA has the largest exposures in extreme but plausible market conditions, consistent with the requirements under the Act as described above.

Therefore, LCH SA does not believe that the proposed rule change would impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

[12] 17 CFR 240.17Ad–22(b)(3).

[13] 17 CFR 240.17Ad–22(e)(4)(ii).

[14] 17 CFR 240.17Ad–22(b)(3) and (e)(4)(ii).

[15] 17 CFR 240.17Ad–22.

[16] 17 CFR 240.17Ad–22(e)(17).

[17] 17 CFR 240. 17Ad–22.

[18] 17 CFR 240. 17Ad–22(e)(6).

[19] 17 CFR 240. 17Ad–22(e)(2).

[20] 15 U.S.C. 78q–1.

[21] 17 CFR 240.17Ad–22(e)(2).

[22] 15 U.S.C. 78q–1(b)(3)(F).

[23] 17 CFR 240.17Ad–22(e)(17).

[24] 17 CFR 240.17Ad–22(e)(2).

[25] 15 U.S.C. 78q–1(b)(3)(I).

C. Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule change have not been solicited or received. LCH SA will notify the Commission of any written comments received by LCH SA.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–LCH SA–2019–005 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–LCH SA–2019–005. 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 LCH SA and on LCH SA's website at: *https://www.lch.com/resources/rules-and-regulations/proposed-rule-changes-0.*

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–LCH SA–2019–005 and should be submitted on or before August 30, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–17108 Filed 8–8–19; 8:45 am]

BILLING CODE 8011–01–P

[26] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15937 and #15938; KENTUCKY Disaster Number KY–00073]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the Commonwealth of Kentucky

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 3.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the Commonwealth of Kentucky (FEMA–4428–DR), dated 04/17/2019.

Incident: Severe Storms, Straight-Line Winds, Flooding, Landslides, and Mudslides.

Incident Period: 02/06/2019 through 03/10/2019.

DATES: Issued on 08/01/2019.

Physical Loan Application Deadline Date: 06/17/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 01/17/2020.

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 Private Non-Profit organizations in the Commonwealth of Kentucky, dated 04/17/2019, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Hickman.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2019–17089 Filed 8–8–19; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16068 and #16069; WEST VIRGINIA Disaster Number WV–00051]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of West Virginia

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 West Virginia (FEMA–4455–DR), dated 08/03/2019.

Incident: Severe Storms, Flooding, Landslides, and Mudslides.

Incident Period: 06/29/2019 through 06/30/2019.

DATES: Issued on 08/03/2019.

Physical Loan Application Deadline Date: 10/02/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 05/04/2020.

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 08/03/2019, 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: Grant, Pendleton, Preston, Randolph, Tucker.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere	2.750
Non-Profit Organizations without Credit Available Elsewhere	2.750
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	2.750

The number assigned to this disaster for physical damage is 160686 and for economic injury is 160690.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2019–17088 Filed 8–8–19; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16041 and #16042; OKLAHOMA Disaster Number OK–00132]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of Oklahoma

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Oklahoma (FEMA–4438–DR), dated 07/16/2019.

Incident: Severe Storms, Straight-line Winds, Tornadoes, and Flooding.

Incident Period: 05/07/2019 through 06/09/2019.

DATES: Issued on 07/16/2019.

Physical Loan Application Deadline Date: 09/16/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 04/16/2020.

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 Private Non-Profit organizations in the State of Oklahoma, dated 07/16/2019, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Caddo, Kay, Kiowa, Woodward.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2019–17090 Filed 8–8–19; 8:45 am]

BILLING CODE 8026–03–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36319]

Texas Pacifico Transportation, Ltd.—Trackage Rights Exemption—Union Pacific Railroad Company

Texas Pacifico Transportation, LTD. (TXPF), has filed a verified notice of exemption under 49 CFR 1180.2(d)(7) to acquire overhead trackage rights from Union Pacific Railroad Company (UP). TXPF states that UP, pursuant to a written trackage rights agreement, has granted TXPF overhead trackage rights over approximately 11.18 miles of UP's rail line between UP's connection with TXPF at Alpine, Tex., in the vicinity of UP's milepost 608.46, and UP's connection with TXPF at Paisano Junction, Tex., in the vicinity of UP's milepost 619.64.[1]

The verified notice states that TXPF leases a line of railroad owned by the State of Texas extending from San Angelo Junction to Alpine and from Paisano Junction to the U.S.-Mexico border at Presidio, Tex., and that the trackage rights at issue here will provide connectivity between the two parts of TXPF's current operation.[2]

The transaction is scheduled to be consummated on the effective date of the notice of exemption. The earliest this transaction may be consummated is August 23, 2019, the effective date of the exemption (30 days after the verified notice of exemption was filed).

As a condition to this exemption, any employees affected by the acquisition of the trackage rights will be protected by the conditions imposed in *Norfolk & Western Railway—Trackage Rights—Burlington Northern, Inc.,* 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Railway—Lease & Operate—California Western Railroad,* 360 I.C.C. 653 (1980).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed by August 16, 2019 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36319, must be filed with the Surface Transportation Board, either via e-filing or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on TXPF's representative, Jeffrey S. Lisson, Carter, Boyd, Lisson & Hohensee, P.C., 515 W. Harris, Ste. 100, San Angelo, TX 76903.

According to TXPF, this transaction does not require environmental documentation under 49 CFR 1105.6(c) and is exempt from historic preservation reporting under 49 CFR 1105.8(b)(3).

Board decisions and notices are available at *www.stb.gov.*

Decided: August 6, 2019.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2019–17092 Filed 8–8–19; 8:45 am]

BILLING CODE 4915–01–P

[1] A redacted copy of the agreement, dated March 5, 2019, is attached to the verified notice. An unredacted copy has been filed under seal along with a motion for protective order pursuant to 49 CFR 1104.14. That motion is addressed in a separate decision.

[2] The verified notice states that, in 1992, Southern Pacific Transportation Company (SP) granted trackage rights to the South Orient Railroad Company, Ltd. (SORC), in ICC Docket No. FD 32032, and that those rights were assigned to TXPF when TXPF acquired SORC's operations pursuant to *Texas Pacifico Transportation, Ltd.—Acquisition & Operation Exemption—South Orient Railroad,* FD 33851 (STB served Mar. 3, 2000). According to TXPF, that trackage rights agreement was terminated by UP following expiration of its initial term, and TXPF and UP negotiated a new trackage rights agreement, which is the subject of TXPF's verified notice here. The verified notice states that the mileposts on UP's line were changed following merger between UP and SP, therefore, the new agreement mileposts do not match the mileposts in the prior agreement.

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Graham County, North Carolina

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Rescinding of Notice of Intent.

SUMMARY: On Wednesday, July 25, 2007, FHWA issued a Notice of Intent (NOI) to advise the public that a Supplemental Final Environmental Impact Statement (Supp. FEIS) would be prepared for the proposed relocation of US 74 from US 129 in Robbinsville top NC 28 in Stecoah, Graham County, North Carolina (STIP Project A–0009BC). The FHWA is issuing this notice to advise the public that it is rescinding the public notice to prepare a Supp. FEIS and the Draft Supp. FEIS issued in June 2008 for STIP No. A–0009BC, Graham County, North Carolina.

FOR FURTHER INFORMATION CONTACT: Clarence W. Coleman, P.E., Director of Preconstruction, Federal Highway Administration, 310 New Bern Avenue, Suite 410, Raleigh, North Carolina 27601–1418, Telephone: (919) 747–7014; or Mr. Brian Burch, P.E., North Carolina Department of Transportation, Division 14 Engineer, 253 Webster Street, Sylva, North Carolina 28779, Telephone: (828) 586–2141.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the North Carolina Department of Transportation (NCDOT), is rescinding the NOI to prepare a Supp. FEIS issued on July 25, 2007 (72 FR 40922), for proposed relocation of US 74 from US 129 in Robbinsville to NC 28 in Stecoah, Corridor K of the Appalachian Highway System (ADHS), Graham County, North Carolina. The FHWA is also rescinding the Draft Supp. FEIS released in June 2008. The FHWA and NCDOT are working with local governments, along with federal and state permitting and resource agency partners and the public, to reevaluate the scope for improvements along Corridor K of the ADHS. Following the development of the scope for proposed improvements, FHWA will determine the appropriate action to comply with the National Environmental Policy Act (NEPA). Comments or questions concerning this rescinding notice and future activities associated with Corridor K of the ADHS in Cherokee and Graham Counties should be directed to FHWA and NCDOT at the addresses provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139

Issued on: August 2, 2019.

Clarence W. Coleman,

Director of Preconstruction, Raleigh, North Carolina.

[FR Doc. 2019–17087 Filed 8–8–19; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2019–0023]

Agency Information Collection Activities: Request for Comments for a New Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: FHWA invites public comments about our intention to request the Office of Management and Budget's (OMB) approval for a new information collection, which is summarized below under **SUPPLEMENTARY INFORMATION.** We published a **Federal Register** Notice with a 60-day public comment period on this information collection on June 5, 2019. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by September 9, 2019.

ADDRESSES: You may send comments within 30 days to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, Attention DOT Desk Officer. You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burden; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. All comments should include the Docket number FHWA– 2016–0013.

FOR FURTHER INFORMATION CONTACT: Marthy Kenley, 202–366–8110, Office of Civil Rights, Federal Highway Administration, Department of Transportation, 1200 New Jersey Ave. SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Federal-Aid Highway Construction Equal Employment Opportunity.

Background: Title 23, part 140(a), requires the FHWA to ensure equal opportunity regarding contractors' employment practices on Federal-aid highway projects. To carry out this requirement, the contractors must submit to the State Transportation Agencies (STAs) on all work being performed on Federal-aid contracts during the month of July, a report on its employment workforce data. This report provides the employment workforce data on these contracts and includes the number of minorities, women, and non-minorities in specific highway construction job categories. This information is reported on Form PR–1391, Federal-Aid Highway Construction Contractors Summary of Employment Data. The statute also requires the STAs to submit a report to the FHWA summarizing the data entered on the PR–1391 forms. This summary data is provided on Form PR–1392, Federal-Aid Highway Construction Contractors Summary of Employment Data. The STAs and FHWA use this data to identify patterns and trends of employment in the highway construction industry, and to determine the adequacy and impact of the STA's and FHWA's contract compliance and on-the-job (OJT) training programs. The STAs use this information to monitor the contractors-employment and training of minorities and women in the traditional highway construction crafts. Additionally, the data is used by FHWA to provide summarization, trend analyses to Congress, DOT, and FHWA officials as well as others who request information relating to the Federal-aid highway construction EEO program. The information is also used in making decisions regarding resource allocation; program emphasis; marketing and promotion activities; training; and compliance efforts.

Respondents: 11,077 annual respondents for form PR–1391, and 52 STAs annual respondents for Form PR–1392, total of 11,129.

Frequency: Annually.

Estimated Average Burden per Response: FHWA estimates it takes 30 minutes for Federal-aid contractors to complete and submit Form PR–1391 and 8 hours for STAs to complete and submit Form PR–1392.

Estimated Total Amount Burden Hours: Form PR–1391—5,539 hours per

year; *Form PR–1392*—416 hours per year, total of 5,955 hours annually.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, 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.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued On: August 6, 2019.

Michael Howell,

Information Collections Officer.

[FR Doc. 2019–17086 Filed 8–8–19; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA—2019–0027; Notice 3]

Withdrawal of Notice for State Notification to Consumers of Motor Vehicle Recall Status

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

ACTION: Notice withdrawal.

On July 25, 2019, NHTSA inadvertently published, at 84 FR 35927, a notice seeking comments on the proposed burden estimates related to a proposed funding opportunity regarding state notification to consumers of motor vehicle recall status. NHTSA is withdrawing the July 25, 2019 notice.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, *as amended;* and 49 CFR 1:48

Stephen A. Ridella,

Director, Office of Defects Investigation Enforcement.

[FR Doc. 2019–17058 Filed 8–8–19; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is updating the **Federal Register** notice for the entry of one person on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of this are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel. 202–622–4855; or the Department of the Treasury's Office of the General Counsel: Office of the Chief Counsel (Foreign Assets Control), tel.: 202–622–2410.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treasury.gov/ofac*).

Notice of OFAC Action(s)

On August 5, 2019, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following person are blocked under the relevant sanctions authorities listed below. OFAC is updating the **Federal Register** notice for the entry of one person on OFAC's Specially Designated National and Blocked Persons List (SDN List) in order to identify the bases for designation for the individual listed below.

Individual

1. SERHAN, Fadi Hussein (a.k.a. SARHAN, Fadi Husayn; a.k.a. SIRHAN, Fadi), Own Building, Kanisat Marmkhael, Saliba Street, Corniche, Al-Mazraa, Beirut, Lebanon; Jaafar Building, Mazraa Street, Beirut, Lebanon; Jaafar Building, Mseytbi Street, Beirut, Lebanon; Jaafar Building, Salim Slam Street, Beirut, Lebanon; Jishi Building, Salim Slam Street, Beirut, Lebanon; Own Building, Main Street, Kfar Kila, Lebanon; Mazraa, Salim Slam St., Borj Al Salam Bldg., Beirut, Lebanon; DOB 01 Apr 1961; POB Kafr Kila, Lebanon; alt. POB Kfarkela, Lebanon; nationality Lebanon; Gender Male; Passport RL 0962973 (Lebanon) expires 08 Feb 2012; alt. Passport RL 3203273 expires 20 May 2020; VisaNumberID 87810564 (United States); alt. VisaNumberID F0962973 (individual) [SDGT] [HIFPAA].

Designated pursuant to section 1(d)(ii) of Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism'' (E.O. 13224) for assisting in, sponsoring, or providing financial, material, or technological support for, or financial or other services to or in support of, AL MANAR TV, an entity whose property and interests in property are blocked pursuant to E.O. 13224.

Also designated pursuant to section 101(a)(2) of the Hizballah International Financing Prevention Act of 2015, as amended by section 101 of the Hizballah International Financing Prevention Amendments Act of 2018, for knowingly providing significant financial, material, or technological support for or to AL MANAR TV.

Dated: August 5, 2019.

Andrea Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2019–17049 Filed 8–8–19; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Proposed Collection; Comment Request; Primary Dealer Meeting Agenda

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to comment on the proposed information collections listed below, in accordance with the Paperwork Reduction Act of 1995.

DATES: Written comments must be received on or before October 8, 2019.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW, Suite 8100, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Jennifer Quintana by emailing *PRA@treasury.gov,* calling

(202) 622–0489, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Title: Primary Dealer Meeting Agenda.

OMB Control Number: 1505–0261.

Type of Review: Extension without change of a currently approved collection.

Description: The Primary Dealer Meeting Agenda a quarterly survey sent to all primary dealers, of which there are currently 24 financial institutions. Primary dealers are trading counterparties of the Federal Reserve Bank of New York in its implementation of monetary policy. Primary dealers are also expected to have a substantial presence as a market maker for Treasury securities and bid on a pro-rata basis in all Treasury auctions.

The Treasury's mission to manage the U.S government's finances and resources effectively includes financing the government's borrowing needs at the lowest cost over time. Treasury meets this objective by issuing debt in a regular and predictable pattern, providing transparency in its decision-making process, and seeking continuous improvements in the Treasury auction process. The risks to regular and predictable debt issuance result from unexpected changes in our borrowing requirements, changes in the demand for Treasury securities, and anything that inhibits timely sales of securities. To reduce these risks, Treasury closely monitors economic conditions, market activity, and, if necessary, responds with appropriate changes in debt issuance based on analysis and consultation with market participants, including the primary dealers through the quarterly survey and subsequent meetings.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Number of Respondents: 24.

Frequency of Response: Quarterly.

Estimated Total Number of Annual Responses: 96.

Estimated Time per Response: 2 hours.

Estimated Total Annual Burden Hours: 192.

Request for Comments: Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services required to provide information.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: August 5, 2019.

Frederick Pietrangeli,

Director, Office of Debt Management.

[FR Doc. 2019–17096 Filed 8–8–19; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0465]

Agency Information Collection Activity: Student Verification of Enrollment

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before October 8, 2019.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefit Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger@va.gov* . Please refer to ''OMB Control No. 2900–0465'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Danny S. Green at (202) 421–1354.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: 38 U.S.C. 3680(g).

Title: Student Verification of Enrollment, VA Form 22–8979.

OMB Control Number: 2900–0465.

Type of Review: Revision of a currently approved collection.

Abstract: VA Form 22–8979 is used by students to submit their verification of enrollment on a monthly basis to allow for a frequent and periodic release of payment. Without this information, VA could not pay benefits based on proof of attendance and/or change in enrollment.

Affected Public: Individuals.

Estimated Annual Burden: 15,479.

Estimated Average Burden per Respondent: 1 minute.

Frequency of Response: On occasion (5 certifications per student per year).

Estimated Number of Respondents: 185,008 (928,740 responses).

By direction of the Secretary.

Danny S. Green,

VA Clearance Officer, Office of Quality, Performance, and Risk, Department of Veterans Affairs.

[FR Doc. 2019–17054 Filed 8–8–19; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 84 Friday,
No. 154 August 9, 2019

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services
42 CFR Parts 405, 410, 412. 416, et al.
Office of the Secretary
45 Part 180
Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 412, 416, 419, and 486

Office of the Secretary

45 CFR Part 180

[CMS–1717–P]

RIN 0938–AT74

Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals

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

ACTION: Proposed rule.

SUMMARY: This proposed rule proposes revisions to the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2020 based on 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. In addition, in this proposed rule, we are proposing to establish requirements for all hospitals in the United States for making hospital standard charges available to the public; establish a process and requirements for prior authorization for certain covered outpatient department services; revise the conditions for coverage of organ procurement organizations; and revise the regulations to allow grandfathered children's hospitals-within-hospitals to increase the number of beds without resulting in the loss of grandfathered status. We also solicit comments on potential revisions to the laboratory date of service policy under the Clinical Laboratory Fee Schedule. Finally, we solicit comments on an appropriate remedy in litigation involving our OPPS payment policy for 340B-acquired drugs, which would inform future rulemaking in the event of an adverse decision on appeal in that litigation.

DATES: *Comment period:* 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 27, 2019.

ADDRESSES: In commenting, please refer to file code CMS–1717–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–1717–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–1717–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.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

2-Midnight Rule (Short Inpatient Hospital Stays), contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov* or at 410–786–3213.

Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact the HOP Panel mailbox at *APCPanel@cms.hhs.gov.*

Ambulatory Surgical Center (ASC) Payment System, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

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 Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov* or at 410–786–9732.

Cancer Hospital Payments, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver via email *Chuck.Braver@cms.hhs.gov* or at 410–786–6719.

Control for Unnecessary Increases in Volume of Outpatient Services, contact Elise Barringer via email *Elise.Barringer@cms.hhs.gov* or at 410–786–9222.

Composite APCs (Low Dose Brachytherapy and Multiple Imaging), contact Elise Barringer via email *Elise.Barringer@cms.hhs.gov* or at 410–786–9222.

Comprehensive APCs (C–APCs), contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov* or at 410–786–3213, or Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov* or at 410–786–4329.

CPT and Level II HCPCS Codes, contact Marjorie Baldo via email *Marjorie.Baldo@cms.hhs.gov* or at 410–786–4617.

Grandfathered Children's Hospitals-within-Hospitals, contact Michele Hudson via email *Michele.Hudson@cms.hhs.gov* or 410–786–4487.

Hospital Cost Reporting and Chargemaster Comment Solicitation, contact Dr. Terri Postma via email at *PriceTransparencyHospitalCharges@cms.hhs.gov.*

Hospital Outpatient Quality Reporting (OQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email *Anita.Bhatia@cms.hhs.gov* or at 410–786–7236.

Hospital Outpatient Quality Reporting (OQR) Program Measures, contact Vinitha Meyyur via email *Vinitha.Meyyur@cms.hhs.gov* or at 410–786–8819.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Elise Barringer via email

Elise.Barringer@cms.hhs.gov or at 410–786–9222.

Inpatient Only (IPO) Procedures List, contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov* or at 410–786–3213, or Au'Sha Washington via email at *Ausha.Washington@cms.hhs.gov* or at 410–786–3736.

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

No Cost/Full Credit and Partial Credit Devices, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

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, Steven Johnson via email *Steven.Johnson@cms.hhs.gov* or at 410–786–3332, or Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142, or Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov* or at 410–786–9732.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov* or at 410–786–9732.

OPPS New Technology Procedures/Services, contact the New Technology APC mailbox at *NewTechAPCapplications@cms.hhs.gov*.

OPPS Packaged Items/Services, contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov* or at 410–786–3213, or Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov* or at 410–786–4329.

OPPS Pass-Through Devices, contact the Device Pass-Through mailbox at *DevicePTapplications@cms.hhs.gov*.

OPPS Status Indicators (SI) and Comment Indicators (CI), contact Marina Kushnirova via email *Marina.Kushnirova@cms.hhs.gov* or at 410–786–2682.

Organ Procurement Organization (OPO) Conditions for Coverage (CfCs), contact Alpha-Banu Wilson via email at *AlphaBanu.Wilson@cms.hhs.gov* or at 410–786–8687, or Diane Corning via email at *Diane.Corning@cms.hhs.gov* or at 410–786–8486.

Partial Hospitalization Program (PHP) and Community Mental Health Center (CMHC) Issues, contact the PHP Payment Policy Mailbox at *PHPPaymentPolicy@cms.hhs.gov*.

Price Transparency of Hospital Standard Charges, contact Dr. Terri Postma or Elizabeth November via email at *PriceTransparencyHospitalCharges@cms.hhs.gov*.

Prior Authorization Process and Requirements for Certain Hospital Outpatient Department Services, contact Thomas Kessler via email at *Thomas.Kessler@cms.hhs.gov* or at 410–786–1991.

Quality Measurement Relating to Price Transparency, contact Dr. Reena Duseja or Dr. Terri Postma via email at *PriceTransparencyHospitalCharges@cms.hhs.gov*

Rural Hospital Payments, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov* or at 410–786–9732.

Skin Substitutes, contact Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov* or at 410–786–9732.

Supervision of Outpatient Therapeutic Services in Hospitals and CAHs, contact Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov* or at 410–786–9732, or Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov* or at 410–786–4329.

All Other Issues Related to Hospital Outpatient and Ambulatory Surgical Center Payments Not Previously Identified, contact Elise Barringer via email *Elise.Barringer@cms.hhs.gov* or at 410–786–9222.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov/*. Follow the search instructions on that website to view public comments.

Addenda Available Only Through the Internet on the CMS Website

In the past, a majority of the Addenda referred to in our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 OPPS/ASC proposed rule, all of the Addenda no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these Addenda are published and available only on the CMS website. The Addenda relating to the OPPS are available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. The Addenda relating to the ASC payment system are available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

Current Procedural Terminology (CPT) Copyright Notice

Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2018 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR and Defense Federal Acquisition Regulations (DFAR) apply.

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, 2020. Section 1833(t) of the Social Security Act (the Act) requires us to

annually review and update the payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). Specifically, section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i) of the Act, we annually review and update the ASC payment rates. 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 proposing to: Establish requirements for all hospitals (including hospitals not paid under the OPPS) in the United States for making hospital standard charges available to the public; establish a process and requirements for prior authorization for certain covered outpatient department services; revise the conditions for coverage for organ procurement organizations; and revise the regulations to allow grandfathered children's hospitals-within-hospitals to increase the number of beds without resulting in the loss of grandfathered status. We also solicit comments on potential revisions to the laboratory date of service policy under the Clinical Laboratory Fee Schedule.

2. Summary of the Major Provisions

- *OPPS Update:* For CY 2020, we are proposing to increase the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 2.7 percent. This increase factor is based on the proposed hospital inpatient market basket percentage increase of 3.2 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the proposed multifactor productivity (MFP) adjustment of 0.5 percentage point. 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 2020 would be approximately $79 billion, an increase of approximately $6 billion compared to estimated CY 2019 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.

- *2-Midnight Rule (Short Inpatient Hospital Stays):* For CY 2020, we are proposing to establish a 1-year exemption from Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC–QIOs) referrals to Recovery Audit Contractors (RACs) and RAC reviews for ''patient status'' (that is, site-of-service) for procedures that are removed from the inpatient only (IPO) list under the OPPS beginning on January 1, 2020.

- *Comprehensive APCs:* For CY 2020, we are proposing to create two new comprehensive APCs (C–APCs). These proposed new C–APCs include the following: C–APC 5182 (Level 2 Vascular Procedures) and proposed C–APC 5461 (Level 1 Neurostimulator and Related Procedures). This proposal would increase the total number of C–APCs to 67.

- *Proposed Changes to the Inpatient Only (IPO) List:* For CY 2020, we are proposing to remove one procedure from the inpatient only list and we are seeking public comment on the removal of six procedures from the inpatient only (IPO) list.

- *Method to Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs):* For CY 2020, we are completing the phase-in of the reduction in payment for the clinic visit services described by HCPCS code G0463 furnished in expected off-campus provider-based departments as a method to control uncessary increases in the volume of this service.

- *Device Pass-Through Payment Applications:* For CY 2020, we are evaluating seven applications for device pass-through payments and are seeking public comments in this CY 2020 proposed rule on whether these applications meet the criteria for device pass-through payment status.

- *Proposed Changes to Substantial Clinical Improvement Criterion:* For CY 2020, we are proposing an alternative pathway to the substantial clinical improvement criterion for devices approved under the FDA Breakthrough Devices Program to qualify for device pass-through status beginning with applications received on or after January 1, 2020.

- *Cancer Hospital Payment Adjustment:* For CY 2020, we are proposing to continue to provide additional payments to cancer hospitals so that a cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. However, section 16002(b) of the 21st Century Cures Act requires that this weighted average PCR be reduced by 1.0 percentage point. Based on the data and the required 1.0 percentage point reduction, a proposed target PCR of 0.89 will be used to determine the CY 2020 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustment will be the additional payments needed to result in a PCR equal to 0.89 for each cancer hospital.

- *Rural Adjustment:* For 2020 and subsequent years, we are continuing the 7.1 percent adjustment to OPPS payments for certain rural SCHs, including essential access community hospitals (EACHs). We intend to continue such 7.1 percent adjustment in the absence of data to suggest a different percentage adjustment should apply.

- 340B-*Acquired Drugs:* We are proposing to continue to pay ASP − 22.5 percent for 340B-acquired drugs including when furnished in nonexcepted off-campus PBDs paid under the PFS. On December 27, 2018, in the case of *American Hospital Association et al.* v. *Azar et al.,* the United States District Court for the District of Columbia (hereinafter referred to as ''the district court'') concluded in the context of reimbursement requests for CY 2018 that the Secretary exceeded his statutory authority by adjusting the Medicare payment rates for drugs acquired under the 340B Program to ASP minus 22.5 percent for that year. CMS respectfully disagreed with the district court's understanding of the scope of CMS' adjustment authority and asked the district court to enter final judgment so as to permit an immediate appeal. On July 10, 2019, the district court granted the government's request and entered final judgment, and the agency does intend to pursue its appeal rights. Nonetheless, CMS is taking the steps necessary to craft an appropriate remedy in the event of an unfavorable decision on appeal. We are soliciting public comments on the appropriate OPPS payment rate for 340B-acquired drugs, including whether a rate of ASP+3 percent could be an appropriate payment amount for these drugs, both for CY 2020 and for purposes of determining the remedy for CYs 2018 and 2019. In addition to comments on the appropriate payment amount for

calculating the remedy for CYs 2018 and 2019 and for use for CY 2020, we also seek public comment on how to structure the remedy for CYs 2018 and 2019. This request for public comment includes comments on whether such a remedy should be retrospective in nature (for example, made on a claim-by-claim basis), whether such a remedy could be prospective in nature (for example, an upward adjustment to 340B claims in the future to account for any underpayments in the past), and whether there is some other mechanism that could produce a result equitable to hospitals that do not acquire drugs through the 340B program while respecting the budget neutrality mandate. In the event of an adverse decision on appeal, we would anticipate proposing the specific remedy for CYs 2018 and 2019, and, if necessary, to the CY 2020 rates, in the next available rulemaking vehicle, which is the CY 2021 OPPS/ASC proposed rule. Those proposals will be informed by the comments solicited in this proposed rule.

• *ASC Payment Update:* For CYs 2019 through 2023, we update the ASC payment system using the hospital market basket update. Using the hospital market basket methodology, for CY 2020, we are proposing to increase payment rates under the ASC payment system by 2.7 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This proposed increase is based on a proposed hospital market basket of 3.2 percent minus a proposed multifactor productivity adjustment required by the Affordable Care Act of 0.5 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 2020 would be approximately $4.89 billion, an increase of approximately $200 million compared to estimated CY 2019 Medicare payments.

• *Proposed Changes to the List of ASC Covered Surgical Procedures:* For CY 2020, we are proposing to add 8 procedures to the ASC list of covered surgical procedures. Additions to the list include a total knee arthroplasty procedure, a mosaicplasty procedure, as well as six coronary intervention procedures. We are soliciting public comments with respect to whether certain other surgical procedures related to the cardiovascular system should be added to the ASC list of covered surgical procedures.

• *Proposed Changes to the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals:* For CY 2020, we are proposing to change the minimum required level of supervision from direct supervision to general supervision for all hospital outpatient therapeutic services provided by all hospitals and CAHs. This proposal would ensure a standard minimum level of supervision for each hospital outpatient service furnished incident to a physician's service.

• *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program, we are proposing to remove OP–33: External Beam Radiotherapy for Bone Metastases for the CY 2022 payment determination and subsequent years.

• *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program, we are proposing to adopt one new measure, ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers, beginning with the CY 2024 payment determination and for subsequent years.

• *Proposed Requirements for Hospitals to Make Public a List of Their Standard Charges:* We are proposing to add a new Part 180—Hospital Price Transparency to Title 45 of the Code of Federal Regulations (CFR) which would contain our proposed regulations on price transparency for purposes of section 2718(e) of the PHS Act. In this section, we make proposals related to: (1) A definition of ''hospital''; (2) different reporting requirements that would apply to certain hospitals; (3) definitions for two types of ''standard charges'' (specifically, gross charges and payer-specific negotiated charges) that hospitals would be required to make public, and a request for public comment on other types of standard charges that hospitals should be required to make public; (4) a definition of hospital ''items and services'' that would include all items and services (including individual items and services and service packages) provided by the hospital to a patient in connection with an inpatient admission or an outpatient department visit; (5) requirements for making public a machine-readable file that contains a hospital's gross charges and payer-specific negotiated charges for all items and services provided by the hospital; (6) requirements for making public payer-specific negotiated charges for select hospital-provided items and services that are ''shoppable'' and that are displayed in a consumer-friendly manner; (7) monitoring for hospital noncompliance with public disclosure requirements to make public standard charges; (8) actions that would address hospital noncompliance, which include issuing a written warning notice, requesting a corrective action plan, and imposing civil monetary penalties (CMPs) on noncompliant hospitals and publicizing these penalties on a CMS website; and (9) appeals of CMPs.

• *Proposed Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services:* We are proposing a prior authorization process using the authority in section 1833(t)(2)(F) of the Act as a method for controlling unnecessary increases in the volume of the following five categories of services: (1) Blepharoplasty, (2) botulinum toxin injections, (3) panniculectomy, (4) rhinoplasty, and (5) vein ablation.

• *Organ Procurement Organizations (OPOs) Conditions for Coverage (CfCs) Proposed Revision of the Definition of ''Expected Donation Rate'':* We are proposing to revise the definition of ''expected donation rate'' that is included in the second outcome measure to match the Scientific Registry of Transplant Recipients (SRTR) definition.

We are also proposing to reduce the time period for the second outcome measure and calculate the expected donation rate using 12 out of the 24 months of data (from January 1, 2020 through December 31, 2020) for the 2022 recertification cycle only.

• *Request for Information Regarding Potential Changes to the Organ Procurement Organization and Transplant Center Regulations:* We are soliciting public comments regarding what revisions may be appropriate for the current OPO CfCs and the current transplant center CoPs. In addition, we are seeking public comments on two potential outcome measures for OPOs.

3. Summary of Costs and Benefits

In sections XXVI. and XXVII. 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 All OPPS Proposed Changes

Table 41 in section XXVI. of this proposed rule displays the distributional impact of all the proposed OPPS changes on various groups of hospitals and CMHCs for CY 2020 compared to all estimated OPPS payments in CY 2019. We estimate that the policies in this proposed rule would result in a 2.0 percent overall increase in OPPS payments to providers. We estimate that total OPPS payments for

CY 2020, including beneficiary cost-sharing, to the approximately 3,734 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) would increase by approximately $940 million compared to CY 2019 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 3.9 percent increase in CY 2020 payments to CMHCs relative to their CY 2019 payments.

b. Impacts of the Proposed Updated Wage Indexes

We estimate that our proposed update of the wage indexes based on the FY 2020 IPPS proposed rule wage indexes would result in no estimated payment change for urban hospitals under the OPPS and an estimated increase of 0.8 percent for rural hospitals. 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.

c. Impacts of the Proposed Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our proposed CY 2020 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 proposing to implement the reduction to the cancer hospital payment adjustment required by section 16002 of the 21st Century Cures Act for CY 2020, the target payment-to-cost ratio (PCR) for CY 2020 is 0.89, compared to 0.88 for CY 2019, and therefore has a slight impact on budget neutrality adjustments.

d. Impacts of the Proposed OPD Fee Schedule Increase Factor

For the CY 2020 OPPS/ASC, we are proposing an OPD fee schedule increase factor of 2.7 percent and applying that increase factor to the conversion factor for CY 2020. As a result of the proposed OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that urban hospitals would experience an increase of approximately 2.8 percent and that rural hospitals would experience an increase of 3.0 percent. Classifying hospitals by teaching status, we estimate nonteaching hospitals would experience an increase of 3.0 percent, minor teaching hospitals would experience an increase of 3.1 percent, and major teaching hospitals would experience an increase of 2.3 percent. We also classified hospitals by the type of ownership. We estimate that hospitals with voluntary ownership would experience an increase of 2.7 percent in payments, while hospitals with government ownership would experience an increase of 2.8 percent in payments. We estimate that hospitals with proprietary ownership would an experience an increase of 3.6 percent in payments.

e. 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 2020 payment rates, compared to estimated CY 2019 payment rates, generally ranges between an increase of 2 and 5 percent, depending on the service, with some exceptions. We estimate the impact of applying the hospital market basket update to proposed ASC payment rates would increase payments by $100 million under the ASC payment system in CY 2020.

f. 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: If all proposals are adopted as final, there is a net reduction of one measure reported by hospitals, which would result in a minimal net reduction in burden of $21,379.

g. 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 not result in changes to costs and burdens related to information collection for the ASCQR Program, compared to previously adopted requirements.

h. Impact of the Proposed Requirements for Hospitals To Make Public a List of Their Standard Charges

We estimate the total annual burden for hospitals to review and post their standard charges to be 12 hours per hospital at $1,017.24 per hospital for a total burden of 72,024 hours (12 hours $\times$ 6,002 hospitals) and total cost of $6,105,474 ($1,017.24 $\times$ 6,002 hospitals) if our policies, as discussed in section XVI. of this proposed rule are finalized as proposed.

i. Impact of the Proposed Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services

Across all providers, we estimate that the total burden for year one (6 months) would be 73,647 hours and $2,604,281 (Table 48—Year 1 (6 Month) Private Sector Costs of this proposed rule) for the five categories of services for which we are proposing to require prior authorization. In addition, we estimate that the total annual burden, allotted across all providers, would be 125,242 hours and $4,475,116 per year for the services. An annualized burden is estimated at 108,044 hours and $3,851,504. The annualized burden is based on an average of 3 years, that is, 1 year at the 6-month burden and 2 years at the 12-month burden. This accounts for the time associated with submitting the prior authorization request package and related medical documentation to support Medicare payment of the service(s). Medicare would incur $5,787,055 for the first 6 months (Table 49—Year 1 (6 Month) Estimated Annual Medicare Costs of this proposed rule) and $11,571,179 annually therafter, in additional costs associated with processing the prior authorization requests, as well as education, outreach, and systems. Benefits include decreased unnecessary utilization of these OPD services, and subsequently, reduced improper payments made for claims for these services that do not meet Medicare requirements.

j. Impacts of the Proposed Revision of the Definition of ''Expected Donation Rate'' for Organ Procurement Organizations

All 58 OPOs are required to meet two out of three outcome measures detailed in the OPO CfC regulations at 42 CFR 486.318(b). We are proposing to revise the definition of ''expected donation rate'' in the OPO CfCs. This revision would eliminate the potential for confusion in the OPO community due to different definitions of the same term.

The proposal would not affect data collection or reporting by the OPTN and SRTR, nor their statistical evaluation of OPO performance. Therefore, it would not result in any quantifiable financial impact.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the Social Security Act (the Act) was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added section 1833(t) to the Act, authorizing implementation of a PPS for hospital outpatient services. The OPPS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPPS are located at 42 CFR parts 410 and 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) made major changes in the hospital OPPS. The following Acts made additional changes to the OPPS: The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) (Pub. L. 109–432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010 (these two public laws are collectively known as the Affordable Care Act); the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111–309); the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA, Pub. L. 112–78), enacted on December 23, 2011; the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112–96), enacted on February 22, 2012; the American Taxpayer Relief Act of 2012 (Pub. L. 112–240), enacted January 2, 2013; the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) enacted on December 26, 2013; the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113–93), enacted on March 27, 2014; the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114–10), enacted April 16, 2015; the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted November 2, 2015; the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), enacted on December 18, 2015, the 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016; the Consolidated Appropriations Act, 2018 (Pub. L. 115–141), enacted on March 23, 2018; and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271), enacted on October 24, 2018.

Under the OPPS, we generally pay for hospital Part B services on a rate-per-service basis that varies according to the APC group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C. of this proposed rule. Section 1833(t)(1)(B) of the Act provides for payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Medicare Part B.

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use, as required by section 1833(t)(2)(B) of the Act. In accordance with section 1833(t)(2)(B) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group (referred to as the ''2 times rule''). In implementing this provision, we generally use the cost of the item or service assigned to an APC group.

For new technology items and services, special payments under the OPPS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as ''transitional pass-through payments,'' for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercises the authority granted under the statute to also exclude from the OPPS certain services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); certain laboratory services paid under the Clinical Laboratory Fee

Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. In addition, section 1833(t)(1)(B)(v) of the Act does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017 by an off-campus outpatient department of a provider (as defined in subparagraph (B) of paragraph (21). We set forth the services that are excluded from payment under the OPPS in regulations at 42 CFR 419.22.

Under § 419.20(b) of the regulations, we specify the types of hospitals that are excluded from payment under the OPPS. These excluded hospitals 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 the wage and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.*

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)

1. Authority of the Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Public Law 106–113, and redesignated by section 202(a)(2) of Public Law 106–113, requires that we consult with an external advisory panel of experts to annually review the clinical integrity of the payment groups and their weights under the OPPS. In CY 2000, based on section 1833(t)(9)(A) of the Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the Public Health Service Act, which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel). The HOP Panel is not restricted to using data compiled by CMS, and in conducting its review, it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the Panel, and, at that time, named the APC Panel. This expert panel is composed of appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise) who review clinical data and advise CMS about the clinical integrity of the APC groups and their payment weights. Since CY 2012, the Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). The current charter specifies, among other requirements, that the Panel—

- May advise on the clinical integrity of Ambulatory Payment Classification (APC) groups and their associated weights;
- May advise on the appropriate supervision level for hospital outpatient services;
- Continues to be technical in nature;
- Is governed by the provisions of the FACA;
- Has a Designated Federal Official (DFO); and
- Is chaired by a Federal Official designated by the Secretary.

The Panel's charter was amended on November 15, 2011, renaming the Panel and expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and to add critical access hospital (CAH) representation to its membership. The Panel's charter was also amended on November 6, 2014 (80 FR 23009), and the number of members was revised from up to 19 to up to 15 members. The Panel's current charter was approved on November 19, 2018, for a 2-year period.

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 20, 2018. 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). The next meeting will take place on August 19–20, 2019. Complete information on the 2019 summer meeting, including information related to meeting presentations and submittals, meeting attendance/admittance, and web streaming of the meeting, can be found in the meeting notice published in the **Federal Register** on June 5, 2019 (84 FR 26117) and available on the website at: *https://www.govinfo.gov/content/pkg/FR-2019-06-05/pdf/2019-11756.pdf.* Registration to attend the meeting in person may be made through the CMS website at: *https://www.cms.gov/apps/events/event.asp?id=3745.*

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 20, 2018 meeting that the subcommittees continue. We accepted this recommendation.

Discussions of the other recommendations made by the Panel at the August 20, 2018 Panel meeting, namely CPT codes and a comprehensive APC for autologous hematopoietic stem cell transplantation, OPPS payment for outpatient clinic visits and restrictions to service line expansions, and packaging policies, were discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58827). 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 2019 OPPS/ASC Final Rule With Comment Period

We received over 540 timely pieces of correspondence on the CY 2019 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 30, 2018 (83 FR 61567), some of which contained comments on the interim APC assignments and/or status indicators of new or replacement Level II HCPCS codes (identified with comment indicator ''NI'' in OPPS Addendum B, ASC Addendum AA, and ASC Addendum BB to that final rule).

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 2020 OPPS/ASC proposed rule, for CY 2020, we are proposing to recalibrate the APC relative payment weights for services furnished on or after January 1, 2020, and before January 1, 2021 (CY 2020), using the same basic methodology that we described in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58827 through 58828), using updated CY 2018 claims data. That is, 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 2020, we began with approximately 164 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2018, and before January 1, 2019, before applying our exclusionary criteria and other methodological adjustments. After the application of those data processing changes, we used approximately 88 million final action claims to develop the proposed CY 2020 OPPS payment weights. For exact numbers of claims used and additional details on the claims accounting process, we refer readers to the claims accounting narrative under supporting documentation for this CY 2020 OPPS/ASC proposed rule on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

Addendum N to this proposed rule (which is available via the internet on the CMS website) includes the proposed list of bypass codes for CY 2020. The proposed list of bypass codes contains codes that were reported on claims for services in CY 2018 and, therefore, includes codes that were in effect in CY 2018 and used for billing, but were deleted for CY 2019. We retained these deleted bypass codes on the proposed CY 2020 bypass list because these codes existed in CY 2018 and were covered OPD services in that period, and CY 2018 claims data were used to calculate proposed CY 2020 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more ''pseudo'' single procedure claims for ratesetting purposes. ''Overlap bypass codes'' that are members of the proposed multiple imaging composite APCs 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 2020 are identified by asterisks (*) in the fourth column of Addendum N.

Table 1 contains the list of codes that we are proposing to remove from the CY 2020 bypass list.

TABLE 1.—PROPOSED HCPCS CODES TO BE REMOVED FROM THE CY 2020 BYPASS LIST

HCPCS	HCPCS Short Descriptor
G0436	Tobacco-use counsel 3-10 min
71010	Chest x-ray 1 view frontal
71015	Chest x-ray stereo frontal
71020	Chest x-ray 2vw frontal&latl
93965	Extremity study

b. Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2020, in this CY 2020 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 2020 APC payment rates are based, we calculated hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each hospital for which we had CY 2018 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, are from CY 2017. For the proposed CY 2020 OPPS payment rates, we used the set of claims processed during CY 2018. We applied the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code. That crosswalk is available for review and continuous comment on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2018 (the year of claims data we used to calculate the proposed CY 2020 OPPS payment rates) and found that the National Uniform Billing Committee (NUBC) did not add any new revenue codes to the NUBC 2018 Data Specifications Manual.

In accordance with our longstanding policy, we calculate CCRs for the standard and nonstandard cost centers accepted by the electronic cost report database. In general, the most detailed level at which we calculate CCRs is the hospital-specific departmental level. For a discussion of the hospital-specific overall ancillary CCR calculation, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 67983 through 67985). The calculation of blood costs is a longstanding exception (since the CY 2005 OPPS) to this general methodology for calculation of CCRs used for converting charges to costs on each claim. This exception is discussed in detail in the CY 2007 OPPS/ASC final rule with comment period and discussed further in section II.A.2.a.(1) of 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 imaging (MRIs), computed tomography (CT) scans, and cardiac catheterization. However, in response to the CY 2014 OPPS/ASC proposed rule, commenters reported that some hospitals 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 had raised concerns regarding using claims from all providers to calculate CT and MRI CCRs, regardless of the cost allocations statistic employed (78 FR 74840 through 74847). Stakeholders noted that providers continue to use the ''square feet'' cost allocation method and that including claims from such providers would cause significant reductions in the imaging APC payment rates.

Table 2 demonstrates the relative effect on imaging APC payments after removing cost data for providers that report CT and MRI standard cost centers using ''square feet'' as the cost allocation method by extracting HCRIS data on Worksheet B–1. Table 3 provides statistical values based on the CT and MRI standard cost center CCRs using the different cost allocation methods.

TABLE 2.—PERCENTAGE CHANGE IN ESTIMATED COST FOR CT AND MRI APCs WHEN EXCLUDING CLAIMS FROM PROVIDER USING "SQUARE FEET" AS THE COST ALLOCATION METHOD

APC	APC Descriptor	Percentage Change
5521	Level 1 Imaging without Contrast	-2.0%
5522	Level 2 Imaging without Contrast	5.8%
5523	Level 3 Imaging without Contrast	4.6%
5524	Level 4 Imaging without Contrast	6.8%
5571	Level 1 Imaging with Contrast	8.4%
5572	Level 2 Imaging with Contrast	8.3%
5573	Level 3 Imaging with Contrast	2.2%
8005	CT and CTA without Contrast Composite	14.2%
8006	CT and CTA with Contrast Composite	11.5%
8007	MRI and MRA without Contrast Composite	6.7%
8008	MRI and MRA with Contrast Composite	7.4%

TABLE 3.—CCR STATISTICAL VALUES BASED ON USE OF DIFFERENT COST ALLOCATION METHODS

Cost Allocation Method	CT		MRI	
	Median CCR	Mean CCR	Median CCR	Mean CCR
All Providers	0.0359	0.0505	0.0763	0.1027
Square Feet Only	0.0290	0.0443	0.0665	0.0927
Direct Assign	0.0511	0.0609	0.0990	0.1197
Dollar Value	0.0432	0.0583	0.0879	0.1156
Direct Assign and Dollar Value	0.0433	0.0583	0.0886	0.1155

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 17.5 percent to 2,184 providers and the number of valid CT CCRs has increased by 15.1 percent to 2,274 providers. However, as shown in Table 2, nearly all imaging APCs would see an increase in payment rates for CY 2020 if claims from providers that report using the ''square feet'' cost allocation method were removed. This can be attributed to the generally lower CCR values from providers that use a ''square feet'' cost allocation method as shown in Table 2.

For the CY 2019 OPPS, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58831), we extended our transition policy for an additional year and removed 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.

We note that the CT and MRI cost center CCRs have been available for ratesetting since the CY 2014 OPPS in which we established the transition policy. Since the initial 4-year transition, we have extended the transition an additional 2 years to offer provider flexibility in applying cost allocation methodologies for CT and MRI cost centers other than ''square feet.'' We believe we have provided sufficient time for providers to adopt an alternative cost allocation methodology for CT and MRI cost centers if they intended to do so. However, many providers continue to use the ''square feet'' cost allocation methodology, which we believe indicates that these providers believe this methodology is a sufficient method for attributing costs to this cost center. Additionally, we generally believe that increasing the amount of claims data available for use in ratesetting improves our ratesetting process. Therefore, we are proposing that, for the CY 2020 OPPS/ASC proposed rule and final rule with comment period, we will use all claims with valid CT and MRI cost center CCRs, including those that use a ''square feet'' cost allocation method, to estimate costs for the APCs for CT and MRI identified in Table 2. We do not believe another extension is 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.

In addition, as we stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74845), we have noted the potential impact the CT and MRI CCRs may have on other payment systems. We understand that payment reductions for imaging services under the OPPS could have significant payment impacts under the Physician Fee Schedule (PFS) where the technical component payment for many imaging services is capped at the OPPS payment amount. We will continue to monitor OPPS imaging payments in the future and consider the potential impacts of payment changes on the PFS and the ASC payment system.

2. Proposed Data Development 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 2020. 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 2018 claims that were used to calculate the proposed payment rates for this CY 2020 OPPS/ASC proposed rule.

Previously, the OPPS established the scaled relative weights, on which payments are based using APC median costs, a process described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f. of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same, under the methodologies that we used to obtain appropriate claims data and accurate cost information in determining estimated service cost. In this CY 2020 OPPS/ASC proposed rule, we are proposing to continue to use geometric mean costs to calculate the proposed relative weights on which the CY 2020 OPPS payment rates are based.

We used the methodology described in sections II.A.2.a. through II.A.2.c. of this 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 2020 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, under the OPPS, CY 2019 was the first year in which claims data containing lines with the modifier ''PN'' were available, which indicate nonexcepted items and services furnished and billed by off-campus provider-based departments (PBDs) of hospitals. Because nonexcepted services are not paid under the OPPS, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58832), we finalized a policy to remove those claim lines reported with modifier ''PN'' from the claims data used in ratesetting for the CY 2019 OPPS and subsequent years. For the CY 2020 OPPS, we will continue to remove these claim lines with modifier ''PN'' from the ratesetting process.

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 2020 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 2020 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 2020 payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific, simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

We continue to believe that the hospital-specific, simulated blood-specific, CCR methodology better responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. Because this methodology takes into account the unique charging and cost accounting structure of each hospital, we believe that it yields more accurate estimated costs for these products. We continue to

believe that this methodology in CY 2020 would result in costs for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and, therefore, for these blood products in general.

We note that, as discussed in section II.A.2.b.(1). of the CY 2019 OPPS/ASC final rule with comment period (82 FR 58837 through 58843), we defined a comprehensive APC (C–APC) as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Under this policy, we include the costs of blood and blood products when calculating the overall costs of these C–APCs. In this CY 2020 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 CY 2020 OPPS/ASC proposed rule (which is available via the internet on the CMS website) for the proposed CY 2020 payment rates for blood and blood products (which are identified with status indicator ''R''). For a more detailed discussion of the blood-specific CCR methodology, we refer readers to the CY 2005 OPPS proposed rule (69 FR 50524 through 50525). For a full history of OPPS payment for blood and blood products, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810).

(b) Pathogen-Reduced Platelets Payment Rate

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70322 through 70323), we reiterated that we calculate payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. Because HCPCS code P9072 (Platelets, pheresis, pathogen reduced or rapid bacterial tested, each unit), the predecessor code to HCPCS code P9073 (Platelets, pheresis, pathogen-reduced, each unit), was new for CY 2016, there were no claims data available on the charges and costs for this blood product upon which to apply our blood-specific CCR methodology. Therefore, we established an interim payment rate for HCPCS code P9072 based on a crosswalk to existing blood product HCPCS code P9037 (Platelets, pheresis, leukocytes reduced, irradiated, each unit), which we believed provided the best proxy for the costs of the new blood product. In addition, we stated that once we had claims data for HCPCS code P9072, we would calculate its payment rate using the claims data that should be available for the code beginning in CY 2018, which is our practice for other blood product HCPCS codes for which claims data have been available for 2 years.

We stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59233) that, although our standard practice for new codes involves using claims data to set payment rates once claims data become available, we were concerned that there may have been confusion among the provider community about the services that HCPCS code P9072 described. That is, as early as 2016, there were discussions about changing the descriptor for HCPCS code P9072 to include the phrase ''or rapid bacterial tested'', which is a less costly technology than pathogen reduction. In addition, effective January 2017, the code descriptor for HCPCS code P9072 was changed to describe rapid bacterial testing of platelets and, effective July 1, 2017, the descriptor for the temporary successor code (HCPCS code Q9988) for HCPCS code P9072 was changed again back to the original descriptor for HCPCS code P9072 that was in place for 2016.

Based on the ongoing discussions involving changes to the original HCPCS code P9072 established in CY 2016, we believed that claims from CY 2016 for pathogen reduced platelets may have potentially reflected certain claims for rapid bacterial testing of platelets. Therefore, we decided to continue to crosswalk the payment amount for services described by HCPCS code P9073 (the successor code to HCPCS code P9072 established January 1, 2018) to the payment amount for services described by HCPCS code P9037 for CY 2018 (82 FR 59232), as had been done previously, to determine the payment rate for services described by HCPCS code P9072. In the CY 2019 OPPS/ASC proposed rule (83 FR 37058), for CY 2019, we discussed that we had reviewed the CY 2017 claims data for the two predecessor codes to HCPCS code P9073 (HCPCS codes P9072 and Q9988), along with the claims data for the CY 2017 temporary code for pathogen test for platelets (HCPCS code Q9987), which describes rapid bacterial testing of platelets. We found that there were over 2,200 claims billed with either HCPCS code P9072 or Q9988 in the CY 2017 claims data available for CY 2019 rulemaking. Accordingly, we believed that there were a sufficient number of claims to calculate a payment rate for HCPCS code P9073 for CY 2019 without using a crosswalk.

We also performed checks to estimate the share of claims that may have been billed for rapid bacterial testing of platelets as compared to the share of claims that may have been billed for pathogen-reduced, pheresis platelets (based on when HCPCS code P9072 was an active procedure code from January 1, 2017 to June 30, 2017). First, we found that the geometric mean cost for pathogen-reduced, pheresis platelets, as reported by HCPCS code Q9988 when billed separately from rapid bacterial testing of platelets, was $453.87, and that over 1,200 claims were billed for services described by HCPCS code Q9988. Next, we found that the geometric mean cost for rapid bacterial testing of platelets, as reported by HCPCS code Q9987 on claims, was $33.44, and there were 59 claims reported for services described by HCPCS code Q9987, of which 3 were separately paid.

These findings implied that almost all of the claims billed for services reported with HCPCS code P9072 were for pathogen-reduced, pheresis platelets. In addition, the geometric mean cost for services described by HCPCS code P9072, which may have contained rapid bacterial testing of platelets claims, was $468.11, which was higher than the geometric mean cost for services described by HCPCS code Q9988 of $453.87, which should not have contained claims for rapid bacterial testing of platelets. Because the geometric mean for services described by HCPCS code Q9987 was only $33.44, it would be expected that if a significant share of claims billed for services described by HCPCS code P9072 were for the rapid bacterial testing of platelets, the geometric mean cost for services described by HCPCS code P9072 would be lower than the geometric mean cost for services described by HCPCS code Q9988. Instead, we found that the geometric mean cost for services described by HCPCS code Q9988 was higher than the geometric mean cost for services described by HCPCS code P9072.

However, we received many comments from providers and stakeholders requesting that we not implement our proposal for CY 2019, and instead that we should once again establish the payment rate for HCPCS code P9073 by performing a crosswalk from the payment amount for services described by HCPCS code P9073 to the payment amount for services described by HCPCS code P9037. The commenters were concerned that the payment rate for HCPCS code P9073 calculated by using claims data for that service was too low. Several commenters believed the claim costs for pathogen-reduced platelets were lower than actual costs because of coding errors by providers, providers who did not use pathogen-reduced platelets when billing the service, and confusion over whether to use the hospital CCR or the blood center CCR to report charges for pathogen-reduced platelets. We considered the comments we received and decided not to finalize our proposal for CY 2019 to calculate the payment rate for services described by HCPCS code P9073 using claims payment history. Instead, for CY 2019, we established the payment rate for services described by HCPCS code P9073 by crosswalking the payment rate for the services described by HCPCS code P9073 from the payment rate for services described by HCPCS code P9037 (83 FR 58834).

For CY 2020 and subsequent years, we are proposing to calculate the payment rate for services described by HCPCS code P9073 by using claims payment history, which is the standard methodology used under the OPPS to calculate payment rates for HCPCS codes with at least 2 years of claims history. Claims for HCPCS code P9073 and its predecessor codes have been billed under the OPPS for over 3 years and we believe providers have had sufficient time to become familiar with the services covered by the procedure code and the appropriate charges and CCRs used to report the service. Also, it has been more than a year and half since the issue in which payment for pathogen-reduced platelets and payment for rapid bacterial testing were combined under the same code was resolved. In our analysis of claims data from CY 2018, we found that approximately 4,700 claims have been billed for services described by HCPCS code P9073 and the estimated payment rate for services described by HCPCS code P9073 based on the claims data is approximately $585. The claims-based payment rate for services described by HCPCS code P9073 is approximately $60 less than the estimated crosswalked payment rate using HCPCS code P9037 of approximately $645. The claims data show that services described by HCPCS code P9073 have been reported regularly by providers during CY 2018 and the payment rate is close to the payment rate of the crosswalked payment rate for services described by HCPCS code P9037. Therefore, we believe that the payment rate for services described by HCPCS code P9073 can be determined using claims data without a crosswalk from the payment rate for services described by HCPCS code P9037.

We refer readers to Addendum B of 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 2020 OPPS/ASC proposed rule, for CY 2020, we are proposing to use the costs derived from CY 2018 claims data to set the proposed CY 2020 payment rates for brachytherapy sources because CY 2018 is the year of data we are proposing to use to set the proposed payment rates for most other items and services that would be paid under the CY 2020 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 2020 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 2020, 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). However, our CY 2018 claims data include two claims with over 9,000 units of HCPCS code C2645. For the CY 2019 OPPS/ASC final rule with comment period, our CY 2017 claims data only included one claim with one unit of HCPCS code C2645. Therefore, we believe the CY 2018 claims data are adequate to establish an APC payment rate for HCPCS code C2645 and to discontinue our use of external data for this brachytherapy source. Specifically, we are proposing to set the proposed CY 2020 payment rate at the geometric mean cost of HCPCS code C2645 based on CY 2018 claims data, which is $1.02 per mm^2.

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 2020

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910), we finalized a comprehensive payment policy that packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. The policy was finalized in CY 2014, but the effective date was delayed until January 1, 2015, to allow additional time for further analysis, opportunity for public comment, and systems preparation. The comprehensive APC (C–APC) policy was implemented effective January 1, 2015, with modifications and clarifications in response to public comments received regarding specific provisions of the C–APC policy (79 FR 66798 through 66810).

A C–APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We established C–APCs as a category broadly for OPPS payment and implemented 25 C–APCs beginning in CY 2015 (79 FR 66809 through 66810). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70332), we finalized 10 additional C–APCs to be paid under the existing C–APC payment policy and added 1 additional level to both the Orthopedic Surgery and Vascular Procedures clinical families, which increased the total number of C–APCs to 37 for CY 2016. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79584 through 79585), we finalized another 25 C–APCs for a total of 62 C–APCs. In the CY 2018 OPPS/ASC final rule with comment period, we did not change the total number of C–APCs from 62. In the CY 2019 OPPS/ASC final rule with comment period, we created 3 new C–APCs, increasing the total number to 65 (83 FR 58844 through 58846).

Under our C–APC policy, we designate a service described by a HCPCS code assigned to a C–APC as the primary service when the service is identified by OPPS status indicator ''J1''. When such a primary service is reported on a hospital outpatient claim, taking into consideration the few exceptions that are discussed below, we make payment for all other items and services reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service (hereinafter collectively referred to as ''adjunctive services'') and representing components of a complete comprehensive service (78 FR 74865 and 79 FR 66799). Payments for adjunctive services are packaged into the payments for the primary services. This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level.

Services excluded from the C–APC policy under the OPPS include services that are not covered OPD services, services that cannot by statute be paid for under the OPPS, and services that are required by statute to be separately paid. This includes certain mammography and ambulance services that are not covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which also are required by statute to receive separate payment under section 1833(t)(2)(H) of the Act; pass-through payment drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act; and certain preventive services (78 FR 74865 and 79 FR 66800 through 66801). A list of services excluded from the C–APC policy is included in Addendum J to this 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 (Hospital observation services, per hour);
- Contains services provided on the same date of service or 1 day before the date of service for HCPCS code G0378 that are described by one of the following codes: HCPCS code G0379 (Direct admission of patient for hospital observation care) on the same date of service as HCPCS code G0378; CPT code 99281 (Emergency department visit for the evaluation and management of a patient (Level 1)); CPT code 99282 (Emergency department visit for the evaluation and management of a patient (Level 2)); CPT code 99283 (Emergency department visit for the evaluation and management of a patient (Level 3)); CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285

(Emergency department visit for the evaluation and management of a patient (Level 5)) or HCPCS code G0380 (Type B emergency department visit (Level 1)); HCPCS code G0381 (Type B emergency department visit (Level 2)); HCPCS code G0382 (Type B emergency department visit (Level 3)); HCPCS code G0383 (Type B emergency department visit (Level 4)); HCPCS code G0384 (Type B emergency department visit (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient); and

- Does not contain services described by a HCPCS code to which we have assigned status indicator ''J1''.

The assignment of status indicator ''J2'' to a specific combination of services performed in combination with each other allows for all other OPPS payable services and items reported on the claim (excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS) to be deemed adjunctive services representing components of a comprehensive service and resulting in a single prospective payment for the comprehensive service based on the costs of all reported services on the claim (80 FR 70333 through 70336).

Services included under the C–APC payment packaging policy, that is, services that are typically adjunctive to the primary service and provided during the delivery of the comprehensive service, include diagnostic procedures, laboratory tests, and other diagnostic tests and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the service; durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components reported by HCPCS codes that represent services that are provided during the complete comprehensive service (78 FR 74865 and 79 FR 66800).

In addition, payment for hospital outpatient department services that are similar to therapy services and delivered either by therapists or nontherapists is included as part of the payment for the packaged complete comprehensive service. These services that are provided during the perioperative period are adjunctive services and are deemed not to be therapy services as described in section 1834(k) of the Act, regardless of whether the services are delivered by therapists or other nontherapist health care workers. We have previously noted that therapy services are those provided by therapists under a plan of care in accordance with section 1835(a)(2)(C) and section 1835(a)(2)(D) of the Act and are paid for under section 1834(k) of the Act, subject to annual therapy caps as applicable (78 FR 74867 and 79 FR 66800). However, certain other services similar to therapy services are considered and paid for as hospital outpatient department services. Payment for these nontherapy outpatient department services that are reported with therapy codes and provided with a comprehensive service is included in the payment for the packaged complete comprehensive service. We note that these services, even though they are reported with therapy codes, are hospital outpatient department services and not therapy services. We refer readers to the July 2016 OPPS Change Request 9658 (Transmittal 3523) for further instructions on reporting these services in the context of a C–APC service.

Items included in the packaged payment provided in conjunction with the primary service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and SADs, unless they function as packaged supplies (78 FR 74868 through 74869 and 74909 and 79 FR 66800). We refer readers to Section 50.2M, Chapter 15, of the Medicare Benefit Policy Manual for a description of our policy on SADs treated as hospital outpatient supplies, including lists of SADs that function as supplies and those that do not function as supplies.

We define each hospital outpatient claim reporting a single unit of a single primary service assigned to status indicator ''J1'' as a single ''J1'' unit procedure claim (78 FR 74871 and 79 FR 66801). Line item charges for services included on the C–APC claim are converted to line item costs, which are then summed to develop the estimated APC costs. These claims are then assigned one unit of the service with status indicator ''J1'' and later used to develop the geometric mean costs for the C–APC relative payment weights. (We note that we use the term ''comprehensive'' to describe the geometric mean cost of a claim reporting ''J1'' service(s) or the geometric mean cost of a C–APC, inclusive of all of the items and services included in the C–APC service payment bundle.) Charges for services that would otherwise be separately payable are added to the charges for the primary service. This process differs from our traditional cost accounting methodology only in that all such services on the claim are packaged (except certain services as described above). We apply our standard data trims, which exclude claims with extremely high primary units or extreme costs.

The comprehensive geometric mean costs are used to establish resource similarity and, along with clinical similarity, dictate the assignment of the primary services to the C–APCs. We establish a ranking of each primary service (single unit only) to be assigned to status indicator ''J1'' according to its comprehensive geometric mean costs. For the minority of claims reporting more than one primary service assigned to status indicator ''J1'' or units thereof, we identify one ''J1'' service as the primary service for the claim based on our cost-based ranking of primary services. We then assign these multiple ''J1'' procedure claims to the C–APC to which the service designated as the primary service is assigned. If the reported ''J1'' services on a claim map to different C–APCs, we designate the ''J1'' service assigned to the C–APC with the highest comprehensive geometric mean cost as the primary service for that claim. If the reported multiple ''J1'' services on a claim map to the same C–APC, we designate the most costly service (at the HCPCS code level) as the primary service for that claim. This process results in initial assignments of claims for the primary services assigned to status indicator ''J1'' to the most appropriate C–APCs based on both single and multiple procedure claims reporting these services and clinical and resource homogeneity.

Complexity Adjustments. We use complexity adjustments to provide increased payment for certain comprehensive services. We apply a complexity adjustment by promoting qualifying paired ''J1'' service code combinations or paired code combinations of ''J1'' services and certain add-on codes (as described further below) from the originating C–APC (the C–APC to which the designated primary service is first assigned) to the next higher paying C–APC in the same clinical family of C–APCs. We apply this type of complexity adjustment when the paired code combination represents a complex, costly form or version of the primary service according to the following criteria:

- Frequency of 25 or more claims reporting the code combination (frequency threshold); and

• Violation of the 2 times rule in the originating C–APC (cost threshold).

These criteria identify paired code combinations that occur commonly and exhibit materially greater resource requirements than the primary service. The CY 2017 OPPS/ASC final rule with comment period (81 FR 79582) included a revision to the complexity adjustment eligibility criteria. Specifically, we finalized a policy to discontinue the requirement that a code combination (that qualifies for a complexity adjustment by satisfying the frequency and cost criteria thresholds described above) also not create a 2 times rule violation in the higher level or receiving APC.

After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim assigned to status indicator ''J1'' (or certain add-on codes) to determine if there are paired code combinations that meet the complexity adjustment criteria. For a new HCPCS code, we determine initial C–APC assignment and qualification for a complexity adjustment using the best available information, crosswalking the new HCPCS code to a predecessor code(s) when appropriate.

Once we have determined that a particular code combination of ''J1'' services (or combinations of ''J1'' services reported in conjunction with certain add-on codes) represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, we promote the claim including the complex version of the primary service as described by the code combination to the next higher cost C–APC within the clinical family, unless the primary service is already assigned to the highest cost APC within the C–APC clinical family or assigned to the only C–APC in a clinical family. We do not create new APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C–APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any claim including a code combination for services assigned to a C–APC would be the highest paying C–APC in the clinical family (79 FR 66802).

We package payment for all add-on codes into the payment for the C–APC. However, certain primary service add-on combinations may qualify for a complexity adjustment. As noted in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70331), all add-on codes that can be appropriately reported in combination with a base code that describes a primary ''J1'' service are evaluated for a complexity adjustment.

To determine which combinations of primary service codes reported in conjunction with an add-on code may qualify for a complexity adjustment for CY 2020, in this CY 2020 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 proposed complexity adjustments for ''J1'' and add-on code combinations for CY 2020, along with all of the other proposed complexity adjustments, in Addendum J to this CY 2020 OPPS/ASC 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 2020

For CY 2020 and subsequent years, in this CY 2020 OPPS/ASC proposed rule, we are proposing to continue to apply the C–APC payment policy methodology. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79583) for a discussion of the C–APC payment policy methodology and revisions.

Each year, in accordance with section 1833(t)(9)(A) of the Act, we review and revise the services within each APC group and the APC assignments under the OPPS. As a result of our annual review of the services and the APC assignments under the OPPS, in this proposed rule, we are proposing to add two C–APCs under the existing C–APC payment policy in CY 2020: Proposed C–APC 5182 (Level 2 Vascular Procedures); and proposed C–APC 5461 (Level 1 Neurostimulator and Related Procedures). These APCs were selected to be included in this proposed rule because, similar to other C–APCs, these APCs include primary, comprehensive services, such as major surgical procedures, that are typically reported with other ancillary and adjunctive services. Also, similar to other APCs that have been converted to C–APCs, there are higher APC levels within the clinical family or related clinical family of these APCs that have previously been assigned to a C–APC. Table 4 of this proposed rule lists the proposed C–APCs for CY 2020. 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.

We also are considering developing an episode-of-care for skin substitutes and are interested in comments regarding a future C–APC for procedures using skin substitute products furnished in the hospital outpatient department

setting. We note that this comment solicitation is discussed in section V.B.7. of this proposed rule.

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TABLE 4.—PROPOSED CY 2020 C-APCs

C-APC	CY 2020 APC Group Title	Clinical Family	New C-APC
5072	Level 2 Excision/Biopsy/Incision and Drainage	EBIDX	
5073	Level 3 Excision/Biopsy/Incision and Drainage	EBIDX	
5091	Level 1 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5092	Level 2 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5093	Level 3 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5094	Level 4 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5112	Level 2 Musculoskeletal Procedures	ORTHO	
5113	Level 3 Musculoskeletal Procedures	ORTHO	
5114	Level 4 Musculoskeletal Procedures	ORTHO	
5115	Level 5 Musculoskeletal Procedures	ORTHO	
5116	Level 6 Musculoskeletal Procedures	ORTHO	
5153	Level 3 Airway Endoscopy	AENDO	
5154	Level 4 Airway Endoscopy	AENDO	
5155	Level 5 Airway Endoscopy	AENDO	
5163	Level 3 ENT Procedures	ENTXX	
5164	Level 4 ENT Procedures	ENTXX	
5165	Level 5 ENT Procedures	ENTXX	
5166	Cochlear Implant Procedure	COCHL	
5182	Level 2 Vascular Procedures	VASCX	*
5183	Level 3 Vascular Procedures	VASCX	
5184	Level 4 Vascular Procedures	VASCX	
5191	Level 1 Endovascular Procedures	EVASC	
5192	Level 2 Endovascular Procedures	EVASC	
5193	Level 3 Endovascular Procedures	EVASC	
5194	Level 4 Endovascular Procedures	EVASC	
5200	Implantation Wireless PA Pressure Monitor	WPMXX	
5211	Level 1 Electrophysiologic Procedures	EPHYS	
5212	Level 2 Electrophysiologic Procedures	EPHYS	
5213	Level 3 Electrophysiologic Procedures	EPHYS	
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	

C-APC	CY 2020 APC Group Title	Clinical Family	New C-APC
5302	Level 2 Upper GI Procedures	GIXXX	
5303	Level 3 Upper GI Procedures	GIXXX	
5313	Level 3 Lower GI Procedures	GIXXX	
5331	Complex GI Procedures	GIXXX	
5341	Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX	
5361	Level 1 Laparoscopy and Related Services	LAPXX	
5362	Level 2 Laparoscopy and Related Services	LAPXX	
5373	Level 3 Urology and Related Services	UROXX	
5374	Level 4 Urology and Related Services	UROXX	
5375	Level 5 Urology and Related Services	UROXX	
5376	Level 6 Urology and Related Services	UROXX	
5377	Level 7 Urology and Related Services	UROXX	
5414	Level 4 Gynecologic Procedures	GYNXX	
5415	Level 5 Gynecologic Procedures	GYNXX	
5416	Level 6 Gynecologic Procedures	GYNXX	
5431	Level 1 Nerve Procedures	NERVE	
5432	Level 2 Nerve Procedures	NERVE	
5461	Level 1 Neurostimulator and Related Procedures	NSTIM	*
5462	Level 2 Neurostimulator and Related Procedures	NSTIM	
5463	Level 3 Neurostimulator and Related Procedures	NSTIM	
5464	Level 4 Neurostimulator and Related Procedures	NSTIM	
5471	Implantation of Drug Infusion Device	PUMPS	
5491	Level 1 Intraocular Procedures	INEYE	
5492	Level 2 Intraocular Procedures	INEYE	
5493	Level 3 Intraocular Procedures	INEYE	
5494	Level 4 Intraocular Procedures	INEYE	
5495	Level 5 Intraocular Procedures	INEYE	
5503	Level 3 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	
5504	Level 4 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	
5627	Level 7 Radiation Therapy	RADTX	
5881	Ancillary Outpatient Services When Patient Dies	N/A	
8011	Comprehensive Observation Services	N/A	

C-APC Clinical Family Descriptor Key:

AENDO = Airway Endoscopy
AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices.
BREAS = Breast Surgery
COCHL = Cochlear Implant
EBIDX = Excision/ Biopsy/Incision and Drainage
ENTXX = ENT Procedures

EPHYS = Cardiac Electrophysiology
EVASC = Endovascular Procedures
EXEYE = Extraocular Ophthalmic Surgery
GIXXX = Gastrointestinal Procedures
GYNXX = Gynecologic Procedures
INEYE = Intraocular Surgery
LAPXX = Laparoscopic Procedures
NERVE = Nerve Procedures
NSTIM = Neurostimulators
ORTHO = Orthopedic Surgery
PUMPS = Implantable Drug Delivery Systems
RADTX = Radiation Oncology
SCTXX = Stem Cell Transplant
UROXX = Urologic Procedures
VASCX = Vascular Procedures
WPMXX = Wireless PA Pressure Monitor

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(3) Exclusion of Procedures Assigned to New Technology APCs From the C–APC Policy

Services that are assigned to New Technology APCs are typically new procedures that do not have sufficient claims history to establish an accurate payment for the procedures. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected (82 FR 59277).

The C–APC payment policy packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. Prior to CY 2019 when a procedure assigned to a New Technology APC was included on the claim with a primary procedure, identified by OPPS status indicator ''J1'', payment for the new technology service was typically packaged into the payment for the primary procedure. Because the new technology service was not separately paid in this scenario, the overall number of single claims available to determine an appropriate clinical APC for the new service was reduced. This was contrary to the objective of the New Technology APC payment policy, which is to gather sufficient claims data to enable us to assign the service to an appropriate clinical APC.

For example, for CY 2017, there were seven claims generated for HCPCS code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intraocular retinal electrode array, with vitrectomy), which involves the use of the Argus® II Retinal Prosthesis System. However, several of these claims were not available for ratesetting because HCPCS code 0100T was reported with a ''J1'' procedure and, therefore, payment was packaged into the associated C–APC payment. If these services had been separately paid under the OPPS, there would be at least two additional single claims available for ratesetting. As mentioned previously, the purpose of the new technology APC policy is to ensure that there are sufficient claims data for new services, which is particularly important for services with a low volume such as procedures described by HCPCS code 0100T. Another concern is the costs reported for the claims when payment is not packaged for a new technology procedure may not be representative of all of the services included on a claim that is generated, which may also affect our ability to assign the new service to the most appropriate clinical APC.

To address this issue and help ensure that there is sufficient claims data for services assigned to New Technology APCs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58847), we excluded payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599 and APCs 1901 through 1908) from being packaged when included on a claim with a ''J1'' service assigned to a C–APC. For CY 2020, we are proposing to continue to exclude payment for any procedure that is assigned to a New Technology APC from being packaged when included on a claim with a ''J1'' service assigned to a C–APC.

Some stakeholders have raised questions about whether the policy established in the CY 2019 OPPS/ASC final rule with comment period would also apply to comprehensive observation services assigned status indicator ''J2.'' We recognize that the policy described and adopted in the CY 2019 rulemaking may have been ambiguous with respect to this issue. While our intention in the CY 2019 rulemaking was only to exclude payment for services assigned to New Technology APCs from being bundled into the payment for a comprehensive ''J1'' service, we believe that there may also be some instances in which it would be clinically appropriate to provide a new technology service when providing comprehensive observation services. We would not generally expect that to be the case, because procedures assigned to New Technology APCs typically are new or low-volume surgical procedures, or are specialized tests to diagnosis a specific condition. In addition, it is highly unlikely a general observation procedure would be assigned to a New Technology APC because there are clinical APCs already established under the OPPS to classify general observation procedures. As we stated in the CY 2016 OPPS/ASC final rule with comment period, observation services may not be used for post-operative recovery and, as such, observation services furnished with services assigned to status indicator ''T'' will always be packaged (80 FR 70334). Therefore, we are proposing that payment for services assigned to a New Technology APC when included on a claim for a service assigned status indicator ''J2'' assigned to a C–APC will be packaged into the payment for the comprehensive service. Nonetheless, we are seeking public comments on whether it would be clinically appropriate to exclude payment for any New Technology APC procedures from

being packaged into the payment for a comprehensive ''J2'' service starting in CY 2020.

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.

(1) Mental Health Services Composite APC

In this CY 2020 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.

In this CY 2020 OPPS/ASC proposed rule, for CY 2020, 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 2020. 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 2020 OPPS/ASC proposed rule, we are proposing, for CY 2020, 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 2020 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 CY 2018 claims available for the CY 2020 OPPS/ASC proposed rule that qualified for composite payment under the current policy (that is, those claims reporting more than one procedure within the same family on a single date of service). To calculate the proposed geometric mean costs, we used the same methodology that we have used to calculate the geometric mean costs for these composite APCs since CY 2014, as described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918). The imaging HCPCS codes referred to as ''overlap bypass codes'' that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC geometric mean costs, in accordance with our established methodology as stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918), are identified by asterisks in Addendum N to this CY 2020 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 2020 OPPS/ASC proposed rule.

For this CY 2020 OPPS/ASC proposed rule, we were able to identify approximately 700,000 ''single session'' claims out of an estimated 4.9 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 14 percent of all eligible claims, to calculate the proposed CY 2020 geometric mean costs for the multiple imaging composite APCs. Table 5 of this CY 2020 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 2020.

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TABLE 5.—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCs

Family 1 – Ultrasound	
Proposed CY 2020 APC 8004 (Ultrasound Composite)	**Proposed CY 2020 Approximate APC Geometric Mean Cost = $303.10**
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76776	Us exam k transpl w/Doppler
76831	Echo exam, uterus
76856	Us exam, pelvic, complete
76857	Us exam, pelvic, limited
76981	Us parenchyma
76982	Us 1st target lesion
Family 2 - CT and CTA with and without Contrast	
Proposed CY 2020 APC 8005 (CT and CTA without Contrast Composite)*	**Proposed CY 2020 Approximate APC Geometric Mean Cost = $226.32**
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 2020 APC 8006 (CT and CTA with Contrast Composite)	**Proposed CY 2020 Approximate APC Geometric Mean Cost = $435.85**
70487	Ct maxillofacial w/dye
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o & w/dye

70488	Ct maxillofacial w/o & w/dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
71270	Ct thorax w/o & w/dye
71275	Ct angiography, chest
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72191	Ct angiograph pelv w/o & w/dye
72193	Ct pelvis w/dye
72194	Ct pelvis w/o & w/dye
73201	Ct upper extremity w/dye
73202	Ct uppr extremity w/o & w/dye
73206	Ct angio upr extrm w/o & w/dye
73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o & w/dye
73706	Ct angio lwr extr w/o & w/dye
74160	Ct abdomen w/dye
74170	Ct abdomen w/o & w/dye
74175	Ct angio abdom w/o & w/dye
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
74177	Ct angio abd & pelv w/contrast
74178	Ct angio abd & pelv 1+ regns
* If a "without contrast" CT or CTA procedure is performed during the same session as a "with contrast" CT or CTA procedure, the I/OCE assigns the procedure to APC 8006 rather than APC 8005.	
Family 3 - MRI and MRA with and without Contrast	
Proposed CY 2020 APC 8007 (MRI and MRA without Contrast Composite)*	**Proposed CY 2020 Approximate APC Geometric Mean Cost = $519.80**
70336	Magnetic image, jaw joint
70540	Mri orbit/face/neck w/o dye
70544	Mr angiography head w/o dye

70547	Mr angiography neck w/o dye
70551	Mri brain w/o dye
70554	Fmri brain by tech
71550	Mri chest w/o dye
72141	Mri neck spine w/o dye
72146	Mri chest spine w/o dye
72148	Mri lumbar spine w/o dye
72195	Mri pelvis w/o dye
73218	Mri upper extremity w/o dye
73221	Mri joint upr extrem w/o dye
73718	Mri lower extremity w/o dye
73721	Mri jnt of lwr extre w/o dye
74181	Mri abdomen w/o dye
75557	Cardiac mri for morph
75559	Cardiac mri w/stress img
76391	Mr elastography
77046	Mri breast c- unilateral
77047	Mri breast c- bilateral
C8901	MRA w/o cont, abd
C8910	MRA w/o cont, chest
C8913	MRA w/o cont, lwr ext
C8919	MRA w/o cont, pelvis
C8932	MRA, w/o dye, spinal canal
C8935	MRA, w/o dye, upper extr
Proposed CY 2020 APC 8008 (MRI and MRA with Contrast Composite)	**Proposed CY 2020 Approximate APC Geometric Mean Cost = $827.75**
70549	Mr angiograph neck w/o & w/dye
70542	Mri orbit/face/neck w/dye
70543	Mri orbt/fac/nck w/o & w/dye
70545	Mr angiography head w/dye
70546	Mr angiograph head w/o & w/dye
70547	Mr angiography neck w/o dye
70548	Mr angiography neck w/dye
70552	Mri brain w/dye
70553	Mri brain w/o & w/dye
71551	Mri chest w/dye
71552	Mri chest w/o & w/dye
72142	Mri neck spine w/dye
72147	Mri chest spine w/dye

72149	Mri lumbar spine w/dye
72156	Mri neck spine w/o & w/dye
72157	Mri chest spine w/o & w/dye
72158	Mri lumbar spine w/o & w/dye
72196	Mri pelvis w/dye
72197	Mri pelvis w/o & w/dye
73219	Mri upper extremity w/dye
73220	Mri uppr extremity w/o & w/dye
73222	Mri joint upr extrem w/dye
73223	Mri joint upr extr w/o & w/dye
73719	Mri lower extremity w/dye
73720	Mri lwr extremity w/o & w/dye
73722	Mri joint of lwr extr w/dye
73723	Mri joint lwr extr w/o & w/dye
74182	Mri abdomen w/dye
74183	Mri abdomen w/o & w/dye
75561	Cardiac mri for morph w/dye
75563	Card mri w/stress img & dye
C8900	MRA w/cont, abd
C8902	MRA w/o fol w/cont, abd
C8903	MRI w/cont, breast, uni
C8905	MRI w/o fol w/cont, brst, un
C8906	MRI w/cont, breast, bi
C8908	MRI w/o fol w/cont, breast,
C8909	MRA w/cont, chest
C8911	MRA w/o fol w/cont, chest
C8912	MRA w/cont, lwr ext
C8914	MRA w/o fol w/cont, lwr ext
C8918	MRA w/cont, pelvis
C8920	MRA w/o fol w/cont, pelvis
C8931	MRA, w/dye, spinal canal
C8933	MRA, w/o&w/dye, spinal canal
C8934	MRA, w/dye, upper extremity
C8936	MRA, w/o&w/dye, upper extr
* If a "without contrast" MRI or MRA procedure is performed during the same session as a "with contrast" MRI or MRA procedure, the I/OCE assigns the procedure to APC 8008 rather than APC 8007.	

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3. 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 beneficiary. The OPPS packages

payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which 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), the CY 2018 OPPS/ASC final rule with comment period (82 FR 59250), and the CY 2019 OPPS/ASC final rule with comment period (83 FR 58854). As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care, we have expanded the OPPS packaging policies. Most, but not necessarily all, categories of items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b). Our overarching goal is to make payments for all services under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided under the OPPS to determine which OPPS services can be packaged to further achieve the objective of advancing the OPPS toward a more prospective payment system.

For CY 2020, we examined the items and services currently provided under the OPPS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment for the primary service that they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) and outpatient hospital billing patterns to determine whether there were categories of codes for which packaging would be appropriate according to existing OPPS packaging policies or a logical expansion of those existing OPPS packaging policies. In this CY 2020 OPPS/ASC proposed rule, for CY 2020, 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 the proposed changes to the packaging policies beginning in CY 2020.

b. Packaging Policy for Non-Opioid Pain Management Treatments

(1) Background on OPPS/ASC Non-Opioid Pain Management Packaging Policies

In the CY 2018 OPPS/ASC proposed rule (82 FR 33588), within the framework of existing packaging categories, such as drugs that function as supplies in a surgical procedure or diagnostic test or procedure, we requested stakeholder feedback on common clinical scenarios involving currently packaged items and services described by HCPCS codes that stakeholders believe should not be packaged under the OPPS. We also expressed interest in stakeholder feedback on common clinical scenarios involving separately payable HCPCS codes for which payment would be most appropriately packaged under the OPPS. Commenters who responded to the CY 2018 OPPS/ASC proposed rule expressed a variety of views on packaging under the OPPS. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59255), we summarized these public comments. The public comments ranged from requests to unpackage most items and services that are either conditionally or unconditionally packaged under the OPPS, including drugs and devices, to specific requests for separate payment for a specific drug or device.

In terms of Exparel® in particular, we received several requests to pay separately for the drug Exparel® rather than packaging payment for it as a surgical supply. We had previously stated that we considered Exparel® to be a drug that functions as a surgical supply because it is indicated for the alleviation of postoperative pain (79 FR 66874 and 66875). We had also stated before that we considered all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy. (We note that Exparel® is a liposome injection of bupivacaine, an amide local anesthetic, indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia. In 2011, Exparel® was approved by the FDA for single-dose infiltration into the surgical site to provide postsurgical analgesia.[1] [2] Exparel® had pass-through payment status from CYs 2012 through 2014 and was separately paid under both the OPPS and the ASC payment system during this 3-year period. Beginning in CY 2015, Exparel® was packaged as a surgical supply under both the OPPS and the ASC payment system.)

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59345), we reiterated our position with regard to

[1] 2011 product label available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022496s000lbl.pdf.*

[2] 2011 FDA approval letter available at: *https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/022496Orig1s000Approv.pdf.*

payment for Exparel®, stating that we believed that payment for this drug is appropriately packaged with the primary surgical procedure. We also stated in the CY 2018 OPPS/ASC final rule with comment period that CMS would continue to explore and evaluate packaging policies under the OPPS and consider these policies in future rulemaking.

In addition to stakeholder feedback regarding OPPS packaging policies in response to the CY 2018 OPPS/ASC proposed rule, the President's Commission on Combating Drug Addiction and the Opioid Crisis (the Commission) had recommended that CMS examine payment policies for certain drugs that function as a supply, specifically non-opioid pain management treatments. The Commission was established in 2017 to study ways to combat and treat drug abuse, addiction, and the opioid crisis. The Commission's report [3] included a recommendation for CMS to ''. . . review and modify ratesetting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate postsurgical pain. . . .'' [4] With respect to the packaging policy, the Commission's report states that ''. . . the current CMS payment policy for 'supplies' related to surgical procedures creates unintended incentives to prescribe opioid medications to patients for postsurgical pain instead of administering non-opioid pain medications. Under current policies, CMS provides one all-inclusive bundled payment to hospitals for all 'surgical supplies,' which includes hospital administered drug products intended to manage patients' postsurgical pain. This policy results in the hospitals receiving the same fixed fee from Medicare whether the surgeon administers a non-opioid medication or not.'' [5] HHS also presented an Opioid Strategy in April 2017 [6] that aims in part to support cutting-edge research and advance the practice of pain management. On October 26, 2017, the President declared the opioid crisis a national public health emergency under Federal law [7] and this declaration was most recently renewed on April 19, 2019.[8]

For the CY 2019 rulemaking, we reviewed available literature with respect to Exparel®, including a briefing document [9] submitted for 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.'' [10] 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.[11] We stated in the CY 2019 OPPS/ASC proposed rule that, based on our review of currently available OPPS Medicare claims data and public information from the manufacturer of the drug, we did not believe that the OPPS packaging policy had discouraged the use of Exparel® for either of the drug's indications when furnished in the hospital outpatient department setting.

In the CY 2019 OPPS/ASC proposed rule, in response to stakeholder comments on the CY 2018 OPPS/ASC final rule with comment period (82 FR 59345) and in light of the recommendations regarding payment policies for certain drugs, we evaluated the impact of our packaging policy for drugs that function as a supply when used in a surgical procedure on the utilization of these drugs in both the hospital outpatient department and the ASC setting. Our packaging policy is that the costs associated with packaged drugs that function as a supply are included in the ratesetting methodology for the surgical procedures with which they are billed, and the payment rate for the associated procedure reflects the costs of the packaged drugs and other packaged items and services to the extent they are billed with the procedure. In our evaluation, we used currently available data to analyze the utilization patterns associated with specific drugs that function as a supply over a 5-year time period to determine whether this packaging policy reduced the use of these drugs. If the packaging policy discouraged the use of drugs that function as a supply or impeded access to these products, we would expect to see a significant decline in utilization of these drugs over time, although we note that a decline in utilization could also reflect other factors, such as the availability of alternative products.

The results of the evaluation of our packaging policies under the OPPS and the ASC payment system showed decreased utilization for certain drugs that function as a supply in the ASC setting, in comparison to the hospital outpatient department setting. In light of these results, as well as the Commission's recommendation to examine payment policies for non-opioid pain management drugs that function as a supply, we believed it was appropriate to pay separately for evidence-based non-opioid pain management drugs that function as a supply in a surgical procedure in the ASC setting to address the decreased utilization of these drugs and to encourage use of these types of drugs rather than prescription opioids. Therefore, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58855 through 58860), we finalized the proposed policy to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2019. We also stated that we would continue to analyze the issue of access to non-opioid alternatives in the hospital outpatient department setting and in the ASC setting as we implemented section 6082 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act (Pub. L. 115–271) enacted on October 24, 2018 (83 FR 58860 through 58861).

(2) Evaluation and CY 2020 Proposal for Payment for Non-Opioid Alternatives

Section 1833(t)(22)(A)(i) of the Act, as added by section 6082(a) of the SUPPORT Act, states that the Secretary must review payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of

[3] President's Commission on Combating Drug Addiction and the Opioid Crisis, Report (2017). Available at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.*

[4] Ibid, at page 57, Recommendation 19.

[5] Ibid.

[6] Available at: *https://www.hhs.gov/about/leadership/secretary/speeches/2017-speeches/secretary-price-announces-hhs-strategy-for-fighting-opioid-crisis/index.html.*

[7] Available at: *https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html.*

[8] Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.*

[9] Food and Drug Administration, Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee Briefing Document (2018). Available at: *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM596314.pdf.*

[10] Ibid, page 9.

[11] 2018 updated product label available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022496s009lbledt.pdf.*

ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. As part of this review, under section 1833(t)(22)(A)(iii) of the Act, the Secretary must consider the extent to which revisions to such payments (such as the creation of additional groups of covered OPD services to separately classify those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce the payment incentives for using opioids instead of non-opioid alternatives for pain management. In conducting this review and considering any revisions, the Secretary must focus on covered OPD services (or groups of services) assigned to C–APCs, APCs that include surgical services, or services determined by the Secretary that generally involve treatment for pain management. If the Secretary identifies revisions to payments pursuant to section 1833(t)(22)(A)(iii) of the Act, section 1833(t)(22)(C) of the Act requires the Secretary to, as determined appropriate, begin making revisions for services furnished on or after January 1, 2020. Any revisions under this paragraph are required to be treated as adjustments for purposes of paragraph (9)(B), which requires any adjustments to be made in a budget neutral manner. Pursuant to these requirements, in our evaluation of whether there are payment incentives for using opioids instead of non-opioid alternatives, for this CY 2020 OPPS/ASC proposed rule, we used currently available data to analyze the payment and utilization patterns associated with specific non-opioid alternatives, including drugs that function as a supply, nerve blocks, and neuromodulation products, to determine whether our packaging policies have reduced the use of non-opioid alternatives. We focused on covered OPD services for this review, including services assigned to C–APCs, surgical APCs, and other pain management services. We believed that if the packaging policy discouraged the use of these non-opioid alternatives or impeded access to these products, we would expect to see a decline in the utilization over time, although we note that a decline in utilization could also reflect other factors, such as the availability of alternative products.

We evaluated continuous peripheral nerve blocks and neuromodulation alternatives to determine if the current packaging policy represented a barrier to access. For each product, we examined the most recently available Medicare claims data. All of the alternatives examined showed consistent or increasing utilization in recent years, with no products showing decreases in utilization.

We also evaluated drugs that function as surgical supplies over a 6-year time period (CYs 2013 through 2018). During our evaluation, we did not observe significant declines in the total number of units used in the hospital outpatient department for a majority of the drugs included in our analysis. In fact, under the OPPS, we observed the opposite effect for several drugs that function as surgical supplies, including Exparel® (HCPCS code C9290). This trend indicates appropriate packaged payments that adequately reflect the cost of the drug and are not prohibiting beneficiary access.

From CYs 2013 through 2018, we found that there was an overall increase in the OPPS Medicare utilization of Exparel® of approximately 491 percent (from 2.3 million units to 13.6 million units) during this 6-year time period. The total number of claims reporting the use of Exparel® increased by 463 percent (from 10,609 claims to 59,724 claims) over this 6-year time period. This increase in utilization continued, even after the expiration of the 3-year pass-through payment status for this drug in 2014, resulting in a 109-percent overall increase in the total number of units used between CYs 2015 and 2018, from 6.5 million units to 13.6 million units. The number of claims reporting the use of Exparel® increased by 112 percent during this time period, from 28,166 claims to 59,724 claims.

The results of our review and evaluation of our claims data do not provide evidence to indicate that the OPPS packaging policy has had the unintended consequence of discouraging the use of non-opioid treatments for postsurgical pain management in the hospital outpatient department. Therefore, based on this data evaluation, we do not believe that changes are necessary under the OPPS for the packaged drug policy for drugs that function as a surgical supply, nerve blocks, surgical injections, and neuromodulation products when used in a surgical procedure in the OPPS setting at this time.

For Exparel®, we reviewed claims data for development of this CY 2020 OPPS/ASC proposed rule and, based on these data and available literature, we concluded that there is no clear evidence that the OPPS packaging policy discourages the use of Exparel® for either of the drug's indications in the hospital outpatient department setting because the use of Exparel® continues to increase in this setting. Accordingly, we continue to believe it is appropriate to package payment for the use of Exparel®, as we do for other postsurgical pain management drugs, when it is furnished in a hospital outpatient department. In addition, our updated review of claims data showed a continued decline in the utilization of Exparel® in the ASC setting, which we believe supports our proposal to continue paying separately for Exparel® in the ASC setting.

Therefore, for CY 2020, we are proposing to continue our policy to pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting and continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2020. However, we are inviting public comments on this proposal and asking the public to provide peer reviewed evidence, if any, to describe existing evidence-based non-opioid pain management therapies used in the outpatient and ASC setting. We are also inviting the public to provide detailed claims-based evidence to document how specific unfavorable utilization trends are due to the financial incentives of the payment systems rather than other factors.

Multiple stakeholders, largely manufacturers of devices and drugs, have requested separate payments for various non-opioid pain management treatments, such as continuous nerve blocks (including a disposable elastomeric pump that delivers non-opioid local anesthetic to a surgical site or nerve), cooled thermal radiofrequency ablation, and local anesthetics designed to reduce postoperative pain for cataract surgery and other procedures. These stakeholders have suggested various mechanisms through which separate payment or a higher-paying APC assignment for the primary service could be made. The stakeholders have offered surveys, reports, studies, and anecdotal evidence of varying degrees to support why the devices, drugs, or services offer an alternative to or a reduction of the need for opioid prescriptions. The majority of these stakeholder offerings have lacked adequate sample size, contained possible conflicts of interest such as studies conducted by employees of device manufacturers, have not been fully published in peer-reviewed literature, or have only provided anecdotal evidence as to how the drug

or device could serve as an alternative to, or reduce the need for, opioid prescriptions.

After reviewing the data from stakeholders and Medicare claims data, we have not found compelling evidence to suggest that revisions to our OPPS payment policies for non-opioid pain management alternatives are necessary for CY 2020. Additionally, MedPAC's March 2019 Report to Congress supports CMS' conclusion. Specifically, Chapter 16 of MedPAC's report, titled Mandated Report: Opioids and Alternatives in Hospital Settings—Payments, Incentives, and Medicare Data, concludes that there is no clear indication that Medicare's OPPS provides systematic payment incentives that promote the use of opioid analgesics over non-opioid analgesics.[12] However, we are inviting public comments on whether there are other non-opioid pain management alternatives for which our payment policy should be revised to allow separate payment. We are requesting public comments that provide evidence-based support, such as published peer-reviewed literature, that we could use to determine whether these products help to deter or avoid prescription opioid use and addiction as well as evidence that the current packaged payment for such non-opioid alternatives presents a barrier to access to care and therefore warrants revised, including possibly separate, payment under the OPPS. Evidence that current payment policy provides a payment incentive for using opioids instead of non-opioid alternatives should align with available Medicare claims data.

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 2019 OPPS/ASC final rule with comment period (83 FR 58860 through 58861), we applied this policy and calculated the relative payment weights for each APC for CY 2019 that were shown in Addenda A and B to that final rule with comment period (which were made available via the internet on the CMS website) using the APC costs discussed in sections II.A.1. and II.A.2. of that final rule with comment period. For CY 2020, as we did for CY 2019, we are proposing to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2020 using geometric mean-based APC costs.

For CY 2012 and CY 2013, outpatient clinic visits were assigned to one of five levels of clinic visit APCs, with APC 0606 representing a mid-level clinic visit. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75043), we finalized a policy that created alphanumeric HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), representing any and all clinic visits under the OPPS. HCPCS code G0463 was assigned to APC 0634 (Hospital Clinic Visits). We also finalized a policy to use CY 2012 claims data to develop the CY 2014 OPPS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT E/M codes for clinic visits previously recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). In addition, we finalized a policy to no longer recognize a distinction between new and established patient clinic visits.

For CY 2016, we deleted APC 0634 and reassigned the outpatient clinic visit HCPCS code G0463 to APC 5012 (Level 2 Examinations and Related Services) (80 FR 70372). For CY 2020, as we did for CY 2019, we 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 2020, as we did for CY 2019, 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 the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015), we discussed our policy, implemented on January 1, 2019, to control for unnecessary increases in the volume of covered outpatient department services by paying for clinic visits furnished at excepted off-campus provider-based department (PBD) at a reduced rate. While the volume associated with these visits is included in the impact model, and thus used in calculating the weight scalar, the policy has a negligible effect on the scalar. Specifically, under this policy, there was no change to the relativity of the OPPS payment weights because the adjustment is made at the payment level rather than in the cost modeling. Further, under this policy, the savings that would result from the change in payments for these clinic visits would not be budget neutral. Therefore, the impact of this 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 2020 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 2019 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2020 unscaled relative payment weights.

For CY 2019, we multiplied the CY 2019 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2018 claims to calculate the total relative payment weight for each service. We then added together the total relative payment weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2020, we are proposing to apply the same process using the estimated CY 2020 unscaled relative payment weights rather than scaled relative payment weights. We are proposing to calculate the weight scalar by dividing the CY 2019 estimated aggregate weight by the proposed unscaled CY 2020 estimated aggregate weight.

For a detailed discussion of the weight scalar calculation, we refer readers to the OPPS claims accounting document available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. Click on the CY 2020 OPPS 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 2020 to the estimated total relative payment weights in CY

[12] Available at: *http://www.medpac.gov/-documents-/reports*.

2019 using CY 2018 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we are proposing to adjust the calculated CY 2020 unscaled relative payment weights for purposes of budget neutrality. We are proposing to adjust the estimated CY 2020 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4401 to ensure that the proposed CY 2020 relative payment weights are scaled to be budget neutral. The proposed CY 2020 relative payment weights listed in Addenda A and B to 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 2020 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 2020 IPPS/LTCH PPS proposed rule (84 FR 19401), consistent with current law, based on IHS Global, Inc.'s fourth quarter 2018 forecast of the FY 2020 market basket increase, the proposed FY 2020 IPPS market basket update is 3.2 percent. However, sections 1833(t)(3)(F) and 1833(t)(3)(G)(v) of the Act, as added by section 3401(i) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) and as amended by section 10319(g) of that law and further amended by section 1105(e) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), provide adjustments to the OPD fee schedule increase factor for CY 2020.

Specifically, section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment, and then revised this methodology, as discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509). According to the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19402), the proposed MFP adjustment for FY 2020 is 0.5 percentage point.

For CY 2020, we are proposing that the MFP adjustment for the CY 2020 OPPS is 0.5 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 2020 market basket update and the MFP adjustment, which are components in calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and 1833(t)(3)(F) of the Act, in this CY 2020 OPPS/ASC proposed rule.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 percent for a year, and may result in OPPS payment rates being less than rates for the preceding year. As described in further detail below, we are proposing to apply an OPD fee schedule increase factor of 2.7 percent for the CY 2020 OPPS (which is 3.2 percent, the proposed estimate of the hospital inpatient market basket percentage increase, less the proposed 0.5 percentage point MFP 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 XIV. of this proposed rule.

We are proposing to amend 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (11) to reflect the requirement in section 1833(t)(3)(F)(i) of the Act that, for CY 2020, we reduce the OPD fee schedule increase factor by the MFP adjustment as determined by CMS.

To set the OPPS conversion factor for CY 2020, we are proposing to increase the CY 2019 conversion factor of $79.490 by 2.7 percent. In accordance with section 1833(t)(9)(B) of the Act, we are proposing further to adjust the conversion factor for CY 2020 to ensure that any revisions made to the wage index and rural adjustment were made on a budget neutral basis. We are proposing to calculate an overall budget neutrality factor of 0.9993 for wage index changes. This adjustment is comprised of a 1.0005 proposed budget neutrality adjustment, using our standard calculation, of comparing proposed total estimated payments from our simulation model using the proposed FY 2020 IPPS wage indexes to those payments using the FY 2019 IPPS wage indexes, as adopted on a calendar year basis for the OPPS as well as a 0.9988 proposed budget neutrality adjustment for the proposed CY 2020 5 percent cap on wage index decreases to ensure that this transition wage index is implemented in a budget neutral manner, consistent with the proposed FY 2020 IPPS wage index policy (84 FR 19398). We believe it is appropriate to ensure that this proposed wage index transition policy (that is, the proposed CY 2020 5 percent cap on wage index decreases) does not increase estimated aggregate payments under the OPPS beyond the payments that would be made without this transition policy. We are proposing to calculate this budget neutrality adjustment by comparing total estimated OPPS payments using the FY 2020 IPPS wage index, adopted on a calendar year basis for the OPPS, where a 5 percent cap on wage index decreases is not applied to total estimated OPPS payments where the 5 percent cap on wage index decreases is applied. These two proposed wage index budget neutrality adjustments would maintain budget neutrality for the proposed CY 2020 OPPS wage index (which, as discussed in section II.C of this proposed rule, would use the FY 2020 IPPS post-reclassified wage index and any adjustments, including without limitation any proposed adjustments

finalized under the IPPS to address wage index disparities).

For the CY 2020 OPPS, we are maintaining 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 is 1.0000.

For this CY 2020 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 2020 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing estimated total CY 2020 payments under section 1833(t) of the Act, including the proposed CY 2020 cancer hospital payment adjustment, to estimated CY 2020 total payments using the CY 2019 final cancer hospital payment adjustment, as required under section 1833(t)(18)(B) of the Act. The proposed CY 2020 estimated payments applying the proposed CY 2020 cancer hospital payment adjustment are the same as estimated payments applying the CY 2019 final cancer hospital payment adjustment. Therefore, we are proposing to apply a budget neutrality adjustment factor of 0.9998 to the conversion factor for the cancer hospital payment adjustment. In accordance with section 16002(b) of the 21st Century Cures Act, we are proposing to apply a budget neutrality factor calculated as if the proposed cancer hospital adjustment target payment-to-cost ratio is 0.90, not the 0.89 target payment-to-cost ratio we are proposing to apply as stated in section II.F. of this proposed rule.

For this CY 2020 OPPS/ASC proposed rule, we estimate that proposed pass-through spending for drugs, biologicals, and devices for CY 2020 would equal approximately $268.8 million, which represents 0.34 percent of total projected CY 2020 OPPS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 0.14 percent estimate of pass-through spending for CY 2019 and the 0.34 percent estimate of proposed pass-through spending for CY 2020, resulting in a proposed decrease for CY 2020 of 0.20 percent. Proposed estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2020. We estimate for this proposed rule that outlier payments would be 1.03 percent of total OPPS payments in CY 2019; the 1.00 percent for proposed outlier payments in CY 2020 would constitute a 0.03 percent increase in payment in CY 2020 relative to CY 2019.

For this CY 2020 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 0.7 percent (that is, the proposed OPD fee schedule increase factor of 2.7 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2020 of $79.770 for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.628 in the conversion factor relative to hospitals that meet the requirements).

In summary, for CY 2020, we are proposing to amend § 419.32 by adding a new paragraph (b)(1)(iv)(B)(*11*) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2020 to satisfy the statutory requirements of sections 1833(t)(3)(F) and (t)(3)(G)(v) of the Act. We are proposing to use a reduced conversion factor of $79.770 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.628 in the conversion factor relative to hospitals that meet the requirements).

For CY 2020, we are proposing to use a conversion factor of $81.398 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the proposed OPD fee schedule increase factor of 2.7 percent for CY 2020, the required proposed wage index budget neutrality adjustment of approximately 0.9993, the proposed cancer hospital payment adjustment of 0.9998, and the proposed adjustment of −0.20 percentage point of projected OPPS spending for the difference in pass-through spending that resulted in a proposed conversion factor for CY 2020 of $81.398. We refer readers to section XXVI.B. of this proposed rule for a discussion of the estimated effect on the conversion factor of a policy to pay for 340B-acquired drugs at ASP+3 percent, which is a policy on which we solicit comments for potential future rulemaking in the event of an adverse decision on appeal in the ongoing litigation involving our payment policy for 340B-acquired drugs.

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). In this CY 2020 OPPS/ASC proposed rule, we are proposing to continue this policy for the CY 2020 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 would standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2020 pre-reclassified wage index that CMS is proposing to use under the IPPS to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the OPPS April 7, 2000 final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Therefore, the wage index that applies to a particular acute care, short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998 OPPS proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an

adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). Section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a frontier State and amended section 1833(t) of the Act to add paragraph (19), which requires a frontier State wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements at § 419.43(c)(2) and (3) of our regulations. For the CY 2020 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. 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 2019 IPPS/LTCH PPS final rules for discussions regarding this provision, including our methodology for identifying which areas meet the definition of ''frontier States'' as provided for in section 1886(d)(3)(E)(iii)(II) of the Act: For FY 2011, 75 FR 50160 through 50161; for FY 2012, 76 FR 51793, 51795, and 51825; for FY 2013, 77 FR 53369 through 53370; for FY 2014, 78 FR 50590 through 50591; for FY 2015, 79 FR 49971; for FY 2016, 80 FR 49498; for FY 2017, 81 FR 56922; for FY 2018, 82 FR 38142; and for FY 2019, 83 FR 41380.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2020 IPPS wage indexes continue to reflect a number of adjustments implemented over the past few years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, an adjustment for occupational mix, and an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment). In addition, we note that, as discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19393 through 19399), we proposed a number of policies under the IPPS to address wage index disparities between high and low wage index value hospitals. In particular, in the FY 2020 IPPS/LTCH PPS proposed rule, we proposed to (1) calculate the rural floor without including the wage data of urban hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented in § 412.103) (84 FR 19396 through 19398); (2) remove the wage data of urban hospitals that have reclassified as rural under § 412.103 from the calculation of ''the wage index for rural areas in the State'' for purposes of applying section 1886(d)(8)(C)(iii) of the Act (84 FR 19398); (3) increase the wage index values for hospitals with a wage index below the 25th percentile wage index value across all hospitals by half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year, and to offset the estimated increase in payments to hospitals with wage index values below the 25th percentile by decreasing the wage index values for hospitals with wage index values above the 75th percentile wage index value across all hospitals (84 FR 19394 through 19396); and (4) apply a 5-percent cap for FY 2020 on any decrease in a hospital's final wage index from the hospital's final wage index in FY 2019, as a proposed transition wage index to help mitigate any significant negative impacts on hospitals (84 FR 19398). In addition, in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19398), we proposed to apply a budget neutrality adjustment to the standardized amount so that our proposed transition wage index for hospitals that may be negatively impacted (described in item (4) above) would be implemented in a budget neutral manner. Furthermore, in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19398 through 19399), we noted that our proposed adjustment relating to the rural floor calculation also would be budget neutral. We refer readers to the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19373 through 19399) for a detailed discussion of all proposed changes to the FY 2020 IPPS wage indexes.

As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) and in each subsequent IPPS/LTCH PPS final rule, including the FY 2019 IPPS/LTCH PPS final rule (83 FR 41362), the Office of Management and Budget (OMB) issued revisions to the labor market area delineations on February 28, 2013 (based on 2010 Decennial Census data), that included a number of significant changes, such as new Core Based Statistical Areas (CBSAs), urban counties that became rural, rural counties that became urban, and existing CBSAs that were split apart (OMB Bulletin 13–01). This bulletin can be found at: *https://obamawhitehouse.archives.gov/sites/default/files/omb/bulletins/2013/b13-01.pdf*. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49950 through 49985), for purposes of the IPPS, we adopted the use of the OMB statistical area delineations contained in OMB Bulletin No. 13–01, effective October 1, 2014. For purposes of the OPPS, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66826 through 66828), we adopted the use of the OMB statistical area delineations contained in OMB Bulletin No. 13–01, effective January 1, 2015, beginning with the CY 2015 OPPS wage indexes. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), we adopted revisions to statistical areas contained in OMB Bulletin No. 15–01, issued on July 15, 2015, which provided updates to and superseded OMB Bulletin No. 13–01 that was issued on February 28, 2013. For purposes of the OPPS, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79598), we adopted the revisions to the OMB statistical area delineations contained in OMB Bulletin No. 15–01, effective January 1, 2017, beginning with the CY 2017 OPPS wage indexes.

On August 15, 2017, OMB issued OMB Bulletin No. 17–01, which provided updates to and superseded OMB Bulletin No. 15–01 that was issued on July 15, 2015. The attachments to OMB Bulletin No. 17–01 provided detailed information on the update to the statistical areas since July 15, 2015, and were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2014 and July 1, 2015. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58863 through 58865), we adopted the updates set forth in OMB Bulletin No. 17–01, effective January 1, 2019, beginning with the CY 2019 wage index. We continue to believe that it is important for the OPPS to use the latest labor market area delineations available as soon as is reasonably possible in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. For a complete discussion of the adoption of the

updates set forth in OMB Bulletin No. 17–01, we refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58864 through 58865).

As we stated in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19374), for the FY 2020 IPPS wage indexes, we would continue to use the OMB delineations that were adopted, beginning with FY 2015 (based on the revised delineations issued in OMB Bulletin No. 13–01) to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 15–01 and 17–01. Similarly, in this CY 2020 OPPS/ASC proposed rule, for the CY 2020 OPPS wage indexes, we would continue to use the OMB delineations that were adopted under the OPPS, beginning with CY 2015 (based on the revised delineations issued in OMB Bulletin No. 13–01) to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 15–01 and 17–01.

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. The FY 2018 IPPS/LTCH PPS final rule (82 FR 38130) discussed the two different lists of codes to identify counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the IPPS and OPPS wage indexes. However, the SSA county codes are no longer being maintained and updated, although the FIPS codes continue to be maintained by the U.S. Census Bureau. The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2015. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at: *https://www.census.gov/geo/reference/county-changes.html* (which, as of May 6, 2019, migrated to: *https://www.census.gov/programs-surveys/geography.html*). In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), for purposes of crosswalking counties to CBSAs for the IPPS wage index, we finalized our proposal to discontinue the use of the SSA county codes and begin using only the FIPS county codes. Similarly, for the purposes of crosswalking counties to CBSAs for the OPPS wage index, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59260), we finalized our proposal to discontinue the use of SSA county codes and begin using only the FIPS county codes for the purposes of crosswalking counties to CBSAs for the OPPS wage index. For CY 2020, under the OPPS, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs.

In this CY 2020 OPPS/ASC proposed rule, we are proposing to use the FY 2020 hospital IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment standardized amount for CY 2020. Therefore, any adjustments for the FY 2020 IPPS post-reclassified wage index, including, but not limited to, any proposed policies finalized under the IPPS to address wage index disparities between low and high wage index value hospitals as discussed above and in the FY 2020 IPPS/LTCH PPS proposed rule at 84 FR 19393 through19399, would be reflected in the final CY 2020 OPPS wage index beginning on January 1, 2020. (We refer readers to the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19373 through 19399) and the proposed FY 2020 hospital wage index files posted on the CMS website.) With regard to budget neutrality for the CY 2020 OPPS wage index, we refer readers to section II.B. of this proposed rule. We continue to believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall.

Hospitals that are paid under the OPPS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPPS, it is our longstanding policy to assign the wage index that would be applicable if the hospital were paid under the IPPS, based on its geographic location and any applicable wage index adjustments. In this CY 2020 OPPS/ASC proposed rule, we are proposing to continue this policy for CY 2020, and are including a brief summary of the major proposed FY 2020 IPPS wage index policies and adjustments that we are proposing to apply to these hospitals under the OPPS for CY 2020, which we have summarized below. We refer readers to the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19373 through 19399) for a detailed discussion of the proposed changes to the FY 2020 IPPS wage indexes.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)). Applying this adjustment is consistent with our policy of adopting IPPS wage index policies for hospitals paid under the OPPS. We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage index adjustment if they are located in a section 505 out-migration county. This is the same out-migration adjustment policy that applies if the hospital were paid under the IPPS. For CY 2020, we 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). In addition, for non-IPPS hospitals paid under the OPPS, we are proposing to apply any proposed policies that are finalized under the IPPS relating to wage index disparities as discussed earlier in this proposed rule and in the FY 2020 IPPS/LTCH PPS proposed rule at 84 FR 19393 through 19399. We also are proposing that the wage index that would apply to non-IPPS hospitals for CY 2020 would include the rural floor adjustment.

For CMHCs, for CY 2020, 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. We also are proposing to apply any proposed policies that are finalized under the IPPS relating to wage index disparities as discussed earlier in this proposed rule and in the FY 2020 IPPS/LTCH PPS proposed rule at 84 FR 19393 through 19399. In addition, we are proposing that the wage index that would apply to CMHCs for CY 2020 would include the rural floor adjustment. Also, we are proposing that the wage index that would apply to CMHCs would not include the out-migration adjustment because that adjustment only applies to hospitals.

Table 4 associated with the FY 2020 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. Table 2 associated with the FY 2020 IPPS/LTCH PPS proposed rule (available for download via the website above) identifies IPPS hospitals that would receive the out-migration adjustment for FY 2020. We are including the out-migration adjustment information from Table 2 associated with the FY 2020 IPPS/LTCH PPS 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 this CY

2020 OPPS/ASC proposed rule. 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 2020 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. For certain hospitals, under the regulations at 42 CFR 419.43(d)(5)(iii), CMS uses the statewide average default CCRs to determine the payments mentioned earlier if it is unable to determine an accurate CCR for a hospital in certain circumstances. This includes hospitals that are new, hospitals that have not accepted assignment of an existing hospital's provider agreement, and hospitals that have not yet submitted a cost report. CMS also uses the statewide average default CCRs to determine payments for hospitals whose CCR falls outside the predetermined ceiling threshold for a valid CCR or for hospitals in which the most recent cost report reflects an all-inclusive rate status (Medicare Claims Processing Manual (Pub. 100–04), Chapter 4, Section 10.11).

We discussed our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009. For details on our process for calculating the statewide average CCRs, we refer readers to the CY 2020 OPPS proposed rule Claims Accounting Narrative that is posted on the CMS website. In this CY 2020 OPPS/ASC proposed rule, we are proposing to update the default ratios for CY 2020 using the most recent cost report data. We will update these ratios in the final rule if more recent cost report data are available.

Beginning with this CY 2020 proposed rule, we are no longer publishing a table in the **Federal Register** containing the statewide average CCRs in the annual OPPS proposed rule and final rule. These CCRs with the upper limit will be available for download with each OPPS calendar year proposed rule and final rule on the CMS website. We refer the reader to the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*; click on the link on the left of the page titled ''Hospital Outpatient Regulations and Notices'' and then select the relevant regulation to download the statewide CCRs and upper limit in the downloads section of the web page.

E. 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 2020

In the CY 2006 OPPS final rule with comment period (70 FR 68556), we finalized a payment increase for rural sole community hospitals (SCHs) of 7.1 percent for all services and procedures paid under the OPPS, excluding drugs, biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised § 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 2019. Further, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68590), we updated the regulations at § 419.43(g)(4) to specify, in general terms, that items paid at charges adjusted to costs by application of a hospital-specific CCR are excluded from the 7.1 percent payment adjustment.

For the CY 2020 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, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy.

F. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2020

1. Background

Since the inception of the OPPS, which was authorized by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), Medicare has paid the 11 hospitals that meet the criteria for cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act under the OPPS for covered outpatient hospital services. These cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113), Congress established section 1833(t)(7) of the Act, ''Transitional Adjustment to Limit Decline in Payment,'' to determine OPPS payments to cancer and children's hospitals based on their pre-BBA payment amount (often referred to as ''held harmless'').

As required under section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient services under the OPPS and a ''pre-BBA amount.'' That is, cancer hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive transitional outpatient payments (TOPs) or hold harmless payments to ensure that they do not

receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The ''pre-BBA amount'' is the product of the hospital's reasonable costs for covered outpatient services occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The ''pre-BBA amount'' and the determination of the base PCR are defined at 42 CFR 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital Cost Report or the Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10, respectively), as applicable each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Affordable Care Act amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed outpatient costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. Section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by cancer hospitals and other hospitals. Section 1833(t)(18)(B) of the Act provides that, if the Secretary determines that cancer hospitals' costs are higher than those of other hospitals, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. In 2011, after conducting the study required by section 1833(t)(18)(A) of the Act, we determined that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPPS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 through 74201).

Based on these findings, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects their higher outpatient costs, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74202 through 74206). Specifically, we adopted a policy to provide additional payments to the cancer hospitals so that each cancer hospital's final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the ''target PCR'') for other hospitals paid under the OPPS. The target PCR is set in advance of the calendar year and is calculated using the most recently submitted or settled cost report data that are available at the time of final rulemaking for the calendar year. The amount of the payment adjustment is made on an aggregate basis at cost report settlement. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs are assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period. For CYs 2012 and 2013, the target PCR for purposes of the cancer hospital payment adjustment was 0.91. For CY 2014, the target PCR was 0.90. For CY 2015, the target PCR was 0.90. For CY 2016, the target PCR was 0.92, as discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70362 through 70363). For CY 2017, the target PCR was 0.91, as discussed in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79603 through 79604). For CY 2018, the target PCR was 0.88, as discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59265 through 59266). For CY 2019, the target PCR was 0.88, as discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58871 through 58873).

2. Proposed Policy for CY 2020

Section 16002(b) of the 21st Century Cures Act (Pub. L. 114–255) amended section 1833(t)(18) of the Act by adding subparagraph (C), which requires that in applying 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 2020, 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 were 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 2020. To calculate the proposed CY 2020 target PCR, we are using the same extract of cost report data from HCRIS, as discussed in section II.A. of this proposed rule, used to estimate costs for the CY 2020 OPPS. Using these cost report data, we are including data from Worksheet E, Part B, for each hospital, using data from each hospital's most recent cost report, whether as submitted or settled.

We then limited the dataset to the hospitals with CY 2018 claims data that we used to model the impact of the proposed CY 2020 APC relative payment weights (3,770 hospitals) because it is appropriate to use the same set of hospitals that are being used to calibrate the modeled CY 2020 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2016 to 2018. We then removed the cost report data of the 49 hospitals located in Puerto Rico from our dataset because we did not believe their cost structure reflected the costs of most hospitals paid under the OPPS, and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 23 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a proposed analytic file of 3,539 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS were approximately 90 percent of reasonable cost (weighted average PCR of 0.90). Therefore, after applying the 1.0 percentage point reduction, as required by section 16002(b) of the 21st Century Cures Act, we 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 0.89 for each cancer hospital.

Table 6 shows the estimated percentage increase in OPPS payments to each cancer hospital for CY 2020, due to the cancer hospital payment adjustment policy. The actual amount of the CY 2020 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2020 payments and costs. We note that the requirements contained in section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

TABLE 6.—ESTIMATED CY 2020 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2020 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	36.7%
050660	USC Norris Cancer Hospital	23.0%
100079	Sylvester Comprehensive Cancer Center	23.3%
100271	H. Lee Moffitt Cancer Center & Research Institute	7.1%
220162	Dana-Farber Cancer Institute	37.6%
330154	Memorial Sloan-Kettering Cancer Center	49.7%
330354	Roswell Park Cancer Institute	22.1%
360242	James Cancer Hospital & Solove Research Institute	22.4%
390196	Fox Chase Cancer Center	10.7%
450076	M.D. Anderson Cancer Center	43.7%
500138	Seattle Cancer Care Alliance	51.9%

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 2019, the outlier threshold was met when the hospital's cost of furnishing a service exceeded 1.75 times (the multiplier threshold) the APC payment amount and exceeded the APC payment amount plus $4,825 (the fixed-dollar amount threshold) (83 FR 58874 through 58875). If the cost of a service exceeds both the multiplier threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount. Beginning with CY 2009 payments, outlier payments are subject to a reconciliation process similar to the IPPS outlier reconciliation process for cost reports, as discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the OPPS. Our estimate of total outlier payments as a percent of total CY 2018 OPPS payments, using CY 2018 claims available for this CY 2020 OPPS/ASC proposed rule, is approximately 1.0 percent of the total aggregated OPPS payments. Therefore, for CY 2018, we estimated that we paid the outlier target of 1.0 percent of total aggregated OPPS payments. Using an updated claims dataset for this CY 2020 OPPS proposed rule, we estimate that we paid

approximately 1.03 percent of the total aggregated OPPS payments in outliers for CY 2018.

For this CY 2020 OPPS/ASC proposed rule, using CY 2018 claims data and CY 2019 payment rates, we estimate that the aggregate outlier payments for CY 2019 would be approximately 1.03 percent of the total CY 2019 OPPS payments. We are providing estimated CY 2020 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital—Specific Impacts—Provider-Specific Data file on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

2. Proposed Outlier Calculation for CY 2020

For CY 2020, 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 2020 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 $4,950.

We calculated the proposed fixed-dollar threshold of $4,950 using the standard methodology most recently used for CY 2019 (83 FR 58874 through 58875). For purposes of estimating outlier payments for the proposed rule, we are using the hospital-specific overall ancillary CCRs available in the April 2019 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCRs, which are maintained by the MACs and used by the OPPS Pricer to pay claims. The claims that we use to model each OPPS update lag by 2 years.

In order to estimate the CY 2020 hospital outlier payments for this proposed rule, we inflate the charges on the CY 2018 claims using the same inflation factor of 1.11189 that we used to estimate the proposed IPPS fixed-dollar outlier threshold for the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19596). We used an inflation factor of 1.05446 to estimate CY 2019 charges from the CY 2018 charges reported on CY 2018 claims. The methodology for determining this charge inflation factor is discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41717 through 41718). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65845), we believe that the use of these charge inflation factors is appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and outpatient cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we do 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 2020 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2020 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2020, we are proposing to apply an adjustment factor of 0.97517 to the CCRs that were in the April 2019 OPSF to trend them forward from CY 2019 to CY 2020. The methodology for calculating the proposed adjustment is discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19597).

To model hospital outlier payments for the proposed rule, we are applying the overall CCRs from the April 2019 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.97517 to approximate CY 2020 CCRs) to charges on CY 2018 claims that were adjusted (using the proposed charge inflation factor of 1.11189 to approximate CY 2020 charges). We simulated aggregated CY 2020 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiplier threshold constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2020 OPPS payments. We are estimating that a proposed fixed-dollar threshold of $4,950, combined with the proposed multiplier threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments. For CMHCs, we 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 continuing the policy that we implemented in CY 2010 that the hospitals' costs will be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we referred readers to section XIV. of this 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 2020 OPPS/ASC proposed rule, the payment rate for most services and procedures for which payment is made under the OPPS is the product of the

conversion factor calculated in accordance with section II.B. of this proposed rule and the 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 2020 scaled weight for the APC by the proposed CY 2020 conversion factor.

We note that section 1833(t)(17) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to submit data required to be submitted on quality measures selected by the Secretary, in the form and manner and at a time specified by the Secretary, incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP)) requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XIV. of this proposed rule.

Below we demonstrate the steps used to determine the APC payments that will 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 will receive for a specific service from the 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 national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the ''full'' national unadjusted payment rate. We refer to the national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the ''reduced'' national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.980 times the ''full'' national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements in order to receive the full CY 2020 OPPS fee schedule increase factor.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPPS, we have used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. During our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553), we confirmed that this labor-related share for hospital outpatient services is appropriate.

The formula below is a mathematical representation of Step 1 and identifies the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

$X = .60 * (\text{national unadjusted payment rate})$.

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. We note that, under the proposed CY 2020 OPPS policy for continuing to use the OMB labor market area delineations based on the 2010 Decennial Census data for the wage indexes used under the IPPS, a hold harmless policy for the wage index may apply, as discussed in section II.C. of this proposed rule. The wage index values assigned to each area reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2020 under the IPPS, reclassifications through the Medicare Geographic Classification Review Board (MGCRB), section 1886(d)(8)(B) ''Lugar'' hospitals, reclassifications under section 1886(d)(8)(E) of the Act, as defined in § 412.103 of the regulations, and hospitals designated as urban under section 601(g) of Public Law 98–21. For further discussion of the proposed changes to the FY 2020 IPPS wage indexes, as applied to the CY 2020 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 2020 IPPS, which are listed in Table 2 associated with the FY 2020 IPPS/LTCH PPS proposed rule and available via the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* (Click on the link on the left side of the screen titled ''FY 2020 IPPS Proposed Rule Home Page'' and select ''FY 2020 Proposed Rule Tables.'') This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1 that represents the labor-related portion of the national unadjusted payment rate.

The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national unadjusted payment rate for the specific service by the wage index.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

X_a = .60 * (national unadjusted payment rate) * applicable wage index.

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not attributable to labor, and the adjusted payment for the specific service.

Y is the nonlabor-related portion of the national unadjusted payment rate.

Y = .40 * (national unadjusted payment rate).

Adjusted Medicare Payment = $Y + X_a$.

Step 6. If a provider is an SCH, as set forth in the regulations at § 412.92, or an EACH, which is considered to be an SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index adjusted payment rate by 1.071 to calculate the total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071.

We are providing examples below of the calculation of both the full and reduced national unadjusted payment rates that will apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined above. For purposes of this example, we are using a provider that is located in Brooklyn, New York that is assigned to CBSA 35614. This provider bills one service that is assigned to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage). The proposed CY 2020 full national unadjusted payment rate for APC 5071 is approximately $617.00. The proposed reduced national unadjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is approximately $604.66. This reduced rate is calculated by multiplying the reporting ratio of 0.980 by the full unadjusted payment rate for APC 5071.

The proposed FY 2020 wage index for a provider located in CBSA 35614 in New York, which includes the proposed adoption of IPPS 2020 wage index policies, is 1.2747. The labor-related portion of the proposed full national unadjusted payment is approximately $471.89 (.60 * $617.00 * 1.2747). The labor-related portion of the proposed reduced national unadjusted payment is approximately $462.46 (.60 * 604.66 * 1.2747). The nonlabor-related portion of the proposed full national unadjusted payment is approximately $246.80 (.40 * $617.00). The nonlabor-related portion of the proposed reduced national unadjusted payment is approximately $241.86. (.40 * $604.66). The sum of the labor-related and nonlabor-related portions of the proposed full national adjusted payment is approximately $718.69 ($471.89. + $246.80). The sum of the portions of the proposed reduced national adjusted payment is approximately $704.32 ($462.46. + $241.86).

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 2020, 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 discussed our rationale for applying these rounding principles.) The proposed national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2020 are included in Addenda A and B to this proposed rule (which are available via the internet on the CMS website).

As discussed in section XIV.E. of this proposed rule, for CY 2020, 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, $617.00 is approximately 20 percent of the proposed full national unadjusted payment rate of $123.40. 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, 2020, 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 2020 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 and Revised HCPCS Codes

Payment for OPPS procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on HOPD claims. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of CPT (Current Procedural Terminology), a numeric and alphanumeric coding system maintained by the American Medical Association (AMA), and consist of Category I, II, and III CPT codes. Level II, which is maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. HCPCS codes are used to report surgical procedures, medical services, items, and supplies under the hospital OPPS. Specifically, CMS recognizes the following codes on OPPS claims:

• Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;

• Category III CPT codes, which describe new and emerging technologies, services, and procedures; and

• Level II HCPCS codes (also known as alphanumeric codes), which are used primarily to identify drugs, devices, ambulance services, durable medical equipment, orthotics, prosthetics, supplies, temporary surgical procedures, and medical services not described by CPT codes.

CPT codes are established by the American Medical Association (AMA) while the Level II HCPCS codes are established by the CMS HCPCS Workgroup. These codes are updated and changed throughout the year. CPT and Level II HCPCS code changes that affect the OPPS are published through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). Generally, these code changes are effective January 1, April 1, July 1, or October 1. CPT code changes are released by the AMA while Level II HCPCS code changes are released to the public via the CMS HCPCS website. CMS recognizes the release of new CPT and Level II HCPCS codes and makes the codes effective (that is, the codes can be reported on Medicare claims) outside of the formal rulemaking process via OPPS quarterly update CRs. Based on our review, we assign the new codes to interim status indicators (SIs) and APCs. These interim assignments are finalized in the OPPS/ASC final rules. This quarterly process offers hospitals access to codes that more accurately describe items or services furnished and provides payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public comments on the new CPT and Level II HCPCS codes and finalize our proposals through our annual rulemaking process.

We note that, under the OPPS, the APC assignment determines the payment rate for an item, procedure, or service. Those items, procedures, or services not paid separately under the hospital OPPS are assigned to appropriate status indicators. Certain payment status indicators provide separate payment while other payment status indicators do not. In section XI. of this proposed rule (Proposed CY 2020 OPPS Payment Status and Comment Indicators), we discuss the various status indicators used under the OPPS. We also provide a complete list of the status indicators and their definitions in Addendum D1 to this CY 2020 OPPS/ASC proposed rule.

1. April 2019 Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For the April 2019 update, there were no new CPT codes. However, eight new Level II HCPCS codes were established and made effective on April 1, 2019. These codes and their long descriptors are listed in Table 7. Through the April 2019 OPPS quarterly update CR (Transmittal 4255, Change Request 11216, dated March 15, 2019), we recognized several new Level II HCPCS codes for separate payment under the OPPS. In this CY 2020 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for the codes listed Table 7. The proposed status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B to this proposed rule. The complete list of status indicators and corresponding definitions used under the OPPS can be found in Addendum D1 to this proposed rule. These new codes that are effective April 1, 2019 are assigned to comment indicator ''NP'' in Addendum B to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments. Also, the complete list of comment indicators and definitions used under the OPPS can be found in Addendum D2 to this proposed rule. We note that OPPS Addendum B, Addendum D1, and Addendum D2 are available via the internet on the CMS website.

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TABLE 7.—NEW HCPCS CODES EFFECTIVE APRIL 1, 2019

CY 2019 HCPCS Code	CY 2019 Long Descriptor	Proposed CY 2020 CI	Proposed CY 2020 SI	Proposed CY 2020 APC
C9040	Injection, fremanezumab-vfrm, 1mg	NP	G	9197
C9041	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	NP	G	9198
C9042*	Injection, bendamustine hcl (belrapzo), 1 mg	CH	D	N/A
C9043	Injection, levoleucovorin, 1 mg	NP	G	9303
C9044	Injection, cemiplimab-rwlc, 1 mg	NP	G	9304
C9045	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	NP	G	9305
C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	NP	G	9307
C9141**	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	CH	D	N/A

*HCPCS code C9042, which was effective April 1, 2019, was deleted June 30, 2019 and replaced with HCPCS code J9036 (Injection, bendamustine hydrochloride, (Belrapzo/bendamustine), 1 mg) effective July 1, 2019.

**HCPCS code C9141, which was effective April 1, 2019, was deleted June 30, 2019 and replaced with HCPCS code J7208 (Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, (jivi), 1 i.u.), 1 mg) effective July 1, 2019.

2. July 2019 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For the July 2019 update, 58 new codes were established and made effective July 1, 2019. The codes and long descriptors are listed in Table 8. Through the July 2019 OPPS quarterly update CR (Transmittal 4313, Change Request 11318, dated May 24, 2019), we recognized several new codes for separate payment and assigned them to appropriate interim OPPS status indicators and APCs. In this CY 2020 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for the codes implemented on July 1, 2019, all of which are listed in Table 8. The proposed status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B to this proposed rule. The complete list of status indicators and corresponding definitions used under the OPPS can be found in Addendum D1 to this proposed rule. These new codes that are effective July 1, 2019 are assigned to comment indicator ''NP'' in Addendum B to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments. Also, the complete list of comment indicators and definitions used under the OPPS can be found in Addendum D2 to this proposed rule. We note that OPPS Addendum B, Addendum D1, and Addendum D2 are available via the internet on the CMS website.

TABLE 8.—NEW HCPCS CODES EFFECTIVE JULY 1, 2019

CY 2019 HCPCS Code	CY 2019 Long Descriptor	Proposed CY 2020 CI	Proposed CY 2020 SI	Proposed CY 2020 APC
C9047	Injection, caplacizumab-yhdp, 1 mg	NP	G	9199
C9048	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	NP	G	9308
C9049	Injection, tagraxofusp-erzs, 10 mcg	NP	G	9309
C9050	Injection, emapalumab-lzsg, 1 mg	NP	G	9310
C9051	Injection, omadacycline, 1 mg	NP	G	9311
C9052	Injection, ravulizumab-cwvz, 10 mg	NP	G	9312
C9756	Intraoperative near-infrared fluorescence lymphatic mapping of lymph node(s) (sentinel or tumor draining) with administration of indocyanine green (ICG) (List separately in addition to code for primary procedure)	NP	N	N/A
J1444	Injection, ferric pyrophosphate citrate powder, 0.1 mg of iron	NP	N	N/A
J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, (jivi), 1 i.u.	NP	G	9299
J7677	Revefenacin inhalation solution, fda-approved final product, non-compounded, administered through DME, 1 microgram	NP	M	N/A
J9030	BCG live intravesical instillation, 1 mg	NP	K	9322
J9036	Injection, bendamustine hydrochloride, (Belrapzo/bendamustine), 1 mg	NP	G	9313
J9356	Injection, trastuzumab, 10 mg and Hyaluronidase-oysk	NP	K	9314
Q5112	Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg	NP	E2	N/A
Q5113	Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg	NP	E2	N/A
Q5114	Injection, Trastuzumab-dkst, biosimilar, (Ogivri), 10 mg	NP	E2	N/A
Q5115	Injection, rituximab-abbs, biosimilar, (Truxima), 10 mg	NP	E2	N/A

CY 2019 HCPCS Code	CY 2019 Long Descriptor	Proposed CY 2020 CI	Proposed CY 2020 SI	Proposed CY 2020 APC
0543T	Transapical mitral valve repair, including transthoracic echocardiography, when performed, with placement of artificial chordae tendineae	NP	C	N/A
0544T	Transcatheter mitral valve annulus reconstruction, with implantation of adjustable annulus reconstruction device, percutaneous approach including transseptal puncture	NP	C	N/A
0545T	Transcatheter tricuspid valve annulus reconstruction with implantation of adjustable annulus reconstruction device, percutaneous approach	NP	C	N/A
0546T	Radiofrequency spectroscopy, real time, intraoperative margin assessment, at the time of partial mastectomy, with report	NP	N	N/A
0547T	Bone-material quality testing by microindentation(s) of the tibia(s), with results reported as a score	NP	E1	N/A
0548T *	Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy	NP	J1	5376
0549T	Transperineal periurethral balloon continence device; unilateral placement, including cystoscopy and fluoroscopy	NP	J1	5375
0550T	Transperineal periurethral balloon continence device; removal, each balloon	NP	J1	5374
0551T	Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume	NP	T	5371
0552T	Low-level laser therapy, dynamic photonic and dynamic thermokinetic energies, provided by a physician or other qualified health care professional	NP	M	N/A

CY 2019 HCPCS Code	CY 2019 Long Descriptor	Proposed CY 2020 CI	Proposed CY 2020 SI	Proposed CY 2020 APC
0553T	Percutaneous transcatheter placement of iliac arteriovenous anastomosis implant, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention	NP	E1	N/A
0554T	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; retrieval and transmission of the scan data, assessment of bone strength and fracture risk and bone mineral density, interpretation and report	NP	M	N/A
0555T	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; retrieval and transmission of the scan data	NP	S	5731
0556T	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; assessment of bone strength and fracture risk and bone mineral density	NP	S	5523
0557T	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; interpretation and report	NP	M	N/A
0558T	Computed tomography scan taken for the purpose of biomechanical computed tomography analysis	NP	S	5521
0559T	Anatomic model 3D-printed from image data set(s); first individually prepared and processed component of an anatomic structure	NP	Q1	5733

CY 2019 HCPCS Code	CY 2019 Long Descriptor	Proposed CY 2020 CI	Proposed CY 2020 SI	Proposed CY 2020 APC
0560T	Anatomic model 3D-printed from image data set(s); each additional individually prepared and processed component of an anatomic structure (List separately in addition to code for primary procedure)	NP	N	N/A
0561T	Anatomic guide 3D-printed and designed from image data set(s); first anatomic guide	NP	Q1	5733
0562T	Anatomic guide 3D-printed and designed from image data set(s); each additional anatomic guide (List separately in addition to code for primary procedure)	NP	N	N/A
0084U	Red blood cell antigen typing, DNA, genotyping of 10 blood groups with phenotype prediction of 37 red blood cell antigens	NP	A	N/A
0085U	Cytolethal distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA)	NP	Q4	N/A
0086U	Infectious disease (bacterial and fungal), organism identification, blood culture, using rRNA FISH, 6 or more organism targets, reported as positive or negative with phenotypic minimum inhibitory concentration (MIC)-based antimicrobial susceptibility	NP	A	N/A
0087U	Cardiology (heart transplant), mRNA gene expression profiling by microarray of 1283 genes, transplant biopsy tissue, allograft rejection and injury algorithm reported as a probability score	NP	A	N/A
0088U	Transplantation medicine (kidney allograft rejection), microarray gene expression profiling of 1494 genes, utilizing transplant biopsy tissue, algorithm reported as a probability score for rejection	NP	A	N/A

CY 2019 HCPCS Code	CY 2019 Long Descriptor	Proposed CY 2020 CI	Proposed CY 2020 SI	Proposed CY 2020 APC
0089U	Oncology (melanoma), gene expression profiling by RTqPCR, PRAME and LINC00518, superficial collection using adhesive patch(es)	NP	Q4	N/A
0090U	Oncology (cutaneous melanoma), mRNA gene expression profiling by RT-PCR of 23 genes (14 content and 9 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a categorical result (ie, benign, indeterminate, malignant)	NP	A	N/A
0091U	Oncology (colorectal) screening, cell enumeration of circulating tumor cells, utilizing whole blood, algorithm, for the presence of adenoma or cancer, reported as a positive or negative result	NP	E1	N/A
0092U	Oncology (lung), three protein biomarkers, immunoassay using magnetic nanosensor technology, plasma, algorithm reported as risk score for likelihood of malignancy	NP	Q4	N/A
0093U	Prescription drug monitoring, evaluation of 65 common drugs by LC-MS/MS, urine, each drug reported detected or not detected	NP	Q4	N/A
0094U	Genome (eg, unexplained constitutional or heritable disorder or syndrome), rapid sequence analysis	NP	A	N/A
0095U	Inflammation (eosinophilic esophagitis), ELISA analysis of eotaxin-3 (CCL26 [C-C motif chemokine ligand 26]) and major basic protein (PRG2 [proteoglycan 2, pro eosinophil major basic protein]), specimen obtained by swallowed nylon string, algorithm reported as predictive probability index for active eosinophilic esophagitis	NP	Q4	N/A
0096U	Human papillomavirus (HPV), high-risk types (ie, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68), male urine	NP	Q4	N/A

CY 2019 HCPCS Code	CY 2019 Long Descriptor	Proposed CY 2020 CI	Proposed CY 2020 SI	Proposed CY 2020 APC
0097U	Gastrointestinal pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 22 targets (Campylobacter [C. jejuni/C. coli/C. upsaliensis], Clostridium difficile [C. difficile] toxin A/B, Plesiomonas shigelloides, Salmonella, Vibrio [V. parahaemolyticus/V. vulnificus/V. cholerae], including specific identification of Vibrio cholerae, Yersinia enterocolitica, Enteroaggregative Escherichia coli [EAEC], Enteropathogenic Escherichia coli [EPEC], Enterotoxigenic Escherichia coli [ETEC] lt/st, Shiga-like toxin-producing Escherichia coli [STEC] stx1/stx2 [including specific identification of the E. coli O157 serogroup within STEC], Shigella/Enteroinvasive Escherichia coli [EIEC], Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia [also known as G. intestinalis and G. duodenalis], adenovirus F 40/41, astrovirus, norovirus GI/GII, rotavirus A, sapovirus [Genogroups I, II, IV, and V])	NP	Q4	N/A
0098U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 14 targets (adenovirus, coronavirus, human metapneumovirus, influenza A, influenza A subtype H1, influenza A subtype H3, influenza A subtype H1-2009, influenza B, parainfluenza virus, human rhinovirus/enterovirus, respiratory syncytial virus, Bordetella pertussis, Chlamydophila pneumoniae, Mycoplasma pneumoniae)	NP	Q4	N/A

CY 2019 HCPCS Code	CY 2019 Long Descriptor	Proposed CY 2020 CI	Proposed CY 2020 SI	Proposed CY 2020 APC
0099U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 20 targets (adenovirus, coronavirus 229E, coronavirus HKU1, coronavirus, coronavirus OC43, human metapneumovirus, influenza A, influenza A subtype, influenza A subtype H3, influenza A subtype H1-2009, influenza, parainfluenza virus, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, human rhinovirus/enterovirus, respiratory syncytial virus, Bordetella pertussis, Chlamydophila pneumonia, Mycoplasma pneumoniae)	NP	Q4	N/A
0100U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 21 targets (adenovirus, coronavirus 229E, coronavirus HKU1, coronavirus NL63, coronavirus OC43, human metapneumovirus, human rhinovirus/enterovirus, influenza A, including subtypes H1, H1-2009, and H3, influenza B, parainfluenza virus 1, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, respiratory syncytial virus, Bordetella parapertussis [IS1001], Bordetella pertussis [ptxP], Chlamydia pneumoniae, Mycoplasma pneumoniae)	NP	Q4	N/A

CY 2019 HCPCS Code	CY 2019 Long Descriptor	Proposed CY 2020 CI	Proposed CY 2020 SI	Proposed CY 2020 APC
0101U	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated (15 genes [sequencing and deletion/duplication], EPCAM and GREM1 [deletion/duplication only])	NP	A	N/A
0102U	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated (17 genes [sequencing and deletion/duplication])	NP	A	N/A
0103U	Hereditary ovarian cancer (eg, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated (24 genes [sequencing and deletion/duplication], EPCAM [deletion/duplication only])	NP	A	N/A

CY 2019 HCPCS Code	CY 2019 Long Descriptor	Proposed CY 2020 CI	Proposed CY 2020 SI	Proposed CY 2020 APC
0104U	Hereditary pan cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated (32 genes [sequencing and deletion/duplication], EPCAM and GREM1 [deletion/duplication only])	NP	A	N/A

*The predecessor code for CPT code 0548T was HCPCS code C9746 (Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed), which was effective July 1, 2017 and deleted on June 30, 2019.

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3. October 2019 HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2020 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we will solicit comments on the new CPT and Level II HCPCS codes that will be effective October 1, 2019 in the CY 2020 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2021 OPPS/ASC final rule with comment period. The Level II HCPCS codes will be released to the public through the October 2019 OPPS Update CR and the CMS HCPCS website while the CPT codes will be released to the public through the AMA website.

For CY 2020, 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 HCPCS codes that are effective October 1, 2019 to indicate that we are assigning them an interim status indicator, which is subject to public comment. We will be inviting public comments in the CY 2020 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2021 OPPS/ASC final rule with comment period.

4. January 2020 HCPCS Codes

a. New Level II HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2020 OPPS/ASC Final Rule With Comment Period

Consistent with past practice, we will solicit comments on the new Level II HCPCS codes that will be effective January 1, 2020 in the CY 2020 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2021 OPPS/ASC final rule with comment period. Unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the G-codes listed in Addendum O of this proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Therefore, these Level II HCPCS codes will be released to the public through the CY 2020 OPPS/ASC final rule with comment period, January 2020 OPPS Update CR, and the CMS HCPCS website.

For CY 2020, 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 the new HCPCS codes that will be effective January 1, 2020 to indicate that we are assigning them an interim status indicator, which is subject to public comment. We will be inviting public comments in the CY 2020 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2021 OPPS/ASC final rule with comment period.

b. CPT Codes for Which We Are Soliciting Public Comments in This Proposed Rule

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. Specifically, for the new/revised CPT codes that we receive in a timely manner from the AMA's CPT Editorial Panel, we finalized our proposal to include the codes that would be effective January 1 in the OPPS/ASC proposed rules, along with proposed APC and status indicator assignments for them, and to finalize the APC and status indicator assignments in the OPPS/ASC final rules beginning with the CY 2016 OPPS update. For those new/revised CPT codes that were received too late for inclusion in the OPPS/ASC proposed rule, we finalized our proposal to establish and use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle. We note that even if we find that we need to create HCPCS G-codes in place of certain CPT codes for the PFS proposed rule, we do not anticipate that these HCPCS G-codes will always be necessary for OPPS purposes. We will make every effort to

include proposed APC and status indicator assignments for all new and revised CPT codes that the AMA makes publicly available in time for us to include them in the proposed rule, and to avoid the resort to HCPCS G-codes and the resulting delay in utilization of the most current CPT codes. Also, we finalized our proposal to make interim APC and status indicator assignments for CPT codes that are not available in time for the proposed rule and that describe wholly new services (such as new technologies or new surgical procedures), solicit public comments, and finalize the specific APC and status indicator assignments for those codes in the following year's final rule.

For the CY 2020 OPPS update, we received the CPT codes that will be effective January 1, 2020 from AMA in time to be included in this proposed rule. The new, revised, and deleted 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 CPT codes are assigned to comment indicator ''NP'' in Addendum B of this proposed rule to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year with a proposed APC assignment, and that comments will be accepted on the proposed APC assignment and status indicator.

Further, we note 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 the long descriptors for the new and revised CY 2020 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 2020 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code''. The final CPT code numbers will be included in the CY 2020 OPPS/ASC final rule with comment period.

In summary, we are soliciting public comments on the proposed CY 2020 status indicators and APC assignments for the new and revised CPT codes that will be effective January 1, 2020. Because the CPT codes listed in Addendum B appear with short descriptors only, we list them again in Addendum O to this proposed rule with long descriptors. In addition, we are proposing to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2020 OPPS/ASC final rule with comment period. The proposed status indicator and APC assignment for these codes can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website).

Finally, in Table 9, we summarize our current process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these codes under the OPPS.

TABLE 9.—COMMENT TIMEFRAME FOR NEW AND REVISED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2019	HCPCS (CPT and Level II codes)	April 1, 2019	CY 2020 OPPS/ASC proposed rule	CY 2020 OPPS/ASC final rule with comment period
July 2019	HCPCS (CPT and Level II codes)	July 1, 2019	CY 2020 OPPS/ASC proposed rule	CY 2020 OPPS/ASC final rule with comment period
October 2019	HCPCS (CPT and Level II codes)	October 1, 2019	CY 2020 OPPS/ASC final rule with comment period	CY 2021 OPPS/ASC final rule with comment period
January 2020	CPT Codes	January 1, 2020	CY 2020 OPPS/ASC proposed rule	CY 2020 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2020	CY 2020 OPPS/ASC final rule with comment period	CY 2021 OPPS/ASC final rule with comment period

B. 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 (also known as CPT codes) and Level II HCPCS codes (also known as alphanumeric codes) to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the procedure.

We have packaged into the payment for each procedure or service within an APC group the costs associated with those items and services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support. Therefore, we do not make separate payment for these packaged items or services. In general, packaged items and services include, but are not limited to, the items and services listed in regulations at 42 CFR 419.2(b). A further discussion of packaged services is included in section II.A.3. of this 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 2020, 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 2020 OPPS update will be discussed in the relevant specific sections throughout the CY 2020 OPPS/ASC final rule with comment period.

In addition, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group (referred to as the ''2 times rule''). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act). In determining the APCs with a 2 times rule violation, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant procedure codes for examination under the 2 times rule, we consider procedure codes that have more than 1,000 single major claims or procedure codes that both have more than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). This longstanding definition of when a procedure code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 or fewer claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a procedure code for which there are fewer than 99 single claims and that comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost (75 FR 71832). In this section of this proposed rule, for CY 2020, 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 2020 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 2020 OPPS/ASC proposed rule. Rather, it is published and made available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. To eliminate a violation of the 2 times rule and improve clinical and resource homogeneity, we 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 2020 included in this proposed rule are related to changes in costs of services that were observed in the CY 2018 claims data newly available for CY 2020 ratesetting. Addendum B to this CY 2020 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, 2019 OPPS Addendum B Update (available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html*).

3. Proposed APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we are proposing to make for CY 2020, we reviewed all of the APCs to determine which APCs would not meet the requirements of the 2 times rule. We used the following criteria to evaluate whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity;

- Clinical homogeneity;
- Hospital outpatient setting utilization;
- Frequency of service (volume); and
- Opportunity for upcoding and code fragments.

Based on the CY 2018 claims data available for this CY 2020 proposed rule, we found 18 APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs for which we are proposing to make exceptions under the 2 times rule for CY 2020, and found that all of the 18 APCs we identified meet the criteria for an exception to the 2 times rule based on the CY 2018 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 10 of this proposed rule lists the 18 APCs that we are proposing to make an exception for under the 2 times rule for CY 2020 based on the criteria cited above and claims data submitted between January 1, 2018, and December 31, 2018, and processed on or before December 31, 2018. For the final rule with comment period, we intend to use claims data for dates of service between January 1, 2018, and December 31, 2018, that were processed on or before June 30, 2019, and updated CCRs, if available. 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 10.—PROPOSED APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2020

Proposed CY 2020 APC	Proposed CY 2020 APC Title
5112	Level 2 Musculoskeletal Procedures
5161	Level 1 ENT Procedures
5181	Level 1 Vascular Procedures
5311	Level 1 Lower GI Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5571	Level 1 Imaging with Contrast
5612	Level 2 Therapeutic Radiation Treatment Preparation
5672	Level 2 Pathology
5691	Level 1 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5733	Level 3 Minor Procedures
5734	Level 4 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 CY 2002 OPPS final rule (66 FR 59903), we finalized changes to the time period in which a service can be eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

In the CY 2004 OPPS final rule with comment period (68 FR 63416), we restructured the New Technology APCs to make the cost intervals more

consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs, one set with a status indicator of ''S'' (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment) and the other set with a status indicator of ''T'' (Significant Procedure, Multiple Reduction Applies. Paid under OPPS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

For CY 2019, there were 52 New Technology APC levels, ranging from the lowest cost band assigned to APC 1491 (New Technology—Level 1A ($0–$10)) through the highest cost band assigned to APC 1908 (New Technology—Level 52 ($145,001–$160,000)). We note that the cost bands for the New Technology APCs, specifically, APCs 1491 through 1599 and 1901 through 1908, vary with increments ranging from $10 to $14,999. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for New Technology APC 1507 (New Technology—Level 7 ($501–$600)) is made at $550.50.

Under the OPPS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is budget neutral and increases are limited to the annual hospital inpatient market basket increase adjusted for multifactor productivity. We believe that our payment rates generally reflect the costs that are associated with providing care to Medicare beneficiaries. Furthermore, we believe that our payment rates are adequate to ensure access to services (80 FR 70374).

For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the technologies and their clinical utility. Quite often, parties request that Medicare make higher payment amounts under the New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per-use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on projected utilization for Medicare beneficiaries and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment. For the OPPS, we rely on hospitals to make informed business decisions regarding the acquisition of high-cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers' payment policies. (We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68314) for further discussion regarding this payment policy.)

We note that, in a budget neutral system, payments may not fully cover hospitals' costs in a particular circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high-cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPPS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPS payments remain appropriate for procedures as they transition into mainstream medical practice (77 FR 68314). For CY 2020, we are including the proposed payment rates for New Technology APCs 1491 through 1599 and 1901 through 1908 in Addendum A to this CY 2020 OPPS/ASC 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. As we explained in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58890), we were concerned that the methodology we use to estimate the cost of a procedure under the OPPS by calculating the geometric mean for all separately paid claims for a HCPCS procedure code from the most recent available year of claims data may not generate an accurate estimate of the actual cost of the procedure for these low-volume procedures.

In accordance with section 1833(t)(2)(B) of the Act, services classified within each APC must be comparable clinically and with respect to the use of resources. As described earlier, assigning a procedure to a new technology APC allows us to gather claims data to price the procedure and assign it to the APC with services that use similar resources and are clinically comparable. However, where utilization of services assigned to a New Technology APC is low, it can lead to wide variation in payment rates from year to year, resulting in even lower utilization and potential barriers to access to new technologies, which ultimately limits our ability to assign the service to the appropriate clinical APC. To mitigate these issues, we determined in the CY 2019 OPPS/ASC final rule with comment period that it was appropriate to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how we determined the costs for low-volume services assigned to New Technology APCs (83 FR 58892 through 58893). We have utilized our equitable adjustment authority at section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to estimate an appropriate payment amount for low-volume new technology procedures in the past (82 FR 59281). Although we

have used this adjustment authority on a case-by-case basis in the past, we stated in the CY 2019 OPPS/ASC final rule with comment period that we believe it is appropriate to adopt an adjustment for low-volume services assigned to New Technology APCs in order to mitigate the wide payment fluctuations that have occurred for new technology services with fewer than 100 claims and to provide more predictable payment for these services.

For purposes of this adjustment, we stated that we believe that it is appropriate to use up to 4 years of claims data in calculating the applicable payment rate for the prospective year, rather than using solely the most recent available year of claims data, when a service assigned to a New Technology APC has a low annual volume of claims, which, for purposes of this adjustment, we define as fewer than 100 claims annually. We adopted a policy to consider procedures with fewer than 100 claims annually as low-volume procedures because there is a higher probability that the payment data for a procedure may not have a normal statistical distribution, which could affect the quality of our standard cost methodology that is used to assign services to an APC. We explained that we were concerned that the methodology we use to estimate the cost of a procedure under the OPPS by calculating the geometric mean for all separately paid claims for a HCPCS procedure code from the most recent available year of claims data may not generate an accurate estimate of the actual cost of the low-volume procedure. Using multiple years of claims data will potentially allow for more than 100 claims to be used to set the payment rate, which would, in turn, create a more statistically reliable payment rate.

In addition, to better approximate the cost of a low-volume service within a New Technology APC, we stated that we believe using the median or arithmetic mean rather than the geometric mean (which ''trims'' the costs of certain claims out) could be more appropriate in some circumstances, given the extremely low volume of claims. Low claim volumes increase the impact of ''outlier'' claims; that is, claims with either a very low or very high payment rate as compared to the average claim, which would have a substantial impact on any statistical methodology used to estimate the most appropriate payment rate for a service. We also explained that we believe having the flexibility to utilize an alternative statistical methodology to calculate the payment rate in the case of low-volume new technology services would help to create a more stable payment rate. Therefore, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58893), we established that, in each of our annual rulemakings, we will seek public comments on which statistical methodology should be used for each low-volume service assigned to a New Technology APC. In the preamble of each annual rulemaking, we stated that we would present the result of each statistical methodology and solicit public comment on which methodology should be used to establish the payment rate for a low-volume new technology service. In addition, we will use our assessment of the resources used to perform a service and guidance from the developer or manufacturer of the service, as well as other stakeholders, to determine the most appropriate payment rate. Once we identify the most appropriate payment rate for a service, we will assign the service to the New Technology APC with the cost band that includes its payment rate.

Accordingly for CY 2020, we are proposing to continue our policy adopted in CY 2019 under which we will utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median using multiple years of claims data to select the appropriate payment rate for purposes of assigning services with fewer than 100 claims per year to a New Technology APC. Additional details on our policy is available in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58892 through 58893).

3. Procedures Assigned to New Technology APC Groups for CY 2020

As we explained in the CY 2002 OPPS final rule with comment period (66 FR 59902), we generally retain a procedure in the New Technology APC to which it is initially assigned until we have obtained sufficient claims data to justify reassignment of the procedure to a clinically appropriate APC.

In addition, in cases where we find that our initial New Technology APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), where we obtain new information that was not available at the time of our initial New Technology APC assignment, or where the New Technology APCs are restructured, we may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that more appropriately reflects its cost (66 FR 59903).

Consistent with our current policy, for CY 2020, in this 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 1575, 5114, and 5414)

Currently, there are four CPT/HCPCS codes that describe magnetic resonance image-guided, high-intensity focused ultrasound (MRgFUS) procedures, three of which we are proposing to continue to assign to standard APCs, and one that we are proposing to continue to assign to a New Technology APC for CY 2020. These codes include CPT codes 0071T, 0072T, and 0398T, and HCPCS code C9734. CPT codes 0071T and 0072T describe procedures for the treatment of uterine fibroids, CPT code 0398T describes procedures for the treatment of essential tremor, and HCPCS code C9734 describes procedures for pain palliation for metastatic bone cancer.

As shown in Table 11 of this CY 2020 OPPS/ASC proposed rule, and as listed in Addendum B to this CY 2020 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) for CY 2020. We also are proposing to continue to assign the APC to status indicator ''J1'' (Hospital Part B services paid through a comprehensive APC). 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) for CY 2020. We also are proposing to continue to assign HCPCS code C9734 to status indicator ''J1''. We refer readers to Addendum B to this proposed rule for the proposed payment rates for CPT codes 0071T and 0072T and HCPCS code C9734 under the OPPS. Addendum B is available via the internet on the CMS website.

For the procedure described by CPT code 0398T, we have identified 37 paid claims from CY 2016 through CY 2018 (1 claim in CY 2016, 11 claims in CY 2017, and 25 claims in CY 2018). We note that the procedure described by CPT code 0398T was first assigned to a New Technology APC in CY 2016. Accordingly, there are 3 years of claims data available for the OPPS ratesetting purposes. The payment amounts for the claims vary widely, with a cost of approximately $29,254 for the sole CY 2016 claim, a geometric mean cost of approximately $4,647 for the 11 claims from CY 2017, and a geometric mean cost of approximately $11,716 for the 25 claims from CY 2018. We are concerned about the large fluctuation in the cost of the procedure described by CPT code 0398T from year to year and the relatively small number of claims available to establish a payment rate for the service. To be 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 apply the policy we adopted in CY 2019, under which we will utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median costs using multiple years of claims data to select the appropriate payment rate for purposes of assigning CPT code 0398T to a New Technology APC. We believe using this approach to assign CPT code 0398T to a New Technology APC is more likely to yield a payment rate that will be representative of the cost of the procedure described by CPT code 0398T, despite the fluctuating geometric mean costs for the procedure available in the claims data used for this proposed rule. We continue to believe that the situation for the procedure described by CPT code 0398T is unique, given the limited number of claims for the procedure and the high variability for the cost of the claims, which makes it challenging to determine a reliable payment rate.

Our analysis found that the estimated geometric mean cost of the 37 claims was approximately $8,829, the estimated arithmetic mean cost of the claims was approximately $10,021, and the median cost of the claims was approximately $11,985. While the results of using different methodologies range from approximately $8,800 to nearly $12,000, two of the estimates fall within the cost bands of New Technology APC 1575 (New Technology—Level 38 ($10,001–$15,000)), with a proposed payment rate of $12,500.50. Consistent with our policy stated in section III.C.2. of this proposed rule, we are presenting the result of each statistical methodology in this preamble, and we are seeking public comments on which methodology should be used to establish payment for the procedures described by CPT code 0398T. We note that we believe that the median cost estimate is the most appropriate representative cost of the procedure described by CPT code 0398T because it is consistent with the payment rates established for the procedure from CY 2017 to CY 2019 and does not involve any trimming of claims. Calculating the payment rate using either the geometric mean cost or the arithmetic mean cost would involve trimming the one paid claim from CY 2016, because the paid amount for the claim of $29,254 is substantially larger than the amount for any other paid claim reported for the procedure described by CPT code 0398T. The median cost estimate for CPT code 0398T also falls within the same New Technology APC cost band that was used to set the payment rate for CY 2019, which is $12,500.50 for this procedure. Therefore, for purposes of determining the proposed CY 2020 payment rate, we are proposing to estimate the cost for the procedure described by CPT code 0398T by calculating the median cost of the 37 paid claims for the procedures in CY 2016 through CY 2018, and assigning the procedure described by CPT code 0398T to the New Technology APC that includes the estimated cost. Accordingly, we are proposing to maintain the procedure described by CPT code 0398T in APC 1575 (New Technology—Level 38 ($10,001–$15,000)), with a proposed payment rate of $12,500.50 for CY 2020. We refer readers to Addendum B to 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.

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TABLE 11.—PROPOSED CY 2020 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR THE MAGNETIC RESONANCE IMAGE GUIDED HIGH INTENSITY FOCUSED ULTRASOUND (MRgFUS) PROCEDURES

CPT/ HCPCS Code	Long Descriptor	CY 2019 OPPS SI	CY 2019 OPPS APC	CY 2019 OPPS Payment Rate	Proposed CY 2020 OPPS SI	Proposed CY 2020 OPPS APC	Proposed CY 2020 OPPS Payment Rate
0071T	Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume less than 200 cc of tissue.	J1	5414	$2,361.27	J1	5414	Refer to OPPS Addendum B.
0072T	Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume greater or equal to 200 cc of tissue.	J1	5414	$2,361.27	J1	5414	Refer to OPPS Addendum B.
0398T	Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed.	S	1575	$12,500.50	S	1575	Refer to OPPS Addendum B.

CPT/ HCPCS Code	Long Descriptor	CY 2019 OPPS SI	CY 2019 OPPS APC	CY 2019 OPPS Payment Rate	Proposed CY 2020 OPPS SI	Proposed CY 2020 OPPS APC	Proposed CY 2020 OPPS Payment Rate
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance.	J1	5115	$10,713.88	J1	5115	Refer to OPPS Addendum B.

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b. Retinal Prosthesis Implant Procedure

CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy) describes the implantation of a retinal prosthesis, specifically, a procedure involving the use of the Argus® II Retinal Prosthesis System. This first retinal prosthesis was approved by the Food and Drug Administration (FDA) in 2013 for adult patients diagnosed with severe to profound retinitis pigmentosa. Pass-through payment status was granted for the Argus® II device under HCPCS code C1841 (Retinal prosthesis, includes all internal and external components) beginning October 1, 2013, and this status expired on December 31, 2015. We note that after pass-through payment status expires for a medical device, the payment for the device is packaged into the payment for the associated surgical procedure. Consequently, for CY 2016, the device described by HCPCS code C1841 was assigned to OPPS status indicator ''N'' to indicate that payment for the device is packaged and included in the payment rate for the surgical procedure described by CPT code 0100T. For CY 2016, the procedure described by CPT code 0100T was assigned to New Technology APC 1599, with a payment rate of $95,000, which was the highest paying New Technology APC for that year. This payment included both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841). However, stakeholders (including the device manufacturer and hospitals) believed that the CY 2016 payment rate for the procedure involving the Argus® II System was insufficient to cover the hospital cost of performing the procedure, which includes the cost of the retinal prosthesis at the retail price of approximately $145,000.

For CY 2017, analysis of the CY 2015 OPPS claims data used for the CY 2017 OPPS/ASC final rule with comment period showed 9 single claims (out of 13 total claims) for the procedure described by CPT code 0100T, with a geometric mean cost of approximately $142,003 based on claims submitted between January 1, 2015, through December 31, 2015, and processed through June 30, 2016. Based on the CY 2015 OPPS claims data available for the final rule with comment period and our understanding of the Argus® II procedure, we reassigned the procedure described by CPT code 0100T from New Technology APC 1599 to New Technology APC 1906, with a final payment rate of $150,000.50 for CY 2017. We noted that this payment rate included the cost of both the surgical procedure (CPT code 0100T) and the retinal prosthesis device (HCPCS code C1841).

For CY 2018, the reported cost of the Argus® II procedure based on CY 2016 hospital outpatient claims data for 6 claims used for the CY 2018 OPPS/ASC final rule with comment period was approximately $94,455, which was more than $55,000 less than the payment rate for the procedure in CY 2017, but closer to the CY 2016 payment rate for the procedure. We noted that the costs of the Argus® II procedure are extraordinarily high compared to many other procedures paid under the OPPS. In addition, the number of claims submitted has been very low and has not exceeded 10 claims within a single year. We believed that it is important to mitigate significant payment differences, especially shifts of several tens of thousands of dollars, while also basing payment rates on available cost information and claims data. In CY 2016, the payment rate for the Argus® II procedure was $95,000.50. The payment rate increased to $150,000.50 in CY 2017. For CY 2018, if we had established the payment rate based on updated final rule claims data, the payment rate would have decreased to $95,000.50 for CY 2018, a decrease of $55,000 relative to CY 2017. We were concerned that these large fluctuations in payment could potentially create an access to care issue for the Argus® II procedure, and we wanted to establish a payment rate to mitigate the potential sharp decline in payment from CY 2017 to CY 2018.

In accordance with section 1833(t)(2)(B) of the Act, we must establish that services classified within each APC are comparable clinically and with respect to the use of resources. Therefore, for CY 2018, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the payment rate for this procedure, despite the lower geometric mean costs available in the claims data used for the final rule with comment period. For CY 2018, we reassigned the Argus® II procedure to APC 1904 (New Technology—Level 50 ($115,001–$130,000)), which established a payment rate for the Argus® II procedure of $122,500.50, which was the arithmetic mean of the payment rates for the procedure for CY 2016 and CY 2017.

For CY 2019, the reported cost of the Argus® II procedure based on the geometric mean cost of 12 claims from the CY 2017 hospital outpatient claims data was approximately $171,865, which was approximately $49,364 more than the payment rate for the procedure for CY 2018. In the CY 2019 OPPS/ASC

final rule with comment period, we continued to note that the costs of the Argus® II procedure are extraordinarily high compared to many other procedures paid under the OPPS (83 FR 58897 through 58898). In addition, the number of claims submitted continued to be very low for the Argus® II procedure. We stated that we continued to believe that it is important to mitigate significant payment fluctuations for a procedure, especially shifts of several tens of thousands of dollars, while also basing payment rates on available cost information and claims data because we are concerned that large decreases in the payment rate could potentially create an access to care issue for the Argus® II procedure. In addition, we indicated that we wanted to establish a payment rate to mitigate the potential sharp increase in payment from CY 2018 to CY 2019, and potentially ensure a more stable payment rate in future years.

In accordance with section 1833(t)(2)(B) of the Act, we must establish that services classified within each APC are comparable clinically and with respect to the use of resources. Therefore, as discussed in section III.C.2. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58892 through 58893), we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to establish a payment rate that is more representative of the likely cost of the service. We stated that we believed the likely cost of the Argus® II procedure is higher than the geometric mean cost calculated from the claims data used for the CY 2018 OPPS/ASC final rule with comment period but lower than the geometric mean cost calculated from the claims data used for the CY 2019 OPPS/ASC final rule with comment period.

For CY 2019, we analyzed claims data for the Argus® II procedure using 3 years of available data from CY 2015 through CY 2017. These data included claims from the last year that the Argus® II received transitional device pass-through payments (CY 2015) and the first 2 years since device pass-through payment status for the Argus® II expired. We found that the geometric mean cost for the procedure was approximately $145,808, the arithmetic mean cost was approximately $151,367, and the median cost was approximately $151,266. As we do each year, we reviewed claims data regarding hospital costs associated with new procedures. We regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that OPPS payments remain appropriate for procedures like the Argus® II procedure as they transition into mainstream medical practice (77 FR 68314). We noted that the proposed payment rate included both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841). For CY 2019, the estimated costs using all three potential statistical methods for determining APC assignment under the New Technology low-volume policy fell within the cost band of New Technology APC 1908, which is between $145,001 and $160,000. Therefore, we reassigned the Argus® II procedure (CPT code 0100T) to APC 1908 (New Technology—Level 52 ($145,001–$160,000)), with a payment rate of $152,500.50 for CY 2019.

For CY 2020, the number of reported claims for the Argus® II procedure continues to be very low with a substantial fluctuation in cost from year to year.

The high annual variability of the cost of the Argus® II procedure continues to make it difficult to establish a consistent and stable payment rate for the procedure. In accordance with section 1833(t)(2)(B) of the Act, we are required to establish that services classified within each APC are comparable clinically and with respect to the use of resources. Therefore, for CY 2020, we are proposing to apply the policy we adopted in CY 2019, under which we utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median costs using multiple years of claims data to select the appropriate payment rate for purposes of assigning the Argus® II procedure (CPT code 0100T) to a New Technology APC.

We identified 35 claims reporting the procedure described by CPT code 0100T for the 4-year period of CY 2015 through CY 2018. We found the geometric mean cost for the procedure described by CPT code 0100T to be approximately $146,059, the arithmetic mean cost to be approximately $152,123, and the median cost to be approximately $151,267. All of the resulting estimates from using the three statistical methodologies fall within the same New Technology APC cost band ($145,001–$160,000), where the Argus® II procedure is assigned for CY 2019. Consistent with our policy stated in section III.C.2. of this proposed rule, we are presenting the result of each statistical methodology in this preamble, and we are seeking public comments on which method should be used to assign procedures described by CPT code 0100T to a New Technology APC. All three potential statistical methodologies used to estimate the cost of the Argus® II procedure fall within the cost band for New Technology APC 1908, with the estimated cost being between $145,001 and $160,000. Accordingly, we are proposing to maintain the assignment of the procedure described by CPT code 0100T in APC 1908 (New Technology—Level 52 ($145,001–$160,000)), with a proposed payment rate of $152,500.50 for CY 2020. We note that the proposed payment rate includes both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841). We refer readers to Addendum B to 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.

As we discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58898), the claims data from CY 2017 showed another payment issue with regard to the Argus® II procedure. We found that payment for the Argus® II procedure was sometimes bundled into the payment for another procedure. Therefore in CY 2019, we implemented a policy to exclude payment for all procedures assigned to New Technology APCs from being bundled into the payment for procedures assigned to a C–APC. For CY 2020, we are proposing to continue this policy as described in section II.A.2.b.(3) of this proposed rule. Our proposal would continue to exclude payment for any procedure that is assigned to a New Technology APC from being packaged when included on a claim with a service assigned to status indicator ''J1''. While we are not proposing to exclude payment for a procedure assigned to a New Technology APC from being packaged when included on a claim with a service assigned to status indicator ''J2'', we are seeking public comments on this issue.

c. Bronchoscopy With Transbronchial Ablation of Lesion(s) by Microwave Energy

Effective January 1, 2019, CMS established HCPCS code C9751 (Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (*e.g.*,

aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)). This microwave ablation procedure utilizes a flexible catheter to access the lung tumor via a working channel and may be used as an alternative procedure to a percutaneous microwave approach. Based on our review of the New Technology APC application for this service and the service's clinical similarity to existing services paid under the OPPS, we estimated the likely cost of the procedure would be between $8,001 and $8,500. We have not received any claims data for this service. Therefore, we are proposing to continue to assign the procedure described by HCPCS code C9751 to New Technology APC 1571 (New Technology—Level 34 ($8,001–$8,500)), with a proposed payment rate of $8,250.50 for CY 2020. Details regarding HCPCS code C9751 are shown in Table 12.

TABLE 12.—PROPOSED CY 2020 OPPS APC AND STATUS INDICATOR FOR HCPCS CODE C9751 ASSIGNED TO NEW TECHNOLOGY APC

CY 2020 HCPCS Code	Long Descriptor	Proposed CY 2020 OPPS SI	Proposed CY 2020 OPPS APC
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]	T	1571

d. Pathogen Test for Platelets

As stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59281), HCPCS code P9100 is used to report any test used to identify bacterial or other pathogen contamination in blood platelets. Currently, there are two rapid bacterial detection tests cleared by the FDA that are described by HCPCS code P9100. According to their instructions for use, rapid bacterial detection tests should be performed on platelets from 72 hours after collection. Currently, certain rapid and culture-based tests can be used to extend the dating for platelets from 5 days to 7 days. Blood banks and transfusion services may test and use 6-day old to 7-day old platelets if the test results are negative for bacterial contamination.

HCPCS code P9100 was assigned in CY 2019 to New Technology APC 1493 (New Technology—Level 1C ($21–$30)), with a payment rate of $25.50. For CY 2020, based on CY 2018 claims data, there are approximately 1,100 claims reported for this service with a geometric mean cost of approximately $32. This geometric mean cost would result in the assignment of the service described by HCPCS code P9100 to a New Technology APC, based on the associated cost band, with a higher payment rate than where the service is currently assigned. Therefore, for CY 2020, we are proposing to reassign the service described by HCPCS code P9100 to New Technology APC 1494 (New Technology—Level 1D ($31–$40)), with a proposed payment rate of $35.50.

e. Fractional Flow Reserve Derived From Computed Tomography (FFRCT)

Fractional Flow Reserve Derived From Computed Tomography (FFRCT), also known by the trade name HeartFlow, is a noninvasive diagnostic service that allows physicians to measure coronary artery disease in a patient through the use of coronary CT scans. The HeartFlow procedure is intended for clinically stable symptomatic patients with coronary artery disease, and, in many cases, may avoid the need for an invasive coronary angiogram procedure. HeartFlow uses a proprietary data analysis process performed at a central facility to develop a three-dimensional image of a patient's coronary arteries, which allows physicians to identify the fractional flow reserve to assess whether or not patients should undergo further invasive testing (that is, a coronary angiogram).

For many procedures in the OPPS, payment for analytics that are performed after the main diagnostic/image procedure are packaged into the payment for the primary procedure. However, in CY 2018, we determined that HeartFlow should receive a separate payment because the procedure is performed by a separate entity (that is, a HeartFlow technician who conducts computer analysis offsite) rather than the provider performing the CT scan. We assigned CPT code 0503T, which describes the analytics performed, to New Technology APC 1516 (New Technology—Level 16 ($1,401–$1,500)), with a payment rate of $1,450.50 based on pricing information provided by the developer of the procedure that indicated the price of the procedure was approximately $1,500.

For CY 2020, based on our analysis of the CY 2018 claims data, we found that over 840 claims had been submitted for payment for HeartFlow during CY 2018. The estimated geometric mean cost of HeartFlow is $788.19, which is over $660 lower that the payment rate for CY 2019 of $1,450.50. Therefore, for CY 2020, we are proposing to reassign the service described by CPT code 0503T in order to adjust the payment rate to better reflect the cost for the service. We are proposing to reassign the service described by CPT code 0503T to New Technology APC 1509 (New Technology—Level 9 ($701–$800)), with a proposed payment rate of $750.50 for

CY 2020. We are seeking public comments on this proposal.

D. Proposed APC Specific Policies

1. Intraocular Procedures (APCs 5491 Through 5494)

In prior years, CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis) was assigned to the APC 5495 (Level 5 Intraocular Procedures) based on its estimated costs. In addition, its relative payment weight has been based on its median cost under our payment policy for low-volume device-intensive procedures because the APC contained a low volume of claims. The low-volume device-intensive procedures payment policy is discussed in more detail in section III.C.2. of this proposed rule.

In the CY 2019 OPPS/ASC proposed rule, we proposed to reassign CPT code 0308T from APC 5495 to APC 5493 (Level 3 Intraocular Procedures), based on the data for two claims available for ratesetting for the proposed rule, and to delete APC 5495 (83 FR 37096 through 37097). However in the CY 2019 OPPS/ASC final rule with comment period, based on updated data on a single claim available for ratesetting for the final rule, we modified our proposal and reassigned procedure code CPT code 0308T to the APC 5494 (Level 4 Intraocular Procedures) (83 FR 58917 through 58918). We made this change based on the similarity of the estimated cost for the single claim of $12,939.75 compared to that of the APC ($11,427.14). However, this created a discrepancy in payments between the OPPS setting and the ASC setting in which the ASC payments would be higher than the OPPS payments for the same service because of the intersection of the estimated cost for the encounter determined under a comprehensive methodology within the OPPS and the estimated cost determined under the payment methodology for device-intensive services within the ASC payment system.

In reviewing the claims data available for this proposed rule for CY 2020 OPPS ratesetting, we found several claims reporting the procedure described by CPT code 0308T. Based on the claims data, the procedure would have a geometric mean cost of $28,122.51 and a median cost of $19,864.38. These cost statistics are significantly higher than the geometric mean cost of the other procedure assigned to APC 5494, that is, the procedure described by CPT code 67027 (Implant eye drug system), which has a geometric mean cost of $12,296.27. In addition, if we continued to assign the procedure described by CPT code 0308T to APC 5494 (the Level 4 Intraocular Procedures APC), the discrepancy between payments within the OPPS and the ASC payment system would also continue to exist. As a result, we are proposing to reestablish APC 5495 (Level 5 Intraocular Procedures) because we believe that the procedure described by CPT code 0308T would be most appropriately placed in this APC based on its estimated cost. Assignment of the procedure to the Level 5 Intraocular Procedures APC is consistent with its historical placement and would also address the large differential discrepancy in payment for the procedure between the OPPS and the ASC payment system. We note that, based on data available for the proposed rule, the proposed payment rate for this procedure when performed in an ASC, as discussed in more detail in section XIII.D.1.c. of this proposed rule, would be no higher than the OPPS payment rate for this procedure performed in the hospital outpatient setting. We will continue to monitor the volume of claims data available for the procedure for ratesetting purposes.

Therefore, for CY 2020, we are proposing to reestablish APC 5495 (Level 5 Intraocular Procedures) and reassign the procedure described by CPT code 0308T from APC 5494 to APC 5495. Under this proposal, the proposed CY 2020 OPPS payment rate for the service would be established based on its median cost, as discussed in section V.A.5. of this proposed rule, because it is a device-intensive procedure assigned to an APC with fewer than 100 total annual claims within the APC.

2. Musculoskeletal Procedures (APCs 5111 Through 5116)

Prior to the CY 2016 OPPS, payment for musculoskeletal procedures was primarily divided according to anatomy and the type of musculoskeletal procedure. As part of the CY 2016 reorganization to better structure the OPPS payments towards prospective payment packages, we consolidated those individual APCs so that they became a general Musculoskeletal APC series (80 FR 70397 through 70398).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59300), we continued to apply a six-level structure for the Musculoskeletal APCs because doing so provided an appropriate distinction for resource costs at each level and provided clinical homogeneity. However, we indicated that we would continue to review the structure of these APCs to determine whether additional granularity would be necessary.

In the CY 2019 OPPS proposed rule (83 FR 37096), we recognized that commenters had previously expressed concerns regarding the granularity of the current APC levels and, therefore, requested comment on the establishment of additional levels. Specifically, we solicited comments on the creation of a new APC level between the current Level 5 and Level 6 within the Musculoskeletal APC series. While some commenters provided suggested APC reconfigurations and requests for change to APC assignments, many commenters requested that we maintain the current six-level structure and continue to monitor the claims data as they become available. Therefore, in the CY 2019 OPPS/ASC final rule with comment period, we maintained the six-level APC structure for the Musculoskeletal Procedures APCs (83 FR 58920 through 58921).

Based on the claims data available for this CY 2020 OPPS/ASC proposed rule, we continue to believe that the six-level APC structure for the Musculoskeletal Procedures APC series is appropriate. Therefore, we are proposing to maintain the APC structure for the CY 2020 OPPS update.

We note that this is the first year for which claims data are available for the total knee arthroplasty procedure described by CPT code 27447, which was removed from the inpatient only list in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59382 through 59385). Based on approximately 60,000 hospital outpatient claims reporting the procedure that are available for ratesetting in this proposed rule, the geometric mean cost is approximately $12,472.05, which is similar to the geometric mean cost for APC 5115 (Level 5 Musculoskeletal Procedures) of $11,879.66, and within a range of the lowest geometric mean cost of the significant procedure costs of $9,969.37 and the highest geometric mean cost of the significant procedure costs of $12,894.18. Therefore, we believe that the assignment of the procedure described by CPT code 27447 in the Level 5 Musculoskeletal Procedures APC series remains appropriate and, therefore, we are proposing to continue to assign CPT code 27447 to APC 5115 (Level 5 Musculoskeletal Procedures) for CY 2020.

We also are proposing to remove the procedure described by CPT code 27130 (Total hip arthroplasty) from the CY 2020 OPPS inpatient only list. Based on the estimated costs derived from in the available claims data, as well as the 50th

percentile IPPS payment for TKA/THA procedures without major complications or comorbidities (MS–DRG 470) of approximately $11,900 for FY 2020 when the procedure is performed on an inpatient basis, we believe that it is appropriate to assign the procedure described by CPT code 27130 to the Level 5 Musculoskeletal Procedures APC series, which has a geometric mean cost of $11,879.66. Therefore, for CY 2020, we also are proposing to assign the procedure described by CPT code 27130 to APC 5115. We note that we will monitor the claims data reflecting these procedures as they become available. For a more detailed discussion of the procedures that are being proposed to be removed from the inpatient only (IPO) list for CY 2020 under the OPPS, we refer readers to section IX. of this proposed rule.

Table 13 displays the CY 2020 Musculoskeletal Procedures APC series' structure and APC geometric mean costs.

TABLE 13.--PROPOSED CY 2020 MUSCULOSKELETAL PROCEDURES APCs

APC	Group Title	HCPCS Codes Assigned to APC in the CY 2020 OPPS/ASC Proposed Rule	CY 2019 Final APC Geometric Mean Cost	Proposed CY 2020 APC Geometric Mean Cost
5111	Level 1 Musculoskeletal Procedures	102	$227.04	$216.49
5112	Level 2 Musculoskeletal Procedures	133	$1,324.69	$1,346.26
5113	Level 3 Musculoskeletal Procedures	401	$2,646.02	$2,715.66
5114	Level 4 Musculoskeletal Procedures	328	$5,748.86	$5,904.20
5115	Level 5 Musculoskeletal Procedures	69	$10,806.47	$11,675.25
5116	Level 6 Musculoskeletal Procedures	14	$15,535.58	$15,754.05

IV. Proposed OPPS Payment for Devices

A. Pass-Through Payment for Devices

1. Beginning Eligibility Date for Device Pass-Through Status and Quarterly Expiration of Device Pass-Through Payments

a. Background

Under section 1833(t)(6)(B)(iii) of the Act, the period for which a device category eligible for transitional pass-through payments under the OPPS can be in effect is at least 2 years but not more than 3 years. Prior to CY 2017, our regulation at 42 CFR 419.66(g) provided that this pass-through payment eligibility period began on the date CMS established a particular transitional pass-through category of devices, and we based the pass-through status expiration date for a device category on the date on which pass-through payment was effective for the category. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79654), in accordance with section 1833(t)(6)(B)(iii)(II) of the Act, we amended § 419.66(g) to provide that the pass-through eligibility period for a device category begins on the first date on which pass-through payment is made under the OPPS for any medical device described by such category.

In addition, prior to CY 2017, our policy was to propose and finalize the dates for expiration of pass-through status for device categories as part of the OPPS annual update. This means that device pass-through status would expire at the end of a calendar year when at least 2 years of pass-through payments had been made, regardless of the quarter in which the device was approved. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79655), we changed our policy to allow for quarterly expiration of pass-through payment status for devices, beginning with pass-through devices approved in CY 2017 and subsequent calendar years, to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through payment devices. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79648 through 79661) for a full discussion of the 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 is one device category eligible for pass-through payment: HCPCS code C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), which was established effective January 1, 2019. The pass-through payment status of the device category for HCPCS code C2624 will expire on December 31, 2022. Therefore, HCPCS code C2624 will continue to receive device pass-through payments in CY 2020.

2. New Device Pass-Through Applications

a. Background

Section 1833(t)(6) of the Act provides for pass-through payments for devices, and section 1833(t)(6)(B) of the Act requires CMS to use categories in determining the eligibility of devices for pass-through payments. As part of implementing the statute through regulations, we have continued to

believe that it is important for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in the treatment of Medicare beneficiaries to facilitate access by beneficiaries to the advantages of the new technology. Conversely, we have noted that the need for additional payments for devices that offer little or no clinical improvement over previously existing devices is less apparent. In such cases, these devices can still be used by hospitals, and hospitals will be paid for them through appropriate APC payment. Moreover, a goal is to target pass-through payments for those devices where cost considerations might be most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629). We note that, in section IV.A.4. of this proposed rule, we are proposing an alternative pathway that would grant fast-track device pass-through payment under the OPPS for devices approved under the FDA Breakthrough Device Program for OPPS device pass-through payment applications received on or after January 1, 2020. We refer the reader to section IV.A.4. of this proposed rule for a complete discussion on this proposal.

As specified in regulations at 42 CFR 419.66(b)(1) through (3), to be eligible for transitional pass-through payment under the OPPS, a device must meet the following criteria:

- If required by FDA, the device must have received FDA approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA), or meet another appropriate FDA exemption; and the pass-through payment application must be submitted within 3 years from the date of the initial FDA approval or clearance, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA approval or clearance is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability;
- The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act; and
- The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion.

In addition, according to § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker).

Separately, we use the following criteria, as set forth under § 419.66(c), to determine whether a new category of pass-through payment devices should be established. The device to be included in the new category must—

- Not be appropriately described by an existing category or by any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996;
- Have an average cost that is not ''insignificant'' relative to the payment amount for the procedure or service with which the device is associated as determined under § 419.66(d) by demonstrating: (1) The estimated average reasonable costs of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices; (2) the estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent; and (3) the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service (with the exception of brachytherapy and temperature-monitored cryoablation, which are exempt from the cost requirements as specified at § 419.66(c)(3) and (e)); and
- Demonstrate a substantial clinical improvement, that is, substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

Beginning in CY 2016, we changed our device pass-through evaluation and determination process. Device pass-through applications are still submitted to CMS through the quarterly subregulatory process, but the applications will be subject to notice-and-comment rulemaking in the next applicable OPPS annual rulemaking cycle. Under this process, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle, while submitters of applications that are not approved upon quarterly review will have the option of being included in the next applicable OPPS annual rulemaking cycle or withdrawing their application from consideration. Under this notice-and-comment process, applicants may submit new evidence, such as clinical trial results published in a peer-reviewed journal or other materials for consideration during the public comment process for the proposed rule. This process allows those applications that we are able to determine meet all of the criteria for device pass-through payment under the quarterly review process to receive timely pass-through payment status, while still allowing for a transparent, public review process for all applications (80 FR 70417 through 70418).

More details on the requirements for device pass-through payment applications are included on the CMS website in the application form itself at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html*, in the ''Downloads'' section. In addition, CMS is amenable to meeting with applicants or potential applicants to discuss research trial design in advance of any device pass-through application or to discuss application criteria, including the substantial clinical improvement criterion.

b. Applications Received for Device Pass-Through Payment for CY 2020

We received seven complete applications by the March 1, 2019 quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in this CY 2020 OPPS/ASC proposed rule. We received one of the applications in the second quarter of 2018, three of the applications in the fourth quarter of 2018, and three of the applications in the first quarter of 2019. None of the applications were approved for device pass-through payment during the quarterly review process.

Applications received for the later deadlines for the remaining 2019 quarters (June 1, September 1, and December 1), if any, will be presented in the CY 2021 OPPS/ASC proposed rule. We note that the quarterly application process and requirements

have not changed in light of the addition of rulemaking review. Detailed instructions on submission of a quarterly device pass-through payment application are included on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf*. A discussion of the applications received by the March 1, 2019 deadline is presented below.

(1) Surefire® Spark™ Infusion System

TriSalus Life Sciences submitted an application for a new device category for transitional pass-through payment status for the Surefire® Spark™ Infusion System. The Surefire® Spark™ Infusion System is described as a flexible, ultra-thin microcatheter with a self-expanding, nonocclusive one-way microvalve at the distal end. The applicant stated that it has designed the Pressure Enabled Drug Delivery™ technology of the Surefire® Spark™ Infusion System to overcome intratumoral pressure in solid tumors and improve distribution and penetration of therapy during Transcatheter Arterial Chemoembolization (TACE) procedures. TACE is a minimally invasive, image-guided procedure used to infuse a high dose of chemotherapy into liver tumors. According to the applicant, the pliable, one-way valve at the distal tip of the Surefire® Spark™ Infusion System creates a temporary local increase in pressure during infusion, opening up collapsed vessels in tumors, which enables perfusion and therapy delivery in areas inaccessible to the systemic circulation, a positive hydrostatic pressure gradient, and restores convective flow to enable therapy to penetrate deeper into the tumor. During the TACE procedure, the physician first gains catheter access into the arterial system of the hepatic arteries through a small incision in the groin or the wrist. The applicant stated that the physician then uses real-time fluoroscopic guidance to navigate the Surefire® Spark™ Infusion System into the blood vessels feeding the tumors, infusing the chemotherapy and embolic materials through the Surefire® Spark™ Infusion System until the tumor bed is completely saturated.

With respect to the newness criterion at § 419.66(b)(1), the FDA granted 510(k) premarket clearance as of April 3, 2018. The application for a new device category for transitional pass-through payment status for the Surefire® Spark™ Infusion System was received on November 29, 2018, which is within 3 years of the date of the initial FDA approval or clearance. We are inviting public comments on whether the Surefire® Spark™ Infusion System meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the use of the Surefire® Spark™ Infusion System is integral to the service of providing delivery of chemotherapy into liver tumors, is used for one patient only, comes in contact with human skin, and is applied in or on a wound or other skin lesion. The applicant also claimed the Surefire® Spark™ Infusion System meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or items for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We are inviting public comments on whether the Surefire® Spark™ Infusion 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 identified several existing pass-through payment categories that may be applicable to the Surefire® Spark™ Infusion System. The Surefire® Spark™ Infusion System may be described by HCPCS code C1887 (Catheter, guiding (may include infusion/perfusion capability)). The applicant describes the Surefire® Spark™ Infusion System as a device used in vascular interventional procedures to deliver diagnostic and therapeutic agents in the peripheral vasculatures. The CMS List of Device Category Codes for Present or Previous Pass-Through Payment and Related Definitions describes HCPCS code C1887 as intended for the introduction of interventional/diagnostic devices into the coronary or peripheral vascular systems. The Surefire® Spark™ Infusion System may also be described by HCPCS code C1751 (Catheter, infusion, inserted peripherally, centrally or midline (other than hemodialysis)). The applicant describes the Surefire® Spark™ Infusion System as being inserted through a small incision in the groin or the wrist. We 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 four studies to support the claim that their technology represents a substantial clinical improvement over existing technologies. The applicant asserts that the Surefire® Spark™ Infusion System represents a substantial clinical improvement over existing technologies because it offers a treatment option that no other catheters currently available can provide. The manufacturer notes that the self-expanding, nonocclusive, one-way valve can infuse therapy at pressure higher than the baseline mean arterial pressure, and this pressurized delivery opens up collapsed vessels in tumors and enables perfusion and therapy delivery into hypoxic areas of the liver tumors. The applicant also believes that the Surefire® Spark™ Infusion System represents a substantial clinical improvement because the technology has shown improved tumor response rates in hepatocellular carcinoma, as well as a decrease in the rate of disease recurrence and the need for subsequent treatment.

The first pilot study of nine patients being treated for hepatocellular carcinoma, who received infusions via both a conventional end-hole catheter and an antireflux microcatheter, demonstrated statistically significant reductions in downstream distribution of embolic particles with the antireflux catheter and increases in tumor deposition ($p<0.05$).[13] The second singlecenter retrospective study was conducted with 22 patients treated for hepatocellular carcinoma with the Surefire® Spark™ Infusion System and TACE. As assessed by MRI, there appeared to be overall disease response in 91 percent of patients and 85 percent of lesions and complete response in 32 percent of patients and 54 percent of lesions.[14] In the first study for a case-control series, 19 patients undergoing treatment using SIS–TACE had a statistically significant improvement in

[13] Pasciak AS, McElmurray JH, Bourgeois AC, Heidel RE, Bradley YC. Impact of an antireflux catheter on target volume particulate distribution in liver-directed embolotherapy: A pilot study. J Vasc Interv Radiol. 2015 May;26(5):660–9.

[14] Kim AY, Frantz S, Krishnan P, DeMulder D, Caridi T, Lynskey GE, et al. (2017) Short-term imaging response after drug-eluting embolic trans-arterial chemoembolization delivered with the Surefire Infusion System® for the treatment of hepatocellular carcinoma. PloS one 12.9 (2017): e0183861.

disease response rate compared to 19 patients treated with end-hole microcatheters, 78.9 percent compared to 36.8 percent for initial overall response rate (p = 0.008).[15] In the second study, a multi-center registry of 72 patients demonstrated high response rate when compared to historical control at 6 months follow-up.[16]

Based on the information submitted by the applicant, one concern is that large-scale studies with long-term follow-up are limited. Also, the majority of studies presented had a sample size of less than 25 and the highest sample size presented was less than 100 patients. Additionally, patient follow-up occurred mostly within a 3 to 6 month timeframe with few studies occurring beyond this range.

Another concern is that none of the studies presented improvements in mortality with the use of the Surefire® Spark™ Infusion System. Outcomes focused primarily on tumor response rates and lesion size, based upon imaging. Additional data on mortality endpoints would be helpful to fully assess substantial clinical improvement.

We are inviting public comments on whether the Surefire® Spark™ Infusion 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 Surefire® Spark™ Infusion System would be reported with CPT code 37243, which is assigned to APC 5193 (Level 3 Endovascular Procedures). To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5193, which has a CY 2019 payment rate of $9,669.04. Beginning in CY 2017, we calculated the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). CPT code 37243 had a device offset amount of $3,894.69 at the time the application was received. According to the applicant, the cost of the Surefire® Spark™ Infusion System is $7,750.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $7,750 for the Surefire® Spark™ Infusion System is 80.2 percent of the applicable APC payment amount for the service related to the category of devices of $9,669.04 ($7,750/$9,669.04 × 100 = 80.2 percent). Therefore, we believe the Surefire® Spark™ Infusion System meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $7,750 for the Surefire® Spark™ Infusion System exceeds the cost of the device-related portion of the APC payment amount for the related service of $3,894.69 by 199 percent ($7,750/$3,894.69) × 100 = 198.99 percent). Therefore, we believe that the Surefire® Spark™ Infusion System meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $7,750 for the Spark™ Infusion System and the portion of the APC payment amount for the device of $3,894.69 exceeds the APC payment amount for the related service of $9,669.04 by 40 percent (($7,750 − $3,894.69)/$9,669.04) × 100 = 39.87 percent). Therefore, we believe that the Surefire® Spark™ Infusion System meets the third cost significance requirement.

We are inviting public comments on whether the Surefire® Spark™ Infusion System meets the device pass-through payment criteria discussed in this section, including the cost criterion.

(2) TracPatch

According to the applicant, TracPatch is a wearable device which utilizes an accelerometer, temperature sensor and step counter to allow the surgeon and patient to monitor recovery and help ensure critical milestones are being met. The applicant states that TracPatch utilizes wearable monitoring technology and methods in an effort to enhance the rehabilitation experience for both patients and physicians. Accelerometers are utilized to recognize and record the results when patients perform standard physical therapy exercises, in addition to providing standard step count and high-acceleration events that may indicate a fall. A temperature sensor monitors the skin temperature near the joint.

TracPatch is described by the applicant as a 24/7 remote monitoring wearable device that captures a patient's key daily activities: Such as range of motion progress, exercise compliance, and ambulation. TracPatch is used for pre- and post-operative patient monitoring, patient engagement, data analytics and post-op cost reduction.

According to the applicant, the wearable devices stick on the skin above and below the knee. The wearables are applied before total knee surgery to determine a patient's baseline activity levels, and then again after surgery to allow the patient and surgeon to monitor activity, pain, range of motion and physical therapy. The use of the Bluetooth connectivity allows the device to be paired with any smartphone and the TracPatch cloud allows for unlimited data collection and storage. The applicant states that TracPatch includes a web dashboard and computer application, which permit a health care provider to monitor a patient's recovery in real-time, allowing for immediate care adjustments and the ability for providers and patients to respond to issues that may occur during recovery from surgery.

With respect to the newness criterion at § 419.66(b)(1), the applicant stated that TracPatch does not need FDA clearance because it is a Class I device that would be assigned to a generic category of devices described in title 21 of the Code of Federal Regulations, parts 862 through 892 (21 CFR parts 862 through 892) that do not require FDA clearance. However, the applicant did not identify which category of exempted devices that TracPatch would be assigned. The applicant also stated that TracPatch will be introduced into the market in 2019, which would be within 3 years of the device pass-through payment application for TracPatch that

[15] N Apseloff, J Keung, T Caridi, D Buckley, G Lynskey, A Kim. Case-control evaluation of endhole microcatheter versus Surefire Infusion System for use during transarterial chemoembolization for hepatocellular carcinoma. Conference abstract presented at 2017 Society of Intervention Radiology Annual Congress, March 8, 2017.

[16] Kapoor B, Contreras F, Katz M, Arepally A, Fischman A, Rose S, Kim A, Ferraro J. Surefire Infusion System (SIS) hepatocellular carcinoma registry study interim results: A multicenter study of the safety, feasibility, and outcomes of the SIS expandable-tip microcatheter in DEB–TACE.

Conference abstract presented at 2018 Society of Intervention Radiology Annual Congress, March 19, 2017.

was received in March 2019. We are inviting public comments on whether the TracPatch is exempt from FDA clearance and if the TracPatch meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), the applicant claimed that the TracPatch is an integral part of monitoring the range of motion for a knee prior to and after total knee arthroplasty, is used for one patient only, and is placed on the skin above and below the knee and secured by Velcro strips. The applicant stated that the device is not surgically implanted or inserted into the patient and is not applied in or on a wound or other skin lesion. We have concerns with the TracPatch's eligibility with respect to the criterion at § 419.66(b)(3) because to be eligible for pass-through payment a device must be surgically implanted or inserted into the patient or applied in a wound or on other skin lesions. In addition, the applicant stated that the TracPatch meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered. We have determined that TracPatch is not a material or supply furnished incident to a service. We are inviting public comments on whether the TracPatch 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 TracPatch, the applicant suggested a category descriptor of ''Real time patient monitoring surface sensor technology for pre and post-op Total Knee Arthroplasty.'' We have not identified an existing pass-through payment category that describes the TracPatch, but we welcome public comments on this topic.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. The applicant asserted that use of the TracPatch significantly improves clinical outcomes for a patient population because the TracPatch allows both real-time and remote monitoring of the knee after total knee arthroplasty, which allows providers to make care decisions with up-to-the-minute data. The applicant noted that health care providers have instant access to a patient's pre-operative and post-operative data and can adjust care plans based on the data. The applicant stated that physicians will be able to preoperatively monitor patient activity to set a clinical baseline, but surgeons will also be able to monitor how their patients are recovering long after they have been discharged, which the applicant claims will ultimately result in fewer patients being readmitted to the hospital and higher success rates of surgery. The applicant asserted that the use of the TracPatch will result in decreased rate of subsequent diagnostics and therapeutic interventions and physician visits. The applicant also noted that the TracPatch system will allow physicians to monitor their patients in real-time and take corrective actions in a timely manner, which will result in reduced recovery time as well as improved patient outcomes.

Although the applicant presented these claims, the applicant provided no clinical research evidence to support them; only the testimonials from practicing physicians and large hospital systems were presented. The testimonials addressed the benefits of remote data monitoring and stated that the real-time data would provide better information to understand the effectiveness of surgeries performed, according to one provider. However, there were no reference articles submitted to support the claims made in the application and the testimonials nor were any data provided on the clinical effectiveness of the use of the TracPatch. We are concerned that, without clinical data to support the applicant's claims, we do not have sufficient information to determine whether the use of the TracPatch is a substantial clinical improvement over the current methods to monitor recovery from total knee arthroplasty. We are inviting public comments on whether the TracPatch 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 use of the TracPatch would be reported with either CPT code 99453 (Remote monitoring of physiologic parameter(s) (*e.g.,* weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment) or CPT code 99454 (Remote monitoring of physiologic parameter(s) (*e.g.,* weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days). CPT code 99453 is assigned to APC 5012 (Clinic Visits and Related Services), with a proposed CY 2020 payment rate of $120.16, and there is no device offset for the procedure. CPT code 99454 is assigned to APC 5741 (Level 1 Electronic Analysis of Devices), with a proposed CY 2020 payment rate of $38.04, and there is no device offset for the procedure. The applicant stated that the cost of the TracPatch device is $3,250.

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 cost of $3,250 for the TracPatch exceeds the applicable APC amount for CPT code 99454 of $38.04 by 8,543.64 percent ($3,250/$38.04 × 100 = 8,543.64 percent). Therefore, the TracPatch appears to meet the first cost significance requirement.

The second cost significance requirement, 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 two procedure codes that would be billed for the use of the TracPatch do not have a device offset amount, which means the TracPatch would appear to meet the second cost significance requirement.

Section 419.66(d)(3), the third cost significance requirement, provides 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 cost of $3,250 for the TracPatch and the portion of the APC payment for the device of $0.00 exceeds 10 percent at 8,543.64 percent (($3,250 − $0.00)/$38.04 × 100 = 8,543.64 percent). Therefore, the TracPatch

appears to meet the third cost significance requirement and, therefore, satisfies the cost significance criterion. We are inviting public comments on whether the TracPatch meets the device pass-through payment criteria discussed in this section.

(3) Vagus Nerve Stimulation (VNS) Therapy® System for Treatment Resistant Depression (TRD)

LivaNova USA Inc. submitted an application for the Vagus Nerve Stimulation (VNS) Therapy® System for Treatment Resistant Depression (TRD). According to the applicant, the VNS Therapy® System consists of two implantable components: A programmable electronic pulse generator and a bipolar electrical lead that is connected to the programmable electronic pulse generator. The applicant stated that the surgical procedure to implant the VNS Therapy® System involves subcutaneous implanting of the pulse generator in the intraclavicular region as well as insertion of the bipolar electrical lead which entails wrapping two spiral electrodes around the cervical portion of the left vagus nerve within the carotid sheath.

According to the applicant, following implant and recovery, the physician programs the pulse generator to intermittently stimulate the vagus nerve at a level that balances efficacy and patient tolerability. The pulse generator delivers electrical stimulation via the bipolar electrical lead to the cervical portion of the left vagus nerve within the carotid sheath thereby relaying information to the brain stem modulating structures relevant to depression. Stimulation typically consists of a 30-second period of ''on time,'' during which the device stimulates at a fixed level of output current, followed by a 5-minute ''off time'' period of no stimulation.

The applicant states that a hand-held programmer is utilized to program the pulse generator stimulation parameters, including the current charge, pulse width, pulse frequency, and the on/off stimulus time, which is also known as the on/off duty cycle. Initial settings can be adjusted to enhance the tolerability of the device as well as its clinical effects on the patient. The generator runs continuously, but patients can temporarily turn off the device by holding a magnet over it. The generator can also be turned on and off by the programmer.

The applicant states that the VNS Therapy® System provides indirect modulation of brain activity through the stimulation of the vagus nerve. The vagus nerve, the tenth cranial nerve, has parasympathetic outflow that regulates the autonomic (that is, involuntary) functions of heart rate and gastric acid secretion, and also includes the primary functions of sensation from the pharynx, muscles of the vocal cords and swallowing. It is a nerve that carries both sensory and motor information to and from the brain. Importantly, the vagus nerve has influence over widespread brain areas and it is believed that electrical stimulation of the vagus nerve alters various networks of the brain in order to treat psychiatric disease.

With respect to the newness criterion at § 419.66(b)(1), the applicant received FDA clearance for the VNS Therapy® System for TRD through the premarket approval (PMA) process on July 15, 2005, and the VNS Therapy® for TRD device was introduced to the market in September 2005. However, on May 4, 2007, a national coverage determination (NCD 160.18) was released prohibiting Medicare from covering the use of the VNS Therapy® System for TRD. This NCD remained in effect until February 15, 2019, when CMS determined that the VNS Therapy® for TRD could receive payment if the service was performed in CMS-approved coverage with evidence development (CED) studies. Although the VNS Therapy® System for TRD was introduced to the market in September 2005, Medicare has only covered it for slightly more than 1½ years. However, § 419.66(b)(1) states that a pass-through payment application for a device must be received within 3 years of when the device either received FDA approval or was introduced to the market. The applicant stated that the VNS Therapy® System for TRD was introduced to the market in September 2005, which means the device pass-through payment application would have needed to have been submitted to CMS by September 2008. However, the pass-through application for the device was not received by CMS until March 2019.

In addition, it appears that the neurostimulator device for the VNS Therapy® System for TRD is the same device that has been used since 1997 to treat epilepsy.[17] The applicant stated the following three differences between the two devices: (1) How the device is programmed to treat epilepsy versus TRD; (2) how the external magnets of the device are used for epilepsy treatment as compared to TRD treatment; and (3) that the battery life of the device to treat epilepsy is different than the battery life of the device when treating TRD. However, it is not clear that these differences demonstrate that the actual device used to treat TRD is any different than the device used to treat epilepsy.

Based on the information presented, we are inviting public comments on whether the VNS Therapy® System for TRD meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), the applicant claimed that the VNS Therapy® System for TRD is an integral part of a procedure to provide adjunctive treatment of chronic or recurrent depression in adult patients that have failed four or more antidepressant treatments. The VNS Therapy® System for TRD is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted into the patient. In addition, the applicant stated that the VNS Therapy® System for TRD meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered. We have determined that the VNS Therapy® for TRD is not a material or supply furnished incident to a service. We are inviting public comments on whether the VNS Therapy® for TRD 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 device used for the VNS Therapy® System for TRD, the applicant suggested a category descriptor of ''Generator, neurostimulator (implantable), treatment resistant depression, non-rechargeable.'' However, the device category represented by HCPCS code C1767 is described as ''Generator, neurostimulator (implantable), non-rechargeable,'' which appears to encompass the device category descriptor for the VNS Therapy® System for TRD suggested by the applicant. The applicant asserts that the device category descriptor for HCPCS code C1767 is overly broad and noted the establishment of HCPCS code C1823 (Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads), effective January 1, 2019, as an

[17] Current Behavioral Neuroscience Reports. 2014 Jun; 1(2): 64–73.

example of where a new device category for a nonrechargeable neurostimulation system to treat central sleep apnea was carved out from the broad category described by HCPCS code C1767.

The applicant believes its proposed category for the device for the VNS Therapy® System for TRD should qualify for a similar carve-out. However, HCPCS code C1823 was established due to specific device features which distinguish that device category from HCPCS code C1767. The applicant for the VNS Therapy® System for TRD requested a new device category based on a beneficiary's diagnosis, but OPPS does not differentiate payment by diagnosis. We welcome public comments on whether the proposed device category for the VNS Therapy® for TRD is not described by any existing categories or by any category previously in effect and meets the requirements of § 419.66(c)(1).

The second criterion for establishing a device category, at 419.66(c)(2), provides that CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. The applicant stated that the VNS Therapy® System for TRD would be a substantial clinical improvement because it is a treatment option for beneficiaries that have failed four or more antidepressant treatments. Patients with residual depressive symptoms despite treatment may be demonstrating TRD, but a universally accepted definition of TRD has yet to be achieved.[18] The applicant described the VNS Therapy® System for TRD as a treatment option for beneficiaries who have exhausted all other available options to treat depression. The applicant also provided studies to show how beneficial impacts on the quality of life by using the VNS Therapy® System for TRD can be maintained for multiple years. These studies have been fully reviewed and discussed by the CMS Coverage and Analysis Group's (CAG) national coverage determination with coverage with evidence development for VNS therapy for TRD.[19]

We reviewed the studies provided by the applicant to determine if the VNS Therapy® for TRD and its associated device offered a treatment option for patients unresponsive to or ineligible for currently available treatments. Our review also examined whether the VNS Therapy® System for TRD provides a benefit relative to a previously established device category or other available treatment. To show that the VNS Therapy® for TRD provides a relative benefit, the applicant submitted the same studies it had submitted to the CMS CAG in October 2017. These studies had been submitted as a part of a request to reconsider the NCD in place at that time that prohibited Medicare from providing coverage for the VNS Therapy® System for TRD. Therefore, our review focuses on and is consistent with the eight studies discussed in detail in the ''Decision Memo for Vagus Nerve Stimulation (VNS) for Treatment Resistant Depression (TRD)'' (CAG–00313R2).[20] We also reviewed an additional study submitted by the applicant for this device pass-through application.

The first study was a randomized control trial.[21] The study was a double-blind, randomized, multi-centered study and its goal was to compare the clinical outcomes in patients diagnosed with TRD of three VNS dose response curves with variable output currents and pulse widths, but with the same duty cycle and pulse frequency. Groups were designated high, medium and low dose and a total of 331 patients participated in the study. Enrollment criteria included: Individuals 18 years of age or older with a diagnosis of a chronic (>2 years) or recurrent (≥2 prior episodes) MDD or bipolar disorder and a current diagnosis of MDE as defined by the DSM–4 and determined using the Mini-International Neuropsychiatric Interview; a history of failure to respond to four or more adequate dose/duration of antidepressant treatment trials from at least two different antidepressant treatment categories as documented through medical history and record review; a minimum pre-study and baseline score of 24 on the MADRS, with no greater than a 25-percent decrease between the pre-study and baseline visits; current recipient of at least one antidepressant treatment (medication or ECT); and a stable regimen of all current antidepressant treatments for at least 4 weeks before the baseline visit. Furthermore, patients with bipolar disease had to be receiving a mood stabilizer at baseline. Exclusion criteria included a history of psychotic disorder, a history of rapid cycling bipolar disorder, a current history of bipolar disorder mixed phase, a history of borderline personality disorder, clinically significant suicidal intent at the time of screening, a history of drug/alcohol dependence in the last year, and a previous history of use of VNS. The only study personnel unblinded to the assignment of treatment groups were study programmers at each site and clinical engineers who were employed by the sponsor to monitor the programmers.

Eligible patients were implanted with a VNS Therapy® System for TRD device and then randomized to low, medium or high target settings. The low dose was chosen to deliver active stimulation at the lowest available setting for amplitude of output current with a narrow pulse width (0.25 mA; 130 μs). The high dose was chosen to be consistent with higher levels of stimulation, often seen in the treatment of epilepsy (1.25–1.5mA; 250 μs). The medium dose was chosen to track closely to the high dose, but without overlap (0.5–1.0 mA; 250 μs), potentially providing a better opportunity to demonstrate efficacy versus the low dose.

The study authors reported that in neither the acute nor the long-term phase were there any significant differences in response or remission rates among the treatment groups (response was defined as ≥50 percent improvement from baseline; remission was defined as ≤14 on the Inventory of Depressive Symptomatology Clinician Administered Version (IDS–C)). However, the authors stated that although effect sizes were limited, statistically significant decreases in mean depression scores (based on IDS–C) were observed in all groups. Mean IDS–C scores decreased approximately 15 points from baseline through week 50. The authors concluded that within the limits of this study, the VNS Therapy® System for TRD provided as adjunctive treatment to patients diagnosed with TRD as described above offers significant improvement at study endpoint as compared with baseline and that the effect is durable over 1 year. The authors also stated that higher electrical dose parameters were associated with higher response durability.

The second study by Aaronson et al. was a prospective, multi-center, open label, nonrandomized, longitudinal, naturalistic, observational post

[18] ''Decision Memo for Vagus Nerve Stimulation (VNS) for Treatment Resistant Depression (TRD) (CAG–00313R2).'' Available at: *https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=292&NCDId=230&ncdver=2&IsPopup=y&bc=AAAAAAAAQAAA&.*

[19] Ibid.

[20] Ibid.

[21] Aaronson ST, Carpenter LL, Conway CR, et al. Vagus Nerve Stimulation Therapy Randomized to Different Amounts of Electrical Charge for Treatment-Resistant Depression: Acute and Chronic Effects. Brain Stimul. 2013; 6(4):631–40.

marketing FDA surveillance study for which a registry was designed to follow the clinical response and outcome over 5 years of patients with a major depressive disorder (MDD), including those with unipolar or bipolar depression.[22] Patients participating in this study were recruited by physician referral and received treatment as usual (TAU) and VNS or just TAU. Subjects included those who were being evaluated for surgery or anesthesia to undergo VNS implantation, patients who had signed consent forms to receive a VNS device, patients who had scheduled VNS implantation surgery, and patients who had completed participation in a previous study termed the D–21 study [NCT 00305565: Study Comparing Outcomes for Patients With Treatment Resistant Depression Who Receive VNS Therapy at Different Doses].

The VNS arm included 335 patients without prior VNS treatment as well as 159 patients who received VNS treatment in the previous D–21 investigation. The TAU arm contained 301 patients. Eligibility criteria for the study included: Age 18 years or older; a current major depressive disorder diagnosed according to DSM–IV–TR criteria and confirmed by the Mini International Neuropsychiatric Interview of at least 2 years in duration (unipolar or bipolar depression) or a history of at least three depressive episodes including the current major depression episode; and a history of inadequate response to at least four depression treatments (including maintenance pharmacotherapy, psychotherapy and ECT). Maintenance pharmacotherapy was defined as dosage per Physician's Desk Reference labeling for a minimum of 4 weeks. Exclusion criteria included a history of schizophrenia, schizoaffective disorder, other psychotic disorder, current psychosis, history of rapid cycling bipolar disorder and a CGI score <4. Other than the patients from the D–21 study, the individuals in the study had not previously experienced VNS.

All patients (except those who participated in the D–21 study) were allowed to choose the treatment arm of their choice. However, the patients could be assigned to receive the alternate treatment due to various reasons (for example, availability of surgical implantation at a site, failure to receive insurance coverage for the procedure, availability of donated VNS devices, among others). There were no restrictions on concomitant treatments.

Post baseline follow-up visits for all patients were scheduled to occur at 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, and 60 months. During these scheduled visits, data were collected on medical status, need for adjustment of mood disorder therapy and concomitant treatments. Also, various depression scale ratings were collected as well as data concerning mortality and suicidality. Central raters (un-blinded nurses with special training) conducted an assessment of suicidality via telephone after each patient visit.

Propensity scores were used to adjust for imbalance of baseline prognostic factors between treatment arms. The ITT population included those study participants who completed a baseline visit, received their respective treatment and completed at least one post-baseline treatment.

Of the 494 patients in the VNS arm, 300 (61 percent) completed all 5 years of data. It is noted that the D–21 patients rolled over into this study at various time points after implantation. Of the 301 TAU patients, 138 (46 percent) completed all 5 years of data.

Approximately 70 percent of all study participants were female and over 90 percent were Caucasian in both groups. A diagnosis of severe recurrent major depressive disorder was reported in 46 percent of the patients in the VNS arm and 32 percent in the TAU arm. A diagnosis of primary bipolar I or bipolar II disorder was reported in 28 percent of patients in the VNS arm and 24 percent in the TAU arm. Other psychiatric diagnoses included moderate recurrent major depression, moderate single episode major depression, severe recurrent major depression, and severe single episode major depression. Fifty-seven percent of the VNS group and 40 percent of the TAU group had experienced past treatments of ECT.

Of the patients who withdrew early, 40 percent (195) were from the VNS arm and 54 percent (163) were from the TAU arm. The investigators observed that reasons for early withdrawal were similar between the treatment arms. It was also noted that after premature closure of a study site where 48 patients were participating in the TAU arm, most of the patients at that site were either lost to follow up or were dropped from the study for nonadherence.

The primary efficacy measure was a response rate, defined as a decrease of ≥50 percent in baseline Montgomery-Äsberg Depression Rating Scale (MADRS) score at any post-baseline visit during the study. The study authors report a 5-year cumulative response rate of 67.6 percent [95 percent CI = 63.4, 71.7] in the VNS group and 40.9 percent [95 percent CI = 35.4, 47.1] in the TAU group ($p < 0.001$). Also, the authors note that the cumulative percentage of first-time responders in the VNS Therapy® System arm was approximately double that in the TAU arm at all post-baseline points in time through the 5 years of the study. The authors concluded that adjunctive treatment with the use of the VNS Therapy® System device resulted in superior outcomes in both effectiveness and mortality over a 5-year period compared with treatment as usual for patients diagnosed with chronic, severe TRD.

A third study by Conway et al. compared quality of life (QoL) changes associated with treatment using VNS + TAU versus TAU in patients diagnosed with unipolar and bipolar TRD.[23] QoL data were gathered on all patients using the patient reported Quality of Life Enjoyment and Satisfaction Questionnaire Short Form (Q–LES–Q–SF), as well as the clinician reported CGI–I scale.

The data were collected as part of the 5 year registry described in Aaronson et al. (2017), noted above. However, the patient population analyzed was somewhat different, in that patients who rolled over from the previous D–21 study (Aaronson et al., 2017) were excluded so that all subjects had the same follow-up period. Furthermore, patients who were not depressed at baseline according to their MADRS scores, were also excluded. Therefore, the data from 328 patients treated with VNS + TAU and 271 patients treated with TAU were analyzed.

Females comprised 68.6 percent of the VNS + TAU group and 70.8 percent of the TAU group; 97 percent of the VNS + TAU group and 90.8 percent of the TAU group were Caucasian. Major depressive disorder was diagnosed in 70.4 percent of the VNS + TAU group and 78.2 percent of the TAU group. Bipolar I or II disorder (most recent episode depressed) was diagnosed in 29.6 percent of the VNS + TAU group and 21.7 percent of the TAU group.

Paired data analysis (for example, change in Q–LES–Q–SF versus percent change in MADRS score) were matched by assigned visit number; however these assessments for any given month might have taken place on separate visits (visit window was ±45 days until 1 year of

[22] Aaronson ST, Sears P, Ruvuna F, et al.: A 5-Year Observational Study of Patients With Treatment—Resistant Depression Treated With Vagus Nerve Stimulation or Treatment as Usual: Comparison of Response, Remission, and Suicidality. Am J Psychiatry. 2017; 174(7):640–648.

[23] Conway CR, Kumar A, Xiong W, et al. Chronic Vagus Nerve Stimulation Significantly Improves Quality of Life in Treatment-Resistant Major Depression. J Clin Psychiatry. 2018; 79:e1–e7.

follow-up; thereafter ±90 days). The authors report that the time difference between the paired measures was similar between the two groups and was a median of 4 weeks. Missing data were excluded if one component of a paired observation was lacking.

Among the results, the authors reported that on average, there was a comparative QoL advantage observed for the VNS + TAU group as early as 3 months, which was sustained throughout the 5-year study. The VNS + TAU treatment group demonstrated a significantly greater improvement in Q–LES–Q–SF scores than the TAU treatment group for the same percentage drop in MADRS score from baseline. The authors reported a similar pattern when the Clinical Global Impression (CGI) score was used. The authors concluded that adjunctive treatment using the VNS Therapy® System for TRD provided greater and sustained improvements in QoL as compared to TAU alone. Further, TRD patients treated with THE VNS Therapy® System for TRD experienced clinically meaningful QoL improvements even with symptom reduction less than the traditional 50 percent reduction used to describe a ''response'' to treatment.

The goal of the fourth study by Olin et al. was to characterize all-cause mortality rate and suicide risk in patients diagnosed with TRD who were treated with standard TAU and those treated with VNS + TAU.[24]

The study was an observational, open label, longitudinal, multi-center registry. The registry was a post-market surveillance study required by the FDA as a condition of approval of the TRD indication for VNS therapy to evaluate long-term patient outcomes. Patients were followed for 60 months, until withdrawal from the study, death or study completion.

Patients in the VNS + TAU group had been followed for an average of 3.2 years; those in the TAU group had been followed for 2.1 years. Because baseline characteristics of each group showed areas of imbalance, the use of propensity score modeling was required.

Suicidal ideation was evaluated by a central ratings group using both the Assessment of Suicidality (AOS) [*Has the patient made a suicidal gesture or attempt since the last visit; yes or no*] and MADRS Item 10, score ≥4, [''*Probably better off dead. Suicide thoughts are common, and suicide is considered a possible solution, but without specific plans or intention*'']. Among other criteria, eligible patients for the Registry were: Individuals who had been diagnosed with a current MDE according to the DSM–IV–TR criteria; individuals who had been in the current depressive episode for at least 2 years or had experienced at least three lifetime MDEs (including the current episode); individuals who had an inadequate response to four or more adequate antidepressive treatments; and individuals who had a CGI–S of 4 or greater. Exclusion criteria included schizophrenia, schizoaffective disorder, any other psychotic disorder, a history of rapid cycling bipolar disorder, or previous use of VNS.

After completing a screening visit, patients self-selected the treatment course that they believed was the best medical option. However, after the study started, there were some treatment arm changes due to the implementation of a Medicare noncoverage policy and subsequent lack of reimbursement for the VNS procedure. The authors stated that they believed that the majority of individuals who chose VNS + TAU did so as a final alternative when all other treatments failed.

There were 335 patients in the VNS + TAU group and 301 subjects in the TAU group. Average age of all patients was between 48 and 50 years. In the VNS + TAU group, 68.4 percent of patients were female; 96.4 percent were Caucasian. In the TAU group, 70.1 percent of the patients were female; 91 percent were Caucasian. Major depressive disorder was diagnosed in 71.1 percent of the VNS + TAU group and 76.4 percent of the TAU group. Bipolar disorder was diagnosed in 28.9 percent of the VNS + TAU group and 23.6 percent of the TAU group. In the VNS + TAU group, 58.2 percent of patients had a history of ECT; in the TAU group, 45.2 percent had a history of ECT treatment.

The authors found that the standardized all-cause mortality (4.46 [VNS + TAU] versus 8.06 [TAU only] per 1,000 person years) and suicide rates (0.88 [VNS + TAU] versus 1.61 [TAU only] per 1,000 person years) for patients treated with VNS + TAU were approximately half that of the patients treated only with TAU. However, the specific results were not statistically different due to the low mortality rates in both groups. Similar results were noted when stratifying by propensity score quintiles.

However, both groups had a significantly higher rate of suicide relative to the U.S. population; VNS + TAU 5.72 (95 percent CI; 0.07, 31.82) and TAU 9.98 (95 percent CI; 0.13, 55.55). The authors stated that individuals treated with VNS + TAU had a 10 percent—20 percent reduction in the risk of suicidality as compared to individuals treated with TAU alone, as measured by the MADRS Item 10 score. However, when the Assessment of Suicidality was used, no statistical difference was noted between treatment groups.

The authors further noted that the side effects profiles as measured by the Frequency, Intensity and Burden of Side Effects Rating questionnaire demonstrated that the percentage of unacceptable side effects for VNS + TAU was higher than that of TAU; however, this difference lessens over time.

The authors concluded that treatment with adjunctive VNS in this population can potentially lower the risk of all-cause mortality, suicide and suicide attempts.

The fifth study by Berry et al. performed a Bayesian meta-analysis of patient level data from six clinical studies that had been previously performed and supported by the manufacturer of the VNS Therapy® System for TRD device (Cyberonics).[25] The investigations included in the meta-analysis were two single arm studies of VNS + TAU, a randomized trial of VNS + TAU versus TAU, a single arm study of patients receiving only TAU, a randomized trial of VNS + TAU comparing different VNS intensities, and a nonrandomized registry of patients who received either VNS + TAU or TAU.

The MADRS and CGI–I were selected as the primary endpoints for the meta-analysis, though they were not necessarily the primary outcome measures in the individual studies analyzed. Outcomes of interest were response, remission and sustained response based on these scales of disease severity. Response was assessed across five of the six studies using the MADRS and defined as a follow up score of at least a 50 percent reduction compared to baseline score. Response per the CGI Improvement subscale (CGI–I) was defined as a follow-up score of 1—''very much improved'' or 2—''much improved.'' Remission was assessed using the MADRS (score at follow up <10 points). The study designs of the original investigations included in the meta-analysis necessitated that the TAU group data be

[24] Olin B, Jayewardene AK, Bunker M, Moreno F. Mortality and Suicide Risk in Treatment-Resistant Depression: An Created on 04/12/2019. Page 19 of 49 Observational Study of the Long-Term Impact of Intervention. PLOS ONE. 2012.

[25] Berry SM, Broglio K, Bunker M, Jayewardene A, Olin B, Rush AJ. A patient-level meta-analysis of studies evaluating vagus nerve stimulation therapy for treatment-resistant depression. Med Devices (Auckl). 2013.

limited to two trials for the CGI–I scale and one trial for the MADRS scale.

Because only one of the studies randomized patients to VNS + TAU or TAU groups, the authors used propensity scores to control for potential differences between treatment groups. The researchers calculated propensity scores using standard methods and included the score in mixed effects repeated measures models to account for the fact that the patients in all of the different studies arrived at their assessment points at different points in real time.

In the final analysis, there were 425 TAU patients, and 1,035 VNS + TAU patients. The authors reported that while outcomes for both groups tended to improve, those who were treated with VNS + TAU demonstrated better outcomes over 96 weeks of treatment. The repeated measures analysis showed that, compared to patients who received TAU only, those who received VNS + TAU had lower MADRS scores (mean difference −3.26 points; 95 percent CI: −3.99, −2.54). The odds of a MADRS response in the VNS + TAU group was 3.19 times greater (95 percent CI: 2.12, 4.66) and the odds of a MADRS remission was 4.99 times greater (95 percent CI: 2.93, 7.76) than those individuals who received TAU alone. Similarly, those in the VNS + TAU group had lower CGI–I scores (mean difference of −0.49 points; 95 percent CI: −0.59, −0.39) and had 7 times the odds of a CGI–I response (95 percent CI: 4.63, 10.83) compared to individuals receiving TAU alone. The authors concluded that the Bayesian meta-analysis demonstrated consistent superiority of VNS + TAU as compared to the use of TAU alone. The authors stated that, for patients diagnosed with TRD, treatment using VNS + TAU has greater response and remission rates that are more likely to persist than TAU.

The sixth study was another meta-analysis study, by Cimpianu et al., involving a systematic review that summarized the evidence regarding the use of invasive and noninvasive VNS for the treatment of TRD and other psychiatric disorders.[26] The study authors searched through the PubMed/MEDLINE database (up to September 2016) to identify relevant publications for their review.

The authors noted that very few studies exhibited a double-blind randomized sham controlled design; instead the majority were single blinded, open label observational or cohort investigations. Nonetheless, the text of the review pertaining to invasive VNS in the treatment of depressive disorders focused on those studies that used a randomized double blind design in at least one period (beginning) of a trial. However, of those investigations described, the authors observed that, for the most part, effect sizes were either not reported at all or were not reported in detail.

The authors found that the application of the VNS Therapy® System for TRD received a mixed recommendation in national guidelines. They stated that there is a consensus in the field that further randomized controlled studies, as well as long term naturalistic studies are needed for the future evaluation of the efficacy of VNS for the treatment of depression.

The seventh study was a meta-analysis study as well. Daban et al. performed a systematic review of studies published between 2000 and September 2007, found in the Medline, Psychological Abstracts and Current Content databases, that evaluated the safety and efficacy of VNS therapy in TRD patients.[27] The authors reviewed 6 short-term studies and 12 long-term studies. The measured outcomes consisted of baseline depression severity compared to ratings 2 weeks after implantation and after 3 months in acute and long-term studies and also after 6, 9, 12, and subsequent months in long-term studies. The authors stated their review demonstrated that VNS therapy has been reported to have antidepressant effects in open and long-term studies and that these effects may be sustained. However, they also noted that the evidence base is weak and the only blinded randomized trial was inconclusive, and they suggest more double-blinded, sham-controlled, randomized studies be conducted.

The eighth and final study discussed in the NCD with CED reconsideration decision memo was also a meta-analysis study. This study, by Martin et al., performed a systematic review to determine the efficacy of VNS for the treatment of depression.[28] In order to achieve this goal, a review of the pertinent scientific literature available until December 2010 was conducted. The databases searched were Medline/PubMed, Embase, The Cochrane Controlled Trials Register, Pascal Biomed and CINAL. References found on the web pages of ongoing clinical trials were also examined. Selection criteria included any RCT or pre/post design study, in which depressive symptomatology was measured and the intervention studied was VNS. The outcomes assessed were levels of depression severity as measured by depression symptomatology scales and percentage of responders, defined as subjects whose symptomatology scores demonstrated ≥50 percent change from baseline. The outcomes were analyzed in the short term (≤12 weeks), medium term (>12 and <48 weeks) and long term (>48 weeks).

In their literature search, the authors found only one randomized controlled trial involving VNS for treatment of depression. The primary outcome was a response rate as measured by the Hamilton Depression Rating Scale (HDRS). No statistically significant differences between the active and the placebo group were noted. However, the meta analysis of efficacy for the uncontrolled pre/post studies, showed a significant reduction in HDRS scores and the percentage of responders was 31.8 percent ([23.2 percent–41.8 percent]. p<0.001). To study the cause of this heterogeneity, a meta-regression was performed, which implied that an 84 percent variation in effect size across the studies was explained by baseline severity of depression (p<0.0001). In the uncontrolled pre/post studies that were meta-analyzed, the incidence density of suicide or attempted suicides was practically identical in the studies of the use of VNS and selective serotonin reuptake inhibitors. Therefore, the authors stated that the use of VNS did not appear to provoke suicide conduct any more than treatment with the comparator antidepressant.

The authors concluded that insufficient data exist to describe VNS as an effective treatment for depression. Moreover, they stated that the ability of the uncontrolled studies to show causality is limited and positive outcomes might be caused by placebo effect, regression to the mean, spontaneous remission, differences in patient characteristics or the Hawthorn effect (the alteration of behavior by subjects in a study because they are aware of being observed). They stated that evidence to determine the benefit (or not) of VNS therapy should be based on long-term clinical trials with a control group aimed at monitoring the possible latency involved in the effect of the use of VNS, as well as the associated adverse effects.

[26] Cimpianu C, Strube W, Falkai P, Palm U, Hasan A. Vagus nerve stimulation in psychiatry: A systematic review of the available evidence. J Neural Transm (Vienna). 2017.

[27] Daban C., Martinez-Aran A., Cruz N., Vieta E. Safety and efficacy of Vagus Nerve Stimulation in treatment-resistant depression. A systematic review. *J Affect Disord.* 2008; 110(1–2):1–15.

[28] Martin JLR and Martin-Sanchez E. Systematic review and meta-analysis of vagus nerve stimulation in the treatment of depression: Variable results based on study designs. *Eur Psychiatry.* 2012; 27(3).

The applicant submitted an additional study by Kumar et al. This was an observational study attempting to compare the duration of treatment response for patients that received VNS and treatment as usual (TAU) together as compared to the duration of response for patients receiving only TAU.[29] Data from 271 participants receiving TAU and 328 participants receiving VNS + TAU were analyzed. Response was defined as ≥50 percent decrease in baseline MADRS score at post-baseline visit and was considered retained until the decrease was <40 percent. In the VNS + TAU group, 62.5 percent (205/328) of participants had a first response over 5 years compared with 39.9 percent (108/271) in the TAU group. The time to first response was significantly shorter for VNS + TAU participants than for TAU participants (P<0.01). The authors of the study concluded that combining VNS therapy with TAU for patients having severe TRD leads to a faster response and a greater likelihood of response to treatment as compared to TAU alone. Also, the duration of the treatment response is longer for those receiving VNS + TAU.

With regard to the studies presented, we are concerned that the clinical utility of the VNS Therapy® System for TRD has not been well demonstrated by the applicant. The majority of the studies presented were case series, open labeled, or not randomized. The literature presented did not appear to have comparator arms with current treatment options like Magnetic Stimulation (TMS). We note that the CMS CAG found that all of the studies they reviewed and submitted for this application indicated some positive findings regarding clinical improvement with the use of VNS therapy. However, the CMS CAG also identified significant issues with the studies that either reduced the overall quality and strength of evidence and/or the clinical significance of the outcomes. Nevertheless, some of the published evidence suggests that the use of VNS is a promising treatment for patients diagnosed with TRD, which contributed to CMS CAG's decision to propose coverage with evidence development.

We are inviting public comments on whether the VNS Therapy® System for TRD 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. With respect to the cost criterion, the applicant stated that the VNS Therapy® System for TRD would be reported with CPT code 64568 (Incision for implantation of cranial nerve (*e.g.,* vagus nerve) neurostimulator electrode array and pulse generator), which is assigned to APC 5464 (Level 4 Neurostimulator and Related Services). The proposed CY 2020 payment rate for CPT code 64568 is $28,511.24, with a device offset of $24,168.98. The applicant stated that the cost of the VNS Therapy® System for TRD device is $42,000.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The cost of $42,000 for the VNS Therapy® System for TRD device exceeds the applicable APC amount for CPT code 64568 of $28,511.24 by 147.31 percent ($42,000/$28,511.24 × 100 = 147.31 percent). Therefore, the VNS Therapy® System for TRD appears to meet the first cost significance requirement.

The second cost significance requirement, 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 cost of $42,000 for the VNS Therapy® System for TRD device exceeds the device-related portion of the APC amount for the related service of $24,168.98 by 173.78 percent ($42,000/$24,168.98 × 100 = 173.78 percent). Therefore, the VNS Therapy® System for TRD appears to meet the second cost significance requirement.

Section 419.66(d)(3), the third cost significance requirement, 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 cost of $42,000 for the VNS Therapy® System for TRD and the portion of the APC payment for the device of $24,168.98 exceeds 10 percent at 62.54 percent (($42,000 − $24,168.98)/$28,511.24 × 100 = 62.54 percent). Therefore, the VNS Therapy® System for TRD appears to meet the third cost significance requirement and, therefore, satisfies the cost significance criterion. We are inviting public comments on whether the VNS Therapy® System for TRD meets the device pass-through payment criteria discussed in this section, including the cost criterion.

(4) Optimizer® System

Impulse Dynamics submitted an application for a new device category for transitional pass-through payment status for the Optimizer® System. According to the applicant, the Optimizer® System is an implantable device that delivers Cardiac Contractility Modulation (CCM) therapy for the treatment of patients with moderate to severe chronic heart failure. CCM therapy is intended to treat patients with persistent symptomatic heart failure despite receiving guideline directed medical therapy (GDMT). The applicant stated that the Optimizer System consists of the Optimizer Implantable Pulse Generator (IPG), Optimizer Mini Charger, and Omni II Programmer with Omni Smart Software. Lastly, the applicant stated that the Optimizer® System delivers CCM signals to the myocardium. CCM signals are nonexcitatory electrical signals applied during the cardiac absolute refractory period that, over time, enhance the strength of cardiac muscle contraction.

With respect to the newness criterion at § 419.66(b)(1), the applicant received a Category B–3 Investigational Device Exemption (IDE) from the FDA on April 6, 2017. Subsequently, the applicant received its premarket approval (PMA) application from the FDA on March 21, 2019. We received the application for a new device category for transitional pass-through payment status for the Optimizer® System on February 26, 2019, which is within 3 years of the date of the initial FDA approval or clearance. We are inviting public comments on whether the Optimizer® System meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Optimizer® System is integral to the CCM therapy service provided, is used for one patient only, comes in contact with human skin, and is applied in or on a wound or other skin lesion. The applicant also stated that the Optimizer® System meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or items for which depreciation and financing expenses are recovered, and it

[29] Kumar A, Bunker M, Aaronson S, Conway C, Rothschild A, Mordenti G, Rush A. Durability of symptomatic responses obtained with adjunctive vagus nerve stimulation in treatment-resistant depression. *Neuropsychiatr Dis Treat.* 2019:15 457–468.

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 Optimizer® System.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. The applicant stated that the use of CCM significantly improves clinical outcomes for a patient population compared to currently available treatments. With respect to this criterion, the applicant submitted studies that examined the impact of CCM on quality of life, exercise tolerance, hospitalizations, and mortality.

The applicant noted that the use of the Optimizer® System significantly improves clinical outcomes for patients with moderate-to-severe chronic heart failure, and specifically improves exercise tolerance, quality of life, and functional status of patients that are otherwise underserved. The applicant claims that the Optimizer® System fulfills an unmet need because there is currently no therapeutic medical device therapies available for the 70 percent of heart failure patients who have New York Heart Association (NYHA) Class III heart failure, normal QRS duration and reduced ejection fraction (EF).

The applicant presented several studies to support these claims. According to the applicant, the results of a randomized clinical study in which patients with NYHA functional Class III, ambulatory Class IV heart failure despite OMT, an EF from 25–45 percent, or a normal sinus rhythm with QRS duration <130 ms (n=160) were randomized to continued medical therapy (n=86) or CCM with the Optimizer® System (n=74) for 24 weeks showed a statistically significant improvement in the primary endpoint of peak oxygen consumption (pVO2 = 0.84, 95 percent Bayesian credible interval 0.123 to 1.52) compared with the patients who were randomized to continued medical therapy.[30] The secondary endpoint of quality of life, measured by Minnesota Living with Heart Failure Questionnaire (MLWHFQ) (p<0.001), 6-minute hall walk test (p=0.02), and an NYHA function class assessment (p<0.001) were better in the treatment group versus control group. The secondary endpoint of heart failure-related hospitalizations was lowered from 10.8 percent to 2.9 percent (p=0.048). The applicant also reported a registry study of 140 patients with a left ventricular ejection fraction from 25–45 percent receiving CCM therapy with a primary endpoint of comparing observed survival to Seattle Heart Failure Model (SHFM) predicted survival over 3 years of follow-up. All patients implanted with the Optimizer® System at participating centers were offered participation and 72 percent of patients agreed to enroll in the registry. There were improvements in quality of life markers (MLWHFQ) and a 75-percent reduction in heart failure hospitalizations (p<0.0001). Survival at 3 years was similar between the two study arms with CCM at 82.8 percent [73.4 percent–89.1 percent] and SHFM at 76.7 percent (p = 0.16). However, for patients with a left ventricular ejection fraction from 35–45 percent receiving CCM therapy, the 3-year mortality for CCM therapy was significantly better than predicted with 88 percent for CCM compared to 74.7 percent for SHFM (p=0.0463).[31] The applicant presented a randomized, double blind, crossover study of CCM signals with 164 patients with EF ≤35 percent and NYHA Class II (24 percent) or III (76 percent) symptoms who received a CCM pulse generator. After the 6-month treatment period, results indicated statistically significantly improved peak VO2 and MLWHFQ (p=0.03 for each parameter), concluding that CCM signals appear to be safe for patients and that exercise tolerance and quality of life were significantly better while patients were receiving active CCM treatment.[32]

A study was conducted with 68 consecutive heart failure patients with NYHA Class II or III symptoms, QRS duration ≤130 ms, and who had been implanted with a CCM device between May 2002 and July 2013 in Germany. Based upon pre-implant SHFM survival rates, 4.5 years mean follow-up, and an average patient age of 61 years old, the study found lower mortality rates for CCM therapy group with 0 percent at 1 year, 3.5 percent at 2 years, and 14.2 percent at 5 years, compared to 6.1 percent, 11.8 percent, and 27.7 percent predicted by SHFM, respectively (p=0.007).[33] In a study on long-term outcomes, 41 consecutive heart failure patients with left ventricular ejection fraction (EF) <40 percent receiving CCM therapy were compared to a control group of 41 similar heart failure patients and primarily evaluated for all-cause mortality, as well as heart failure hospitalization, cardiovascular death, and a death and heart failure hospitalization composite. After 6 years of follow-up, the results showed that all-cause mortality was lower for the CCM group as compared to the control group (39 percent versus 71 percent respectively, p=0.001), especially among patients with EF ≥25–40 percent with 36 percent for the CCM group versus 80 percent for the control group (p<0.001). Although heart failure hospitalization was similar between the treatment and control cohorts, there was a significantly lower heart failure hospitalization rate for CCM patients with EF ≥25–40 percent (36 percent versus 64 percent respectively, p=0.005).[34] The applicant also presented additional studies[35] [36] that presented similar conclusions to the studies discussed above, noting that CCM therapy provided improvements in quality of life, exercise capacity, NYHA class, and mortality rates.

We noted several concerns with the studies presented by the applicant. One

[30] Abraham, W.T., Kuck, K.H., Goldsmith, R.L., Lindenfeld, J., Reddy, V.Y., Carson, P.E., & Wiegn, P. (2018). A randomized controlled trial to evaluate the safety and efficacy of cardiac contractility modulation. JACC: Heart Failure, 6(10), 874–883.

[31] Anker, S.D., Borggrefe, M., Neuser, H., Ohlow, M. A., Röger, S., Goette, A., & Rousso, B. Cardiac contractility modulation improves long-term survival and hospitalizations in heart failure with reduced ejection fraction. *Eur J Heart Fail.* 2019 Jan 16. doi: 10.1002/ejhf.1374. [Epub ahead of print]

[32] Borggrefe MM, Lawo T, Butter C, Schmidinger H, Lunati M, Pieske B, Misier AR, Curnis A, Bocker D, Remppis A, Kautzner J, Stuhlinger M, Leclerq C, Taborsky M, Frigerio M, Parides M, Burkhoff D and Hindricks G. Randomized, double blind study of non-excitatory, cardiac contractility modulation electrical impulses for symptomatic heart failure. *Eur Heart J.* 2008;29:1019–28.

[33] Kloppe A, Lawo T, Mijic D, et al. Long-term survival with Cardiac Contractility Modulation in patients with NYHA II or III symptoms and normal QRS duration. *Int J Cardiol.* 2016 Apr 15;209:291–5.

[34] Liu M, Fang F, Luo XX, Shlomo BH, Burkhoff D, Chan JY, Chan CP, Cheung L, Rousso B, Gutterman D, Yu CM. Improvement of long-term survival by cardiac contractility modulation in heart failure patients: A case-control study. *Int J Cardiol.* 2016 Mar 1;206:122–6.

[35] Müller D, Remppis A, Schauerte P, et al. Clinical effects of long-term cardiac contractility modulation (CCM) in subjects with heart failure caused by left ventricular systolic dysfunction. *Clin Res. Cardiol.* 2017 Nov 1;106(11):893–904.

[36] Kuschyk J, Roeger S, Schneider R, et al. Efficacy and survival in patients with cardiac contractility modulation: Long-term single center experience in 81 patients. *Int J Cardiol.* 2015;183C:76–81.

concern regarding the evidence for the Optimizer® System involves the mixed mortality outcomes presented. Three studies showed significantly lower mortality rates with the use of CCM compared to controls or predicted mortality. Each of these studies focused on slightly different mortality outcomes, including all-cause mortality, a composite of death and heart failure hospitalization, and cardiac mortality rates from 1 to 5 years. Two studies show mixed results. For the first, 3-year survival was not significant for the overall population, despite a significantly higher survival rate found in a subpopulation. For the second, mortality rates were significant compared to predictions at 1 year, but not 3 years. The final study did not report significance in its overall survival at 2 years. Although the studies and trials presented show improvements in mortality when evaluating CCM therapy with comparators, the studies have small sample sizes and limited timeframes for measuring survival. Additionally, three studies compared observed mortality rates to statistically projected mortality rates. In the two studies with observed mortality rates, the overall improvement in mortality was not significant, despite some significance found in subanalyses. These issues raise concerns about the strength of the conclusions related to the use of CCM therapy improving patient outcomes.

Another concern with the studies presented for the Optimizer® System is that the included study population may not be necessarily representative of the Medicare beneficiary population. Several studies had a predominantly white, male patient population, which could make generalization of study results to a more diverse Medicare population difficult. Additionally, the average age of patients for several studies was under 65 years old, which may also be a limitation in applying these study results to the Medicare population.

Overall, there is a lack of evidence from large trials for the CCM therapy provided by the Optimizer® System. The studies presented had sample sizes fewer than 500 patients. Other limitations include the potential placebo effects and selection bias that may have impacted study results. Only two studies presented were randomized and only one of those two was a double-blinded study. For the remaining studies, no blinding occurred to minimize potential biases, which indicates that patients and researchers knew they were receiving CCM therapy. This is a limitation because observed outcomes may be impacted by the placebo effect. Although most studies matched participants for similar demographics, there could be systematic differences and unmeasured bias between the two groups beyond the similarities addressed in the study that could affect outcomes. The lack of randomization may have implications for the strength of the studies' conclusions.

Based upon the evidence presented, we are inviting public comments on whether the Optimizer® 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 Optimizer® System would be reported with CPT codes 0408T, 0409T, 0410T, 0411T, 0412T, 0413T, 0414T, 0415T, 0416T, 0417T, and 0418T. The associated APCs are APC 5231 (Level 1 ICD and Similar Procedures) and APC 5222 (Level 2 Pacemaker and Similar Procedures). To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5222, which had a CY 2019 payment rate of $7,404.11 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). CPT code 0410T had a device offset amount of $2,295.27 at the time the application was received. According to the applicant, the cost of the Optimizer® System was $15,700.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $15,700 for the Optimizer® System exceeds 212 percent of the applicable APC payment amount for the service related to the category of devices of $7,404.11 ($15,700/$7,404.11 × 100 = 212 percent). Therefore, we believe the Optimizer® System meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $15,700 for the Optimizer® System exceeds the cost of the device-related portion of the APC payment amount for the related service of $2,295.27 by 684 percent ($15,700/$2,295.27) × 100 = 684 percent. Therefore, we believe that the Optimizer® System meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $15,700 for the Optimizer® System and the portion of the APC payment amount for the device of $2,295.27 exceeds the APC payment amount for the related service of $7,404.11 by 181 percent (($15,700 − $2,295.27)/$7,404.11) × 100 = 181 percent). Therefore, we believe that the Optimizer® System meets the third cost significance requirement.

We are inviting public comments on whether the Optimizer® System meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(5) AquaBeam® System

PROCEPT BioRobotics Corporation submitted an application for a new device category for transitional pass-through payment status for the AquaBeam® System as a resubmission of their CY 2019 application. The AquaBeam® System is intended for the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). The applicant stated that this is a very common condition typically occurring in elderly men. The clinical symptoms of this condition can include diminished urinary stream and partial urethral obstruction.[37] According to the applicant, the AquaBeam® system resects the prostate to relieve symptoms of urethral compression. The resection is performed robotically using a high

[37] Chungtai B. Forde JC. Thomas DDM et al. Benign Prostatic Hyperplasia. Nature Reviews Disease Primers 2 (2016) article 16031.

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), the 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 2019 OPPS/ASC proposed and final rules, we cited the CY 2000 OPPS interim final rule with comment period (65 FR 67804 through 67805), where we explained how we interpreted § 419.43(e)(4)(iv). We stated that we consider a device to be surgically implanted or inserted if is surgically inserted or implanted via a natural or surgically created orifice, or inserted or implanted via a surgically created incision. We also stated that we do not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted. We consider items used to create incisions, such as scalpels, electrocautery units, biopsy apparatuses, or other commonly used operating room instruments, to be supplies or capital equipment, not eligible for transitional pass-through payments. We stated that we believe the function of these items is different and distinct from that of devices that are used for surgical implantation or insertion. Finally, we stated that, generally, we would expect that surgical implantation or insertion of a device occurs after the surgeon uses certain primary tools, supplies, or instruments to create the surgical path or site for implanting the device. In the CY 2006 OPPS final rule with comment period (70 FR 68329 and 68630), we adopted as final our interpretation that surgical insertion or implantation criteria include devices that are surgically inserted or implanted via a natural or surgically created orifice, as well as those devices that are inserted or implanted via a surgically created incision. We reiterated that we maintain all of the other criteria in § 419.66 of the regulations, namely, that we do not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted.

The applicant resubmitted their application with additional information that they believe supports their stance that the device should be considered eligible under the device pass-through payment eligibility criteria. The applicant stated that the AquaBeam® System's handpiece is temporarily surgically inserted into the urethra via the urinary meatus. The applicant indicated that the AquaBeam® System's handpiece does not create an incision or surgical opening or pathway, but instead ablates prostate tissue. The applicant further stated that the device only cuts the prostatic tissue after being inserted into the prostatic urethra and therefore it should be considered eligible. The applicant also stated that the prostatic urethra tissue is cut because it is at the center of the obstruction in the prostate. Additionally, the applicant explained that to relieve the symptoms of BPH, both the prostatic urethra and prostate tissue encircling the prostatic urethra must be ablated, or cut, to relieve the symptoms of BPH and provide some additional clearance for future swelling or growth of the prostate. The applicant stated that the prostatic urethra tissue is not cut or disturbed to access the prostate tissue underneath, but the removal of the prostatic urethra is a key aspect of treating the obstruction that causes BPH symptoms. Finally, the applicant believes that clinically the distinction between the prostatic urethra tissue and the prostate tissue are not meaningful in the context of a BPH surgical intervention. We 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 whether the AquaBeam® System meets this criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. The applicant stated that the AquaBeam® System provides a substantial clinical improvement as the first autonomous tissue resection robot for the treatment of lower urinary tract symptoms due to BPH. The applicant further provided that the AquaBeam® System is also a substantial clinical improvement because the Aquablation procedure demonstrated superior efficacy and safety for larger prostates (prostates sized 50–80 mL) as compared to transurethral resection of the prostate (TURP). The applicant also believes that the Aquablation procedure would provide better outcomes for patients with large prostates (>80 mL) who may undergo open prostatectomy whereas the open prostatectomy procedure would require a hospital inpatient admission. With respect to this criterion, the applicant submitted several articles that examined the use of a current standard treatment for BPH—transurethral prostatectomy TURP, including complications associated with the procedure and the comparison of the effectiveness of TURP to other modalities used to treat BPH, including holmium laser enucleation of the

prostate (HoLEP) [38] and photoselective vaporization (PVP).[39]

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.[40] This was a multicenter study in 4 countries with 17 sites, 6 of which contributed 5 patients or fewer. Patients were randomized to receive treatment with either the AquaBeam® System or TURP in a two-to-one ratio. With exclusions and dropouts, 117 patients were treated with the AquaBeam® System and 67 patients with TURP. The data on efficacy supported the equivalence of the two procedures based upon noninferiority analysis. The safety data were reported as showing superiority of the AquaBeam® System over TURP, although the data were difficult to track because adverse consequences were combined into categories. The applicant claimed that the International Prostate Symptom Scores (IPPS) were significantly improved in AquaBeam® System patients as compared to TURP patients in men whose prostate was greater the 50 ml in size. The applicant also claimed that the proportion of men with a worsening of sexual function (as shown with a decrease in Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ) score of at least 2 points or a decrease in International Index of Erectile Function (IIEF–5) score of at least 6 points by 6 months) was lower for the Aquablation procedure at 32.9 percent compared to the TURP groups at 52.8 percent.

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 were cited to show that the AquaBeam® System is a significant improvement over other available procedures.

Based on the evidence submitted with the application, we are concerned that there is a lack of sufficient evidence that the AquaBeam® System provides a substantial clinical improvement over other similar products, particularly in the outpatient setting where large prostates are less likely to be treated. We are inviting public comments on whether the AquaBeam® 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 AquaBeam® System would be reported with CPT code 0421T. CPT code 0421T is assigned to APC 5375 (Level 5 Urology and Related Services). To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5375, which has a CY 2018 payment rate of $3,706.03. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). CPT code 0421T had device offset amount of $0.00 at the time the application was received. According to the applicant, the cost of the handpiece for the AquaBeam® System is $2,500.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $2,500 for the AquaBeam® System exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices of $3,706.03 ($2,500/$3,706.03 × 100 = 67.5 percent). Therefore, we believe the AquaBeam® System meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). 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 requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $2,500 for the AquaBeam® System and the portion of the APC payment amount for the device of $0.00 exceeds the APC payment amount for the related service of $3,706.03 by 68 percent (($2,500 − $0.00)/$3,706.03 × 100 = 67.5 percent). Therefore, we believe that the AquaBeam® System meets the third cost significance requirement.

We are inviting public comments on whether the AquaBeam® System meets the device pass-through payment criteria discussed in this section, including the cost criterion.

(6) Eluvia™ Drug-Eluting Vascular Stent System

Boston Scientific Corporation submitted an application for new technology add-on payments for the Eluvia™ Drug-Eluting Vascular Stent System for FY 2020. According to the applicant, the Eluvia™ system is a sustained-release drug-eluting stent indicated for improving luminal diameter in the treatment of peripheral artery disease (PAD) with symptomatic de novo or restenotic lesions in the native superficial femoral artery (SFA) and/or the proximal popliteal artery (PPA) with reference vessel diameters (RVD) ranging from 4.0 to 6.0 mm and total lesion lengths up to 190 mm.

The applicant stated that PAD is a circulatory condition in which narrowed arteries reduce blood flow to the limbs, usually in the legs. Symptoms of PAD may include lower extremity pain due to varying degrees of ischemia, claudication which is characterized by pain induced by exercise and relieved with rest. According to the applicant, risk factors for PAD include individuals who are age 70 years old and older; individuals who are between the ages of 50 years old and 69 years old with a history of smoking or diabetes; individuals who are between the ages of 40 years old and 49 years old with diabetes and at least one other risk factor for atherosclerosis; leg symptoms

[38] Montorsi, F. et al.: Holmium Laser Enucleation Versus Transurethral Resection of The Prostate: Results from A 2-Center, Prospective, Randomized Trial In Patients With Obstructive Benign Prostatic Hyperplasia. *J. Urol.* 172, 1926–1929 (2004).

[39] Bachmann A, et al.: 180–W XPS GreenLight laser vaporisation versus transurethral resection of the prostate for the treatment of benign prostatic obstruction: 6-month safety and efficacy results of a European Multicentre Randomised Trial—the GOLIATH study. *Eur Urol,* 2014;65(5):931–42.

[40] 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.

suggestive of claudication with exertion, or ischemic pain at rest; abnormal lower extremity pulse examination; known atherosclerosis at other sites (for example, coronary, carotid, renal artery disease); smoking; hypertension, hyperlipidemia, and homocysteinemia.[41] PAD is primarily caused by atherosclerosis—the buildup of fatty plaque in the arteries. PAD can occur in any blood vessel, but it is more common in the legs than the arms. Approximately 8.5 million people in the United States have PAD, including 12 to 20 percent of individuals who are age 60 years old and older.[42]

Management of the disease is aimed at improving symptoms, improving functional capacity, and preventing amputations and death. Management of patients who have been diagnosed with lower extremity PAD may include medical therapies to reduce the risk for future cardiovascular events related to atherosclerosis, such as myocardial infarction, stroke, and peripheral arterial thrombosis. Such therapies may include antiplatelet therapy, smoking cessation, lipid-lowering therapy, and treatment of diabetes and hypertension. For patients with significant or disabling symptoms unresponsive to lifestyle adjustment and pharmacologic therapy, intervention (percutaneous, surgical) may be needed. Surgical intervention includes angioplasty, a procedure in which a balloon-tip catheter is inserted into the artery and inflated to dilate the narrowed artery lumen. The balloon is then deflated and removed with the catheter. For patients with limb-threatening ischemia (for example, pain while at rest and/or ulceration), revascularization is a priority to reestablish arterial blood flow. According to the applicant, treatment of the SFA is problematic due to multiple issues including high rate of restenosis and significant forces of compression.

The applicant describes the Eluvia™ Drug-Eluting Vascular Stent System as a sustained-release drug-eluting self-expanding, nickel titanium alloy (nitinol) mesh stent used to reestablish blood flow to stenotic arteries. According to the applicant, the Eluvia™ stent is coated with the drug paclitaxel, which helps prevent the artery from restenosis. The applicant stated that Eluvia™'s polymer-based drug delivery system is uniquely designed to sustain the release of paclitaxel beyond 1 year to match the restenotic process in the SFA. According to the applicant, the Eluvia™ Drug-Eluting Vascular Stent System is comprised of: (1) The implantable endoprosthesis; and (2) the stent delivery system (SDS). On both the proximal and distal ends of the stent, radiopaque markers made of tantalum increase visibility of the stent to aid in placement. The tri-axial designed delivery system consists of an outer shaft to stabilize the stent delivery system, a middle shaft to protect and constrain the stent, and an inner shaft to provide a guide wire lumen. The delivery system is compatible with 0.035 in (0.89 mm) guide wires. The Eluvia™ stent is available in a variety of diameters and lengths. The delivery system is offered in 2 working lengths (75 cm and 130 cm).

With respect to the newness criterion at § 419.66(b)(1), Eluvia™ received FDA premarket approval (PMA) on September 18, 2018. The application for a new device category for transitional pass-through payment status for Eluvia™ was received on November 15, 2018, which is within 3 years of the date of the initial FDA approval or clearance. We are inviting public comments on whether the Eluvia™ Drug-Eluting Vascular Stent System meets the newness criterion. With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Eluvia™ Drug-Eluting Vascular Stent System is integral to the service provided, is used for one patient only, comes in contact with human skin, and is applied in or on a wound or other skin lesion. The applicant also claimed that the Eluvia™ Drug-Eluting Vascular Stent System meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or items for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We are inviting public comments on whether the Eluvia™ Drug-Eluting Vascular Stent System meets the eligibility criterion 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 Eluvia™ Drug-Eluting Vascular Stent System. The applicant proposed a category descriptor for the Eluvia™ Drug-Eluting Vascular Stent System of ''Stent, non-coronary, polymer matrix, minimum 12-month sustained drug release, with delivery system.'' We 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 peripheral artery disease (PAD) with symptomatic de novo or restenotic lesions in the native superficial femoral artery (SFA) and/or proximal popliteal artery (PPA), with claims of substantial clinical improvement in achieving superior primary patency; reducing the rate of subsequent therapeutic interventions; decreasing the number of future hospitalizations or physician visits; reducing hospital readmission rates; reducing the rate of device-related complications; and achieving similar functional outcomes and EQ–5D index values while associated with half the rate of target lesion revascularizations (TLRs) procedures.

The applicant submitted the results of the MAJESTIC study, a single-arm, first-in-human study of the Eluvia™ Drug-Eluting Vascular Stent System. The MAJESTIC[43] study is a prospective, multi-center, single-arm, open-label study. According to the applicant, the MAJESTIC study demonstrated long-term treatment durability among patients whose femoropopliteal arteries were treated with the Eluvia™ stent. The applicant asserts that the MAJESTIC study demonstrates the sustained impact of the Eluvia™ stent on primary patency. The MAJESTIC study enrolled 57 patients who had been diagnosed with symptomatic lower limb ischemia and lesions in the SAF or PPA. Efficacy measures at 2 years included primary patency, defined as duplex ultrasound peak systolic velocity ratio of less than 2.5 and the absence of

[41] Neschis, David G. & MD, Golden, M., ''Clinical features and diagnosis of lower extremity peripheral artery disease.'' Available at: *https://www.uptodate.com/contents/clinical-features-and-diagnosis-of-lower-extremity-peripheral-artery-disease.*

[42] Centers for Disease Control and Prevention, ''Peripheral Arterial Disease (PAD) Fact Sheet,'' 2018, Available at: *https://www.cdc.gov/DHDSP/data_statistics/fact_sheets/fs_PAD.htm.*

[43] Müller-Hülsbeck, S., et al., ''Long-Term Results from the MAJESTIC Trial of the Eluvia Paclitaxel-Eluting Stent for Femoropopliteal Treatment: 3-Year Follow-up,'' *Cardiovasc Intervent Radiol,* December 2017, vol. 40(12), pp. 1832–1838.

TLR or bypass. Safety monitoring through 3 years included adverse events and TLR. The 24-month clinic visit was completed by 53 patients; 52 had Doppler ultrasound evaluable by the core laboratory, and 48 patients had radiographs taken for stent fracture analysis. The 3-year follow-up was completed by 54 patients. At 2 years, 90.6 percent (48/53) of the patients had improved by 1 or more Rutherford categories as compared with the pre-procedure level without the need for TLR (when those with TLR were included, 96.2 percent sustained improvement); only 1 patient exhibited a worsening in level, 66.0 percent (35/53) of the patients exhibited no symptoms (Category 0) and 24.5 percent (13/53) had mild claudication (Category 1) at the 24-month visit. Mean ABI improved from 0.73 ± 0.22 at baseline to 1.02 ± 0.20 at 12 months and 0.93 ± 0.26 at 24 months. At 24 months, 79.2 percent (38/48) of the patients had an ABI increase of at least 0.1 compared with baseline or had reached an ABI of at least 0.9. The applicant also noted that at 12 months the Kaplan-Meier estimate of primary patency was 96.4 percent.

With regard to the Eluvia™ stent achieving superior primary patency, the applicant submitted the results of the IMPERIAL [44] study in which the Eluvia™ stent is compared, head-to-head, to the Zilver® PTX Drug-Eluting stent. The IMPERIAL study is a global, multi-center, randomized controlled trial consisting of 465 subjects. Eligible patients were aged 18 years old or older and had a diagnosis of symptomatic lower-limb ischaemia, defined as Rutherford Category 2, 3, or 4 and stenotic, restenotic (treated with a drug-coated balloon greater than 12 months before the study or standard percutaneous transluminal angioplasty only), or occlusive lesions in the native SFA or PPA, with at least 1 infrapopliteal vessel patent to the ankle or foot. Patients had to have stenosis of 70 percent or more (via angiographic assessment), vessel diameter between 4 mm and 6 mm, and total lesion length between 30 mm and 140 mm.

Patients who had previously stented target lesion/vessels treated with drug-coated balloon less than 12 months prior to randomization/enrollment and patients who had undergone prior surgery of the SFA/PPA in the target limb to treat atherosclerotic disease were excluded from the study. Two concurrent single-group (Eluvia™ only) substudies were done: A nonblinded, nonrandomized pharmacokinetic sub-study and a nonblinded, nonrandomized study of patients who had been diagnosed with long lesions (greater than 140 mm in diameter).

The IMPERIAL study is a prospective, multi-center, single-blinded randomized, controlled (RCT) noninferiority trial. Patients were randomized (2:1) to implantation of either a paclitaxel-eluting polymer stent (Eluvia™) or a paclitaxel-coated stent (Zilver® PTX) after the treating physician had successfully crossed the target lesion with a guide wire. The primary endpoints of the study are Major Adverse Events defined as all causes of death through 1 month, Target Limb Major Amputation through 12 months and/or Target Lesion Revascularization (TLR) procedure through 12 months and primary vessel patency at 12 months post-procedure. Secondary endpoints included the Rutherford categorization, Walking Impairment Questionnaire, and EQ–5D assessments at 1 month, 6 months, and 12 months post-procedure. Patient demographic and characteristics were balanced between the Eluvia™ stent and Zilver® PTX stent groups.

The applicant noted that lesion characteristics for the patients in the Eluvia™ stent versus the Zilver® PTX stent arms were comparable. Clinical follow-up visits related to the study were scheduled for 1 month, 6 months, and 12 months after the procedure, with follow-up planned to continue through 5 years, including clinical visits at 24 months and 5 years and clinical or telephone follow-up at 3 and 4 years.

The applicant asserted that in the IMPERIAL study the Eluvia™ stent demonstrated superior primary patency over the Zilver® PTX stent, 86.8 percent versus 77.5 percent, respectively (p=0.0144). The noninferiority primary efficacy endpoint was also met. The applicant asserts that the superior primary patency results at the SFA are noteable because the SFA presents unique challenges with respect to maintaining long-term patency. There are distinct pathological differences between the SFA and coronary arteries. The SFA tends to have higher levels of calcification and chronic total occlusions when compared to coronary arteries. Following an intervention within the SFA, the SFA produces a healing response which often results in restenosis or re-narrowing of the arterial lumen. This cascade of events leading to restenosis starts with inflammation, followed by smooth muscle cell proliferation and matrix formation.[45] Because of the unique mechanical forces in the SFA, this restenotic process of the SFA can continue well beyond 300 days from the initial intervention. Results from the IMPERIAL study showed that primary patency at 12 months, by Kaplan-Meier estimate, was significantly greater for Eluvia™ than for Zilver® PTX, 88.5 percent and 79.5 percent, respectively (p=0.0119). According to the applicant, these results are consistent with the 96.4 percent primary patency rate at 12 months in the MAJESTIC study.

The IMPERIAL study included two concurrent single-group (Eluvia™ only) substudies: A nonblinded, nonrandomized pharmacokinetic substudy and a nonblinded, nonrandomized study of patients with long lesions (greater than 140 mm in diameter). For the pharmacokinetic sub-study, patients had venous blood drawn before stent implantation and at intervals ranging from 10 minutes to 24 hours post implantation, and again at either 48 hours or 72 hours post implantation. The pharmacokinetics sub-study confirmed that plasma paclitaxel concentrations after Eluvia™ stent implantation were well below thresholds associated with toxic effects in studies in patients who had been diagnosed with cancer (0.05 μM or ~43 ng/mL).

The IMPERIAL substudy long lesion subgroup consisted of 50 patients with average lesion length of 162.8 mm that were each treated with two Eluvia™ stents. According to the applicant, 12-month outcomes for the long lesion subgroup are 87 percent primary patency and 6.5 percent TLR. According to the applicant, in a separate subgroup analysis of patients 65 years old and older (Medicare population), the primary patency rate in the Eluvia™ stent group is 92.6 percent, compared to 75.0 percent for the Zilver® PTX stent group (p=0.0386).

With regard to reducing the rate of subsequent therapeutic interventions, secondary outcomes in the IMPERIAL study included repeat re-intervention on the same lesion, referred to as target lesion revascularization (TLR), over the 12 months following the index procedure. The rate of subsequent interventions, or TLRs, in the Eluvia™ stent group was 4.5 percent compared to 9.0 percent in the Zilver® PTX stent group. The applicant asserted that the TLR rate in the Eluvia™ stent group

[44] Gray, W.A., et al., ''A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial,'' *Lancet,* September 24, 2018.

[45] Forrester, J.S., Fishbein, M., Helfant, R., Fagin, J., ''A paradigm for restenosis based on cell biology: Clues for the development of new preventive therapies,'' *J Am Coll Cardiol,* March 1, 1991, vol. 17(3), pp. 758–69.

represents a substantial reduction in reintervention on the target lesion compared to that of the Zilver® PTX stent group (at a p=0.067 p-value). The Eluvia® stent group clinically driven TLR rates through 12 months following the index procedure were likewise lower for U.S. patients age 65 and older as well as for those with medically treated diabetes (confidential and unpublished as of the date of the device transitional pass-through payment application, data on file with Boston Scientific). In the subgroup of U.S. patients age 65 and older, the rates of TLR were 2.4 percent in the Eluvia™ group compared to 3.1 percent in the Zilver® PTX group, and in the subgroup of medically treated diabetes patients, the rates of TLR were 3.7 percent compared to 13.6 percent in the Zilver® PTX group (p=0.0269).

With regard to decreasing the number of future hospitalizations or physician visits, the applicant asserted that the substantial reduction in the lesion revascularization rate led to a reduced need to provide additional intensive care, distinguishing the Eluvia™ stent group from the Zilver® PTX stent group. In the IMPERIAL study, the Eluvia™-treated patients required fewer days of re-hospitalization. Patients in the Eluvia™ group averaged 13.9 days of rehospitalization for all adverse events compared to 17.7 days of rehospitalization for patients in the Zilver® PTX stent group. Patients in the Eluvia™ group were rehospitalized for 2.8 days for TLR/Total Vessel Revascularization (TVR) compared to 7.1 days in the Zilver® PTX stent group. Lastly, patients in the Eluvia™ stent group were rehospitalized for 2.7 days for procedure/device-related adverse events compared to 4.5 days from the Zilver® PTX stent group.

Regarding reduction in hospital readmission rates, the applicant asserted that patients treated in the Eluvia™ stent group experienced reduced rates of hospital readmission following the index procedure compared to those in the Zilver® PTX stent group. Hospital readmission rates at 12 months were 3.9 percent for the Eluvia™ stent group compared to 7.1 percent for the Zilver® PTX stent group. Similar results were noted at 1 and 6 months; 1.0 percent versus 2.6 percent and 2.4 percent versus 3.8 percent, respectively.

With regard to reducing the rate of device-related complications, the applicant asserted that while the rates of adverse events were similar in total between treatment arms in the IMPERIAL study, there were measurable differences in device-related complications. Device-related adverse-events were reported in 8 percent of the patients in the Eluvia™ stent group compared to 14 percent of the patients in the Zilver® PTX stent group.

Lastly, the applicant asserted that while functional outcomes appear similar between the Eluvia™ and Zilver® PTX stent groups at 12 months, these improvements for the Zilver® PTX stent group are associated with twice as many TLRs to achieve similar EQ–5D index values.[46] Secondary endpoints improved after stent implantation and were generally similar between the groups. At 12 months, of the patients with complete Rutherford assessment data, 241 (86 percent) of the 281 patients in the Eluvia™ group and 120 (85 percent) of the 142 patients in the Zilver® PTX group had symptoms reported as Rutherford Category 0 or 1 (none to mild claudication). The mean ankle-brachial index was 1.0 (SD 0.2) in both groups at 12 months (baseline mean ankle-brachial index 0.7 [SD 0.2] for Eluvia™; 0.8 [0.2] for Zilver® PTX), with sustained hemodynamic improvement for approximately 80 percent of the patients in both groups. Walking function improved significantly from baseline to 12 months in both groups, as measured with the Walking Impairment Questionnaire and the 6-minute walk test. In both groups, the majority of patients had sustained improvement in the mobility dimension of the EQ–5D, and approximately half had sustained improvement in the pain or discomfort dimension. No significant between-group differences were observed in the Walking Impairment Questionnaire, 6-minute walk test, or EQ–5D. Secondary endpoint results for the Eluvia™ stent and Zilver® PTX stent groups are as follows:

Functional Measure	Eluvia	Zilver PTX
Walking Impairment		
12 months	79.1	77.8
Change from baseline	40.8	35.8
Distance Scores		
12 months	64.6	63.4
Change from baseline	33.2	29.5
Speed Scores		
12 months	43.7	43.7
Change from baseline	18.3	18.1
Stair Climbing Scores		
12 months	61	59.8
Change from baseline	19.4	21.1
Total Walk Time (mins), 12 mos	5.7	5.6
Total Distance Walked (m), 12 mos	323.8	323.4
Speed (m/min), 12 mos	55.5	56.1

[46] Gray, W.A., Keirse, K., Soga, Y., et al., ''A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): a randomized, non-inferiority trial,'' *Lancet,* 2018. Available at: *http://dx.doi.org/10.1016/S0140-6736(18)32262-1.*

We note that the IMPERIAL study, which showed significant differences in primary patency at 12 months, was designed for noninferiority and not superiority. Therefore, we are concerned that results showing primary patency at 12 months may not be valid given the study design. We also are concerned that the results of a recently published meta-analysis of randomized controlled trials of the risk of death associated with the use of paclitaxel-coated balloons and stents in the femoropopliteal artery of the leg, which found that there is increased risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the lower limbs and that further investigations are urgently warranted,[47] although the Eluvia™ system was not included in the meta-analysis. We are concerned that the findings from this study indicate that the data suggesting that drug-coated stents are substantially clinically improved are unconfirmed. We are inviting public comments on whether the Eluvia™ Drug-Eluting Vascular Stent System meets the substantial clinical improvement criterion, including the implications of the meta-analysis results with respect to a finding of substantial clinical improvement for the Eluvia™ system.

We further note that the applicant for the Eluvia™ Drug Eluting Vascular Stent System also applied for the IPPS new technology add-on payment (FY 2020 IPPS/LTCH PPS proposed rule; 86 FR 19314). In the FY 2020 IPPS/LTCH PPS proposed rule, we discuss several publicly available comments that also raised concerns relating to substantial clinical improvement. We list several of those concerns below. While the Eluvia™ IMPERIAL study does cite a reduced rate of ''Subsequent Therapeutic Interventions'', public comments for the IPPS proposed rule note that ''Subsequent Therapeutic Interventions'' was not further defined in the New Technology Town Hall presentation nor in the IMPERIAL study. The commenters stated that it would appear from the presentation materials, however, that this claim refers specifically to ''target lesion revascularizations (TLR)'', which does not appear statistically significant.

With regard to the applicant's assertion that the use of the Eluvia™ stent reduces hospital readmission rates, a commenter noted that during the New Technology Town Hall presentation, the presenter noted that the Eluvia™ group had a hospital readmission rate at 12 months of 3.9 percent compared to the Zilver® PTX group's rate of 7.1 percent, and that no p-value was included on the slide used for the presentation to offer an assessment of the statistical significance of this difference. The commenter noted that the manufacturer of the Eluvia™ stent did not discuss this particular hospital readmission rate data comparison in the main body of the Lancet paper; however, the data could be found in the online appendix and is shown as not statistically significant.

With regards to longer-term data on the Zilver® PTX stent and the Eluvia™ stent, the commenter noted that in the commentary in The Lancet paper accompanying the IMPERIAL study, Drs. Salvatore Cassese and Robert Byrne write that a follow-up duration of 12 months is insufficient to assess late failure, which is not infrequently observed. According to Drs. Cassese and Byrne, the preclinical models of restenosis after stenting of peripheral arteries have shown that stents permanently overstretch the arterial wall, thus stimulating persistent neointimal growth, which might cause a catch-up phenomenon and late failure. The Lancet paper noted that, in this regard, data on outcomes beyond 1 year will be important to confirm the durability of the efficacy of the Eluvia™ stent.[48] The commenter stated that, at this point in time, very limited longer-term data are available on the use of the Eluvia™ stent and that the IMPERIAL study offers only 12-month data, although data out to 3 years have been published from the relatively small 57-patient single-arm MAJESTIC study. The commenter noted that the MAJESTIC study demonstrates a decrease in primary patency from 96.4 percent at 1 year to 83.5 percent at 2 years; and a doubling in TLR rates from 1 year to 2 years (3.6 percent to 7.2 percent) and again from 2 years to 3 years (7.2 percent to 14.7 percent). The commenter stated that this is not inconsistent with Drs. Cassese and Byrne's commentary regarding late failure, and that the relatively small, single-arm design of the study does not lend itself well to direct comparison to other SFA treatment options such as the Zilver® PTX stent.

The commenter also stated that Eluvia™'s lack of long-term data contrasts with 5-year data that is available from the Zilver® PTX stent's pivotal 479-patient RCT comparing the use of the Zilver® PTX stent to angioplasty (with a sub-randomization comparing provisional use of Zilver® PTX stenting to bare metal Zilver stenting in patients experiencing an acute failure of percutaneous transluminal angioplasty (PTA)). The commenter believed that these 5-year data demonstrate that the superiority of the use of the Zilver® PTX stent demonstrated at 12 and 24 months is maintained through 5 years compared to PTA and provisional bare metal stenting, and actually increases rather than decreases over time. The commenter also believed that, given that these stent devices are permanent implants and they are used to treat a chronic disease, long-term data are important to fully understand an SFA stent's clinical benefits. The commenter stated that with 5-year data available to support the ongoing safety and effectiveness of the use of the Zilver® PTX stent, but no such corresponding data available for the use of the Eluvia™ stent, it seems incongruous to suggest that the use of the Eluvia™ stent results in a substantial clinical improvement compared to the Zilver® PTX stent.

The commenter further stated that, in addition to the limited long-term data available for the Eluvia™ stent, there is also a lack of clinical data for the use of the Eluvia™ stent to confirm the benefit of the device outside of a strictly controlled clinical study population. The commenter stated that, in contrast, the Zilver® PTX stent has demonstrated comparable outcomes across a broad patient population, including a 787 patient study conducted in Europe with 2-year follow-up and a 904-patient study of all-comers (no exclusion criteria) in Japan with 5-year follow-up completed. The commenter believed that, with no corresponding data for the use of the Eluvia™ stent in a broad patient population, it seems unreasonable to suggest that the use of the Eluvia™ stent results in a substantial clinical improvement compared to the Zilver® PTX stent.

Based on the evidence submitted with the application, we are concerned that there is a lack of sufficient evidence that the Eluvia™ Vascular Drug-Eluting Stent System provides a substantial clinical improvement over other similar products. We are inviting public comments on whether Eluvia™ Vascular Drug-Eluting Stent 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

[47] Katsanos, K., et al., ''Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials,'' *JAHA,* vol. 7(24).

[48] Cassese, S., & Byrne, R.E., ''Endovascular stenting in femoropopliteal arteries,'' *The Lancet,* 2018, vol. 392(10157), pp. 1491–1493.

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 use of the Eluvia™ stent would be reported with CPT code 37226, which is assigned to APC 5193 (Level 3 Endovascular Procedures). To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5193, which has a CY 2019 payment rate of $10,509.72. 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 37226 had a device offset amount of $4,996.32. According to the applicant, the cost of the Eluvia™ Vascular Drug-Eluting Stent System is $1,995 to $2,895 per stent, with each procedure requiring approximately 2.2 stents per procedure at an average device cost of $5,768 per procedure.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of the Eluvia™ stent exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices of $10,509.72 − (($5,768/$10,509.72) × 100 = 55 percent). Therefore, we believe that the Eluvia™ Vascular Drug-Eluting Stent System meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $5,768 for the Eluvia™ stent exceeds the cost of the device-related portion of the APC payment amount for the related service of $4,996.32 by less than 25 percent (($5,768/$4,996.32) × 100 = 115 percent). Therefore, we do not believe that the Eluvia™ Vascular Drug-Eluting Stent System meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $5,768 for the Eluvia™ stent and the portion of the APC payment amount for the device of $4,996.32 does not exceed 10 percent of the APC payment amount for the related service of $10,509.72 (($5,768 − $4,996.32)/$10,509.72 × 100 = 7.3 percent). Therefore, we do not believe that the Eluvia™ Vascular Drug-Eluting Stent System meets the third cost significance requirement.

We are inviting public comments on whether the Eluvia™ Vascular Drug-Eluting Stent System meets the device pass-through payment criteria discussed in this section, including the cost criterion.

(7) AUGMENT® Bone Graft

Wright Medical submitted an application for a new device category for transitional pass-through payment status for the AUGMENT® Bone Graft. The applicant describes AUGMENT® Bone Graft as a device/drug indicated for use as an alternative to autograft in arthrodesis of the ankle and/or hindfoot where the need for supplemental graft material is required. The applicant stated that the product has two components: Recombinant human platelet-derived growth factor-BB (rhPDGF–BB) solution (0.3 mg/mL) and Beta-tricalcium phosphate (β-TCP) granules (1000 − 2000 μm). The two components are combined at the point of use and applied to the surgical site. The beta-TCP provides a porous osteoconductive scaffold for new bone growth and the rhPDGF–BB, which act as an osteoinductive chemo-attractant and mitogen for cells involved in wound healing and through promotion of angiogenesis.

According to the applicant, the AUGMENT® Bone Graft is indicated for use in arthrodesis of the ankle and/or hindfoot due to osteoarthritis, post-traumatic arthritis (PTA), rheumatoid arthritis, psoriatic arthritis, avascular necrosis, joint instability, joint deformity, congenital defect or joint arthropathy as an alternative to autograft in patients needing graft material. Osteoarthritis is the most common joint disease among middle aged and older individuals and has been shown to also have health related mental and physical disabilities, which can be compared to the severity as patients with end-stage hip arthritis.[49] Additionally, post-traumatic arthritis develops after an acute direct trauma to the joint and can cause 12 percent of all osteoarthritis cases.[50] Common causes leading to PTOA include intra-articular fractures and meniscal, ligamentous and chondral injuries.[51] The ankle is cited as the most affected joint, reportedly accounting for 54 to 78 percent of over 300,000 injuries occurring in the USA annually. The applicant stated that autologous bone graft has often been used in ankle arthrodesis. Autologous bone is retrieved from a donor site, which may require an incision separate from the arthrodesis.[52] The applicant stated that, in these procedures, harvested autologous bone graft is implanted to stimulate healing between the bones across a diseased joint. The applicant further stated that the procedures may require the use of synthetic bone substitutes to fill the bony voids or gaps or to serve as an alternative to the autograft where autograft is not feasible. The applicant stated that the AUGMENT® Bone Graft removes the need for autologous retrieval. The applicant noted that during the procedure, the surgeon prepares the joint for the graft application and locates any potential bony defect, then applying and packing the AUGMENT® Bone Graft into the joint defects intended for arthrodesis.

With respect to the newness criterion at § 419.66(b)(1), the FDA granted the AUGMENT® Bone Graft premarket approval on September 1, 2015. The application for a new device category for transitional pass-through payment status for the AUGMENT® Bone Graft was received May 31, 2018, which is within 3 years of the date of the initial FDA approval or clearance. We are inviting public comments on whether the AUGMENT® Bone Graft meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the use of the AUGMENT® Bone Graft is integral to the service provided, is used for one patient only, comes in contact with human skin, and is applied in or on a wound or other skin lesion. The applicant also claimed that the AUGMENT® Bone Graft meets the device eligibility requirements of § 419.66(b)(4) because it is not an

[49] Greaser M, Ellington JK. 2014. ''Ankle arthritis.'' *Journal of Arthritis,* 3:129. doi:10.4172/2167–7921.1000129.

[50] Punzi, Leonardo et al. 2016. ''Post-traumatic arthritis: overview on pathogenic mechanisms and role of inflammation.'' Rheumatic & Musculoskeletal Diseases. *RMD open, 2*(2), e000279. doi:10.1136/rmdopen-2016–000279.

[51] Ibid.

[52] Lareau, Craig R. et al. 2015.''Does autogenous bone graft work? A logistic regression analysis of data from 159 papers in the foot and ankle literature.'' *Foot and Ankle Surgery.* 21(3): 150–59.

instrument, apparatus, implement, or items for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. We have not identified an existing pass-through payment category that describes the AUGMENT® Bone Graft. The applicant proposed a category descriptor for the AUGMENT® of ''rhPDGF–BB and β-TCP as an alternative to autograft in arthrodesis of the ankle and/or hindfoot.''

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. The applicant claims that the AUGMENT® Bone Graft provides a substantial clinical improvement over autograft procedures by reducing pain at the autograft donor site. With respect to this criterion, the applicant submitted data that examined the use of autograft arthrodesis of the ankle and/or hind foot and arthrodesis with the use of the AUGMENT® Bone Graft.

In a randomized, nonblinded, placebo controlled, noninferiority trial of the AUGMENT® Bone Graft versus autologous bone graft, the AUGMENT® arm showed equivalence bone bridging as demonstrated by CT, pain on weight bearing, The American Orthopaedic Foot & Ankle Society Ankle-Hindfoot (AOFAS–AHS) score, and the Foot Function Index to autologous bone graft. The study noted that patients experienced significantly decreased (in fact no) pain due to elimination of the donor site procedure. In the autograft group, at 6 months, 18/142 patients (13 percent) experienced pain >20 mm (of 100 mm) on the Visual Analog Scale (VAS) at the autograft donor site as compared to 0/272 in the AUGMENT® Bone Graft group. At 12 months, 13/142 autograft patients (9 percent) had pain defined as >20 mm VAS as compared to 0/272 AUGMENT® patients.[53] The VAS has patients mark a visual representation of pain on a ruler based scale from 1 to 100. The measured distance (in mm) on the 10-cm line between the ''no pain'' anchor and the patient's mark represents the level of pain. We are concerned that we are unable to sufficiently determine substantial clinical improvement using the provided data, given that a comparison to alternatives to autologous bone graft, such as the reamer-irrigator-aspirator (RIA) technique were not evaluated. Specifically, the RIA technique has been suggested in a number of studies to be a viable alternative to bone autograft, because autogenous bone graft can be readily obtained without the need for additional incisions, therefore eliminating pain from an incisional site.[54] Another concern is the time period of the study because certain ankle arthrodesis complications such as ankle replacement and repeat arthrodesis can happen more than 2 years after the initial surgery.[55] A long-term study of at least 60 months is currently underway in order to assess long-term safety and efficacy, looking at the following 4 primary outcomes: Bone bridging as demonstrated by CT, pain on weight bearing, The American Orthopaedic Foot & Ankle Society Ankle-Hindfoot (AOFAS–AHS) score, and the Foot Function Index. We believe that this long-term study is necessary for meaningful information about long-term efficacy of the Augment® Bone Graft. Further, there was a notable difference in the infection rate, musculoskeletal and tissue disorders, and pain in extremity for those in the AUGMENT® Bone Graft group. These findings were unfortunately not tested for significance and also were not necessarily focused on relevance to the procedure. Should these be significant and related to the device, these findings would suggest that the adverse outcomes due to the Augment® Bone Graft may outweigh its potential benefits.

We are inviting public comments on whether the AUGMENT® Bone Graft meets the substantial clinical improvement criterion.

[53] DiGiovanni CW, Lin SS, Baumbauer JF, et al. 2013. ''Recombinant Human Platelet-Derived Growth Factor-BB and Beta-Tricalcium Phosphate (rhPDGF-BB/b-TCP): An Alternative to Autogenous Bone Graft.'' *J Bone Joint Surg Am.,* 95: 1184–92.

[54] Herscovici, D., Scaduto, J.M. 2012. ''Use of the reamer-irrigator-aspirator technique to obtain autograft for ankle and hindfoot arthrodesis.'' *The Journal of Bone & Joint Surgery.* 94–B: 75–9.

[55] Stavrakis, AL., SooHoo, NF. 2016. ''Trends in complication rates following ankle arthrodesis and total ankle replacement.'' *The Journal of Bone & Joint Surgery.* JBJS 1453–1458.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the use of the AUGMENT® Bone Graft would be reported with CPT code 27870 (Arthrodesis, ankle, open), which is assigned to APC 5115 (Level 5 Musculoskeletal Procedures). To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5115, which has a CY 2019 payment rate of $10,122.92. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). CPT code 27870 had a device offset amount of $4,553.29. According to the applicant, the cost of the AUGMENT® Bone Graft is $3,077 per device/drug combination. The applicant further provided a weighted average cost of the graft, accounting for how many procedures required one, two, or three AUGMENT® Bone Graft device/drug kits, equaling a weighted average cost of $6,020.22.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of the AUGMENT® Bone Graft is more than 25 percent of the applicable APC payment amount [56] for the service related to the category of devices of $10,122.92 (($6,020.22/$10,122.92) × 100 = 59 percent)). Therefore, we believe that the AUGMENT® Bone Graft meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $6,020.22 for AUGMENT® Bone Graft

[56] Due to the timing of the application, the AUGMENT® Bone Graft cost values were calculated using the 2018 proposed rule data.

exceeds the cost of the device-related portion of the APC payment amount for the related service of $4,553.29 by at least 25 percent (($6,020.22/$4,553.29) × 100 = 132 percent). Therefore, we have concerns about whether the AUGMENT® Bone Graft meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $6,020.22 for the AUGMENT® Bone Graft and the portion of the APC payment amount for the device of $4,553.29 exceeds the APC payment amount for the related service of $10,122.92 by more than 10 percent (($6,020.22 − $4,553.29)/$10,122.92 × 100 = 15 percent). Therefore, we believe that AUGMENT® Bone Graft meets the third cost significance test. We are inviting public comments on whether the AUGMENT® Bone Graft meets the device pass-through payment criteria discussed in this section, including the cost criterion.

3. Request for Information and Potential Revisions to the OPPS Device Pass-Through Substantial Clinical Improvement Criterion in the FY 2020 IPPS/LTCH PPS Proposed Rule

As mentioned earlier, section 1833(t)(6) of the Act provides for pass-through payments for devices, and section 1833(t)(6)(B) of the Act requires CMS to use categories in determining the eligibility of devices for pass-through payments. Separately, the criteria as set forth under § 419.66(c) are used to determine whether a new category of pass-through payment devices should be established. One of these criteria, at § 419.66(c)(2), states that CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. CMS considers the totality of the substantial clinical improvement claims and supporting data, as well as public comments, when evaluating this aspect of each application. CMS summarizes each applicant's claim of substantial clinical improvement as part of its discussion of the entire application in the relevant proposed rule, as well as any concerns regarding those claims. In the relevant final rule for the OPPS, CMS responds to public comments and discusses its decision to approve or deny the application for separate transitional pass-through payments.

Over the years, applicants and commenters have indicated that it would be helpful for CMS to provide greater guidance on what constitutes ''substantial clinical improvement.'' In the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19368 through 19371), we requested information on the substantial clinical improvement criterion for OPPS transitional pass-through payments for devices and stated that we were considering potential revisions to that criterion. In particular, we sought public comments in the FY 2020 IPPS/LTCH PPS proposed rule on the type of additional detail and guidance that the public and applicants for device pass-through transitional payment would find useful (84 FR 19367 to 19369). This request for public comments was intended to be broad in scope and provide a foundation for potential rulemaking in future years. We refer readers to the FY 2020 IPPS/LTCH proposed rule for the full text of this request for information.

In addition to this broad request for public comments for potential rulemaking in future years, in order to respond to stakeholder feedback requesting greater understanding of CMS' approach to evaluating substantial clinical improvement, we also solicited comments from the public in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19369 through 19371) on specific changes or clarifications to the IPPS and OPPS substantial clinical improvement criterion that CMS might consider making in the FY 2020 IPPS/LTCH PPS final rule to provide greater clarity and predictability. We refer readers to the FY 2020 IPPS/LTCH PPS proposed rule for complete details on those potential revisions. We note that any responses to public comments we receive on potential revisions to the OPPS substantial clinical improvement criterion in response to the FY 2020 IPPS/LTCH PPS proposed rule, as well as any revisions that might be adopted, will be included in the CY 2020 OPPS/ASC final rule and will inform future OPPS rulemaking. We further invite public comment on this topic in this rule.

4. Proposed Alternative Pathway to the OPPS Device Pass-Through Substantial Clinical Improvement Criterion for Transformative New Devices

Since 2001 when we first established the substantial clinical improvement criterion, the FDA programs for helping to expedite the development and review of transformative new technologies that are intended to treat serious conditions and address unmet medical needs (referred to as FDA's expedited programs) have continued to evolve in tandem with advances in medical innovations and technology. There is currently one expedited FDA program for devices, the Breakthrough Devices Program. The 21st Century Cures Act (Cures Act) (Pub. L. 144–255) established the Breakthrough Devices Program to expedite the development of, and provide for priority review of, medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions and which meet one of the following four criteria: (1) That represent breakthrough technologies; (2) for which no approved or cleared alternatives exist; (3) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or (4) the availability of which is in the best interest of patients.

Some stakeholders over the years have requested that devices that receive marketing authorization and are part of an FDA expedited program be deemed as representing a substantial clinical improvement for purposes of OPPS device pass-through status. We understand this request would arguably create administrative efficiency because the commenters currently view the two sets of criteria as the same, overlapping, similar, or otherwise duplicative or unnecessary.

The Administration is committed to addressing barriers to health care innovation and ensuring Medicare beneficiaries have access to critical and life-saving new cures and technologies that improve beneficiary health outcomes. As detailed in the President's FY 2020 Budget (we refer readers to HHS FY 2020 Budget in Brief, Improve Medicare Beneficiary Access to Breakthrough Devices, pp. 84–85), HHS is pursuing several policies that will instill greater transparency and consistency around how Medicare covers and pays for innovative technology.

Therefore, given the FDA programs for helping to expedite the development

and review of transformative devices that meet expedited program criteria (that is, new devices that treat serious or life-threatening diseases or conditions for which there is an unmet medical need), we considered whether it would also be appropriate to similarly facilitate access to these transformative new technologies for Medicare beneficiaries taking into consideration that marketing authorization (that is, Premarket Approval (PMA); 510(k) clearance; or the granting of a De Novo classification request) for a product that is the subject of one of FDA's expedited programs could lead to situations where the evidence base for demonstrating substantial clinical improvement in accordance with CMS' current standard has not fully developed at the time of FDA marketing authorization (that is, PMA; 510(k) clearance; the granting of a De Novo classification request) (as applicable). We also considered whether FDA marketing authorization of a product that is part of an FDA expedited program is evidence that the product is sufficiently different from existing products for purposes of newness.

After consideration of these issues, and consistent with the Administration's commitment to addressing barriers to health care innovation and ensuring Medicare beneficiaries have access to critical and life-saving new cures and technologies that improve beneficiary health outcomes, we concluded that it would be appropriate to develop an alternative pathway for transformative medical devices. In situations where a new medical device is part of the Breakthrough Devices Program and has received FDA marketing authorization (that is, the device has received PMA; 510(k) clearance; or the granting of a De Novo classification request), we are proposing an alternative outpatient pass-through pathway to facilitate access to this technology for Medicare beneficiaries beginning with applications received for pass-through payment on or after January 1, 2020.

We continue to believe that hospitals should receive pass-through payments for devices that offer clear clinical improvement and that cost considerations should not interfere with patient access. In light of the criteria applied under the FDA's Breakthrough Devices Program, and because we recognize that the technology may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization, we are proposing to amend the OPPS device transitional pass-through payment regulations to create an alternative pathway to demonstrating substantial clinical improvement that would enable devices approved under the FDA Breakthrough Devices Program to qualify for our quarterly approval process for device pass-through payment under the OPPS for pass-through payment applications received on or after January 1, 2020. With this proposal, OPPS device pass-through payment applicants approved under the FDA Breakthrough Devices Program would not be evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2) for the purposes of determining device pass-through payment status, but would continue to need to meet the other requirements for pass-through payment status in our regulation at § 419.66. Devices approved under the Breakthrough Devices Program that are approved for OPPS device transitional pass-through payment can be approved through the quarterly process and would be announced through that process (81 FR 79655). Finally, we would include proposals regarding these devices and whether pass-through payment status should continue to apply in the next applicable OPPS rulemaking cycle.

As such, we are proposing to revise paragraph (c)(2) under § 419.66. Under proposed revised paragraph (c)(2), we are proposing to establish an alternative pathway where applications for device pass-through payment status for new medical devices received on or after January 1, 2020 that are a part of FDA's Breakthrough Devices Program and have received FDA marketing authorization (that is, the device has received PMA, 510(k) clearance, or the granting of a De Novo classification request) will not be evaluated for substantial clinical improvement for the purposes of determining device pass-through payment status. Under this proposed alternative pathway, a medical device that has received FDA marketing authorization (that is, has been approved or cleared by, or had a De Novo classification request granted by, the FDA) and that is part of the FDA's Breakthrough Devices Program would still need to meet the eligibility criteria under § 419.66(b), the other criteria for establishing device categories under § 419.66(c), and the cost criterion under § 419.66(d). We note that this proposal aligns with a proposal in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19371 through 19373) and will help achieve the goals of expedited access to innovative therapies and further reduce administrative burden.

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) applies 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 APC. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we changed our methodology to assign device-intensive status at the individual HCPCS code level rather than at the APC level. Under this policy, a procedure could be assigned device-intensive status regardless of its APC assignment, and device-intensive APCs were no longer applied under the OPPS or the ASC payment system.

We believe that a HCPCS code-level device offset is, in most cases, a better representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all of the procedures assigned to an APC. Unlike a device offset calculated at

the APC level, which is a weighted average offset for all devices used in all of the procedures assigned to an APC, a HCPCS code-level device offset is calculated using only claims for a single HCPCS code. We believe that this methodological change results in a more accurate representation of the cost attributable to implantation of a high-cost device, which ensures consistent device-intensive designation of procedures with a significant device cost. Further, we believe a HCPCS code-level device offset removes inappropriate device-intensive status for procedures without a significant device cost that are granted such status because of APC assignment.

Under our existing policy, procedures that meet the criteria listed below in section IV.B.1.b. of this proposed rule are identified as device-intensive procedures and are subject to all the policies applicable to procedures assigned device-intensive status under our established methodology, including our policies on device edits and no cost/full credit and partial credit devices discussed in sections IV.B.3. and IV.B.4. of 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. Device-Intensive Procedure Policy for CY 2019 and Subsequent Years

As part of CMS' effort to better capture costs for procedures with significant device costs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948), for CY 2019, we modified our criteria for device-intensive procedures. We had heard from stakeholders that the criteria excluded some procedures that stakeholders believed should qualify as device-intensive procedures. Specifically, we were persuaded by stakeholder arguments that procedures requiring expensive surgically inserted or implanted devices that are not capital equipment should qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We agreed that a broader definition of device-intensive procedures was warranted, and made two modifications to the criteria for CY 2019 (83 FR 58948). First, we 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. We established this policy because we no longer believe that whether a device remains in the patient's body should affect its designation as a device-intensive procedure, as such devices could, nonetheless, comprise a large portion of the cost of the applicable procedure. Second, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent, to allow a greater number of procedures to qualify as device-intensive. We stated that we believe allowing these additional procedures to qualify for device-intensive status will help ensure these procedures receive more appropriate payment in the ASC setting, which will help encourage the provision of these services in the ASC setting. In addition, we stated that this change would help to ensure that more procedures containing relatively high-cost devices are subject to the device edits, which leads to more correctly coded claims and greater accuracy in our claims data. Specifically, for CY 2019 and subsequent years, we finalized that device-intensive procedures will be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost (83 FR 58945).

In addition, to further align the device-intensive policy with the criteria used for device pass-through payment status, we finalized, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE), and has been classified as a Category B device by 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 either of the following:

(a) Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or

(b) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker) (83 FR 58945).

In addition, for new HCPCS codes describing procedures requiring the implantation of medical devices that do not yet have associated claims data, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we finalized a policy for CY 2017 to apply device-intensive status with a default device offset set at 41 percent for new HCPCS codes describing procedures requiring the implantation or insertion of a medical device that did not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. This default device offset

amount of 41 percent was not calculated from claims data; instead, it was applied as a default until claims data were available upon which to calculate an actual device offset for the new code. The purpose of applying the 41-percent default device offset to new codes that describe procedures that implant or insert medical devices was to ensure ASC access for new procedures until claims data become available.

As discussed in the CY 2019 OPPS/ASC proposed rule and final rule with comment period (83 FR 37108 through 37109 and 58945 through 58946, respectively), in accordance with our policy stated above to lower the device offset percentage threshold for procedures to qualify as device-intensive from greater than 40 percent to greater than 30 percent, for CY 2019 and subsequent years, we modified this policy to apply a 31-percent default device offset to new HCPCS codes describing procedures requiring the implantation of a medical device that do not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. In conjunction with the policy to lower the default device offset from 41 percent to 31 percent, we continued our current policy of, in certain rare instances (for example, in the case of a very expensive implantable device), temporarily assigning a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer (81 FR 79658). Once claims data are available for a new procedure requiring the implantation of a medical device, device-intensive status is applied to the code if the HCPCS code-level device offset is greater than 30 percent, according to our policy of determining device-intensive status by calculating the HCPCS code-level device offset.

In addition, in the CY 2019 OPPS/ASC final rule with comment period, we clarified that since the adoption of our policy in effect as of CY 2018, the associated claims data used for purposes of determining whether or not to apply the default device offset are the associated claims data for either the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. Additionally, for CY 2019 and subsequent years, in limited instances where a new HCPCS code does not have a predecessor code as defined by CPT, but describes a procedure that was previously described by an existing code, we use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining whether or not to apply the default device offset to the new HCPCS code (83 FR 58946). Clinically related and similar procedures for purposes of this policy are procedures that have little or no clinical differences and use the same devices as the new HCPCS code. In addition, clinically related and similar codes for purposes of this policy are codes that either currently or previously describe the procedure described by the new HCPCS code. Under this policy, claims data from clinically related and similar codes are included as associated claims data for a new code, and where an existing HCPCS code is found to be clinically related or similar to a new HCPCS code, we apply the device offset percentage derived from the existing clinically related or similar HCPCS code's claims data to the new HCPCS code for determining the device offset percentage. We stated that we believe that claims data for HCPCS codes describing procedures that have minor differences from the procedures described by new HCPCS codes will provide an accurate depiction of the cost relationship between the procedure and the device(s) that are used, and will be appropriate to use to set a new code's device offset percentage, in the same way that predecessor codes are used. If a new HCPCS code has multiple predecessor codes, the claims data for the predecessor code that has the highest individual HCPCS-level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status. Similarly, in the event that a new HCPCS code does not have a predecessor code but has multiple clinically related or similar codes, the claims data for the clinically related or similar code that has the highest individual HCPCS level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status.

As we indicated in the CY 2019 OPPS/ASC proposed rule and final rule with comment period, additional information for our consideration of an offset percentage higher than the default of 31 percent for new HCPCS codes describing procedures requiring the implantation (or, in some cases, the insertion) of a medical device that do not yet have associated claims data, such as pricing data or invoices from a device manufacturer, should be directed to the Division of Outpatient Care, Mail Stop C4–01–26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850, or electronically at *outpatientpps@cms.hhs.gov*. Additional information can be submitted prior to issuance of an OPPS/ASC proposed rule or as a public comment in response to an issued OPPS/ASC proposed rule. Device offset percentages will be set in each year's final rule.

For CY 2020, we are not proposing any changes to our device-intensive policy. The full listing of the proposed CY 2020 device-intensive procedures can be found in Addendum P to this CY 2020 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

3. Device Edit Policy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795), we finalized a policy and implemented claims processing edits that require any of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the APCs listed in Table 5 of the CY 2015 OPPS/ASC final rule with comment period (the CY 2015 device-dependent APCs) is reported on the claim. In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422), we modified our previously existing policy and applied the device coding requirements exclusively to procedures that require the implantation of a device that are assigned to a device-intensive APC. In the CY 2016 OPPS/ASC final rule with comment period, we also finalized our policy that the claims processing edits are such that any device code, when reported on a claim with a procedure assigned to a device-intensive APC (listed in Table 42 of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422)) will satisfy the edit.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658 through 79659), we changed our policy for CY 2017 and subsequent years to apply the CY 2016 device coding requirements to the newly defined device-intensive procedures. For CY 2017 and subsequent years, we also specified that any device code, when reported on a claim with a device-intensive procedure, will satisfy the edit. In addition, we created HCPCS code C1889 to recognize devices furnished during a device-intensive procedure that are not described by a specific Level II HCPCS Category C-code. Reporting HCPCS code C1889 with a device-intensive procedure will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure. In the CY 2019 OPPS/ASC final rule with comment period, we revised the description of

HCPCS code C1889 to remove the specific applicability to device-intensive procedures (83 FR 58950). For CY 2019 and subsequent years, the description of HCPCS code C1889 is ''Implantable/insertable device, not otherwise classified''.

We are not proposing any changes to this policy for CY 2020.

4. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

a. Background

To ensure equitable OPPS payment when a hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals were instructed to report no cost/full credit device cases on the claim using the ''FB'' modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, hospitals were instructed to report a token device charge of less than $1.01. In cases in which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, hospitals were instructed to report as the device charge the difference between the hospital's usual charge for the device being implanted and the hospital's usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals were instructed to append the ''FC'' modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the ''FB'' and ''FC'' modifiers payment adjustment policies (72 FR 66743 through 66749).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), beginning in CY 2014, we modified our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy had been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we reduced OPPS payment, for the applicable APCs, by the full or partial credit a hospital receives for a replaced device. Specifically, under this modified policy, hospitals are required to report on the claim the amount of the credit in the amount portion for value code ''FD'' (Credit Received from the Manufacturer for a Replaced Medical Device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. For CY 2014, we also limited the OPPS payment deduction for the applicable APCs to the total amount of the device offset when the ''FD'' value code appears on a claim. For CY 2015, we continued our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit and to use the three criteria established in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68072 through 68077) for determining the APCs to which our CY 2015 policy will apply (79 FR 66872 through 66873). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), we finalized our policy to no longer specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would apply and instead apply this APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device.

b. Policy for No Cost/Full Credit and Partial Credit Devices

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79659 through 79660), for CY 2017 and subsequent years, we finalized our policy to reduce OPPS payment for device-intensive procedures, by the full or partial credit a provider receives for a replaced device, when a hospital furnishes a specified device without cost or with a full or partial credit. Under our current policy, hospitals continue to be required to report on the claim the amount of the credit in the amount portion for value code ''FD'' when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device.

We are not proposing any changes to our no cost/full credit and partial credit device policies in this proposed rule.

5. Proposed Payment Policy for Low-Volume Device-Intensive Procedures

In CY 2016, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act and used the median cost (instead of the geometric mean cost per our standard methodology) to calculate the payment rate for the implantable miniature telescope procedure described by CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis), which is the only code assigned to APC 5494 (Level 4 Intraocular Procedures) (80 FR 70388). We noted that, as stated in the CY 2017 OPPS/ASC proposed rule (81 FR 45656), we proposed to reassign the procedure described by CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures) for CY 2017, but it would be the only procedure code assigned to APC 5495. The payment rates for a procedure described by CPT code 0308T (including the predecessor HCPCS code C9732) were $15,551 in CY 2014, $23,084 in CY 2015, and $17,551 in CY 2016. The procedure described by CPT code 0308T is a high-cost device-intensive surgical procedure that has a very low volume of claims (in part because most of the procedures described by CPT code 0308T are performed in ASCs). We believe that the median cost is a more appropriate measure of the central tendency for purposes of calculating the cost and the payment rate for this procedure because the median cost is impacted to a lesser degree than the geometric mean cost by more extreme observations. We stated that, in future rulemaking, we would consider proposing a general policy for the payment rate calculation for very low-volume device-intensive APCs (80 FR 70389).

For CY 2017, we proposed and finalized a payment policy for low-volume device-intensive procedures that is similar to the policy applied to the procedure described by CPT code 0308T in CY 2016. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79660 through 79661), we established our current policy that the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC be calculated using the median cost instead of the geometric mean cost, for the reasons described above for the policy

applied to the procedure described by CPT code 0308T in CY 2016. The CY 2018 final rule geometric mean cost for the procedure described by CPT code 0308T (based on 19 claims containing the device HCPCS C-code, in accordance with the device-intensive edit policy) was 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.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58951), for CY 2019, we continued with our policy of establishing the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC based on calculations using the median cost instead of the geometric mean cost. For more information on the specific policy for assignment of low-volume device-intensive procedures for CY 2019, we refer readers to section III.D.13. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58917 through 58918).

For CY 2020, we are proposing to continue our current policy of establishing the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC using the median cost instead of the geometric mean cost. For CY 2020, this policy would apply to CPT code 0308T, which we are proposing to assign to APC 5495 (Level 5 Intraocular Procedures) in this proposed rule. The CY 2020 proposed rule geometric mean cost for the procedure described by CPT code 0308T (based on 7 claims containing the device HCPCS C-code, in accordance with the device-intensive edit policy) is approximately $28,237, and the median cost is approximately $19,270. The proposed CY 2020 payment rate (calculated using the median cost) is approximately $19,740 and can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website).

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 under section 351 of the Public Health Service Act. As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), this pass-through payment provision requires the Secretary to make additional payments to hospitals for: Current orphan drugs for rare disease and conditions, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. ''Current'' refers to those types of drugs or biologicals mentioned above that are hospital outpatient services under Medicare Part B for which transitional pass-through payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain ''new'' drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996 and whose cost is ''not insignificant'' in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as ''drugs.'' As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the product as a hospital outpatient service under Medicare Part B. Proposed CY 2020 pass-through drugs and biologicals and their designated APCs are assigned status indicator ''G'' in Addenda A and B to 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. Notice of drugs whose pass-through payment status is ending during the calendar year will continue to be included in the quarterly OPPS Change Request transmittals.

3. Proposed Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2019

We are proposing that the pass-through payment status of six drugs and biologicals would expire on December 31, 2019 as listed in Table 14. These drugs and biologicals will have received OPPS pass-through payment for 3 years during the period of January 1, 2017 until December 31, 2019.

In accordance with the policy finalized in CY 2017 and described earlier, pass-through payment status for drugs and biologicals newly approved in CY 2017 and subsequent years will expire on a quarterly basis, with a pass-through payment period as close to 3 years as possible. With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through payment status (specifically, anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including diagnostic radiopharmaceuticals, contrast agents, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), our standard methodology for providing payment for drugs and biologicals with expiring pass-through payment status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which is proposed to be $130 for CY 2020), as discussed further in section V.B.2. of 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 2020, as discussed further in section V.B.3. of this proposed rule).

TABLE 14.—PROPOSED DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS WOULD EXPIRE DECEMBER 31, 2019

CY 2019 HCPCS Code	CY 2019 Long Descriptor	CY 2019 Status Indicator	CY 2019 APC	Pass-Through Payment Effective Date
A9587	Gallium ga-68, dotatate, diagnostic, 0.1 millicurie	G	9056	01/01/2017
A9588	Fluciclovine f-18, diagnostic, 1 millicurie	G	9052	01/01/2017
J0570	Buprenorphine implant, 74.2 mg	G	9058	01/01/2017
J7179	Injection, von willebrand factor (recombinant), (Vonvendi), 1 i.u. vwf:rco	G	9059	01/01/2017
J7210	Injection, factor viii, (antihemophilic factor, recombinant), (afstyla), 1 i.u.	G	9043	01/01/2017
J9034	Injection, bendamustine hcl (Bendeka), 1 mg	G	1861	01/01/2017

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 2020

We are proposing to continue pass-through payment status in CY 2020 for 61 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status between April 1, 2017 and April 1, 2019 are listed in Table 15. The APCs and HCPCS codes for these drugs and biologicals approved for pass-through payment status on or after January 1, 2020 are assigned status indicator ''G'' in Addenda A and B to 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, effective October 1, 2018 under section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018 (Pub. L. 115–141). That means the last 9 months of pass-through status for these drugs will occur in CY 2020. Because of this requirement, these drugs and biologicals are also included in Table 15, which brings the total number of drugs and biologicals with proposed pass-through payment status in CY 2020 to 65.

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the

pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2020, we 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 2020. We are proposing that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2020 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is proposed at ASP+6 percent, is $0.

In the case of policy-packaged drugs (which include the following: Anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), we are proposing that their pass-through payment amount would be equal to ASP+6 percent for CY 2020 minus a payment offset for any predecessor drug products contributing to the pass-through payment as described in section V.A.6. of 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 2020 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2020, consistent with our CY 2019 policy for diagnostic and therapeutic radiopharmaceuticals, we 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 2020, 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. Additional detail and comments on the WAC+3 percent payment policy can be found in section V.B.2.b. of this proposed rule. 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 drugs and biologicals that we are proposing to continue to have pass-through payment status on or after January 1, 2020 or that have been granted pass-through payment status as of April 2019 are shown in Table 15.

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TABLE 15.—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS DURING CY 2020

CY 2019 HCPCS Code	CY 2020 HCPCS Code	Long Descriptor	Proposed CY 2020 Status Indicator	Proposed CY 2020 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
A9513	A9513	Lutetium lu 177, dotatate, therapeutic, 1 millicurie	G	9067	07/01/2018	6/30/2021
A9586	A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	9084	10/01/2018	09/30/2020
C9035	C9035	Injection, aripiprazole lauroxil (aristada initio), 1 mg	G	9179	01/01/2019	12/31/2021
C9036	C9036	Injection, patisiran, 0.1 mg	G	9180	01/01/2019	12/31/2021
C9037	C9037	Injection, risperidone (perseris), 0.5 mg	G	9181	01/01/2019	12/31/2021
C9038	C9038	Injection, mogamulizumab-kpkc, 1 mg	G	9182	01/01/2019	12/31/2021
C9039	C9039	Injection, plazomicin, 5 mg	G	9183	01/01/2019	12/31/2021
C9040	C9040	Injection, fremanezumab-vfrm, 1mg	G	9197	04/01/2019	03/31/2022
C9041	C9041	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	G	9198	04/01/2019	03/31/2022
C9043	C9043	Injection, levoleucovorin, 1 mg	G	9303	04/01/2019	03/31/2022
C9044	C9044	Injection, cemiplimab-rwlc, 1 mg	G	9304	04/01/2019	03/31/2022
C9045	C9045	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	G	9305	04/01/2019	03/31/2022
C9046	C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	G	9307	04/01/2019	03/31/2022
C9141	C9141	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	G	9299	04/01/2019	03/31/2022
C9407	C9407	Iodine i-131 iobenguane, diagnostic, 1 millicurie	G	9184	01/01/2019	12/31/2021
C9408	C9408	Iodine i-131 iobenguane, therapeutic, 1 millicurie	G	9185	01/01/2019	12/31/2021
C9447	C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	9083	10/01/2018	09/30/2020

CY 2019 HCPCS Code	CY 2020 HCPCS Code	Long Descriptor	Proposed CY 2020 Status Indicator	Proposed CY 2020 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9462	C9462	Injection, delafloxacin, 1 mg	G	9462	04/01/2018	03/31/2021
C9488	C9488	Injection, conivaptan hydrochloride, 1 mg	G	9488	04/01/2017	03/31/2020
J0185	J0185	Injection, aprepitant, 1 mg	G	9463	04/01/2018	03/31/2021
J0517	J0517	Injection, benralizumab, 1 mg	G	9466	04/01/2018	03/31/2021
J0565	J0565	Injection, bezlotoxumab, 10 mg	G	9490	07/01/2017	06/30/2020
J0567	J0567	Injection, cerliponase alfa, 1 mg	G	9014	01/01/2018	12/31/2020
J0599	J0599	Injection, c-1 esterase inhibitor (human), (haegarda), 10 units	G	9015	01/01/2018	12/31/2020
J1095	J1095	Injection, dexamethasone 9%, intraocular, 1 microgram	G	9172	10/01/2018	09/30/2021
J1301	J1301	Injection, edaravone, 1 mg	G	9493	10/01/2017	09/30/2020
J1428	J1428	Injection, eteplirsen, 10 mg	G	9484	04/01/2017	03/31/2020
J1454	J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	G	9099	10/01/2018	09/30/2021
J1627	J1627	Injection, granisetron extended release, 0.1 mg	G	9486	04/01/2017	03/31/2020
J1628	J1628	Injection, guselkumab, 1 mg	G	9029	01/01/2018	12/31/2020
J2326	J2326	Injection, nusinersen, 0.1 mg	G	9489	07/01/2017	06/30/2020
J2350	J2350	Injection, ocrelizumab, 1 mg	G	9494	10/01/2017	09/30/2020
J2797	J2797	Injection, rolapitant, 0.5 mg	G	9464	04/01/2018	03/31/2021
J3245	J3245	Injection, tildrakizumab, 1 mg	G	9306	04/01/2019	03/31/2022
J3304	J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	G	9469	04/01/2018	03/31/2021
J3316	J3316	Injection, triptorelin, extended-release, 3.75 mg	G	9016	01/01/2018	12/31/2020

CY 2019 HCPCS Code	CY 2020 HCPCS Code	Long Descriptor	Proposed CY 2020 Status Indicator	Proposed CY 2020 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J3358	J3358	Ustekinumab, for intravenous Injection, 1 mg	G	9487	04/01/2017	03/31/2020
J3398	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes	G	9070	07/01/2018	06/30/2021
J7170	J7170	Injection, emicizumab-kxwh, 0.5 mg	G	9257	07/01/2018	06/30/2021
J7203	J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu	G	9468	04/01/2018	03/31/2021
J7318	J7318	Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg	G	9174	04/01/2018	03/31/2021
J7328	J7328	Hyaluronan or derivative, gelsyn-3, for intra-articular injection, 0.1 mg	G	1862	04/01/2017	03/31/2020
J7345	J7345	Aminolevulinic acid hcl for topical administration, 10% gel, 10 mg	G	9301	01/01/2018	12/31/2020
J9023	J9023	Injection, avelumab, 10 mg	G	9491	10/01/2017	09/30/2020
J9057	J9057	Injection, copanlisib, 1 mg	G	9030	07/01/2018	06/30/2021
J9153	J9153	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine	G	9302	01/01/2018	12/31/2020
J9173	J9173	Injection, durvalumab, 10 mg	G	9492	10/01/2017	09/30/2020
J9203	J9203	Injection, gemtuzumab ozogamicin, 0.1 mg	G	9495	01/01/2018	12/31/2020
J9229	J9229	Injection, inotuzumab ozogamicin, 0.1 mg	G	9028	01/01/2018	12/31/2020
J9285	J9285	Injection, olaratumab, 10 mg	G	9485	04/01/2017	03/31/2020
J9311	J9311	lnjection, rituximab 10 mg and hyaluronidase	G	9467	04/01/2018	03/31/2021

CY 2019 HCPCS Code	CY 2020 HCPCS Code	Long Descriptor	Proposed CY 2020 Status Indicator	Proposed CY 2020 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
Q2041	Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9035	04/01/2018	03/31/2021
Q2042	Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9194	04/01/2018	03/31/2021
Q4195	Q4195	Puraply, per square centimeter	G	9175	10/01/2018	09/30/2020
Q4196	Q4196	Puraply am, per square centimeter	G	9176	10/01/2018	09/30/2020
Q5103	Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg	G	1847	04/01/2017	03/31/2020
Q5104	Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg	G	9036	04/01/2018	03/31/2021
Q5105	Q5105	Injection, epoetin alfa, biosimilar, (retacrit) (for esrd on dialysis), 100 units	G	9096	10/01/2018	09/30/2021
Q5106	Q5106	Injection, epoetin alfa, biosimilar, (retacrit) (for non-esrd use), 1000 units	G	9097	10/01/2018	09/30/2021
Q5108	Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg	G	9173	04/01/2019	03/31/2022
Q5110	Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	G	9193	04/01/2019	03/31/2022
Q5111	Q5111	Injection, pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg	G	9195	04/01/2019	03/31/2022
Q9950	Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9085	10/01/2018	09/30/2020

CY 2019 HCPCS Code	CY 2020 HCPCS Code	Long Descriptor	Proposed CY 2020 Status Indicator	Proposed CY 2020 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
Q9991	Q9991	Injection, buprenorphine extended-release (sublocade), less than or equal to 100 mg	G	9073	07/01/2018	06/30/2021
Q9992	Q9992	Injection, buprenorphine extended-release (sublocade), greater than 100 mg	G	9239	07/01/2018	06/30/2021

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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 drug and biological pass-through payment status ended on December 31, 2017 and for which payment would have been packaged beginning January 1, 2018. These products were listed in Table 39 of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58962).

Starting in CY 2019, the HCPCS code Q4172 (PuraPly, and PuraPly Antimicrobial, any type, per square centimeter) was discontinued. In its place, two new HCPCS codes were established—Q4195 (Puraply, per square centimeter) and Q4196 (Puraply am, per square centimeter). Because these HCPCS codes are direct successors to HCPCS code Q4172, the provisions of section 1833(t)(6)(G) of the Act apply to HCPCS codes Q4195 and Q4196, and these codes are listed in Table 16. For CY 2020, we are proposing to continue pass-through payment status for the drugs and biologicals listed in Table 16 of this proposed rule (we note that these drugs and biologicals are also listed in Table 15 of this proposed rule) through September 30, 2020 as required in section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018. The APCs and HCPCS codes for these drugs and biologicals approved for pass-through payment status are assigned status indicator ''G'' in Addenda A and B to this proposed rule (which are available via the internet on the CMS website).

We are proposing to continue to update pass-through payment rates for HCPCS codes Q4195 and Q4196 along with the other three drugs and biologicals covered by section 1833(t)(6)(G) of the Act on a quarterly basis on the CMS website during CY 2020 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through drugs or biologicals are necessary. The replacement of HCPCS code Q4172 by HCPCS codes Q4195 and Q4196 means there are five HCPCS codes for drugs and biologicals covered by section 1833(t)(6)(G) of the Act. For a full description of this policy, we refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58960 through 58962).

The five HCPCS codes for drugs and biologicals that we are proposing would have pass-through payment status for CY 2020 under section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018, are shown in Table 16. Included as two of the five HCPCS codes for drugs and biologicals with pass-through payment status for CY 2020 are HCPCS codes Q4195 (Puraply, per square centimeter) and Q4196 (Puraply am, per square centimeter). PuraPly and PuraPly AM are skin substitute products that were approved for pass-through payment status on January 1, 2015 through the drug and biological pass-through payment process. Beginning on April 1, 2015, skin substitute products are evaluated for pass-through payment status through the device pass-through payment process. However, we stated in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66887) that skin substitutes that are approved for pass-through payment status as biologicals effective on or before January 1, 2015 would continue to be paid as pass-through biologicals for the duration of their pass-through payment period. Because PuraPly and PuraPly AM were approved for pass-through payment status through the drug and biological pass-through payment pathway, we finalized a policy to consider both PuraPly and PuraPly AM to be drugs or biologicals as described by section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018, and to be eligible for extended pass-through payment under our proposal for CY 2020 (83 FR 58961 through 58962).

TABLE 16.—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2020 IN ACCORDANCE WITH PUB. L. 115-141

CY 2019 HCPCS Code	CY 2020 HCPCS Code	Long Descriptor	Proposed CY 2020 Status Indicator	Proposed CY 2020 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
A9586	A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	9084	10/01/2018	09/30/2020
C9447	C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	9083	10/01/2018	09/30/2020
Q4195	Q4195	Puraply, per square centimeter	G	9175	10/01/2018	09/30/2020
Q4196	Q4196	Puraply AM, per square centimeter	G	9176	10/01/2018	09/30/2020
Q9950	Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9085	10/01/2018	09/30/2020

6. 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 2020, as we did in CY 2019, 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 17.

TABLE 17.—PROPOSED APCS TO WHICH A POLICY-PACKAGED DRUG OR RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2020

Proposed CY 2020 APC	Proposed CY 2020 APC Title
Diagnostic Radiopharmaceutical	
5591	Level 1 Nuclear Medicine and Related Services
5592	Level 2 Nuclear Medicine and Related Services
5593	Level 3 Nuclear Medicine and Related Services
5594	Level 4 Nuclear Medicine and Related Services
Contrast Agent	
5571	Level 1 Imaging with Contrast
5572	Level 2 Imaging with Contrast
5573	Level 3 Imaging with Contrast
Stress Agent	
5722	Level 2 Diagnostic Tests and Related Services
5593	Level 3 Nuclear Medicine and Related Services
Skin Substitute	
5054	Level 4 Skin Procedures
5055	Level 5 Skin Procedures

We 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 $125 for CY 2019 (83 FR 58963 through 58964).

Following the CY 2007 methodology, for this CY 2020 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 2020 and rounded the resulting dollar amount ($131.19) to the nearest $5 increment, which yielded a figure of $130. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from CMS' Office of the Actuary. For this CY 2020 OPPS/ASC proposed rule, based on these calculations using the CY 2007 OPPS methodology, we are proposing a packaging threshold for CY 2020 of $130.

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 2020 packaging status for all nonpass-through drugs and biologicals that are not policy packaged, we calculated, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals (collectively called ''threshold-packaged'' drugs) that had a HCPCS code in CY 2018 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2018 claims processed before January 1, 2019 for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.1.d. of this proposed rule, or for the following policy-packaged items that we are proposing to continue to package in CY 2020: Anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure.

In order to calculate the per day costs for drugs, biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2020, we used the methodology that was

described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638). For each drug and biological HCPCS code, we used an estimated payment rate of ASP+6 percent (which is the payment rate we are proposing for separately payable drugs and biologicals for CY 2020, as discussed in more detail in section V.B.2.b. of this proposed rule) to calculate the CY 2020 proposed rule per day costs. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2018 (data that were used for payment purposes in the physician's office setting, effective April 1, 2019) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2020, we are proposing to use payment rates based on the ASP data from the first quarter of CY 2019 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to 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, 2019. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we used their mean unit cost derived from the CY 2018 hospital claims data to determine their per day cost.

We are proposing to package items with a per day cost less than or equal to $130, and identify items with a per day cost greater than $130 as separately payable unless they are policy-packaged. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2018 HCPCS codes that were reported to the CY 2019 HCPCS codes that we display in Addendum B to this proposed rule (which is available via the internet on the CMS website) for proposed payment in CY 2020.

Our policy during previous cycles of the OPPS has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. Only HCPCS codes that are identified as separately payable in the final rule with comment period are subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs and biologicals in this CY 2020 OPPS/ASC proposed rule, we are proposing to use ASP data from the fourth quarter of CY 2018, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective April 1, 2019, along with updated hospital claims data from CY 2018. We note that we also are proposing to use these data for budget neutrality estimates and impact analyses for this CY 2020 OPPS/ASC proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B for the final rule with comment period will be based on ASP data from the third quarter of CY 2019. These data will be the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2019. These payment rates would then be updated in the January 2020 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2020. 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 2018 claims data and updated cost report information available for the CY 2020 final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in this proposed rule may be different from the same drugs' HCPCS codes' packaging status determined based on the data used for the final rule with comment period. Under such circumstances, we 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 costs fluctuate relative to the proposed CY 2020 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2019. These established policies have not changed for many years and are the same as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434). Specifically, for CY 2020, consistent with our historical practice, we 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 2019 and that are proposed for separate payment in CY 2020, and that then have per day costs equal to or less than the CY 2020 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2020 final rule, would continue to receive separate payment in CY 2020.
- HCPCS codes for drugs and biologicals that were packaged in CY 2019 and that are proposed for separate payment in CY 2020, and that then have per day costs equal to or less than the CY 2020 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2020 final rule, would remain packaged in CY 2020.
- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2020 but that then have per-day costs greater than the CY 2020 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2020 final rule, would receive separate payment in CY 2020.

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 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 2020.

For CY 2020, in order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same drug or biological, we aggregated both our CY 2018 claims data and our pricing information at ASP+6 percent across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. The following drugs did not have pricing information available for the ASP methodology for this CY 2020 OPPS/ASC proposed rule, and as is our current policy for determining the packaging status of other drugs, we used the mean unit cost available from the CY 2018 claims data to make the proposed packaging determinations for these drugs: HCPCS code J1840 (Injection, kanamycin sulfate, up to 500 mg); HCPCS code J1850 (Injection, kanamycin sulfate, up to 75 mg); HCPCS code J3472 (Injection, hyaluronidase, ovine, preservative free, per 1,000 usp units); HCPCS code J7100 (Infusion, dextran 40, 500 ml); and HCPCS code J7110 (Infusion, dextran 75, 500 ml).

For all other drugs and biologicals that have HCPCS codes describing different doses, we then multiplied the proposed weighted average ASP+6 percent per unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine the estimated per day cost of each drug or biological at less than or equal to the proposed CY 2020 drug packaging threshold of $130 (so that all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2020 drug packaging threshold of $130 (so that all HCPCS codes for the same drug or biological would be separately payable). The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2020 is displayed in Table 18.

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TABLE 18.—PROPOSED HCPCS CODES TO WHICH THE CY 2020 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY WOULD APPLY

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2020 Status Indicator (SI)
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J1840	Injection, kanamycin sulfate, up to 500 mg	N
J1850	Injection, kanamycin sulfate, up to 75 mg	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	N
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	N
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7030	Infusion, normal saline solution, 1000 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7050	Infusion, normal saline solution, 250 cc	N
J7100	Infusion, dextran 40, 500 ml	N
J7110	Infusion, dextran 75, 500 ml	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	N
J8521	Capecitabine, oral, 500 mg	N
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

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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 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.[57]

It has been our policy since CY 2006 to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. In this CY 2020 OPPS/ASC proposed rule, we 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 2019.

b. Proposed CY 2020 Payment Policy

For CY 2020, 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, but are also soliciting comments on alternative policies as well as the appropriate remedy for CYs 2018 and 2019 in the event that we do not prevail on appeal in the pending litigation, as discussed in greater detail later in this section. We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59371) and the CY 2019 OPPS/ASC final rule with comment period (83 FR 58979 through 58981) for more information about how the payment rate for drugs acquired with a 340B discount was established.

In the case of a drug or biological during an initial sales period in which data on the prices for sales for the drug or biological are not sufficiently available from the manufacturer, section 1847A(c)(4) of the Act permits the Secretary to make payments that are based on WAC. Under section 1833(t)(14)(A)(iii)(II), the amount of payment for a separately payable drug equals the average price for the drug for the year established under, among other authorities, section 1847A of the Act. As explained in greater detail in the CY 2019 PFS final rule, under section 1847A(c)(4), although payments may be based on WAC, unlike section 1847A(b) of the Act (which specifies that payments using ASP or WAC must be made with a 6 percent add-on), section 1847A(c)(4) of the Act does not require that a particular add-on amount be applied to WAC-based pricing for this initial period when ASP data is not available. Consistent with section 1847A(c)(4) of the Act, in the CY 2019 PFS final rule (83 FR 59661 to 59666), we finalized a policy that, effective January 1, 2019, WAC-based payments for Part B drugs made under section 1847A(c)(4) of the Act will utilize a 3-percent add-on in place of the 6-percent add-on that was being used according to our policy in effect as of CY 2018. For the CY 2019 OPPS, we followed the same policy finalized in the CY 2019 PFS final rule (83 FR 59661 to 59666). For the CY 2020 OPPS, we are proposing to continue to utilize a 3 percent add-on instead of a 6-percent add-on for WAC-based drugs pursuant to our authority under section 1833(t)(14)(A)(iii)(II) of the Act, which provides, in part, that the amount of payment for a SCOD is the average price of the drug in the year established under section 1847A of the Act. We also are proposing to 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 reduction because they were acquired under the 340B Program, the 340B Program rate (in this case, WAC minus 22.5 percent) would continue to apply. We refer readers to the CY 2019 PFS final rule (83 FR 59661 to 59666) for additional background on this proposal.

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 not be applied in determining payments for these separately paid drugs and biologicals.

We note that separately payable drug and biological payment rates listed in Addenda A and B to this proposed rule

[57] 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.*

(available via the internet on the CMS website), which illustrate the proposed CY 2020 payment of ASP+6 percent for separately payable nonpass-through drugs and biologicals and ASP+6 percent for pass-through drugs and biologicals, reflect either ASP information that is the basis for calculating payment rates for drugs and biologicals in the physician's office setting effective April 1, 2019, or WAC, AWP, or mean unit cost from CY 2018 claims data and updated cost report information available for this proposed rule. In general, these published payment rates are not the same as the actual January 2020 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2020 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2019 (July 1, 2019 through September 30, 2019) will be used to set the payment rates that are released for the quarter beginning in January 2020 near the end of December 2019. In addition, payment rates for drugs and biologicals in Addenda A and B to this proposed rule for which there was no ASP information available for April 2019 are based on mean unit cost in the available CY 2018 claims data. If ASP information becomes available for payment for the quarter beginning in January 2020, we will price payment for these drugs and biologicals based on their newly available ASP information. Finally, there may be drugs and biologicals that have ASP information available for this proposed rule (reflecting April 2019 ASP data) that do not have ASP information available for the quarter beginning in January 2020. These drugs and biologicals would then be paid based on mean unit cost data derived from CY 2018 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to this proposed rule are not for January 2020 payment purposes and are only illustrative of the CY 2020 OPPS payment methodology using the most recently available information at the time of issuance of 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 is 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 are eligible for pass-through payment and not just the first biosimilar biological product for a reference product. In the CY 2019 OPPS/ASC proposed rule (83 FR 37123), for CY 2019, we proposed to continue the policy in place from CY 2018 to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product.

In addition, in CY 2018, we adopted a policy that biosimilars without pass-through payment status that were acquired under the 340B Program would be paid the ASP of the biosimilar minus 22.5 percent of the reference product's ASP (82 FR 59367). We adopted this policy in the CY 2018 OPPS/ASC final rule with comment period because we believe that biosimilars without pass-through payment status acquired under the 340B Program should be treated in the same manner as other drugs and biologicals acquired through the 340B Program. As noted earlier, biosimilars with pass-through payment status are paid their own ASP+6 percent of the reference product's ASP. Separately payable biosimilars that do not have pass-through payment status and are not acquired under the 340B Program are also paid their own ASP+6 percent of the reference product's ASP. If a biosimilar does not have ASP pricing, but instead has WAC pricing, the WAC pricing add-on of either 3 percent or 6 percent is calculated from the biosimilar's WAC and is not calculated from the WAC price of the reference product.

As noted in the CY 2019 OPPS/ASC proposed rule (83 FR 37123), several stakeholders raised concerns to us that the current payment policy for biosimilars acquired under the 340B Program could unfairly lower the OPPS payment for biosimilars not on pass-through payment status because the payment reduction would be based on the reference product's ASP, which would generally be expected to be priced higher than the biosimilar, thus resulting in a more significant reduction in payment than if the 22.5 percent was calculated based on the biosimilar's ASP. We agreed with stakeholders that the current payment policy could unfairly lower the price of biosimilars without pass-through payment status that are acquired under the 340B Program. In addition, we believed that these changes would better reflect the resources and production costs that biosimilar manufacturers incur. We also believed 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 believed that paying for biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP, rather than 22.5 percent of the reference product's ASP, will more closely approximate hospitals' acquisition costs for these products.

Accordingly, in the CY 2019 OPPS/ASC proposed rule (83 FR 37123), for CY 2019, we proposed changes to our Medicare Part B drug payment methodology for biosimilars acquired under the 340B Program. Specifically, for CY 2019 and subsequent years, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, we proposed to pay nonpass-through biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP. This proposal was finalized without modification in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58977).

For CY 2020, we are proposing to continue our policy to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. We also are proposing to continue our policy to pay nonpass-through biosimilars acquired under the 340B Program at the biosimilar's ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act. In

addition, as discussed further below, we are soliciting comments on the appropriate remedy in the event of an adverse decision on appeal in the litigation related to our policy for payment of 340B-acquired drugs and biologicals, and we are specifically soliciting comments here on whether paying for 340B-acquired biosimilars at ASP+3 percent of the reference product's ASP would be an appropriate policy in line with that discussion.

3. Proposed Payment Policy for Therapeutic Radiopharmaceuticals

For CY 2020, 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 2020. Therefore, we are proposing for CY 2020 to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent, based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). We also are proposing to rely on CY 2018 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable and to update the payment rates for separately payable therapeutic radiopharmaceuticals according to our usual process for updating the payment rates for separately payable drugs and biologicals on a quarterly basis if updated ASP information is unavailable. For a complete history of the OPPS payment policy for therapeutic radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524). The proposed CY 2020 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this proposed rule (which are available via the internet on the CMS website).

4. Proposed Payment for Blood Clotting Factors

For CY 2019, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee (83 FR 58979). That is, for CY 2019, we provided payment for blood clotting factors under the OPPS at ASP+6 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2019 updated furnishing fee was $0.220 per unit.

For CY 2020, we 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 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*.

5. Proposed Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes But Without OPPS Hospital Claims Data

For CY 2020, we are proposing to continue to use the same payment policy as in CY 2019 for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data, which describes how we determine the payment rate for drugs, biologicals, or radiopharmaceuticals without an ASP. For a detailed discussion of the payment policy and methodology, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70442 through 70443). The proposed CY 2020 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B to this proposed rule, which is available via the internet on the CMS website.

The proposed CY 2020 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B to this proposed rule, which is available via the internet on the CMS website.

6. CY 2020 OPPS Payment Methodology for 340B Purchased Drugs

In the CY 2018 OPPS/ASC proposed rule (82 FR 33558 through 33724), we proposed changes to the Medicare Part B drug payment methodology for 340B hospitals. We proposed these changes to better, and more accurately, reflect the resources and acquisition costs that these hospitals incur. We believed that such changes would allow Medicare beneficiaries (and the Medicare program) to pay a more appropriate amount when hospitals participating in the 340B Program furnish drugs to Medicare beneficiaries that are purchased under the 340B Program. Subsequently, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), we finalized our proposal and adjusted the payment rate for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program from average sales price (ASP)+6 percent to ASP minus 22.5 percent. We stated that our goal was to make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs, while recognizing the intent of the 340B

Program to allow covered entities, including eligible hospitals, to stretch scarce resources in ways that enable hospitals to continue providing access to care for Medicare beneficiaries and other patients. Critical access hospitals are not included in this 340B policy change because they are paid under section 1834(g) of the Act. We also excepted rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment in CY 2018. In addition, as stated in the CY 2018 OPPS/ASC final rule with comment period, this policy change does not apply to drugs on pass-through payment status, which are required to be paid based on the ASP methodology, or vaccines, which are excluded from the 340B Program.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79706), we implemented section 603 of the Bipartisan Budget Act of 2015. As a general matter, applicable items and services furnished in certain off-campus outpatient departments of a provider on or after January 1, 2017 are not considered covered outpatient services for purposes of payment under the OPPS and are paid ''under the applicable payment system,'' which is generally the Physician Fee Schedule (PFS). However, consistent with our policy to pay separately payable, covered outpatient drugs and biologicals acquired under the 340B Program at ASP minus 22.5 percent, rather than ASP+6 percent, when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59015 through 59022), we finalized a policy to pay ASP minus 22.5 percent for 340B-acquired drugs and biologicals furnished in nonexcepted off-campus PBDs paid under the PFS. We adopted this payment policy effective for CY 2019 and for subsequent years.

As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37125), another topic that had 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 was whether drugs that do not have ASP pricing but instead receive WAC or AWP pricing are subject to the 340B payment adjustment. We did not receive public comments on this topic in response to the CY 2018 OPPS/ASC proposed rule. However, we since heard from stakeholders that there had been some confusion about this issue. We clarified in the CY 2019 proposed rule that the 340B payment adjustment applies to drugs that are priced using either WAC or AWP, and it has been our policy to subject 340B-acquired drugs that use these pricing methodologies to the 340B payment adjustment since the policy was first adopted. The 340B payment adjustment for WAC-priced drugs is WAC minus 22.5 percent and AWP-priced drugs have a payment rate of 69.46 percent of AWP when the 340B payment adjustment is applied. The 69.46 percent of AWP is calculated by first reducing the original 95 percent of AWP price by 6 percent to generate a value that is similar to ASP or WAC with no percentage markup. Then we apply the 22.5 percent reduction to ASP/WAC-similar AWP value to obtain the 69.46 percent of AWP, which is similar to either ASP minus 22.5 percent or WAC minus 22.5 percent. The number of separately payable drugs receiving WAC or AWP pricing that are affected by the 340B payment adjustment is small—consisting of less than 10 percent of all separately payable Medicare Part B drugs in April 2018.

Furthermore, data limitations previously inhibited our ability to identify which drugs were acquired under the 340B Program in the Medicare OPPS claims data. This lack of information within the claims data has limited researchers' and our ability to precisely analyze differences in acquisition cost of 340B and non-340B acquired drugs with Medicare claims data. Accordingly, in the CY 2018 OPPS/ASC proposed rule (82 FR 33633), we stated our intent to establish a modifier, to be effective January 1, 2018, for hospitals to report with separately payable drugs that were not acquired under the 340B Program. Because a significant portion of hospitals paid under the OPPS participate in the 340B Program, we stated our belief that it is appropriate to presume that a separately payable drug reported on an OPPS claim was purchased under the 340B Program, unless the hospital identifies that the drug was not purchased under the 340B Program. We stated in the CY 2018 proposed rule that we intended to provide further details about this modifier in the CY 2018 OPPS/ASC final rule with comment period and/or through subregulatory guidance, including guidance related to billing for dually eligible beneficiaries (that is, beneficiaries covered under Medicare and Medicaid) for whom covered entities do not receive a discount under the 340B Program. As discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), to effectuate the payment adjustment for 340B-acquired drugs, CMS implemented modifier ''JG'', effective January 1, 2018. Hospitals paid under the OPPS, other than a type of hospital excluded from the OPPS (such as critical access hospitals or those hospitals paid under the Maryland waiver), or excepted from the 340B drug payment policy for CY 2018, are required to report modifier ''JG'' on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. For CY 2018, rural sole community hospitals, children's hospitals and PPS-exempt cancer hospitals are excepted from the 340B payment adjustment. These hospitals are required to report informational modifier ''TB'' for 340B-acquired drugs, and continue to be paid ASP+6 percent.

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59370) for a full discussion and rationale for the CY 2018 policies and use of modifier ''JG''.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37125), for CY 2019, we proposed to continue the 340B Program policies that were implemented in CY 2018 with the exception of the way we calculate payment for 340B-acquired biosimilars (that is, we proposed to pay for nonpass-through 340B-acquired biosimilars at ASP minus 22.5 percent of the biosimilar's ASP, rather than of the reference product's ASP). More information on our revised policy for the payment of biosimilars acquired through the 340B Program is available in section V.B.2.c. of the CY 2019 OPPS/ASC final rule with comment period. For CY 2019, we proposed, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, to pay for separately payable Medicare Part B drugs (assigned status indicator ''K''), other than vaccines and drugs on pass-through payment status, that meet the definition of ''covered outpatient drug'' as defined in section 1927(k) of the Act, that are acquired through the 340B Program at ASP minus 22.5 percent when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment. Medicare Part B drugs or biologicals excluded from the 340B payment adjustment include vaccines (assigned status indicator ''F'', ''L'' or ''M'') and drugs with OPPS transitional pass-through payment status (assigned status indicator ''G''). As discussed in section V.B.2.c. of the CY 2019 OPPS/ASC proposed rule, we proposed to pay nonpass-through biosimilars acquired under the 340B Program at the biosimilar's ASP minus 22.5 percent of the biosimilar's ASP. We also proposed for CY 2019 that Medicare would continue to pay for

drugs or biologicals that were not purchased with a 340B discount at ASP+6 percent.

As stated earlier, to effectuate the payment adjustment for 340B-acquired drugs, CMS implemented modifier ''JG'', effective January 1, 2018. For CY 2019, we proposed that hospitals paid under the OPPS, other than a type of hospital excluded from the OPPS, or excepted from the 340B drug payment policy for CY 2018, continue to be required to report modifier ''JG'' on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. We also proposed for CY 2019 that rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals continue to be excepted from the 340B payment adjustment. We proposed for CY 2019 that these hospitals be required to report informational modifier ''TB'' for 340B-acquired drugs, and continue to be paid ASP+6 percent. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58981), after consideration of the public comments we received, we finalized our proposals without modification.

Our CY 2018 and 2019 OPPS payment policies for 340B-acquired drugs are the subject of ongoing litigation. On December 27, 2018, in the case of *American Hospital Association et al.* v. *Azar et al.,* the United States District Court for the District of Columbia (hereinafter referred to as ''the district court'') concluded in the context of reimbursement requests for CY 2018 that the Secretary exceeded his statutory authority by adjusting the Medicare payment rates for drugs acquired under the 340B Program to ASP minus 22.5 percent for that year.[58] In that same decision, the district court recognized the '''havoc that piecemeal review of OPPS payment could bring about' in light of the budget neutrality requirement,'' and ordered supplemental briefing on the appropriate remedy.[59] On May 6, 2019, after briefing on remedy, the district court issued an opinion that reiterated that the 2018 rate reduction exceeded the Secretary's authority, and declared that the rate reduction for 2019 (which had been finalized since the Court's initial order was entered) also exceeded his authority.[60] Rather than ordering HHS to pay plaintiffs their alleged underpayments, however, the district court recognized that crafting a remedy is ''no easy task, given Medicare's complexity,'' [61] and initially remanded the issue to HHS to devise an appropriate remedy while also retaining jurisdiction. The district court acknowledged that ''if the Secretary were to retroactively raise the 2018 and 2019 340B rates, budget neutrality would require him to retroactively lower the 2018 and 2019 rates for other Medicare Part B products and services.'' [62] *Id.* at 19. ''And because HHS has already processed claims under the previous rates, the Secretary would potentially be required to recoup certain payments made to providers; an expensive and time-consuming prospect.'' [63]

CMS respectfully disagreed with the district court's understanding of the scope of its adjustment authority and asked the district court to enter final judgment so as to permit an immediate appeal. On July 10, 2019, the district court granted the government's request and entered final judgment, and the agency does intend to pursue its appeal rights. Nonetheless, CMS is taking the steps necessary to craft an appropriate remedy in the event of an unfavorable decision on appeal.

Devising an appropriate remedy requires an opportunity for public input. First, these types of changes to the OPPS must be budget neutral, and reversal of the policy change, which raised rates for non-drug items and services to the tune of an estimated $1.7 billion for 2018 alone, could have a significant economic impact on the approximately 3,900 facilities that are reimbursed for outpatient items and services covered under the OPPS. Second, any remedy is likely to significantly affect beneficiary cost-sharing. The items and services that could be affected by the remedy were provided to millions of different Medicare beneficiaries, who, by statute, are required to pay cost-sharing for such items and services, which is usually 20 percent of the total Medicare payment rate.

CMS is soliciting initial public comment on how to formulate a solution that accounts for all of the complexities that the district court recognized. We intend to use this public input to further inform the steps that are required under the Administrative Procedure Act to provide adequate notice and an opportunity for meaningful comment on our proposed policies, which would entail devising the specific remedy itself, presenting the specific budget neutrality implications of that remedy in the proposed rule, and potentially calculating all the different payment rates under the OPPS for 340B-acquired drugs, as well as all other items and services under the OPPS. (In essence, we would need to provide hospitals with sufficient notice of the impact of the remedy on their rates to enable them to comment meaningfully on the proposed rule.) Our own best practices for preparing notices of proposed rulemaking dictate that we begin policy development in the year before the proposed rule is issued, and that we begin the rule drafting process in the first quarter of each year.

In order to comply with the requirements of the Administrative Procedure Act and our regulatory development process and calendar, we would anticipate proposing the specific remedy for CYs 2018 and 2019, as well as changes to the CY 2020 rates, in the next available rulemaking vehicle, which is the CY 2021 OPPS/ASC proposed rule. Those proposals will be informed by the comments solicited in this proposed rule. Specifically, we are using this proposed rule to solicit comment in advance of next year's rulemaking on approaches to the CY 2018 and 2019 remedy, as well as how best to address CY 2020 rates, so we are poised to propose those policies in the CY 2021 rule if necessary.

Thus, for CY 2020 we are proposing to continue to pay ASP–22.5 percent for 340B-acquired drugs including when furnished in nonexcepted off-campus PBDs paid under the PFS. Our proposal would 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, which is discussed in section V.B.2.c. of the CY 2019 OPPS/ASC final rule with comment period, and would continue the policy we finalized in CY 2019 to pay ASP minus 22.5 percent for 340B-acquired drugs and biologicals furnished in nonexcepted off-campus PBDs paid under the PFS.

We also seek public comment on the appropriate OPPS payment rate for 340B-acquired drugs, including whether a rate of ASP+3 percent could be an appropriate remedial payment amount for these drugs, both for CY 2020 and for purposes of determining the remedy for CYs 2018 and 2019. To be sure, this amount would result in payment rates that are well above the actual costs hospitals incur in purchasing 340B drugs, and it is being proposed solely because of the court decision. However, to the extent the courts are limiting the

[58] *American Hosp. Ass'n, et al.* v. *Azar, et al.,* No. 1:18–cv–2084 (D.D.C. Dec. 27, 2018).

[59] *Id.* at 35 (quoting *Amgen, Inc.* v. *Smith,* 357 F.3d 103, 112 (D.C. Cir. 2004) (citations omitted)).

[60] *See* May 6, 2019 Memorandum Opinion, Granting in Part Plaintiffs' Motion for a Permanent Injunction; Remanding the 2018 and 2019 OPPS Rules to HHS at 10–12.

[61] *Id.* at 13.

[62] *Id.* at 19.

[63] *Id.* (citing Declaration of Elizabeth Richter).

size of the payment reduction the agency can permissibly apply, the agency believes it could be appropriate to apply a payment reduction that is at the upper end of that limit, to the extent it has been or could be clearly defined, given the substantial discounts that hospitals receive through the 340B program. For example, absent further guidance from the Court of Appeals on what it believes is an appropriate ''adjustment'' amount, CMS could look to the district court's December 27, 2018 opinion, which cites to payment reductions of 0.2 percent and 2.9 percent as ''not significant enough'' to fall outside of the Secretary's authority to ''adjust'' ASP.[64] This payment rate would apply to 340B-acquired drugs and biologicals billed by a hospital paid under the OPPS that are not excepted from the payment adjustment and to 340B-acquired drugs and biologicals furnished in nonexcepted off-campus PBDs paid under the PFS. We welcome public comments on payment rates other than ASP+3 percent that commenters believe would be appropriate for purposes of addressing CY 2020 payment as an alternative to our proposal above, as well as for potential future rulemaking related to CY 2018 and 2019 underpayments.

In addition to comments on the appropriate payment amount for calculating the remedy for CYs 2018 and 2019 and for use for CY 2020, we also seek public comment on how to structure the remedy for CYs 2018 and 2019. This request for public comment includes comments on whether such a remedy should be retrospective in nature (for example, made on a claim-by-claim basis), whether such a remedy could be prospective in nature (for example, an upward adjustment to 340B claims in the future to account for any underpayments in the past), and whether there is some other mechanism that could produce a result equitable to hospitals that do not acquire drugs through the 340B program while respecting the budget neutrality mandate.

One potential remedy for alleged underpayments in 2018 and 2019 would involve making additional payments to the parties who have demonstrated harm from the alleged underpayments (which could be defined as hospitals that submitted a claim for drug payment with the ''JG'' modifier in CYs 2018 and 2019) outside the normal claims process. Under this approach, we would calculate the amount that such hospitals should have been paid and would utilize our Medicare contractors to make one payment to each affected hospital. This approach—one additional payment made to each affected hospital by our contractors—is a different approach than reprocessing each and every claim submitted by plaintiff hospitals for 2018 and 2019. Then, depending on when a final decision is rendered, the Secretary would propose to budget-neutralize those additional expenditures for each of CYs 2018 and 2019. For example, if the Court of Appeals were to render a decision in February of 2020, under such an approach we might propose those additional payments and an appropriate budget neutrality adjustment for each of CYs 2018, 2019, and, if necessary, 2020, in time for the CY 2021 rule. We note that we would need to receive a final decision from the Court of Appeals sufficiently early in CY 2020 (likely by March 1, 2020) to make it potentially possible for us to propose and finalize an appropriate remedy and budget neutrality adjustments in the CY 2021 rulemaking. We solicit public comment on this approach as well as other suggested approaches from commenters.

In considering these potential future proposals, we note that we would rely on our statutory authority under section 1833(t)(14) for determining the OPPS payment rates for drugs and biologicals as well as section 1833(t)(9)(A) of the Act to review certain components of the OPPS not less often than annually and to revise the groups, relative payment weights, and other adjustments. In addition, we note that under section 1833(t)(14)(H) of the Act, any adjustments made by the Secretary to payment rates using the statutory formula outlined in section 1833(t)(14)(A)(iii)(II) of the Act are required to be taken into account under the budget neutrality requirements outlined in section 1833(t)(9)(B) of the Act. We are soliciting public comments on the best, most appropriate way to maintain budget neutrality, either under a retrospective claim-by-claim approach, with a prospective approach, or any other proposed remedy. We also solicit comments on whether, depending on the amount of those additional expenditures, we should consider spreading out the relevant budget neutrality adjustment across multiple years. We would be interested to receive public comment on the advantages and disadvantages of such an approach.

In addition, we are interested in public comments on the best, most appropriate treatment of Medicare beneficiary cost-sharing responsibilities under any proposed remedy. These issues—the statutory budget neutrality requirement and beneficiary cost-sharing—are extremely difficult to balance, and we are interested in stakeholder comments as we continue to review the viability of alternative remedies in the event of an adverse decision from the Court of Appeals.

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370) and the CY 2019 OPPS/ASC final rule with comment period (83 FR 58976 through 58977 and 59015 through 59022) for more detail on the policies implemented in CY 2018 and CY 2019 for drugs acquired through the 340B Program.

7. 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 2019, the payment rate for

[64] 348 F. Supp. 3d 62, 81 (D.D.C. 2018) (citing to payment reductions of 0.2 percent and 2.9 percent that other decisions have recognized as being within the agency's adjustment authority for Medicare rates under the inpatient prospective payment system).

APC 5053 (Level 3 Skin Procedures) was $482.89, the payment rate for APC 5054 (Level 4 Skin Procedures) was $1,548.96, and the payment rate for APC 5055 (Level 5 Skin Procedures) was $2,766.13. This information also is available in Addenda A and B of the CY 2019 OPPS/ASC final rule with comment period (which is available via the internet on the CMS website).

We have continued the high cost/low cost categories policy since CY 2014, and we are proposing to continue it for CY 2020. Under this current policy, skin substitutes in the high cost category are reported with the skin substitute application CPT codes, and skin substitutes in the low cost category are reported with the analogous skin substitute HCPCS C-codes. For a discussion of the CY 2014 and CY 2015 methodologies for assigning skin substitutes to either the high cost group or the low cost group, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 74932 through 74935) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66882 through 66885).

For a discussion of the high cost/low cost methodology that was adopted in CY 2016 and has been in effect since then, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434 through 70435). For CY 2020, consistent with our policy since CY 2016, we 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 2020, as we did for CY 2019, 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 2020, as we did for CY 2019, 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 2020, we are proposing that any skin substitute product that was assigned to the high cost group in CY 2019 would be assigned to the high cost group for CY 2020, regardless of whether it exceeds or falls below the CY 2020 MUC or PDC threshold. This policy was established in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59346 through 59348).

For this CY 2020 OPPS/ASC proposed rule, consistent with the methodology as established in the CY 2014 through CY 2017 final rules with comment period, we analyzed CY 2018 claims data to calculate the MUC threshold (a weighted average of all skin substitutes' MUCs) and the PDC threshold (a weighted average of all skin substitutes' PDCs). The proposed CY 2020 MUC threshold is $49 per cm^2 (rounded to the nearest $1) and the proposed CY 2020 PDC threshold is $789 (rounded to the nearest $1).

For CY 2020, 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 continue to use WAC+3 percent instead of WAC+6 percent to conform to our proposed policy described in section V.B.2.b. of 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 2020 MUC threshold. For a discussion of our existing policy under which we assign skin substitutes without pricing information to the low cost category until pricing information is available, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70436).

Some skin substitute manufacturers have raised concerns about significant fluctuation in both the MUC threshold and the PDC threshold from year to year. The fluctuation in the thresholds may result in the reassignment of several skin substitutes from the high cost group to the low cost group which, under current payment rates, can be a difference of approximately $1,000 in the payment amount for the same procedure. In addition, these stakeholders were concerned that the inclusion of cost data from skin substitutes with pass-through payment status in the MUC and PDC calculations would artificially inflate the thresholds. Skin substitute stakeholders requested that CMS consider alternatives to the current methodology used to calculate the MUC and PDC thresholds and also requested that CMS consider whether it might be appropriate to establish a new cost group in between the low cost group and the high cost group to allow for assignment of moderately priced skin substitutes to a newly created middle group.

We share the goal of promoting payment stability for skin substitute products and their related procedures as price stability allows hospitals using such products to more easily anticipate future payments associated with these products. We have attempted to limit year-to-year shifts for skin substitute products between the high cost and low cost groups through multiple initiatives implemented since CY 2014, including: Establishing separate skin substitute application procedure codes for low-cost skin substitutes (78 FR 74935); using a skin substitute's MUC calculated from outpatient hospital claims data instead of an average of ASP+6 percent as the primary methodology to assign products to the high cost or low cost group (79 FR 66883); and establishing the PDC threshold as an alternate methodology to assign a skin substitute to the high cost group (80 FR 70434 through 70435).

To allow additional time to evaluate concerns and suggestions from stakeholders about the volatility of the MUC and PDC thresholds, in the CY 2018 OPPS/ASC proposed rule (82 FR 33627), we proposed that a skin substitute that was assigned to the high cost group for CY 2017 would be assigned to the high cost group for CY 2018, even if it does not exceed the CY 2018 MUC or PDC thresholds. We finalized this policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59347). We stated in the CY 2018 OPPS/ASC proposed rule that the goal of our proposal to retain the same skin substitute cost group assignments in CY 2018 as in CY 2017 was to maintain similar levels of payment for skin substitute products for CY 2018 while we study our skin substitute payment methodology to determine whether refinement to the existing policies 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. As discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58967 through 58968), we identified four potential methodologies that have been raised to us that we encouraged the public to review and provide comments on. We stated in the CY 2019 OPPS/ASC final rule with comment period that we were especially interested in any specific feedback on policy concerns with any of the options presented as they relate to skin substitutes with differing per day or per episode costs and sizes and other factors that may differ among the dozens of skin substitutes currently on the market. We also specified in the CY 2019 OPPS/ASC final rule with comment period that we were interested in any new ideas that are not represented below along with an analysis of how different skin substitute products would fare under such ideas. Finally, we stated that we intend to explore the full array of public comments on these ideas for the CY 2020 rulemaking, and we indicated that we will consider the feedback received in response to our requests for comments in developing proposals for CY 2020.

a. Discussion of CY 2019 Comment Solicitation for Episode-Based Payment and Solicitation of Additional Comments for CY 2020

The methodology that commenters discussed most in response to our comment solicitation in CY 2019 and that stakeholders raised in subsequent meetings we have had with the wound care community has been a lump-sum ''episode-based'' payment for a wound care episode. Commenters that supported an episode-based payment believe that it would allow health care professionals to choose the best skin substitute to treat a patient's wound and would give providers flexibility with the treatments they administer. These commenters also believe an episode-based payment helps to reduce incentives for providers to use excessive applications of skin substitute products or use higher cost products to generate more payment for the services they furnish. In addition, they believe that episode-based payment could help with innovations with skin substitutes by encouraging the development of products that require fewer applications. These commenters noted that episode-based payment would make wound care payment more predictable for hospitals and provide incentives to manage the cost of care that they furnish. Finally, commenters for an episode-based payment believe that workable quality metrics can be developed to monitor the quality of care administered under the payment methodology and limit excessive applications of skin substitutes.

However, many commenters opposed establishing an episode-based payment. One of the main concerns of commenters who opposed episode-based payment was that wound care is too complex and variable to be covered through such a payment methodology. These commenters stated that every patient and every wound is different; therefore, it would be very challenging to establish a standard episode length for coverage. They noted that it would be too difficult to risk-stratify and specialty-adjust an episode-based payment, given the diversity of patients receiving wound care and their providers who administer treatment, as well as the variety of pathologies covered in treatment. Also, these commenters questioned how episodes would be defined for patients when they are having multiple wounds treated at one time or had another wound develop while the original wound was receiving treatment. These commenters expressed concerns that episode-based payment would be burdensome both operationally and administratively for providers. They believe that CMS will need to create a large number of new APCs and HCPCS codes to account for all of the patient situations that would be covered with an episode-based payment, which would increase burdens on providers. Finally, these commenters had concerns about the impacts of episode-based payment on the usage of higher cost skin substitute products. They believed that a single payment could discourage the use of higher-cost products because of the large variability in the cost of skin substitute products, which could limit innovations for skin substitute products.

The wide array of views on episode-based payment for skin substitute products and the unforeseen issues that may arise from the implementation of such a policy make us reluctant to present a proposal for this CY 2020 proposed rule without more review of the issues involved with episode-based payment. Therefore, we are seeking further comments from stakeholders and other interested parties regarding skin substitute payment policies that could be applied in future years to address concerns about excessive utilization and spending on skin substitute products, while avoiding administrative issues such as establishing additional HCPCS codes to describe different treatment situations. One possible policy construct that we are seeking comments on would be to establish a payment period for skin substitute application services (CPT codes 15271 through 15278 and HCPCS codes C5271 through C5278) between 4 weeks and 12 weeks. Under this option, we could also assign CPT codes 15271, 15273, 15275, and 15277, and HCPCS codes C5271, C5273, C5275, and C5277 to comprehensive APCs with the option for a complexity adjustment that would allow for an increase in the standard APC payment for more resource-intensive cases. Our research has found that most wound care episodes require one to three skin substitute applications. Those cases would likely receive the standard APC payment for the comprehensive procedure. Then the complexity adjustment could be applied for the relatively small number of cases that require more intensive treatments. We look forward to comments from stakeholders and other interested parties on this possible policy construct.

b. Potential Revisions to the OPPS Payment Policy for Skin Substitutes: Comment Solicitation for CY 2020

In addition to possible future rulemaking based on the responses to the comment solicitations in the preceding section, we are considering adopting for CY 2020 another payment methodology that generated significant public comments in response to the CY 2019 comment solicitation. That option would be to eliminate the high cost and low cost categories for skin substitutes and have only one payment category and set of procedure codes for the application of all graft skin substitute products. The only available procedure codes to bill for skin substitute graft procedures would be CPT codes 15271 through 15278. HCPCS codes C5271 through C5278 would be eliminated. Providers would bill CPT codes 15271 through 15278 without having to consider either the MUC or PDC of the graft skin substitute product used in the procedure. There would be only one APC for the graft skin substitute application procedures described by CPT codes 15271 (Skin sub graft trnk/arm/leg), 15273 (Skin sub grft t/arm/lg child), 15275 (Skin sub graft face/nk/hf/g), and 15277 (Skn sub grft f/n/hf/g child). The payment rate would be the geometric mean of all graft skin substitutes procedures for a given CPT

code that are covered through the OPPS. For example under the current skin substitute payment policy, there are two procedure codes (CPT code 15271 and HCPCS code C5271) that are reported for the procedure described as ''*application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area*''. The geometric mean cost for CPT code 15271 is currently $1,572.17 and the geometric mean cost for HCPCS code C5271 is $728.28. If this policy option was implemented, only CPT code 15271 would be available in the OPPS, and the geometric mean cost for the procedure code would be $1,465.18.

Commenters that supported this option believe this would remove the incentives for manufacturers to develop and providers to use high cost skin substitute products and lead to the use of lower-cost, quality products. Commenters noted that lower Medicare payments for graft skin substitute procedures would lead to lower copayments for beneficiaries. In addition, commenters believed a single payment category would reduce incentives to apply skin substitute products in excessive amounts. Commenters also believed a single payment category is clinically justified because many studies have shown that no one skin substitute product is superior to another. Finally, supporters of a single payment category believed it will simplify coding for providers and reduce administrative burden.

There were also commenters that raised concerns that a single payment category would not offer providers incentives to furnish quality care and would reduce the use of higher-cost skin substitute products. Eliminating the high cost and low cost payment categories also does not maintain homogeneity among APC assignments for services using skin substitutes according to opponents of the single payment category. Commenters stated that instead of having categories grouped by the relative cost of products, there would be only one category to cover the payment of products with a mean unit cost ranging from less than $1 to over $750. Commenters believed a single payment category would favor inexpensive products, which could limit innovation, and could eliminate all but the most inexpensive products from the market. Finally, opponents of a single payment category believed a single payment category would discourage the treatment of wounds that are difficult and costly to treat.

The responses to the comment solicitation show the potential of a single payment category to reduce the cost of wound care services for graft skin substitute procedures for both beneficiaries and Medicare in general. In addition, a single payment category may help to lower administrative burden for providers. Conversely, we are cognizant of other commenters' concerns that a single payment category may hinder innovation of new graft skin substitute products and cause some products that are currently well-utilized to leave the market. Nonetheless, we are persuaded that a single payment category could potentially provide a more equitable payment for many products used with graft skin substitute procedures, while recognizing that procedures performed with expensive skin substitute products would likely receive substantially lower payment.

We believe a more equitable payment rate for graft skin substitute procedures could substantially reduce the amount Medicare pays for these procedures. We welcome suggestions or other information regarding the possibility of utilizing a single payment category to pay for skin substitute products under the OPPS, and, depending on the information we receive in response to this request, we may consider modifying our skin substitute payment policy in the CY 2020 OPPS/ASC final rule with comment period.

We believe some of the concerns commenters who oppose a single payment category for skin substitute products raised might be mitigated if stakeholders have a period of time to adjust to the changes inherent in establishing a single payment category. We are soliciting public comments that provide additional information about how commenters believe we should transition from the current low cost/high cost payment methodology to a single payment category.

Such suggestions to facilitate the payment transition from a low cost/high cost payment methodology to a single payment category methodology could include, but are not limited to—

- Delaying implementation of a single category payment for 1 or 2 years after the payment methodology is adopted; and
- Gradually lowering the MUC and PDC thresholds over 2 or more years to add more graft skin substitute procedures into the current high cost group until all graft skin substitute procedures are assigned to the high cost group and it becomes a single payment category.

We are seeking commenters' feedback on these ideas, or other approaches, to mitigate challenges that could impact providers, manufacturers, and other stakeholders if we establish a single payment category, which we might include as part of a final skin substitute payment policy that we would adopt in the CY 2020 OPPS/ASC final rule with comment period.

c. Proposals for Packaged Skin Substitutes

To allow stakeholders time to analyze and comment on the issues discussed above, we are proposing for CY 2020 to continue our policy established in CY 2018 to assign skin substitutes to the low cost or high cost group. Specifically, we 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 2019, in which case we would assign the product to the high cost group for CY 2020, regardless of whether it exceeds the CY 2020 MUC or PDC threshold. We also are proposing to assign to the high cost group any skin substitute product that exceeds the CY 2020 MUC or PDC thresholds and assign to the low cost group any skin substitute product that does not exceed the CY 2020 MUC or PDC thresholds and was not assigned to the high cost group in CY 2019. We are 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 2020 MUC. In addition, we are proposing to use WAC+3 percent for skin substitute products that do not have ASP pricing information or have claims data to determine if those products' costs exceed the CY 2020 MUC. We are proposing to continue our established policy to assign new skin substitute products without pricing information to the low cost group. We look forward to public comments on our proposals.

Table 19 displays the proposed CY 2020 cost category assignment for each skin substitute product.

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TABLE 19.—PROPOSED SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2020

CY 2020 HCPCS Code	CY 2020 Short Descriptor	CY 2019 High/Low Cost Assignment	Proposed CY 2020 High/Low Cost Assignment
C9363	Integra Meshed Bil Wound Mat	High	High
Q4100	Skin Substitute, NOS	Low	Low
Q4101	Apligraf	High	High
Q4102	Oasis Wound Matrix	Low	Low
Q4103	Oasis Burn Matrix	High	High*
Q4104	Integra BMWD	High	High
Q4105	Integra DRT	High	High
Q4106	Dermagraft	High	High
Q4107	GraftJacket	High	High
Q4108	Integra Matrix	High	High*
Q4110	Primatrix	High	High*
Q4111	Gammagraft	Low	Low
Q4115	Alloskin	Low	Low
Q4116	Alloderm	High	High
Q4117	Hyalomatrix	Low	Low
Q4121	Theraskin	High	High*
Q4122	Dermacell	High	High
Q4123	Alloskin	High	High*
Q4124	Oasis Tri-layer Wound Matrix	Low	Low
Q4126	Memoderm/derma/tranz/integup	High	High
Q4127	Talymed	High	High
Q4128	Flexhd/Allopatchhd/Matrixhd	High	High
Q4132	Grafix core, grafixpl core	High	High
Q4133	Grafix stravix prime pl sqcm	High	High
Q4134	hMatrix	Low	Low
Q4135	Mediskin	Low	Low
Q4136	Ezderm	Low	Low
Q4137	Amnioexcel biodexcel, 1 sq cm	High	High
Q4138	Biodfence DryFlex, 1cm	High	High
Q4140	Biodfence 1cm	High	High
Q4141	Alloskin ac, 1cm	High	High*
Q4143	Repriza, 1cm	High	High
Q4146	Tensix, 1CM	High	High
Q4147	Architect ecm, 1cm	High	High
Q4148	Neox neox rt or clarix cord	High	High
Q4150	Allowrap DS or Dry 1 sq cm	High	High
Q4151	AmnioBand, Guardian 1 sq cm	High	High
Q4152	Dermapure 1 square cm	High	High
Q4153	Dermavest 1 square cm	High	High
Q4154	Biovance 1 square cm	High	High
Q4156	Neox 100 or clarix 100	High	High

CY 2020 HCPCS Code	CY 2020 Short Descriptor	CY 2019 High/Low Cost Assignment	Proposed CY 2020 High/Low Cost Assignment
Q4157	Revitalon 1 square cm	High	High*
Q4158	Kerecis omega3, per sq cm	High	High*
Q4159	Affinity 1 square cm	High	High
Q4160	NuShield 1 square cm	High	High
Q4161	Bio-Connekt per square cm	High	High
Q4163	Woundex, bioskin, per sq cm	High	High
Q4164	Helicoll, per square cm	High	High*
Q4165	Keramatrix, per square cm	Low	Low
Q4166	Cytal, per square cm	Low	Low
Q4167	Truskin, per square cm	Low	Low
Q4169	Artacent wound, per sq cm	High	High
Q4170	Cygnus, per square cm	Low	Low
Q4173	Palingen or palingen xplus	High	High
Q4175	Miroderm, per square cm	High	High
Q4176	Neopatch, per square centimeter	High	High
Q4178	Floweramniopatch, per sq cm	High	High
Q4179	Flowerderm, per sq cm	High	High
Q4180	Revita, per sq cm	High	High
Q4181	Amnio wound, per square cm	High	High*
Q4182	Transcyte, per sq centimeter	Low	Low
Q4183	Surgigraft, 1 sq cm	High	High*
Q4184	Cellesta, 1 sq cm	High	High*
Q4186	Epifix 1 sq cm	High	High
Q4187	Epicord 1 sq cm	High	High
Q4188	Amnioarmor 1 sq cm	Low	Low
Q4190	Artacent ac 1 sq cm	Low	Low
Q4191	Restorigin 1 sq cm	Low	Low
Q4193	Coll-e-derm 1 sq cm	Low	Low
Q4194	Novachor 1 sq cm	High	High*
Q4195+	Puraply 1 sq cm	High	High
Q4196+	Puraply am 1 sq cm	High	High
Q4197	Puraply xt 1 sq cm	High	High
Q4198	Genesis amnio membrane 1sqcm	Low	Low
Q4200	Skin te 1 sq cm	Low	Low
Q4201	Matrion 1 sq cm	Low	Low
Q4203	Derma-gide, 1 sq cm	High	High*
Q4204	Xwrap 1 sq cm	Low	Low

* These products do not exceed either the proposed MUC or PDC threshold for CY 2020, but are assigned to the high cost group because they were assigned to the high cost group in CY 2019.
+ Pass-through payment status in CY 2020.

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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 2020 entails estimating spending for two groups of items. The first group of items consists of device categories that are currently eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2020. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of items that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2019 or beginning in CY 2020. The sum of the proposed CY 2020 pass-through spending estimates for these two groups of device categories equals the proposed total CY 2020 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 methodology for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice) use the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), in 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 2020, we are also 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 2020 for this group of items is $224.1 million, as discussed below, because we are proposing to pay for most nonpass-through separately payable drugs and biologicals under the CY 2020 OPPS at ASP+6 percent with the exception of 340B-acquired separately payable drugs that are paid at ASP minus 22.5 percent, and because we are proposing to pay for CY 2020 pass-through payment drugs and biologicals at ASP+6 percent, as we discuss in section V.A. of this proposed rule. We refer readers to section V.B.6 of this proposed rule where we solicit comments on an appropriate remedy in litigation involving our OPPS payment policy for 340B purchased drugs, which would inform CY 2021 rulemaking in the event of an adverse decision on appeal in that litigation.

Furthermore, payment for certain drugs, specifically diagnostic radiopharmaceuticals and contrast agents without pass-through payment status, is packaged into payment for the associated procedures, and these products will not be separately paid. In addition, we policy-package all nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies when used in a surgical procedure, as discussed in section II.A.3. of this proposed rule. In 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 2020. Therefore, our proposed estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2020 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 2020. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible, in the remaining quarters of CY 2019 or beginning in CY 2020. The sum of the CY 2020 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 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 2020, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004

through CY 2019 (82 FR 59371 through 59373).

For the first group, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2020, there is one active category for CY 2020. The active category is described by HCPCS code C1823 (Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads). Based on the information from the device manufacturer, we are estimating that 100 devices will receive payment in the OPPS in CY 2019 at an estimated cost of $5,655 per device. Therefore, we are proposing an estimate for the first group of devices of $565,500. In estimating our proposed CY 2020 pass-through spending for device categories in the second group, we included: Device categories that we knew at the time of the development of the proposed rule will be newly eligible for pass-through payment in CY 2020; additional device categories that we estimated could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2020; and contingent projections for new device categories established in the second through fourth quarters of CY 2020. For CY 2020, we 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 2020 pass-through spending for this second group of device categories is $10 million.

To estimate proposed CY 2020 pass-through spending for drugs and biologicals in the first group, specifically those drugs and biologicals recently made eligible for pass-through payment and continuing on pass-through payment status for at least one quarter in CY 2020, we 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 2020 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged diagnostic radiopharmaceuticals, contrast agents, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure) that will be continuing on pass-through payment status in CY 2020, we estimated the pass-through payment amount as the difference between ASP+6 percent and the payment rate for nonpass-through drugs and biologicals that will be separately paid. Separately payable drugs are paid at a rate of ASP+6 percent with the exception of 340B-acquired drugs that are paid at ASP minus 22.5 percent. Therefore, the payment rate difference between the pass-through payment amount and the nonpass-through payment amount is $224.1 million for this group of drugs. Because payment for policy-packaged drugs and biologicals is packaged if the product was not paid separately due to its pass-through payment status, we are proposing to include in the CY 2020 pass-through estimate the difference between payment for the policy-packaged drug or biological at ASP+6 percent (or WAC+6 percent, or 95 percent of AWP, if ASP or WAC information is not available) and the policy-packaged drug APC offset amount, if we determine that the policy-packaged drug or biological approved for pass-through payment resembles a predecessor drug or biological already included in the costs of the APCs that are associated with the drug receiving pass-through payment, which we estimate for CY 2020 to be $17.0 million. For this proposed rule, using the proposed methodology described above, we calculated a CY 2020 proposed spending estimate for this first group of drugs and biologicals that includes drugs currently on pass-through payment status that would otherwise be separately payable or policy-packaged of approximately $241.1 million.

To estimate proposed CY 2020 pass-through spending for drugs and biologicals in the second group (that is, drugs and biologicals that we knew at the time of development of the proposed rule were newly eligible for pass-through payment in CY 2020, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of this proposed rule and before January 1, 2020 and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2020), we 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 2020 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 2020 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and biologicals of approximately $17.1 million.

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 2020 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2020 is approximately $268.8 million (approximately $10.6 million for device categories and approximately $258.2 million for drugs and biologicals) which represents 0.34 percent of total projected OPPS payments for CY 2020 (approximately $80 billion). Therefore, we estimate that pass-through spending in CY 2020 would not amount to 2.0 percent of total projected OPPS CY 2020 program spending.

VII. Proposed OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2020, 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 2020. For a description of the current payment policy for critical care services, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70449), and for the history of the payment policy for critical care services, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75043). In 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 commenters to provide the data and analysis necessary to justify any suggested changes.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015), we adopted a method to control unnecessary increases in the

volume of covered outpatient department services under section 1833(t)(2)(F) of the Act by utilizing a Medicare Physician Fee Schedule (PFS)-equivalent payment rate for the hospital outpatient clinic visit (HCPCS code G0463) when it is furnished by excepted off-campus provider-based departments (PBDs). As discussed in section X.D of this proposed rule and the CY 2019 final rule (FR 58818 through 59179), CY 2020 will be the second year of the 2-year transition of this policy, and in CY 2020, these departments will be paid the site-specific PFS rate for the clinic visit service. For a full discussion of this policy, we refer readers to that final rule with comment period.

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. Since a day of care is the unit that defines the structure and scheduling of partial hospitalization services, we established a per diem payment methodology for the PHP APCs, effective for services furnished on or after July 1, 2000 (65 FR 18452 through 18455). Under this methodology, the median per diem costs were used to calculate the relative payment weights for the PHP APCs. Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

We began efforts to strengthen the PHP benefit through extensive data analysis, along with policy and payment changes finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). In that final rule with comment period, we made two refinements to the methodology for computing the PHP median: The first remapped 10 revenue codes that are common among hospital-based PHP claims to the most appropriate cost centers; and the second refined our methodology for computing the PHP median per diem cost by computing a separate per diem cost for each day rather than for each bill.

In CY 2009, we implemented several regulatory, policy, and payment changes, including a two-tier payment approach for partial hospitalization services under which we paid one amount for days with 3 services under PHP APC 0172 (Level 1 Partial Hospitalization) and a higher amount for days with 4 or more services under PHP APC 0173 (Level 2 Partial Hospitalization) (73 FR 68688 through 68693). We also finalized our policy to deny payment for any PHP claims submitted for days when fewer than 3 units of therapeutic services are provided (73 FR 68694). Additionally, for CY 2009, we revised the regulations at 42 CFR 410.43 to codify existing basic PHP patient eligibility criteria and to add a reference to current physician certification requirements under 42 CFR 424.24 to conform our regulations to our longstanding policy (73 FR 68694 through 68695). We also revised the partial hospitalization benefit to include several coding updates (73 FR 68695 through 68697).

For CY 2010, we retained the two-tier payment approach for partial hospitalization services and used only hospital-based PHP data in computing the PHP APC per diem costs, upon which PHP APC per diem payment rates are based. We used only hospital-based PHP data because we were concerned about further reducing both PHP APC per diem payment rates without knowing the impact of the policy and payment changes we made in CY 2009. Because of the 2-year lag between data collection and rulemaking, the changes we made in CY 2009 were reflected for the first time in the claims data that we used to determine payment rates for the CY 2011 rulemaking (74 FR 60556 through 60559).

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71994), we established four separate PHP APC per diem payment rates: Two for CMHCs (APC 0172 (for Level 1 services) and APC 0173 (for Level 2 services)) and two for hospital-based PHPs (APC 0175 (for Level 1 services) and APC 0176 (for Level 2 services)), based on each provider type's own unique data. For CY 2011, we also instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates based solely on CMHC data. Under the transition methodology, CMHC APCs Level 1 and Level 2 per diem costs were calculated by taking 50 percent of the difference between the CY 2010 final hospital-based PHP median costs and the CY 2011 final CMHC median costs and then adding that number to the CY 2011 final CMHC median costs. A 2-year transition under this methodology moved us in the direction of our goal, which is to pay appropriately for partial

hospitalization services based on each provider type's data, while at the same time allowing providers time to adjust their business operations and protect access to care for Medicare beneficiaries. We also stated that we would review and analyze the data during the CY 2012 rulemaking cycle and, based on these analyses, we might further refine the payment mechanism. We refer readers to section X.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994) for a full discussion.

In addition, in accordance with section 1301(b) of the Health Care and Education Reconciliation Act of 2010 (HCERA 2010), we amended the description of a PHP in our regulations to specify that a PHP must be a distinct and organized intensive ambulatory treatment program offering less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting. In accordance with section 1301(a) of HCERA 2010, we revised the definition of a CMHC in the regulations to conform to the revised definition now set forth under section 1861(ff)(3)(B) of the Act (75 FR 71990).

For CY 2012, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74348 through 74352), we determined the relative payment weights for partial hospitalization services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for partial hospitalization services provided by hospital-based PHPs based exclusively on hospital data.

In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs (APCs 0172, 0173, 0175, and 0176), on geometric mean costs rather than on the median costs. We established these four PHP APC per diem payment rates based on geometric mean cost levels calculated using the most recent claims and cost data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68406 through 68412).

In the CY 2014 OPPS/ASC proposed rule (78 FR 43621 through 43622), we solicited comments on possible future initiatives that may help to ensure the long-term stability of PHPs and further improve the accuracy of payment for PHP services, but proposed no changes. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75050 through 75053), we summarized the comments received on those possible future initiatives. We also continued to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75047 through 75050).

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66902 through 66908), we continued to apply our established policies to calculate the four PHP APC per diem payment rates based on PHP APC geometric mean per diem costs, using the most recent claims and cost data for each provider type.

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70455 through 70465), we described our extensive analysis of the claims and cost data and ratesetting methodology. We found aberrant data from some hospital-based PHP providers that were not captured using the existing OPPS ±3 standard deviation trims for extreme cost-to-charge ratios (CCRs) and excessive CMHC charges resulting in CMHC geometric mean costs per day that were approximately the same as or more than the daily payment for inpatient psychiatric facility services. Consequently, we implemented a trim to remove hospital-based PHP service days that use a CCR that was greater than 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 APCs 0172 and 0173 for CMHCs' partial hospitalization Level 1 and Level 2 services, and APCs 0175 and 0176 for hospital-based partial hospitalization Level 1 and Level 2 services to APCs 5851 and 5852 for CMHCs' partial hospitalization Level 1 and Level 2 services, and APCs 5861 and 5862 for hospital-based partial hospitalization Level 1 and Level 2 services, respectively. For a detailed discussion of the PHP ratesetting process, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70467).

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79691), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims and cost data for each provider type. However, we finalized a policy to combine the Level 1 and Level 2 PHP APCs for CMHCs and to combine the Level 1 and Level 2 APCs for hospital-based PHPs because we believed this would best reflect actual geometric mean per diem costs going forward, provide more predictable per diem costs, particularly given the small number of CMHCs, and generate more appropriate payments for these services, for example by avoiding the cost inversions for hospital-based PHPs addressed in the CY 2016 and CY 2017 OPPS/ASC final rules with comment period (80 FR 70459 and 81 FR 79682). We also implemented an 8-percent outlier cap for CMHCs to mitigate potential outlier billing vulnerabilities by limiting the impact of inflated CMHC charges on outlier payments. We stated that we will continue to monitor the trends in outlier payments and consider policy adjustments as necessary.

For a comprehensive description of PHP payment policy, including a detailed methodology for determining PHP per diem amounts, we refer readers to the CY 2016 and CY 2017 OPPS/ASC final rules with comment period (80 FR 70453 through 70455 and 81 FR 79678 through 79680).

In the CYs 2018 and 2019 OPPS/ASC final rules with comment period (82 FR 59373 through 59381, and 83 FR 58983 through 58998, respectively), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims and cost data for each provider type. We also continued to designate a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the

OPPS, excluding outlier payments. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58997 through 58998), we also included proposed updates to the PHP allowable HCPCS codes. Specifically, we proposed to delete 6 psychological and neuropsychological testing CPT codes, which affect PHPs, and to add 9 new codes as replacements. We refer readers to section VIII.D. of this proposed rule for a discussion of those proposed updates and the applicability for CY 2020.

B. Proposed PHP APC Update for CY 2020

1. Proposed PHP APC Geometric Mean Per Diem Costs

In summary, for CY 2020, we are proposing to use the CY 2020 CMHC geometric mean per diem cost and the CY 2020 hospital-based PHP geometric mean per diem cost, each calculated in accordance with our existing methodology, but with a cost floor equal to the CY 2019 final geometric mean per diem cost for CMHCs of $121.62 and for hospital-based PHPs of $222.76 (83 FR 58991), as the basis for developing the CY 2020 PHP APC per diem rates. As part of this proposal, in the final rule with comment period, we are proposing that we would use the most recent updated claims and cost data to calculate CY 2020 geometric mean per diem costs.

Also, 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)). These proposals are discussed in more detail below.

2. Development of the Proposed PHP APC Geometric Mean Per Diem Costs

In preparation for CY 2020 and subsequent years, we followed the PHP ratesetting methodology described in section VIII.B.2. of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70466) to calculate the PHP APCs' geometric mean per diem costs and payment rates for APCs 5853 and 5863, incorporating the modifications made in the CY 2017 OPPS/ASC final rule with comment period. As discussed in section VIII.B.1. of the CY 2017 OPPS/ASC final rule with comment period (81 FR 79680 through 79687), the 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 geometric mean per diem costs, after applying the OPPS budget neutrality adjustments described in section II.A.4. of this proposed rule.

As previously stated, in this CY 2020 OPPS/ASC proposed rule, we applied our established methodologies in calculating the CY 2020 geometric mean per diem costs and payment rates, including the application of a ±2 standard deviation trim on costs per day for CMHCs and a CCR greater than 5 hospital service day trim for hospital-based PHP providers. These two trims were finalized in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70455 through 70462) for CY 2016 and subsequent years.

a. CMHC Data Preparation: Data Trims, Exclusions, and CCR Adjustments

For CY 2020, prior to calculating the 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 41 CMHCs in the PHP claims data file. Under the ±2 standard deviation trim policy, we excluded any data from a CMHC for ratesetting purposes when the CMHC's geometric mean cost per day was more than ±2 standard deviations from the geometric mean cost per day for all CMHCs. In applying this trim for CY 2020 ratesetting, no CMHCs had geometric mean costs per day below the trim's lower limit of $21.13 or had geometric mean costs per day above the trim's upper limit of $506.11. Therefore, we did not exclude any CMHCs because of the ±2 standard deviation trim.

In accordance with our PHP ratesetting methodology, we also remove service days with no wage index values, because we use the wage index data to remove the effects of geographic variation in costs prior to APC geometric mean per diem cost calculation (80 FR 70465). For CY 2020, no CMHC was missing wage index data for all of its service days and, therefore, no CMHC was excluded.

In addition to our trims and data exclusions, before calculating the PHP APC geometric mean per diem costs, we also assess CCRs (80 FR 70463). Our longstanding PHP OPPS ratesetting methodology defaults any CMHC CCR greater than 1 to the statewide hospital CCR (80 FR 70457). For CY 2020, there were no CMHCs in the outpatient provider specific file (OPSF) that showed CCRs greater than 1. Therefore, it was not necessary to default any CMHC to its statewide hospital CCR for ratesetting.

In summary, these data preparation steps did not adjust the CCR for any CMHCs shown in the OPSF with a CCR greater than 1 during our ratesetting process. We also did not exclude any CMHCs for other missing data or for failing the ±2 standard deviation trim, resulting in the inclusion of all 41 CMHCs. There were 188 CMHC claims removed during data preparation steps because they either had no PHP-allowable codes or had zero payment days, leaving 10,271 CMHC claims in our CY 2020 proposed rule ratesetting modeling.

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 a CMHC APC geometric mean per diem cost.[65] The calculated CY 2020 geometric mean per diem cost for all CMHCs for providing 3 or more services per day (CMHC APC 5853) is $103.42, a decrease from

[65] Each revenue code on the CMHC claim must have a HCPCS code and charge associated with it. We multiply each claim service line's charges by the CMHC's overall CCR from the OPSF (or statewide CCR, where the overall CCR was greater than 1) to estimate CMHC costs. Only the claims service lines containing PHP allowable HCPCS codes and PHP allowable revenue codes from the CMHC claims remaining after trimming are retained for CMHC cost determination. The costs, payments, and service units for all service lines occurring on the same service date, by the same provider, and for the same beneficiary are summed. CMHC service days must have 3 or more services provided to be assigned to CMHC APC 5853. The proposed 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 proposed 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.

$121.62 calculated last year for CY 2019 ratesetting (83 FR 58986 through 58989).

Due to this fluctuation, we investigated why the calculated CMHC APC geometric mean per diem cost had decreased from the prior year, and found that a single large provider that reported low costs per day was heavily influencing the calculated geometric mean per diem cost. Because this provider had a high number of paid PHP days, and because the CMHC data set is so small (n=41), this provider had a significant influence on the calculated CY 2020 CMHC APC geometric mean per diem cost. In the case of PHPs provided by CMHCs, we note that we have an unusually low number of PHP providers in our ratesetting dataset (41 CMHCs compared to 364 hospital-based PHPs) that provide a small volume of services and, therefore, account for a limited amount of payments, relative to the rest of OPPS payments (total CY 2018 CMHC payments are estimated to be approximately 0.02 percent of all OPPS payments).

We are concerned that a CMHC APC geometric mean per diem cost of $103.42 would not support ongoing access to PHPs in CMHCs. This cost is nearly a 15 percent decrease from the final CY 2019 CMHC geometric mean per diem cost. We believe access to partial hospitalization services and PHPs is better supported when the geometric mean per diem cost does not fluctuate greatly. In addition, while the CMHC APC 5853 is described as providing 3 or more partial hospitalization services per day (81 FR 79680), 95 percent of CMHC paid days in CY 2018 were for providing 4 or more services per day. To be eligible for a PHP, a patient must need at least 20 hours of therapeutic services per week, as evidenced in the patient's plan of care (42 CFR 410.43(c)(1)). To meet those patient needs, most PHP provider paid days are for providing 4 or more services per day (we refer readers to Table 22.—Percentage of PHP Days by Service Unit Frequency of this proposed rule). Therefore, the CMHC APC 5853 is actually heavily weighted to the cost of providing 4 or more services. The per diem costs for CMHC APC 5853 have been calculated as $124.92, $143.22, and $121.62 for CY 2017 (81 FR 79691), CY 2018 (82 FR 59378), and CY 2019 (83 FR 58991), respectively. We do not believe it is likely that the actual cost of providing partial hospitalization services through a PHP by CMHCs has suddenly declined when costs generally increase over time. We are concerned by this fluctuation, which we believe is influenced by data from a single large provider.

Therefore, rather than simply proposing to use the calculated CY 2020 CMHC APC geometric mean per diem cost for CY 2020 ratesetting, we are instead proposing to use the CY 2020 CMHC APC geometric mean per diem cost, calculated in accordance with our existing methodology, but with a cost floor equal to the CY 2019 final geometric mean per diem cost for CMHCs of $121.62 (83 FR 58991), as the basis for developing the CY 2020 CMHC APC per diem rate. As part of this proposal, in the final rule with comment period, we are proposing that we would use the most recent updated claims and cost data to calculate CY 2020 CMHC geometric mean per diem cost. This proposal aligns with our proposal for hospital-based PHPs. We believe using the CY 2019 CMHC geometric mean per diem cost as the floor is appropriate because it is based on very recent CMHC PHP claims and cost data and would help to protect provider access by preventing wide fluctuation in the per diem costs for CMHC APC 5853. Because the calculated amount of $103.42 is less than the final CY 2019 CMHC APC geometric mean per diem cost of $121.62, the inclusion of a cost floor means that the proposed CY 2020 CMHC geometric mean per diem cost at the time of the development of this proposed rule is $121.62. The inclusion of the cost floor would protect CMHCs if the final CY 2020 calculated per diem cost still results in an amount that is less than $121.62. We believe this proposal for CY 2020 ratesetting allows us to use the most recent or very recent CMHC claims and cost reporting data while still protecting provider access. To be clear, this policy would only apply for the CY 2020 ratesetting.

In crafting this proposal, we also considered proposing a 3-year rolling average calculated using the final PHP geometric mean per diem costs, by provider type, from CY 2018 (82 FR 59378), CY 2019 (83 FR 58991), and the calculated CY 2020 geometric mean per diem costs of $103.42 discussed earlier in this section for CMHCs and the calculated CY 2020 geometric mean per diem costs for hospital-based PHPs discussed in section VIII.B.2.b. of this proposed rule. The 3-year rolling averages results in geometric mean per diem cost for CMHCs that would have been $122.75 and for hospital-based PHPs that would have been $209.79. While we believe this option would have avoided the fluctuation in the geometric mean per diem cost and, therefore, supported access to PHPs provided by CMHCs, it would have maintained the fluctuation in the geometric mean per diem costs used to derive the hospital-based PHP APC per diem payment rates. This is further discussed in the hospital-based PHP section VIII.B.2.b. of this proposed rule. In addition, we believe that it is necessary to recalculate the CMHC geometric mean per diem cost for the final rule with comment period using updated claims and cost data, and simply proposing to use a 3-year rolling average for the CMHC geometric mean per diem cost for CY 2020 would not have allowed us to do so. Therefore, we believe that it is more appropriate to propose to use the final CY 2019 geometric mean per diem costs, by provider type, as the cost floor for use with the calculated CY 2020 PHP geometric mean per diem costs, by provider type, because those CY 2019 per diem costs are based on very recent CMHC and hospital-based PHP claims and cost data, are the easiest to understand, and would result in proposed geometric mean per diem costs which would support access for both CMHCs and hospital-based PHPs.

We estimate the aggregate difference in the (prescaled) CMHC geometric mean per diem costs for CY 2020 from proposing the CMHC cost floor amount of $121.62 rather than the calculated CMHC geometric mean per diem cost of $103.42 to be $1.4 million. We refer readers to section XXVI. of this proposed rule for payment impacts, which are budget neutral.

b. Hospital-Based PHP Data Preparation: Data Trims and Exclusions

For this CY 2020 proposed rule, we prepared data consistent with our policies as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465) for hospital-based PHP providers, which is similar to that used for CMHCs. The CY 2018 PHP claims included data for 427 hospital-based PHP providers for our calculations in this CY 2020 OPPS/ASC proposed rule.

Consistent with our policies as stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465), we prepared the data by applying trims and data exclusions. We applied a trim on hospital service days for hospital-based PHP providers with a CCR greater than 5 at the cost center level. To be clear, the CCR greater than 5 trim is a service day-level trim in contrast to the CMHC ±2 standard deviation trim, which is a provider-level trim. Applying this CCR greater than 5 trim removed affected service days from 1 hospital-based PHP provider with a CCR of 6.944 from our proposed rule ratesetting. However, 100 percent of the

service days for this 1 hospital-based PHP provider had at least 1 service associated with a CCR greater than 5, so the trim removed this provider entirely from our proposed rule ratesetting. In addition, 60 hospital-based PHPs were removed for having no PHP costs and, therefore, no days with PHP payment. Two hospital-based PHPs were removed because none of their days included PHP-allowable HCPCS codes. No hospital-based PHPs were removed for missing wage index data, nor were any hospital-based PHPs removed by the OPPS ±3 standard deviation trim on costs per day. (We refer readers to the OPPS Claims Accounting Document, available online at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1695-FC-2019-OPPS-FR-Claims-Accounting.pdf*.)

Overall, we removed 63 hospital-based PHP providers [(1 with all service days having a CCR greater than 5) + (60 with zero daily costs and no PHP payment) + (2 with no PHP-allowable HCPCS codes)], resulting in 364 (427 total − 63 excluded) hospital-based PHP providers in the data used for calculating ratesetting. In addition, 3 hospital-based PHP providers were defaulted to their overall hospital ancillary CCRs due to outlier cost center CCR values.

After completing these data preparation steps, we calculated the CY 2020 geometric mean per diem cost for hospital-based PHP APC 5863 for hospital-based partial hospitalization services by following the methodology described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70464 through 70465) and modified in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 and 79691).[66] The calculated CY 2020 hospital-based PHP APC geometric mean per diem cost for hospital-based PHP providers that provide 3 or more services per service day (hospital-based PHP APC 5863) is $198.53, a decrease from $222.76 calculated last year for CY 2019 ratesetting (83 FR 58989 through 58991).

Due to this fluctuation, we investigated why this calculated hospital-based PHP APC geometric mean per diem cost decreased from the prior year, and found that a single provider with a large number of paid PHP service days had a significant decrease in its cost per day and, therefore, was heavily influencing the data. We are concerned that a hospital-based PHP APC geometric mean per diem cost of $198.53 would not support ongoing access to hospital-based PHPs. This cost is nearly an 11 percent decrease from the final CY 2019 hospital-based PHP geometric mean per diem cost. We believe access is better supported when the geometric mean per diem cost does not fluctuate greatly. In addition, while the hospital-based PHP APC 5863 is described as providing payment for the cost of 3 or more services per day (81 FR 79680), 89 percent of hospital-based PHP paid service days in CY 2018 were for providing 4 or more services per day. To be eligible for a PHP, a patient must need at least 20 hours of therapeutic services per week, as evidenced in the patient's plan of care (42 CFR 410.43(c)(1)). To meet those patient needs, most PHP paid service days provide 4 or more services (we refer readers to Table 22.—Percentage of PHP Days by Service Unit Frequency in this proposed rule). Therefore, the hospital-based PHP APC 5863 is actually heavily weighted to the cost of providing 4 or more services. The per diem costs for hospital-based PHP APC 5863 have been calculated as $213.14, $208.09, and $222.76 for CY 2017 (81 FR 79691), CY 2018 (82 FR 59378), and CY 2019 (83 FR 58991), respectively. We do not believe that it is likely that the cost of providing hospital-based PHP services has suddenly declined when costs generally increase over time. We are concerned by this fluctuation, which we believe is influenced by data from a single large provider that had low service costs per day.

Therefore, rather than proposing the calculated CY 2020 hospital-based PHP APC geometric mean per diem cost, we are instead proposing to use the CY 2020 hospital-based PHP APC geometric mean per diem cost, calculated in accordance with our existing methodology, but with a cost floor equal to the CY 2019 final geometric mean per diem cost for hospital-based PHPs of $222.76 (83 FR 58991), as the basis for developing the CY 2020 hospital-based PHP APC per diem rate. As part of this proposal, in the final rule with comment period, we are proposing that we would use the most recent updated claims and cost data to calculate CY 2020 geometric mean per diem costs. This proposal aligns with our proposal for CMHCs. We believe using the CY 2019 hospital-based PHP per diem cost as the floor is appropriate because it is based on very recent hospital-based PHP claims and cost data and would help to protect provider access by preventing wide fluctuation in the per diem costs for hospital-based APC 5863. Because the calculated amount of $198.53 is less than the final CY 2019 hospital-based PHP APC geometric mean per diem cost of $222.76, the inclusion of a cost floor means that the proposed CY 2020 hospital-based PHP geometric mean per diem cost, as of the time of this proposed rule, is $222.76. The inclusion of the cost floor would protect hospital-based PHPs if the final CY 2020 calculated hospital-based PHP APC geometric mean per diem cost results in an amount that is still less than $222.76. We believe this proposal for CY 2020 ratesetting allows us to use the most recent or very recent hospital-based PHP claims and cost reporting data while still protecting provider access. To be clear, this policy would only apply for the CY 2020 ratesetting.

In crafting this proposal, we also considered proposing a 3-year rolling average calculated using the final PHP geometric mean per diem costs, by provider type, from CY 2018 (82 FR 59378) and CY 2019 (83 FR 58991), and the calculated CY 2020 geometric mean per diem cost of $198.53 discussed earlier in this section for hospital-based PHPs. As discussed previously in this section, the 3-year rolling average per diem cost floor for CMHCs would have been $122.75, but the resulting rolling average per diem cost floor for hospital-based PHPs would have been $209.79. While we believe that this option would have supported access to CMHCs, as discussed previously, it would have resulted in a geometric mean per diem cost for the hospital-based PHP APC which still would have been a decrease from the hospital-based PHP APC geometric mean per diem cost of $222.76 finalized in CY 2019 (83 FR 58991). In addition, we believe that it is necessary to recalculate the hospital-

[66] Each revenue code on the hospital-based PHP claim must have a HCPCS code and charge associated with it. We multiply each claim service line's charges by the hospital's department-level CCR; in CY 2020 and subsequent years, that CCR is determined by using the PHP-only revenue-code-to-cost-center crosswalk. Only the claims service lines containing PHP-allowable HCPCS codes and PHP-allowable revenue codes from the hospital-based PHP claims remaining after trimming are retained for hospital-based PHP cost determination. The costs, payments, and service units for all service lines occurring on the same service date, by the same provider, and for the same beneficiary are summed. Hospital-based PHP service days must have 3 or more services provided to be assigned to hospital-based PHP APC 5863. The proposed 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 proposed geometric mean per diem cost for hospital-based PHP APC 5863.

based PHP geometric mean per diem cost for the final rule using updated claims and cost data and simply proposing to use a 3-year rolling average per diem cost floor for the hospital-based PHP APC per diem costs for CY 2020 would not have allowed us to do so. We are concerned that this 3-year rolling average per diem cost would continue to result in a fluctuation in the cost of a hospital providing 4 or more hospital-based PHP services per day. We believe that it is important to support access to partial hospitalization services in both CMHCs and in hospital-based PHPs, and note that hospital-based PHPs provide 80 percent of all paid PHP service days. Therefore, we believe that it is more appropriate to propose to use the final CY 2019 geometric mean per diem costs, by provider type, as the cost floor for use with the calculated CY 2020 PHP geometric mean per diem costs, by provider type, because those CY 2019 per diem costs are based on very recent CMHC and hospital-based PHP claims and cost data, are the easiest to understand, and would result in proposed geometric mean per diem costs which would help to protect provider access by preventing wide fluctuation in the per diem costs for both CMHCs and hospital-based PHPs.

We estimate the aggregate difference in the (prescaled) hospital-based PHP geometric mean per diem costs for CY 2020 from proposing the hospital-based PHP cost floor amount of $222.76 rather than the calculated hospital-based PHP geometric mean per diem cost of $198.53 to be $9.3 million. We refer readers to section XXVI. of this proposed rule for payment impacts, which are budget neutral.

In summary, for CY 2020, we are proposing to use the calculated CY 2020 CMHC geometric mean per diem cost and the calculated CY 2020 hospital-based PHP geometric mean per diem cost, each calculated in accordance with our existing methodology, but with a cost floor equal to the CY 2019 final geometric mean per diem costs as the basis for developing the CY 2020 PHP APC per diem rates. Because the CY 2020 calculated geometric mean per diem costs for these provider types were both less than their respective final CY 2019 APC geometric mean per diem costs, the inclusion of a cost floor in this proposal means that both the proposed CY 2020 CMHC geometric mean per diem cost and the proposed CY 2020 hospital-based PHP geometric mean per diem cost, as of the time of this proposed rule, are $121.62 and $222.76, respectively. As part of this proposal, in the final rule with comment period, we are proposing that we would use the most recent updated claims and cost data to calculate CY 2020 geometric mean per diem costs. The inclusion of a cost floor, which is based on very recent data, would protect providers should the final CY 2020 calculated per diem costs for CMHCs or for hospital-based PHPs result in amounts that are still less than the final CY 2019 CMHC and hospital-based PHP geometric mean per diem costs.

These proposed CY 2020 PHP geometric mean per diem costs are shown in Table 20, and are used to derive the proposed CY 2020 PHP APC per diem rates for CMHCs and hospital-based PHPs. The proposed CY 2020 PHP APC per diem rates 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*).[67]

TABLE 20.—CY 2020 PROPOSED PHP APC GEOMETRIC MEAN PER DIEM COSTS

CY 2020 APC	Group Title	Proposed PHP APC Geometric Mean Per Diem Costs
5853	Partial Hospitalization (3 or more services per day) for CMHCs	$121.62
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	$222.76

3. PHP Service Utilization Updates

a. Provision of Individual Therapy

In the CY 2016 OPPS/ASC final rule with comment period (81 FR 79684 through 79685), we expressed concern over the low frequency of individual therapy provided to beneficiaries. The CY 2018 claims data used for this CY 2020 proposed rule revealed some changes in the provision of individual therapy compared to CY 2015, CY 2016, and CY 2017 claims data as shown in the Table 21.

[67] As discussed in section II.A. of this CY 2020 OPPS/ASC proposed rule, proposed OPPS APC geometric mean per diem costs (including proposed PHP APC geometric mean per diem costs) are divided by the proposed 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 proposed PHP APC per diem payment rates. The OPPS Claims Accounting narrative is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*.

TABLE 21.--PROVISION OF INDIVIDUAL THERAPY, BY PROVIDER TYPE AND CLAIMS YEAR

	Percent of Individual Therapy on Days with 3 Services Only	Percent of Individual Therapy on Days with 4 or More Services
CMHCs		
CY 2015 Claims	7.9%	4.4%
CY 2016 Claims	8.5%	5.0%
CY 2017 Claims	4.0%	4.3%
CY 2018 Claims	3.2.%	4.5%
Hospital-based PHPs		
CY 2015 Claims	4.0%	6.2%
CY 2016 Claims	4.7%	5.8%
CY 2017 Claims	3.9%	5.1%
CY 2018 Claims	3.9%	5.2%

As shown in Table 21, the CY 2018 claims show that both CMHCs and hospital-based PHPs have slightly increased the provision of individual therapy on days with 4 or more services, compared to CY 2017 claims. However, on days with 3 services, CMHCs decreased the provision of individual therapy, while hospital-based PHPs provided the same level of individual therapy as in CY 2017.

b. Provision of 3-Service Days

In the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33640 and 82 FR 59378), we stated that we are aware that our single-tier payment policy may influence a change in service provision because providers are able to obtain payment that is heavily weighted to the cost of providing 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 CMHC APC 5853 and hospital-based PHP APC 5863 for providing 3 or more PHP services per day, we are continuing to monitor utilization of days with only 3 PHP services.

For this CY 2020 OPPS/ASC proposed rule, we used the CY 2018 claims data. Table 22 shows the utilization findings based on the most recent claims data.

TABLE 22.—PERCENTAGE OF PHP DAYS BY SERVICE UNIT FREQUENCY

	CY 2015	CY 2016*	CY 2017*	CY 2018*	% Change**
CMHCs:					
Percent of Days with 3 services	4.7%	4.8%	5.6%	5.2%	-7.1%
Percent of Days with 4 services	62.9%	70.3%	74.0%	75.2%	1.6%
Percent of Days with 5 or more services	32.4%	24.9%	20.5%	19.6%	-4.4%
Hospital-based PHPs:					
Percent of Days with 3 services	12.4%	10.9%	9.8%	11.2%	14.3%
Percent of Days with 4 services	69.8%	64.9%	56.4%	63.1%	11.9%
Percent of Days with 5 or more services	17.8%	24.1%	33.9%	25.7%	-24.2%

*May not sum to 100 percent by provider type due to rounding.
**(CY 2018 – CY 2017) / CY 2017.

As shown in Table 22, the CY 2018 claims data used for this proposed rule showed that PHPs maintained an appropriately low utilization of 3 service days compared to the 3 prior claim years. Compared to CY 2017, in CY 2018 hospital-based PHPs provided slightly more days with 3 services only, more days with 4 services only, and fewer days with 5 or more services. Compared to CY 2017, in CY 2018 CMHCs decreased their provision of 3 service days, slightly increased their provision of days with 4 services, but have decreased their provision of days with 5 or more services.

The CY 2017 data are the first year of claims data to reflect the change to the single-tier PHP APCs. As we noted in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79685), we will continue to monitor the provision of days with only 3 services, particularly now that the single-tier PHP APCs 5853 and 5863 are established for providing 3 or more services per day for CMHCs and hospital-based PHPs, respectively.

It is important to reiterate our expectation that days with only 3 services are meant to be an exception and not the typical PHP day. In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68694), we clearly stated that we consider the acceptable *minimum* units of PHP services required in a PHP day to be 3 and explained that it was never our intention that 3 units of service represent the number of services to be provided in a typical PHP day. PHP is furnished in lieu of inpatient psychiatric hospitalization and is intended to be more intensive than a half-day program. We further indicated that a typical PHP day should generally consist of 5 to 6 units of service (73 FR 68689). We explained that days with only 3 units of services may be appropriate to bill in certain limited circumstances, such as when a patient might need to leave early for a medical appointment and, therefore, would be unable to complete a full day of PHP treatment. At that time, we noted that if a PHP were to only provide days with 3 services, it would be difficult for patients to meet the eligibility requirement in 42 CFR 410.43(c)(1) that patients must require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care (73 FR 68689).

C. Proposed Outlier Policy for CMHCs

In this CY 2020 OPPS/ASC proposed rule, for CY 2020, 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). We set our projected target for all OPPS aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS (82 FR 59267). 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 2020. 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 is greater than 0, then (A × 0.50) = Estimated CMHC Outlier Payment (before cap) = B. If B is greater than (0.08 × Provider's Total Estimated Per Diem Payments), then cap-adjusted B = (0.08 × Provider's Total Estimated Per Diem Payments); otherwise, B = B. Sum (B or cap-adjusted B) for Each Provider = Total CMHC Outlier Payments.

- *Step 3:* We 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 2019, we designated approximately 0.01 percent of that estimated 1.0 percent hospital outpatient outlier threshold for CMHCs (83 FR 58996), based on this methodology. In this proposed rule, we are proposing to continue to use the same methodology for CY 2020. Therefore, based on our CY 2020 payment estimates, CMHCs are projected to receive 0.02 percent of total hospital outpatient payments in CY 2020, excluding outlier payments. We 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). For CY 2018, the highest CMHC PHP APC payment rate is the payment rate for CMHC PHP APC 5853. In addition, in CY 2002, the final OPPS outlier payment percentage for costs above the multiplier threshold was set at 50 percent (66 FR 59889). In CY 2018, we continued to apply the same 50 percent outlier payment percentage that applies to hospitals to CMHCs and continued to use the existing cutoff point (82 FR 59381). Therefore, for CY 2018, we continued to pay for partial hospitalization services that exceeded 3.4 times the CMHC PHP APC payment rate at 50 percent of the amount of CMHC PHP APC geometric mean per diem costs over the cutoff point. For example, for CY 2018, if a CMHC's cost for partial hospitalization services paid under CMHC PHP APC 5853 exceeds 3.4 times the CY 2018 payment rate for CMHC PHP APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.4 times the CY 2018 payment rate for CMHC PHP APC 5853 [0.50 × (CMHC Cost − (3.4 × APC 5853 rate))].

In this CY 2020 OPPS/ASC proposed rule, for CY 2020, 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 2020, 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. CMS initiated steps to ensure that outlier payments appropriately account for the financial risk when providing an extraordinarily costly and complex service, but are only being made for services that legitimately qualify for the additional payment.

For a comprehensive description of outlier reconciliation, we refer readers to the CY 2019 OPPS/ASC final rules with comment period (83 FR 58874 through 58875 and 81 FR 79678 through 79680).

In this CY 2020 OPPS/ASC proposed rule, we are proposing to continue these policies for partial hospitalization services provided through PHPs for CY 2020. The current outlier reconciliation policy requires that providers whose outlier payments meet a specified threshold (currently $500,000 for hospitals and any outlier payments for CMHCs) and whose overall ancillary CCRs change by plus or minus 10 percentage points or more, are subject to outlier reconciliation, pending approval of the CMS Central Office and Regional Office (73 FR 68596 through 68599). The policy also includes provisions related to CCRs and to calculating the

time value of money for reconciled outlier payments due to or due from Medicare, as detailed in the CY 2009 OPPS/ASC final rule with comment period and in the Medicare Claims Processing Manual (73 FR 68595 through 68599 and Medicare Claims Processing internet Only Manual, Chapter 4, Section 10.7.2 and its subsections, available online at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf*).

5. Outlier Payment Cap

In the CY 2017 OPPS/ASC final rule with comment period, we implemented a CMHC outlier payment cap to be applied at the provider level, such that in any given year, an individual CMHC will receive no more than a set percentage of its CMHC total per diem payments in outlier payments (81 FR 79692 through 79695). We finalized the CMHC outlier payment cap to be set at 8 percent of the CMHC's total per diem payments (81 FR 79694 through 79695). This outlier payment cap only affects CMHCs, it does not affect other provider types (that is, hospital-based PHPs), and is in addition to and separate from the current outlier policy and reconciliation policy in effect. For CY 2019, we continued this policy in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58997).

For CY 2020 and subsequent years, we are proposing to continue to apply the 8 percent CMHC outlier payment cap to the CMHC's total per diem payments.

6. Fixed-Dollar Threshold

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 through 59268), for the hospital outpatient outlier payment policy, we set a fixed-dollar threshold in addition to an APC multiplier threshold. Fixed-dollar thresholds are typically used to drive outlier payments for very costly items or services, such as cardiac pacemaker insertions. CMHC PHP APC 5853 is the only APC for which CMHCs may receive payment under the OPPS, and is for providing a defined set of services that are relatively low cost when compared to other OPPS services. Because of the relatively low cost of CMHC services that are used to comprise the structure of CMHC PHP APC 5853, it is not necessary to also impose a fixed-dollar threshold on CMHCs. Therefore, in the CY 2018 OPPS/ASC final rule with comment period, we did not set a fixed-dollar threshold for CMHC outlier payments (82 FR 59381).

In this CY 2020 OPPS/ASC proposed rule, we are proposing to continue this policy for CY 2020.

D. Update to PHP Allowable HCPCS Codes

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58997 through 58998), we discussed that, during the CY 2019 rulemaking, we received the Category I and III CPT codes from the AMA that were new, revised, and deleted, effective January 1, 2019. This included the deleting of the following psychological and neuropsychological testing CPT codes, which affect PHPs, as of January 1, 2019:

- CPT code 96101 (Psychological testing by psychologist/physician);
- CPT code 96102 (Psychological testing by technician);
- CPT code 96103 (Psychological testing administered by computer);
- CPT code 96118 (Neuropsychological testing by psychologist/physician)
- CPT code 96119 (Neuropsychological testing by technician); and
- CPT code 96120 (Neuropsychological test administered w/computer).

In addition, the AMA added the following psychological and neuropsychological testing CPT codes to replace the deleted codes, as of January 1, 2019:

- CPT code 96130 (Psychological testing evaluation by physician/qualified health care professional; first hour);
- CPT code 93131 (Psychological testing evaluation by physician/qualified health care professional; each additional hour);
- CPT code 96132 (Neuropsychological testing evaluation by physician/qualified health care professional; first hour);
- CPT code 96133 (Neuropsychological testing evaluation by physician/qualified health care professional; each additional hour);
- CPT code 96136 (Psychological/neuropsychological testing by physician/qualified health care professional; first 30 minutes);
- CPT code 96137 (Psychological/neuropsychological testing by physician/qualified health care professional; each additional 30 minutes);
- CPT code 96138 (Psychological/neuropsychological testing by technician; first 30 minutes);
- CPT code 96139 (Psychological/neuropsychological testing by technician; each additional 30 minutes); and
- CPT code 96146 (Psychological/neuropsychological testing; automated result only).

As we proposed, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58997 through 58998), we included these replacement codes in Addenda B and O. As is our usual practice for including new and revised Category I and III CPT codes under the OPPS, we included interim APC assignments and status indicators for these codes and provided an opportunity under the OPPS for the public to comment on these interim assignments. That is, we included comment indicator ''NP'' to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year with a proposed APC assignment, and that comments will be accepted on the proposed APC and status indicator assignments.

While these interim APC and status indicator assignments under the OPPS were included in Addendum B and Addendum O to the CY 2019 OPPS/ASC proposed rule and final rule with comment period, PHP is a part of the OPPS and PHP providers may not have been aware of those changes because we did not also include these in the PHP discussion presented in the proposed rule. To ensure that PHP providers were aware of the new and replacement codes related to CMHC and hospital-based partial hospitalization programs and had the opportunity to comment on the changes, we utilized a practice similar to the one we use under the OPPS for new Level II HCPCS codes that become effective after the proposed rule is published. Therefore, in the CY 2019 OPPS/ASC final rule with comment period, we proposed to delete the same 6 CPT codes listed above from the PHP-allowable code set for CMHC APC 5853 and hospital-based PHP APC 5863, and replace them with 9 new CPT codes as shown in Table 47 of the final rule with comment period, effective January 1, 2019. We solicited public comments on these proposals and indicated that we will consider the public comments we receive in response to the CY 2019 final rule with comment period and seek to finalize our proposed actions in the CY 2020 OPPS/ASC final rule with comment period.

We also refer readers to section III.A.4. of this proposed rule for a detailed discussion of how we include new and revised Category I and III CPT codes for a related calendar year, assign interim APC and status indicator assignments, and allow for public

comments on these interim assignments for finalization in the next calendar year final rule with comment period.

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 proposed codes that describe procedures that would be paid by Medicare in CY 2020 as inpatient only procedures is included as Addendum E to this CY 2020 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 2020, 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.

2. Procedures Proposed for Removal From the IPO List

Using the above-listed criteria, for the CY 2020 OPPS, we have identified one procedure described by the following code that we are proposing to remove from the IPO list for CY 2020: CPT code 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty) with or without autograft or allograft). The procedure that we are proposing to remove from the IPO list for CY 2020 and subsequent years, including the CPT/HCPCS code, long descriptor, and the proposed CY 2020 payment indicator is displayed in Table 23 of this proposed rule.

For a number of years, total hip arthroplasty (THA) has been a topic of discussion for removal from the IPO list with both stakeholder support and opposition. Most recently, in the CY 2018 OPPS/ASC proposed rule (82 FR 33644 and 33645), we sought public comment on the possible removal of partial hip arthroplasty (PHA), CPT code 27125 (Hemiarthroplasty, hip, partial (eg, femoral stem prosthesis, bipolar arthroplasty)), and total hip arthroplasty (THA) or total hip replacement, CPT code 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft from the IPO list. Both THA and PHA were placed on the original IPO list in the CY 2001 OPPS/ASC final rule with comment period (65 FR 18780).

Among those commenters expressing support in response to the CY 2018 OPPS/ASC proposed rule (which we summarized and responded to in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52527 through 52528) for removal of THA from the IPO list were several surgeons and other stakeholders who believed that, given thorough preoperative screening by medical teams with significant experience and expertise involving hip replacement procedures, the THA procedure could be provided on an outpatient basis for some Medicare beneficiaries. These commenters noted significant success involving same day discharge for patients who met the screening criteria and whose experienced medical teams were able to perform the procedure early enough in the day for the patients to achieve postoperative goals, allowing home discharge by the end of the day. The commenters believed that the benefits of providing the THA procedure on an outpatient basis would lead to significant enhancements in patient well-being, improved efficiency, and cost savings to the Medicare program, including shorter hospital stays resulting in fewer medical complications, improved results, and enhanced patient satisfaction.

We stated in the CY 2018 OPPS/ASC proposed rule that, like most surgical procedures, both PHA and THA need to be tailored to the individual patient's needs. Patients with a relatively low anesthesia risk and without significant comorbidities who have family members at home who can assist them may likely be good candidates for an outpatient PHA or THA procedure. These patients may be determined to also be able to tolerate outpatient rehabilitation in either an outpatient facility or at home postsurgery. On the other hand, patients with multiple medical comorbidities, aside from their osteoarthritis, would more likely require inpatient hospitalization and possibly postacute care in a skilled nursing facility or other facility. Surgeons who discussed outpatient PHA and THA procedures in public comments in response to our CY 2017 OPPS/ASC proposed rule (81 FR 45679) comment solicitation (which we summarized and responded to in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79696)) on the TKA procedure emphasized the importance of careful patient selection and strict protocols to optimize outpatient hip replacement outcomes. These protocols typically manage all aspects of the patient's care, including the at-home preoperative and postoperative environment, anesthesia, pain management, and rehabilitation to maximize rapid recovery, ambulation, and performance of activities of daily living.

Numerous commenters representing a variety of stakeholders, including physicians and other care providers, individual stakeholders, specialty societies, hospital associations, hospital systems, ASCs, device manufacturers, and beneficiaries, responded to our solicitation of comments regarding the removal of PHA and THA from the IPO list (which we summarized and responded to in CY 2018 OPPS/ASC final rule with comment period (82 FR 52527 through 52528)). The comments were diverse and some were similar to the comments we received on our proposal to remove TKA from the IPO

list. Some commenters, including hospital systems and associations as well as specialty societies and physicians, stated that it would not be clinically appropriate to remove PHA and THA from the IPO list, indicating that the patient safety profile of outpatient THA and PHA in the non-Medicare population is not well-established. Commenters representing orthopedic surgeons also stated that patients requiring a hemiarthroplasty (PHA) for fragility fractures are by nature higher risk, suffer more extensive comorbidities and require closer monitoring and preoperative optimization; therefore, it would not be medically appropriate to remove the PHA procedure from the IPO list.

Other commenters, including ambulatory surgery centers, physicians, and beneficiaries, supported the removal of PHA and THA from the IPO list. These commenters stated that the procedures were appropriate for certain Medicare beneficiaries and most outpatient departments are equipped to provide THA to some Medicare beneficiaries. They also referenced their own personal successful experiences with outpatient THA.

After reviewing the clinical characteristics of the procedure described by CPT code 27130, considering the public comments described earlier from past rules, additional feedback from stakeholders, and with further consultation with our clinical advisors regarding this procedure, we believe that this procedure meets criterion 2 (the simplest procedure described by the code may be performed in most outpatient departments) and criterion 3 (the procedure is related to codes that we have already removed from the IPO list). As such, we believe that appropriately selected patients could have this procedure performed on an outpatient basis. Therefore, we are proposing to remove THA from the IPO list and to assign the THA procedure (CPT code 27130) to C–APC 5115 with status indicator ''J1''. We are seeking public comments on our conclusion that the procedure described by CPT code 27130 meets criteria 2 and 3 and our proposal to assign the procedure to C–APC 5115 with status indicator ''J1''. At this time, we are not proposing to remove PHA from the IPO list because we continue to believe that it does not meet the criteria for removal.

3. Solicitation of Public Comments on the Potential Removal of Procedures Described by CPT Codes 22633, 22634, 63265, 63266, 63267, 63268 From the IPO List

Throughout the years, we have received several public comments on additional CPT codes that stakeholders believe fit our criteria and should be removed from the IPO list. In this CY 2020 OPPS/ASC proposed rule, we are seeking public comment on the removal of the following procedures from the IPO list in Table 23.

TABLE 23.—IPO List CPT Codes to be Potentially Removed from the IPO List

CPT Code	Long Descriptor
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/ or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar;
22634	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/ or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar;| each additional interspace and segment
63265	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; cervical
63266	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; thoracic
63267	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar
63268	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; sacral

We have reviewed the clinical characteristics of CPT code 22633 and CPT code 22634 and believe that they are related to codes that we have already removed from the IPO list. Specifically, stakeholders have suggested that CPT codes 22633 and 22634 are related to CPT code 22551(Arthrodesis, anterior interbody, including disc space

preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below c2), which is currently performed in the outpatient hospital setting. However, after reviewing the current data available on CPT codes 22633 and 22634, we are concerned that the available data do not provide a large enough sampling of outpatient procedures and do not directly address the criteria for removal from the IPO list. At this time, we are seeking public comments that would provide additional information on the safety of performing CPT codes 22633 and 22634 in the outpatient hospital setting.

In addition, we have reviewed CPT codes 63265, 63266, 63267, and 63268. Over the years, stakeholders have indicated that this series of CPT codes should be considered minimally invasive, arguing that CPT codes 63265, 63266, 63267, and 63268 meet criteria one and two for removal from the IPO list: Most outpatient departments are equipped to provide the services to the Medicare population and the simplest procedure described by the code may be performed in most outpatient departments. At this time, we do not believe that there is sufficient information to demonstrate that CPT codes 63265, 63266, 63267, and 63268 meet the IPO list removal criteria. However, we are seeking public comment on whether CPT codes 63265 through 63268 meet criteria to be removed from the IPO list, including information from commenters to demonstrate that the codes meet these criteria.

Table 24 contains the proposed change that we are proposing to make to the IPO list for CY 2020.

TABLE 24.—PROPOSED CHANGE TO THE INPATIENT ONLY (IPO) LIST FOR CY 2020

CY 2019 CPT Code	CY 2019 Long Descriptor	Proposed Action	Proposed CY 2020 OPPS APC Assignment	Proposed CY 2020 OPPS Status Indicator
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty) with or without autograft or allograft	Remove from the IPO	5115	J1

X. Proposed Nonrecurring Policy Changes

A. Proposed Changes in the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals (CAHs)

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59390 through 59391) and in the CY 2009 OPPS/ASC proposed rule and final rule with comment period (73 FR 41518 through 41519 and 73 FR 68702 through 68704, respectively), we clarified that direct supervision is required for hospital outpatient therapeutic services covered and paid by Medicare that are furnished in hospitals as well as in provider-based departments (PBDs) of hospitals, as set forth in the CY 2000 OPPS final rule with comment period (65 FR 18525). In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60575 through 60591), we finalized a technical correction to the title and text of the applicable regulation at 42 CFR 410.27 to clarify that this standard applies in critical access hospitals (CAHs) as well as hospitals. In response to concerns expressed by the hospital community, in particular CAHs and small rural hospitals, that they would have difficulty meeting this standard, on March 15, 2010, we instructed all MACs not to evaluate or enforce the supervision requirements for therapeutic services provided to outpatients in CAHs from January 1, 2010 through December 31, 2010, while the agency revisited the supervision policy during the CY 2011 OPPS/ASC rulemaking cycle.

Due to continued concerns expressed by CAHs and small rural hospitals, we extended this notice of nonenforcement (''enforcement instruction'') as an interim measure for CY 2011, and expanded it to apply to small rural hospitals having 100 or fewer beds (75 FR 72007). We continued to consider the issue further in our annual OPPS notice-and-comment rulemaking, and implemented an independent review process in 2012 to obtain advice from the HOP Panel on this matter (76 FR 74360 through 74371). Under this process used since CY 2012, the HOP Panel considers and advises CMS regarding stakeholder requests for changes in the required minimum level of supervision of individual hospital outpatient therapeutic services. In addition, we extended the enforcement instruction through CY 2012 and CY 2013. For the period of CY 2014 through CY 2017, Congress took legislative action (Pub. L. 113–198, Pub. L. 114–112, Pub. L. 114–255, and Pub. L. 115–123) to extend nonenforcement of the direct supervision requirement for hospital outpatient therapeutic services in CAHs and small rural hospitals having 100 or fewer beds through December 31, 2017. Then in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59391), we reinstated the enforcement instruction providing for the nonenforcement of the direct supervision requirement for hospital outpatient therapeutic services in CAHs and small rural hospitals having 100 or fewer beds through December 31, 2019. The current enforcement instruction is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Supervision-Moratorium-on-Enforcement-for-CAHs-and-Certain-Small-Rural-Hospitals.pdf*.

As discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59390 through 59391), stakeholders have consistently requested that CMS continue the nonenforcement of the direct supervision requirement for hospital outpatient therapeutic services for CAHs and small rural hospitals having 100 or fewer beds. Stakeholders stated that some small rural hospitals and CAHs have insufficient staff available to furnish direct supervision. The primary reason stakeholders cited for this request is the difficulty that CAHs and small rural hospitals have in

recruiting physicians and nonphysician practitioners to practice in rural areas. These stakeholders noted that it is particularly difficult to furnish direct supervision for critical specialty services, such as radiation oncology services, that cannot be directly supervised by a hospital emergency department physician or nonphysician practitioner because of the volume of emergency patients or lack of specialty expertise. In addition, we are not aware of any supervision-related complaints from beneficiaries or providers regarding quality of care for services furnished during the several years that the enforcement instruction has been in effect.

The upcoming expiration of the latest enforcement instruction providing for the nonenforcement of the direct supervision requirement for hospital outpatient therapeutic services for CAHs and small rural hospitals having 100 or fewer beds has prompted us to consider whether to change the level of supervision for hospital outpatient therapeutic services for all hospitals and CAHs. The enforcement instructions and legislative actions that have been in place since 2010 have created a two-tiered system of physician supervision requirements for hospital outpatient therapeutic services for providers in the Medicare program, with direct supervision required for most hospital outpatient therapeutic services in most hospital providers, but only general supervision required for most hospital outpatient therapeutic services in CAHs and small rural hospitals with fewer than 100 beds.

However, we have not learned of any data or information from CAHs and small rural hospitals indicating that the quality of outpatient therapeutic services has been affected by requiring only general supervision for these services. It is important to remember that the requirement for general supervision for outpatient therapeutic services does not preclude these hospitals from providing direct supervision for outpatient therapeutic services when the physicians administering the medical procedures decide that it is appropriate to do so. Many outpatient therapeutic services involve a level of complexity and risk such that direct supervision would be warranted even though only general supervision is required.

In addition, CAHs and hospitals in general continue to be subject to conditions of participation (CoPs) that complement the general supervision requirements for hospital outpatient therapeutic services to ensure that the medical services Medicare patients receive are properly supervised. The CoPs for hospitals require Medicare patients to be under the care of a physician (42 CFR 482.12(c)(4))), and for the hospital to ''have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the hospital'' (42 CFR 482.22). The CoPs for CAHs (42 CFR 485.631(b)(1)(i)) require physicians to provide medical direction for the CAHs' health care activities, consultation for, and medical supervision of the health care staff. The physicians' responsibilities in hospitals and CAHs include supervision of all services performed at those facilities. In addition, physicians must also follow State laws regarding scope of practice. Failure of doctors of medicine or osteopathy to provide adequate supervision in accordance with the hospital and CAH CoPs does not cause payment to be denied for that individual service. However, consistent violations of the CoP supervision requirements can lead to a provider having to establish a corrective action plan to address supervision deficiencies, and if the provider still fails to meet the CoP requirements, the hospital or CAH can be terminated from Medicare participation.

Our experience indicates that Medicare providers will provide a similar quality of hospital outpatient therapeutic services, regardless of whether the minimum level of supervision required under the Medicare program is direct or general. We have come to believe that the direct supervision requirement for hospital outpatient therapeutic services places an additional burden on providers that reduces their flexibility to provide medical care. The issues with increased burden and reduced flexibility to provide medical care have a more significant impact on CAHs and small rural hospitals due to their recruiting and staffing challenges, as we have recognized over the years in providing for nonenforcement of the policy for these hospitals. Larger hospitals and hospitals in urban or suburban areas are less affected by the burden and reduced flexibility of the direct supervision requirement. However, given that the direct supervision requirement has not yet been enforced for CAHs and small rural hospitals, we believe it is time to end what is effectively a two-tiered system of supervision levels for hospital outpatient therapeutic services by proposing a policy that sets an appropriate and uniformly enforceable supervision standard for all hospital outpatient therapeutic services.

Therefore, we are proposing to change the generally applicable minimum required level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision for services furnished by all hospitals and CAHs. General supervision, as defined in our regulation at 42 CFR 410.32(b)(3)(i) means that the procedure is furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure. This proposal would ensure a standard minimum level of supervision for each hospital outpatient therapeutic service furnished incident to a physician's service in accordance with the statute. We are proposing to amend the existing regulation at § 410.27(a)(1)(iv) to provide that the default minimum level of supervision for each hospital outpatient therapeutic service is ''general.''

We will continue to have the HOP Panel provide advice on the appropriate supervision levels for hospital outpatient services as described in section I.E.2. of this proposed rule. We will also retain the ability to consider a change to the supervision level of an individual hospital outpatient therapeutic service to a level of supervision that is more intensive than general supervision through notice and comment rulemaking. We are seeking public comments on this proposal. Additionally, we are seeking public comments on whether specific types of services, such as chemotherapy administration or radiation therapy, should be excepted from this proposal.

B. Short Inpatient Hospital Stays

1. Background on the 2-Midnight Rule

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50913 through 50954), we clarified our policy regarding when an inpatient admission is considered reasonable and necessary for purposes of Medicare Part A payment. Under this policy, we established a benchmark providing that surgical procedures, diagnostic tests, and other treatments would be generally considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation. Conversely, when a beneficiary enters a hospital for a surgical procedure not designated as an inpatient-only (IPO) procedure as

described in 42 CFR 419.22(n), a diagnostic test, or any other treatment, and the physician expects to keep the beneficiary in the hospital for only a limited period of time that does not cross 2 midnights, the services would be generally inappropriate for payment under Medicare Part A, regardless of the hour that the beneficiary came to the hospital or whether the beneficiary used a bed. With respect to services designated under the OPPS as IPO procedures, we explained that because of the intrinsic risks, recovery impacts, or complexities associated with such services, these procedures would continue to be appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay. We also indicated that there might be further ''rare and unusual'' exceptions to the application of the benchmark, which would be detailed in subregulatory guidance.

2. Current Policy for Medical Review of Inpatient Hospital Admissions Under Medicare Part A

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70538 through 70549), we revised the previous rare and unusual exceptions policy and finalized a proposal to allow for case-by-case exceptions to the 2-midnight benchmark, whereby Medicare Part A payment may be made for inpatient admissions where the admitting physician does not expect the patient to require hospital care spanning 2 midnights, if the documentation in the medical record supports the physician's determination that the patient nonetheless requires inpatient hospital care.

We note that, in the CY 2016 OPPS/ASC final rule with comment period, we reiterated our position that the 2-midnight benchmark provides clear guidance on when a hospital inpatient admission is appropriate for Medicare Part A payment, while respecting the role of physician judgment. We stated that the following criteria will be relevant to determining whether an inpatient admission with an expected length of stay of less than 2 midnights is nonetheless appropriate for Medicare Part A payment:

- Complex medical factors such as history and comorbidities;
- The severity of signs and symptoms;
- Current medical needs; and
- The risk of an adverse event.

In other words, for purposes of Medicare payment, an inpatient admission is payable under Part A if the documentation in the medical record supports either the admitting physician's reasonable expectation that the patient will require hospital care spanning at least 2 midnights, or the physician's determination based on factors such as those identified above that the patient nonetheless requires care on an inpatient basis. The exceptions for procedures on the IPO list and for ''rare and unusual'' circumstances designated by CMS as national exceptions were unchanged by the CY 2016 OPPS/ASC final rule with comment period.

As we stated in the CY 2016 OPPS/ASC final rule with comment period, the decision to formally admit a patient to the hospital is subject to medical review. For instance, for cases where the medical record does not support a reasonable expectation of the need for hospital care crossing at least 2 midnights, and for inpatient admissions not related to a surgical procedure specified by Medicare as an IPO procedure under 42 CFR 419.22(n) or for which there was not a national exception, payment of the claim under Medicare Part A is subject to the clinical judgment of the medical reviewer. The medical reviewer's clinical judgment involves the synthesis of all submitted medical record information (for example, progress notes, diagnostic findings, medications, nursing notes, and other supporting documentation) to make a medical review determination on whether the clinical requirements in the relevant policy have been met. In addition, Medicare review contractors must abide by CMS' policies in conducting payment determinations, but are permitted to take into account evidence-based guidelines or commercial utilization tools that may aid such a decision. While Medicare review contractors may continue to use commercial screening tools to help evaluate the inpatient admission decision for purposes of payment under Medicare Part A, such tools are not binding on the hospital, CMS, or its review contractors. This type of information also may be appropriately considered by the physician as part of the complex medical judgment that guides their decision to keep a beneficiary in the hospital and formulation of the expected length of stay.

3. Proposed Change for Medical Review of Certain Inpatient Hospital Admissions Under Medicare Part A for CY 2020 and Subsequent Years

As stated earlier in this section, the procedures on the IPO list of procedures under the OPPS are not subject to the 2-midnight benchmark for purposes of inpatient hospital payment. However, the 2-midnight benchmark is applicable once procedures have been removed from the IPO list. Procedures that are removed from the IPO list are also subject to initial medical reviews of claims for short-stay inpatient admissions conducted by Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC–QIOs).

BFCC–QIOs may also refer providers to the Recovery Audit Contractors (RACs) for further medical review due to exhibiting persistent noncompliance with Medicare payment policies, including, but not limited to:

- Having high denial rates;
- Consistently failing to adhere to the 2-midnight rule; or
- Failing to improve their performance after QIO educational intervention.

As part of our continued effort to facilitate compliance with our payment policy for inpatient admissions, we are proposing to establish a 1-year exemption from certain medical review activities for procedures removed from the IPO list under the OPPS in CY 2020 and subsequent years. Specifically, we are proposing that procedures that have been removed from the IPO list would not be eligible for referral to RACs for noncompliance with the 2-midnight rule within the first calendar year of their removal from the IPO list. These procedures would not be considered by the BFCC–QIOs in determining whether a provider exhibits persistent noncompliance with the 2-midnight rule for purposes of referral to the RAC nor would these procedures be reviewed by RACs for ''patient status.'' During this 1-year period, BFCC–QIOs would have the opportunity to review such claims in order to provide education for practitioners and providers regarding compliance with the 2-midnight rule, but claims identified as noncompliant would not be denied with respect to the site-of-service under Medicare Part A. Again, information gathered by the BFCC–QIO when reviewing procedures that are newly removed from the IPO list could be used for educational purposes and would not result in a claim denial during the proposed 1-year exemption period.

We believe that a 1-year exemption from BFCC–QIO referral to RACs and RAC ''patient status'' review of the setting for procedures removed from the IPO list under the OPPS and performed in the inpatient setting would be an adequate amount of time to allow providers to gain experience with application of the 2-midnight rule to these procedures and the

documentation necessary for Part A payment for those patients for which the admitting physician determines that the procedures should be furnished in an inpatient setting. Furthermore, we believe that this 1-year exemption from referrals to RACs, RAC patient status review, and claims denials would be sufficient to allow providers time to update their billing systems and gain experience with respect to newly removed procedures eligible to be paid under either the IPPS or the OPPS, while avoiding potential adverse site-of-service determinations. Nonetheless, we are soliciting public comments regarding the appropriate period of time for this proposed exemption. Commenters may indicate whether and why they believe the proposed 1-year period is appropriate, or whether they believe a longer or shorter exemption period would be more appropriate.

In summary, for CY 2020 and subsequent years, we are proposing to establish a 1-year exemption from site-of-service claim denials, BFCC–QIO referrals to RACs, and RAC reviews for ''patient status'' (that is, site-of-service) for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2020. We encourage BFCC–QIOs to review these cases for medical necessity in order to educate themselves and the provider community on appropriate documentation for Part A payment when the admitting physician determines that it is medically reasonable and necessary to conduct these procedures on an inpatient basis. We note that we will monitor changes in site-of-service to determine whether changes may be necessary to certain CMS Innovation Center models.

C. Method To Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59014), we adopted a method to control unnecessary increases in the volume of the clinic visit service furnished in excepted off-campus provider-based departments (PBDs) by removing the payment differential that drives the site-of-service decision and, as a result, unnecessarily increases service volume. We refer readers to the CY 2019 OPPS/ASC final rule with comment period for a detailed discussion of the background, legislative provisions, and the changes in payment policies we developed to address increases in the volume of covered OPD services. Below we discuss the specific policy we finalized in the CY 2019 OPPS/ASC final rule with comment period and its application under the OPPS for CY 2020.

For the CY 2019 OPPS, using our authority under section 1833(t)(2)(F) of the Act to adopt a method to control unnecessary increases in the volume of covered outpatient department services, we applied an amount equal to the site-specific Medicare Physician Fee Schedule (PFS) payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate) for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier ''PO'' on claim lines). However, we phased in the application of the reduction in payment for the clinic visit service described by HCPCS code G0463 in the excepted provider-based department setting over 2 years. For CY 2019, the payment reduction was transitioned by applying 50 percent of the total reduction in payment that was applied if these departments were paid the site-specific PFS rate for the clinic visit service. The PFS-equivalent rate was 40 percent of the OPPS payment for CY 2019 (that is, 60 percent less than the OPPS rate). We provided for a 2-year phase-in of this policy under which one-half of the total 60-percent payment reduction (a 30-percent reduction) was applied in CY 2019. These departments are paid approximately 70 percent of the OPPS rate (100 percent of the OPPS rate minus the 30-percent payment reduction that is applied in CY 2019) for the clinic visit service in CY 2019.

For CY 2020, the second year of the 2-year phase-in, we stated that we would apply the total reduction in payment that is applied if these departments (departments that bill the modifier ''PO'' on claims lines) are paid the site-specific PFS rate for the clinic visit service described by HCPCS code G0463. The proposed PFS-equivalent rate for CY 2020 is 40 percent of the proposed OPPS payment (that is, 60 percent less than the proposed OPPS rate) for CY 2020. Under this policy, departments will be paid approximately 40 percent of the OPPS rate (100 percent of the OPPS rate minus the 60-percent payment reduction that is applied in CY 2020) for the clinic visit service in CY 2020.

In addition, as we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013), for CY 2020, this policy will be implemented in a non-budget neutral manner. The estimated payment impact of this policy is displayed in Column 5 of Table 44—Estimated Impact of the Proposed CY 2020 Changes for the Hospital Outpatient Prospective Payment System in this CY 2020 OPPS/ASC proposed rule. In order to effectively establish a method for controlling the unnecessary growth in the volume of clinic visits furnished by excepted off-campus PBDs that does not simply 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 policy is further described in section XXVI. of this CY 2020 OPPS/ASC proposed rule.

XI. Proposed CY 2020 OPPS Payment Status and Comment Indicators

A. Proposed CY 2020 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system, and also, whether particular OPPS policies apply to the code.

For CY 2020, we are not proposing to make any changes to the definitions of status indicators that were listed in Addendum D1 to the CY 2019 OPPS/ASC final rule with comment period available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1717-P.html?DLPage=1&DLEntries=10&10DLSort=2DLSortDir=descending.*

We are requesting public comments on the proposed definitions of the OPPS status indicators for CY 2020. The complete list of the proposed payment status indicators and their definitions that would apply for CY 2020 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 2020 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 2020 Comment Indicator Definitions

In this proposed rule, we are proposing to use four comment indicators for the CY 2020 OPPS. These comment indicators, ''CH'', ''NC'', ''NI'', and ''NP'', are in effect for CY 2019 and we are proposing to continue their use in CY 2020. The proposed CY 2020 OPPS comment indicators are as follows:

- ''CH''—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.
- ''NC''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year for which we requested comments in the proposed rule, final APC assignment; comments will *not* be accepted on the final APC assignment for the new code.
- ''NI''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.
- ''NP''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.

The definitions of the proposed OPPS comment indicators for CY 2020 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. MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) was established under section 1805 of the Act in large part to advise the U.S. Congress on issues affecting the Medicare program. As required under the statute, MedPAC submits reports to the Congress no later than March and June of each year that present its Medicare payment policy recommendations. The March report typically provides discussion of Medicare payment policy across different payment systems and the June report typically discusses selected Medicare issues. We are including this section of the proposed rule to make stakeholders aware of certain MedPAC recommendations for the OPPS and ASC payment systems as discussed in its March 2019 report.

A. OPPS Payment Rates Update

The March 2019 MedPAC ''Report to the Congress: Medicare Payment Policy'' recommended that Congress update Medicare OPPS payment rates of 2 percent, with the difference between this and the update amount specified in current law to be used to increase payments in a new suggested Medicare quality program, the ''Hospital Value Incentive Program (HVIP).'' We refer readers to the March 2019 MedPAC report, which is available for download at *www.medpac.gov*, for a complete discussion on these recommendations. We appreciate MedPAC's recommendations, but as MedPAC acknowledged in its report, Congress would need to change current law to enable us to implement its recommendations.

B. ASC Conversion Factor Update

In the March 2019 MedPAC ''Report to the Congress: Medicare Payment Policy'' MedPAC found that, based on its analysis of indicators of payment adequacy, the number of Medicare-certified ASCs had increased, beneficiaries' use of ASCs had increased, and ASC access to capital has been adequate.[68] As a result, for CY 2020, MedPAC stated that payments to ASCs are adequate and recommended that no payment update should be given for 2020 (that is, the update factor would be 0 percent).

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59079), we adopted a policy, which we codified at 42 CFR 416.171(a)(2), to apply the hospital market basket update to ASC payment system rates for an interim period of 5 years. We refer the reader to the CY 2019 OPPS/ASC final rule with comment period for complete details regarding our policy to use the hospital market basket update for the ASC payment system. Therefore, consistent with our policy for the ASC payment system, we are proposing to apply a 2.7 percent MFP-adjusted hospital market basket update factor to the CY 2019 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2020 ASC payment amounts. See section XIII of this proposed rule for a complete explanation of our relevant policies.

C. ASC Cost Data

MedPAC recommended that Congress require ASCs to report cost data to enable the Commission to examine the growth of ASCs' costs over time and analyze Medicare payments relative to the costs of efficient providers, and that CMS could use ASC cost data to examine whether an existing Medicare price index is an appropriate proxy for ASC costs or an ASC specific market basket should be developed. Further, MedPAC suggested that CMS could limit the scope of the cost reporting system to minimize administrative burden on ASCs and the program.[69]

We recognize that the submission of cost data places additional administrative burden on ASCs. We are interested in methods that would mitigate the burden of reporting costs on ASCs while also collecting enough data to reliably use such data in the determination of ASC costs. We are not proposing any cost reporting requirements for ASCs in this CY 2020 OPPS/ASC proposed rule.

The full March 2019 MedPAC report can be downloaded from MedPAC's website at: *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec.pdf*.

XIII. 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, 2018 and 2019 OPPS/ASC final rules with comment period (76 FR 74378 through 74379; 77 FR 68434 through 68467; 78 FR 75064 through 75090; 79 FR 66915 through 66940; 80 FR 70474 through 70502; 81 FR 79732 through 79753; 82 FR 59401 through 59424; and 83 FR 59028 through 59080, respectively).

[68] Medicare Payment Advisory Committee. March 2019 Report to the Congress. Chapter 5: Ambulatory surgical center services. Available at: *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch5_sec.pdf?sfvrsn=0*.

[69] Medicare Payment Advisory Committee. March 2019 Report to the Congress. Chapter 5: Ambulatory surgical center services. Available at: *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch5_sec.pdf?sfvrsn=0*.

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. Historically, we have defined surgical procedures as those described by Category I CPT codes in the surgical range from 10000 through 69999 as well as those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined do not pose a significant safety risk, that we would not expect to require an overnight stay when performed in ASCs, and that are separately paid under the OPPS (72 FR 42478).

In the August 2, 2007 final rule (72 FR 42495), we also established our policy to make separate ASC payments for the following ancillary items and services when they are provided integral to ASC covered surgical procedures: (1) Brachytherapy sources; (2) certain implantable items that have pass-through payment status under the OPPS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; and (5) certain radiology services for which separate payment is allowed under the OPPS. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66932 through 66934), we expanded the scope of ASC covered ancillary services to include certain diagnostic tests within the medicine range of 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 74384).

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures (including all procedures newly proposed for removal from the OPPS inpatient list), new codes, and codes with revised descriptors, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of ASC covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of many covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

3. Definition of ASC Covered Surgical Procedures

Since the implementation of the ASC prospective payment system, we have historically defined a ''surgical'' procedure under the payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the 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 that 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).

However, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59029 through 59030), after consideration of public comments received in response to the CY 2019 proposed rule and earlier OPPS/ASC rulemaking cycles, we revised our definition of a surgical procedure under the ASC payment system. We now

define a surgical procedure under the ASC payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the American Medical Association (AMA) defines as ''surgery'' (CPT codes 10000 through 69999) (72 FR 42476), as well as procedures that are described by Level II HCPCS codes or by Category I CPT codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined are not expected to pose a significant risk to beneficiary safety when performed in an ASC, for which standard medical practice dictates that the beneficiary would not typically be expected to require an overnight stay following the procedure, and are separately paid under the OPPS.

B. Proposed ASC Treatment of New and Revised Codes

1. Background on Current Process for Recognizing New and Revised HCPCS Codes

Payment for ASC procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on ASC claims. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system maintained by the American Medical Association (AMA), and includes Category I, II, and III CPT codes. Level II of the HCPCS, which is maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Together, Level I and II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes (also known as alphanumeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 final rule (72 FR 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 2020 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 2020 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2020 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2021 OPPS/ASC final rule with comment period).

2. April 2019 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For the April 2019 update, there were no new CPT codes, however, there were several new Level II HCPCS codes. In the April 2019 ASC quarterly update (Transmittal 4263, CR 11232, dated March 22, 2019), we added eight new Level II HCPCS codes to the list of covered ancillary services. Table 25 list the new Level II HCPCS codes that were implemented April 1, 2019, along with their proposed payment indicators for CY 2020. The proposed comment indicators, payment indicators and payment rates, where applicable, for these April codes can be found in Addendum BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. These new codes that are effective April 1, 2019 are assigned to comment indicator ''NP'' in Addendum BB to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments. Also, the list of comment indicators and definitions used under the ASC can be found in Addendum DD2 to this proposed rule. We note that ASC Addendum BB, Addendum DD1, and Addendum DD2 are available via the internet on the CMS website.

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TABLE 25.—NEW LEVEL II HCPCS CODES FOR ANCILLARY SERVICES EFFECTIVE ON APRIL 1, 2019

CY 2019 HCPCS Code	CY 2019 Long Descriptor	Proposed CY 2020 CI	Proposed CY 2020 PI
C9040	Injection, fremanezumab-vfrm, 1mg	NP	K2
C9041	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	NP	K2
C9042*	Injection, bendamustine hcl (belrapzo), 1 mg	CH	D5
C9043	Injection, levoleucovorin, 1 mg	NP	K2
C9044	Injection, cemiplimab-rwlc, 1 mg	NP	K2
C9045	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	NP	K2
C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	NP	K2
C9141**	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	CH	D5

*HCPCS code C9042, which was effective April 1, 2019, was deleted June 30, 2019 and replaced with HCPCS code J9036 (Injection, bendamustine hydrochloride, (Belrapzo/bendamustine), 1 mg) effective July 1, 2019.

**HCPCS code C9141, which was effective April 1, 2019, was deleted June 30, 2019 and replaced with HCPCS code J7208 (Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, (jivi), 1 i.u.), 1 mg) effective July 1, 2019.

We are inviting public comments on these proposed payment indicators and payment rates for the new HCPCS codes that were recognized as ASC ancillary services in April 2019 through the quarterly update CRs, as listed in Table 25. We are proposing to finalize their payment indicators in the CY 2020 OPPS/ASC final rule with comment period.

3. July 2019 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

In the July 2019 ASC quarterly update (Transmittal 4076, Change Request 10788, dated June 14, 2019), we added several separately payable Category III CPT and Level II HCPCS codes to the list of covered surgical procedures and ancillary services. Table 26 lists the new HCPCS codes that are effective July 1, 2019. The proposed payment indicators and payment rates for these codes can be found in Addendum AA and Addendum BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. These new codes that are effective July 1, 2019 are assigned to comment indicator ''NP'' in Addendum BB to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments. Also, the list of comment indicators and definitions used under the ASC can be found in Addendum DD2 to this proposed rule. We note that ASC Addendum BB, Addendum DD1, and Addendum DD2 are available via the internet on the CMS website.

TABLE 26.—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES AND ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2019

CY 2019 HCPCS Code	CY 2019 Long Descriptor	Proposed CY 2020 CI	Proposed CY 2020 PI
C9047	Injection, caplacizumab-yhdp, 1 mg	NP	K2
C9048	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	NP	K2
C9049	Injection, tagraxofusp-erzs, 10 mcg	NP	K2
C9050	Injection, emapalumab-lzsg, 1 mg	NP	K2
C9051	Injection, omadacycline, 1 mg	NP	K2
C9052	Injection, ravulizumab-cwvz, 10 mg	NP	K2
J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, (jivi), 1 i.u.	NP	K2
J9030	BCG live intravesical instillation, 1 mg	NP	K2
J9036	Injection, bendamustine hydrochloride, (Belrapzo/bendamustine), 1 mg	NP	K2
J9356	Injection, trastuzumab, 10 mg and Hyaluronidase-oysk	NP	K2
0548T*	Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy	NP	J8
0549T	Transperineal periurethral balloon continence device; unilateral placement, including cystoscopy and fluoroscopy	NP	J8
0550T	Transperineal periurethral balloon continence device; removal, each balloon	NP	G2
0551T	Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume	NP	R2

*The predecessor code for CPT code 0548T was HCPCS code C9746 (Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed), which was effective July 1, 2017 and deleted on June 30, 2019.

In addition, through the July 2019 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, 2019. This code is listed in Table 27, along with the proposed comment indicator and payment indicator. The CY 2020 proposed payment rate for this new Category III CPT code can be found in Addendum BB. As noted above, the list of payment indicators and comment indicators used under the ASC can be found in Addendum DD1 and DD2, respectively, of this proposed rule. We note that ASC Addendum BB, Addendum DD1, and Addendum DD2 are available via the internet on the CMS website.

TABLE 27.—NEW CATEGORY III CPT CODE FOR COVERED ANCILLARY SERVICE EFFECTIVE ON JULY 1, 2019

CY 2019 HCPCS Code	CY 2019 Long Descriptor	Proposed CY 2020 CI	Proposed CY 2020 PI
0558T	Computed tomography scan taken for the purpose of biomechanical computed tomography analysis	NP	Z2

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We are inviting public comments on these proposed payment indicators for the new Category III CPT code and Level II HCPCS codes newly recognized as ASC covered surgical procedures or covered ancillary services in July 2019 through the quarterly update CRs, as listed in Tables 25, 26, and 27. We are proposing to finalize the payment indicators in the CY 2020 OPPS/ASC final rule with comment period.

4. October 2019 HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2020 OPPS/ASC Final Rule With Comment Period

For CY 2020, consistent with our established policy, we are proposing that the Level II HCPCS codes that will be effective October 1, 2019, would be flagged with comment indicator ''NI'' in Addendum BB to the CY 2020 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim ASC payment status for CY 2020. We will invite public comments in the CY 2020 OPPS/ASC final rule with comment period on the interim payment indicators, which would then be finalized in the CY 2021 OPPS/ASC final rule with comment period.

5. January 2020 HCPCS Codes

a. Level II HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2020 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Level II HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the ASC payment system for the calendar year. We note that unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the G-codes listed in Addendum O to this proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Therefore, these Level II HCPCS codes will be released to the public through the CY 2020 OPPS/ASC final rule with comment period, January 2020 ASC Update CR, and the CMS HCPCS website.

In addition, for CY 2020, we will propose to continue our established policy of assigning comment indicator ''NI'' in Addendum AA and Addendum BB to the OPPS/ASC final rule with comment period to the new Level II HCPCS codes that will be effective January 1, 2020 to indicate that we are assigning them an interim payment indicator, which is subject to public comment. We will be inviting public comments in the CY 2020 OPPS/ASC final rule with comment period on the payment indicator assignments, which would then be finalized in the CY 2021 OPPS/ASC final rule with comment period.

b. CPT Codes for Which We Will Be Soliciting Public Comments in This Proposed Rule

For new and revised CPT codes effective January 1, 2020 that were received in time to be included in this proposed rule, we are proposing the appropriate payment indicator assignments, and soliciting public comments on the payment assignments. We will accept comments and finalize the payment indicators in the CY 2020 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 2020 ASC update, the new and revised Category I and III CPT codes that will be effective on January 1, 2020, 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 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 2020 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 to this proposed rule, specifically under the column labeled ''CY 2020 OPPS/ASC Proposed Rule 5-Digit Placeholder Code.'' The final CPT code numbers will be included in the CY 2020 OPPS/ASC final rule with comment period where possible.

In summary, we are soliciting public comments on the proposed CY 2020 payment indicators for the new and revised Category I and III CPT codes that will be effective January 1, 2020. Because these codes are listed in Addendum AA and Addendum BB with short descriptors only, we are listing them again in Addendum O with the long descriptors. We are also proposing to finalize the payment indicator for these codes (with their final CPT code numbers) in the CY 2020 OPPS/ASC final rule with comment period. The proposed payment indicator and comment indicator for these codes can be found in Addendum AA and Addendum BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. The new CPT codes that will be effective January 1, 2020 are assigned to comment indicator ''NP'' in Addendum AA and Addendum BB to this proposed rule to indicate that the codes are assigned to an interim payment indicator and that comments will be accepted on their interim ASC payment assignments. Also, the list of comment indicators and definitions used under the ASC can be found in Addendum DD2 to this proposed rule. We note that ASC Addendum BB, Addendum DD1, and Addendum DD2 are available via the internet on the CMS website.

Finally, in Table 28, we summarize our process for updating codes through our ASC quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the ASC.

TABLE 28.—COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED HCPCS CODES

ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2019	HCPCS (CPT and Level II codes)	April 1, 2019	CY 2020 OPPS/ASC proposed rule	CY 2020 OPPS/ASC final rule with comment period
July 2019	HCPCS (CPT and Level II codes)	July 1, 2019	CY 2020 OPPS/ASC proposed rule	CY 2020 OPPS/ASC final rule with comment period
October 2019	HCPCS (CPT and Level II codes)	October 1, 2019	CY 2020 OPPS/ASC final rule with comment period	CY 2021 OPPS/ASC final rule with comment period
January 2020	CPT Codes	January 1, 2020	CY 2020 OPPS/ASC proposed rule	CY 2020 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2020	CY 2020 OPPS/ASC final rule with comment period	CY 2021 OPPS/ASC final rule with comment period

C. 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 Covered Procedures List (CPL) in CY 2008 or later years that we determine are performed predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC CPL beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that rule by payment indicator ''P2'' (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight); ''P3'' (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or ''R2'' (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated the procedure would be paid according to the standard ASC payment methodology based on its OPPS relative payment weight or at the MPFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the ASC CPL to include all covered surgical procedures eligible for payment in ASCs, each year we identify covered surgical procedures as either temporarily office-based (these are new procedure codes with little or no utilization data that we have determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or nonoffice-based, after taking into account updated volume and utilization data.

(2) Proposed Changes for CY 2020 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 2018 volume and utilization data and the clinical characteristics for all covered surgical procedures that are assigned payment indicator ''G2'' (Nonoffice-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) in CY 2018, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2'', ''P3'', or ''R2'' in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59039 through 59040).

As we stated in the CY 2019 final rule with comment period (83 FR 59036), the office-based utilization for CPT codes 36902 and 36905 (dialysis vascular

access procedures) was greater than 50 percent. However, we did not designate CPT codes 36902 and 36905 as office-based procedures for CY 2019. These codes became effective January 1, 2017 and CY 2017 was the first year we had claims volume and utilization data for CPT codes 36902 and 36905. We shared commenters' concerns that the available data were not adequate to make a determination that these procedures should be office-based, and believed it was premature to assign office-based payment status to those procedures for CY 2019. For CY 2019, CPT codes 36902 and 36905 were assigned payment indicators of ''G2''—Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative weight.

In reviewing the CY 2018 volume and utilization data for CPT code 36902 we determined that the procedure was performed more than 50 percent of the time in physicians' offices based on 2018 volume and utilization data.

However, the office-based utilization for CPT code 36902 has fallen from 62 percent based on 2017 data to 52 percent based on 2018 data. In addition, there was a sizeable increase in claims for this service in ASCs—from approximately 14,000 in 2017 to 38,000 in 2018. As previously stated in the CY 2019 OPPS/ASC final rule (83 FR 59036), when we believe that the available data for our review process are inadequate to make a determination that a procedure should be office-based, we either make no change to the procedure's payment status or make the change on a temporary basis, and reevaluate our decision when more data become available for our next evaluation. In light of these changes in utilization and due to the high utilization of this procedure in all settings (over 125,000 claims in 2018), we believe it may be premature to assign office-based payment status to CPT code 36902 at this time.

Therefore, for CY 2020, we are not proposing to designate CPT code 36902 as an office-based procedure and continue to assign CPT code 36902 a payment indicator of ''G2''—nonoffice-based surgical procedure paid based on OPPS relative weights.

The CY 2018 volume and utilization data for CPT code 36905 show the procedure was not performed more than 50 percent of the time in physicians' offices. Therefore, we are not considering assigning an office-based designation for CPT code 36905 and the procedure will retain its payment indicator of ''G2''—non office-based surgical procedure based on OPPS relative weights.

Our review of the CY 2018 volume and utilization data resulted in our identification of 9 other covered surgical procedures that we believe meet the criteria for designation as permanently 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 2020 are listed in Table 29.

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TABLE 29.—ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2020

CY 2020 CPT Code	CY 2020 Long Descriptor	CY 2019 ASC Payment Indicator	Proposed CY 2020 ASC Payment Indicator*
31298	Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (eg, balloon dilation)	G2	P2*
31634	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, with assessment of air leak, with administration of occlusive substance (eg, fibrin glue), if performed	G2	P3*
31647	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe	G2	R2*
36465	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (eg, great saphenous vein, accessory saphenous vein)	G2	P2*
36466	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (eg, great saphenous vein, accessory saphenous vein), same leg	G2	P2*
36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated	G2	P3*
50727	Revision of urinary-cutaneous anastomosis (any type urostomy)	G2	R2*
59414	Delivery of placenta (separate procedure)	G2	R2*
61880	Revision or removal of intracranial neurostimulator electrodes	G2	R2*

* Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the PFS proposed rates. For a discussion of the PFS rates, we refer readers to the CY 2020 PFS proposed rule.

We also reviewed CY 2018 volume and utilization data and other information for 12 procedures designated as temporarily office-based in Tables 57 and 58 in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59039 through 59040). Of these 12 procedures, there were very few claims in our data and no claims data for 11 procedures described by CPT codes 10005, 10007, 10009, 10011, 11102, 11104, 11106, 65785, 67229, 0402T and 0512T. Consequently, we are proposing to maintain the temporary office-based designations for these 11 CPT codes for CY 2020. We list all of those codes for which we proposed to maintain the temporary office-based designations for CY 2020 in Table 30. The procedures for which the proposed office-based designations for CY 2020 are temporary also are 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 one remaining procedure that has a temporary office-based designation for CY 2019, described by CPT code 38222 (Diagnostic bone marrow; biopsy(ies) and aspiration(s)), are sufficient to indicate that this covered surgical procedures was not performed predominantly in physicians' offices and, therefore, we are proposing to assign a nonoffice-based payment indicator—''G2''—to this code for CY 2020.

TABLE 30.—PROPOSED CY 2020 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2019 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2020 CPT/HCPCS Code	CY 2020 Long Descriptor	CY 2019 ASC Payment Indicator	Proposed CY 2020 ASC Payment Indicator*
10005	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	P3	P3*
10007	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion	P3	P3*
10009	Fine needle aspiration biopsy, including CT guidance; first lesion	P2	P2*
10011	Fine needle aspiration biopsy, including MR guidance; first lesion	R2	R2*
11102	Tangential biopsy of skin (eg, shave, scoop, saucerize, curette); single lesion	P3	P3*
11104	Punch biopsy of skin (including simple closure, when performed); single lesion	P2	P2*
11106	Incisional biopsy of skin (eg, wedge) (including simple closure, when performed); single lesion	P3	P3*
38222	Diagnostic bone marrow; biopsy(ies) and aspiration(s)	P3	G2
65785	Implantation of intrastromal corneal ring segments	P2	P2*
67229	Treatment of extensive or progressive retinopathy, 1 or more sessions, preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (eg, retinopathy of prematurity), photocoagulation or cryotherapy	R2	R2*

CY 2020 CPT/HCPCS Code	CY 2020 Long Descriptor	CY 2019 ASC Payment Indicator	Proposed CY 2020 ASC Payment Indicator*
0402T	Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)	R2	R2*
0512T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2	R2*

* Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the PFS proposed rates. For a discussion of the PFS rates, we refer readers to the CY 2020 PFS proposed rule.

For CY 2020, we are proposing to designate 7 new CY 2020 CPT codes for ASC covered surgical procedures as temporarily office-based, as displayed in Table 31. After reviewing the clinical characteristics, utilization, and volume of related procedure codes, we determined that the procedures in Table 30 described by the new CPT codes would be predominantly performed in physicians' offices. We believe the procedure described by CPT codes 93X00 (Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study) and 93X01 (Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study) is clinically similar to HCPCS code G0365 (Vessel mapping of vessels for hemodialysis access (services for preoperative vessel mapping prior to creation of hemodialysis access using an autogenous hemodialysis conduit, including arterial inflow and venous outflow)), which is currently on the list of covered surgical procedures and assigned a proposed payment indicator ''R2''—Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight—for CY 2020. As such, we are proposing to add CPT codes 93X00 and 93X01 in Table 30 to the list of temporarily office-based covered surgical procedures.

Because we have no utilization data for the procedures specifically described by these new CPT codes, we 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 2020 is temporary are indicated by asterisks in Addendum AA to this proposed rule (which is available via the internet on the CMS website).

TABLE 31.—PROPOSED CY 2020 PAYMENT INDICATORS FOR NEW CY 2020 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED

CY 2019 OPPS/ASC proposed rule 5-digit CMS placeholder code	CY 2020 Long Descriptor	Proposed CY 2020 ASC Payment Indicator**
64XX0	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	P3**
64XX1	Destruction by neurolytic agent, genicular nerve branches, including imaging guidance, when performed	P3**
93X00	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study	R2**
93X01	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study	R2**
0551T	Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume	R2**
05X4T	Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; injection of cellular implant into knee joint including ultrasound guidance, unilateral	R2**
0X71T	Health and well-being coaching face-to-face; group (2 or more individuals), at least 30 minutes	R2**

**Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the PFS proposed rates. For a discussion of the MPFS rates, we refer readers to the CY 2020 PFS proposed rule.

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b. Proposed ASC Covered Surgical Procedures To Be Designated as Device-Intensive

(1) Background

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59041), for a summary of our existing policies regarding ASC covered surgical procedures that are designated as device-intensive.

(2) Proposed Changes To List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2020

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 590401 through 59043), for CY 2019 we modified our criteria for device-intensive procedures to better capture costs for procedures with significant device costs. We adopted a policy to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. In addition, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent. Specifically, for CY 2019 and subsequent years, we adopted a policy that device-intensive procedures would be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost. Corresponding to this change in the cost criterion we adopted a policy that the default device offset for new codes that describe procedures that involve the implantation of medical devices will be 31 percent beginning in CY 2019. For new codes describing procedures that are payable when furnished in an ASC involving the implantation of a medical device, we adopted a policy that the default device offset would be applied in the same manner as the policy we adopted in section IV.B.2. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948). We amended § 416.171(b)(2) of the regulations to reflect these new device criteria.

In addition, as also adopted in section IV.B.2. of that final rule with comment period, to further align the device-intensive policy with the criteria used for device pass-through status, we specified, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received 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).

Based on our modified device-intensive criteria, for CY 2020, we are proposing to update the ASC CPL to indicate procedures that are eligible for payment according to our device-intensive procedure payment methodology, based on the proposed individual HCPCS code device-offset percentages using the CY 2018 OPPS claims and cost report data available for 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 2020, are assigned payment indicator ''J8'' and are included in ASC Addendum AA to this proposed rule (which is available via the internet on the CMS website). The CPT code, the CPT code short descriptor, and the proposed CY 2020 ASC payment indicator, and an indication of whether the full credit/partial credit (FB/FC) device adjustment policy would apply because the procedure is designated as device-intensive also are included in Addendum AA to this proposed rule (which is available via the internet on the CMS website). In addition, we note that in our CY 2019 OPPS/ASC proposed rule (83 FR 37158 through 37159), we proposed to apply our device-intensive procedure payment methodology to device-intensive procedures under the ASC payment system only when the device-intensive procedure is furnished with a surgically-inserted or implanted device (including single-used medical devices). We inadvertently omitted language finalizing this policy for CY 2019. For CY 2020 and subsequent calendar years, we are proposing to only apply our device-intensive procedure payment methodology to device-intensive procedures under the ASC payment system when the device-intensive procedure is furnished with a surgically inserted or implanted device (including single use medical devices). The payment rate under the ASC payment system for device-intensive procedures furnished 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. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC payment policy for costly devices implanted in ASCs at no cost/full credit or partial credit, as set forth in § 416.179 of our regulations, is consistent with the OPPS policy that was in effect until CY 2014. Specifically, the OPPS policy that was in effect through CY 2013 provided a reduction in OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device (77 FR 68356 through 68358). The established ASC policy reduces payment to ASCs when a specified device is furnished without cost or with full credit or partial credit for the cost of the device for those ASC covered surgical procedures that are assigned to APCs under the OPPS to which this policy applies. We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68742 through 68744) for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37159), we noted that, as discussed in section IV.B. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75006), we finalized our proposal to modify our former policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. Formerly, under the OPPS, our policy was to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnished a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital received partial credit in the amount of 50 percent or more (but less than 100 percent) of the cost for the specified device. For CY 2014, we finalized our proposal to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a replaced device, capped at the device offset amount.

Although we finalized our proposal to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPS, in 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.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044), for partial credit, we adopted a policy to reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the new device. The ASC will append the HCPCS ''FC'' modifier to the HCPCS code for the device-intensive surgical procedure when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a new device, ASCs have the option of either: (1) Submitting the claim for the device replacement procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the replacement device. Beneficiary coinsurance would be based on the reduced payment amount. As finalized in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), to ensure our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost or receive full credit or partial credit for the device, we apply our ''FB''/''FC'' modifier policy to all device-intensive procedures.

In this proposed rule, we are not proposing any changes to these policies.

d. Proposed Additions to the List of ASC Covered Surgical Procedures

(1) Proposed Additions to the List of ASC Covered Surgical Procedures for CY 2020

As finalized in section XII.A.3. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 59029 through 59030), we revised our definition of ''surgery'' for CY 2019 to include certain ''surgery-like'' procedures that are assigned codes outside the CPT surgical range. For CY 2020 and subsequent years we are proposing to adopt the modified definition we finalized for CY 2019, to include procedures that are described by Category I CPT codes that are not in the surgical range but directly crosswalk or are clinically similar to procedures in the Category I CPT code surgical range that we have determined do not pose a significant safety risk, would not be expected to require an overnight stay when performed in an ASC, and are separately paid under the OPPS. We also are proposing to continue to include in our definition of surgical procedures those procedures described by Category I CPT codes in the surgical range from 10000 through 69999 as well as those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined do not pose a significant safety risk, that we would not expect to require an overnight stay when performed in ASCs, and that are separately paid under the OPPS.

We conducted a review of HCPCS codes that currently are paid under the OPPS, but not included on the ASC CPL, and that meet our proposed definition of surgery to determine if changes in technology 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 a mosiacplasty procedure and three coronary intervention procedures to the list for CY 2020, as shown in Table 32. After reviewing the clinical characteristics of these procedures and consulting with stakeholders and our clinical advisors, we determined that these four 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 primarily on factors relating to safety, including procedures that generally result in extensive blood loss, require major or prolonged invasion of body cavities, or directly involve major blood vessels. We 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 coronary intervention procedures may involve blood vessels that could be considered major, as stated in the August 2, 2007 ASC final rule (72 FR 42481), we believe the involvement of major blood vessels is best considered in the context of the clinical characteristics of individual procedures, and we do not believe that it is logically or clinically consistent to exclude certain cardiac procedures from the list of ASC covered surgical procedures on the basis of the involvement of major blood vessels, yet continue to provide ASC payment for similar procedures involving major blood vessels that have a history of safe performance in ASCs, such as CPT code 36473 (Mechanicochemical destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance) and CPT code 37223 (Insertion of stents into groin artery, endovascular, accessed through the skin or open procedure). Based on our review of the clinical characteristics of the procedures and their similarity to other procedures that are currently included on the ASC CPL, we believe these procedures can be safely performed in an ASC. Therefore, we are proposing to include these 3 coronary intervention procedures on the list of ASC covered surgical procedures for CY 2020. We are also proposing to add their respective add-on procedures which are packaged under the ASC payment system.

In the CY 2018 OPPS/ASC proposed rule, we solicited public comments on whether the total knee arthroplasty (TKA) procedure, CPT code 27447 (Arthroplasty, knee, condyle and plateau; medial and lateral compartments with or without patella resurfacing (total knee arthroplasty)), should be added to the ASC CPL. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59411 through 59412) we noted that some commenters argued that many ASCs are equipped to perform these procedures and orthopedic surgeons in ASCs are increasingly performing these procedures safely and effectively on non-Medicare patients and appropriate Medicare patients. However, other commenters noted that the majority of ASCs were not well-equipped to safely perform TKA procedures on patients and that the majority of Medicare patients are not suitable candidates to receive ''overnight'' joint arthroplasty procedures in an ASC setting. For CY 2018, we did not finalize adding TKA to the ASC covered surgical procedures list, but noted that we would take the

suggestions and recommendations into consideration for future rulemaking.

In this CY 2020 OPPS/ASC proposed rule, we continue to promote site-neutrality, where possible, between the hospital outpatient department and ASC settings. Further, we agree with commenters that there is a small subset of Medicare beneficiaries who may be suitable candidates to receive TKA procedures in an ASC setting based on their clinical characteristics. For example, based on Medicare Advantage encounter data, we estimate over 800 TKA procedures were performed in an ASC on Medicare Advantage enrollees in 2016. We believe that beneficiaries not enrolled in an MA plan should also have the option of choosing to receive the TKA procedure in an ASC setting based on their physicians' determinations.

As we stated in the August 2, 2007 final rule (72 FR 42483 through 42484), we exclude procedures that would otherwise pose a significant safety risk to the typical Medicare beneficiary. However, we believe physicians should continue to play an important role in exercising their clinical judgment when making site-of-service determinations, including for TKA. In light of the information commenters submitted in support of adding TKA to the ASC CPL in response to our CY 2018 public comment solicitation, we are proposing to add TKA to the ASC CPL in CY 2020.

We note that TKA procedures were still predominantly performed in the inpatient hospital setting in CY 2018 (82 percent of the time) based on professional claims data, and we are cognizant of the fact that the majority of beneficiaries may not be suitable candidates to receive TKA in an ASC setting. We believe that appropriate limits are necessary to ensure that Medicare Part B payment will only be made for TKA procedures performed in the ASC setting when that setting is clinically appropriate. Therefore, we are soliciting public comment on the appropriate approach to provide safeguards for Medicare beneficiaries who should not receive the TKA procedure in an ASC setting. Specifically, we are soliciting public comment on methods to ensure beneficiaries receive surgical procedures in the ASC setting only as clinically appropriate. For instance, CMS could issue a new modifier that indicates the physician believes that the beneficiary would not be expected to require active medical monitoring and care at midnight following a particular procedure furnished in the ASC setting. CMS could require that such a modifier be included on the claims line for a surgical procedure performed in an ASC. Alternatively, given the importance of post-operative care in making determinations about whether the ASC is an appropriate setting for a procedure, CMS could require that an ASC has a defined plan of care for each beneficiary following a surgical procedure. We could also establish certain requirements for ASCs that choose to perform certain surgical procedures on Medicare patients, such as requiring an ASC to have a certain amount of experience in performing a procedure before being eligible for payment for performing the procedure under Medicare. We are soliciting comment on these options, and other options, for ensuring that beneficiaries receive surgical procedures, including TKA, that do not pose a significant safety risk when performed in an ASC.

In light of the information we received from commenters in support of adding TKA to the ASC–CPL in response to our comment solicitation in the CY 2018 OPPS/ASC proposed rule, we believe TKA would meet our regulatory requirements established under 42 CFR 416.2 and 416.166(b) for covered surgical procedures in the ASC setting. Therefore, we are proposing to add TKA to the ASC CPL as shown in Table 31 below. Based on the public comments we receive, we will consider appropriate safeguards and limitations for surgical procedures furnished in the ASC setting.

As we stated in the CY 2019 OPPS/ASC proposed rule (83 FR 59054 through 59055), section 1833(i)(1) of the Act requires us, in part, to specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately performed on an inpatient basis in a hospital, but can be safely performed in an ASC, and to review and update the ASC covered surgical procedures list at least every 2 years.

We are also soliciting comment on how CMS should think about the role of the ASC–CPL compared to State regulations and market forces in providing payment for certain surgical procedures in an ASC and whether any modifications should be made to the ASC–CPL. Comments on this topic could help formulate the basis for future policy development regarding how we determine what procedures are payable for Medicare fee-for-service beneficiaries in the ASC setting and maintain the balance between safety and access. Finally, we are soliciting comment on how our proposed additions to the list of ASC covered surgical procedures might affect rural hospitals to the extent rural hospitals rely on providing such procedures.

The 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 2020 payment indicators, are displayed in Table 32.

TABLE 32.—PROPOSED ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2020

CY 2020 CPT Code	CY 2020 Long Descriptor	Proposed CY 2020 ASC Payment Indicator
27447	Arthroplasty, knee, condyle and plateau; medial and lateral compartments with or without patella resurfacing (total knee arthroplasty)	J8
29867	Arthroscopy, knee, surgical; osteochondral allograft (eg, mosaicplasty)	J8
92920	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch	G2
92921	Percutaneous transluminal coronary angioplasty; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	N1
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	J8
92929	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	N1
C9600	Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	J8
C9601	Percutaneous transcatheter placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	N1

(2) Comment Solicitation on Coronary Intervention Procedures

For CY 2020, as discussed above, we are proposing to add three coronary intervention procedures (along with the codes describing their respective add-on procedures) that involve major blood vessels that we believe can be safely performed in an ASC setting and would not pose a significant safety risk to beneficiaries if performed in an ASC setting. For this CY 2020 OPPS/ASC proposed rule, in addition to the three coronary intervention procedures we are proposing to add to the ASC CPL, we also reviewed several other coronary intervention procedures. While we do not believe the procedures included in Table 33 meet our criteria for inclusion on the ASC CPL at this time, and we are not proposing to add such procedures to the ASC CPL for CY 2020, we are soliciting public comments on whether stakeholders believe they can be safely performed in an ASC setting and to provide any materials supporting their position. In considering whether or not these procedures should be added to the ASC CPL, we are requesting that commenters provide information and data that specifically address the requirements in our regulations at 42 CFR 416.2 and 416.166. For example, commenters should provide information to support their position as to whether each of these procedures would be expected to pose a significant risk to beneficiary safety when performed in an ASC, whether standard medical practice dictates that the beneficiary would typically be expected to require active medical monitoring and care at midnight following the procedure (''overnight stay''), and whether the procedure would fall under our general exclusions for covered surgical procedures at 42 CFR 416.166(c) (for example, would it generally result in extensive blood loss). We will consider public comments we receive in future rulemaking cycles.

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TABLE 33.—POTENTIAL PROCEDURES ON WHICH WE REQUEST COMMENT FOR ADDITION TO THE CY 2020 ASC LIST OF COVERED SURGICAL PROCEDURES

CY 2020 CPT Code	CY 2020 Long Descriptor
92924	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; single major coronary artery or branch
92925	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch
92934	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)
92937	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel
92938	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)
92943	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel
92944	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)
92973	Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch

CY 2020 CPT Code	CY 2020 Long Descriptor
C9602	Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch
C9604	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel
C9605	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)
C9607	PCI of chronic total occlusion, any method(s), with drug-eluting stent
C9608	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; each additional corona

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2. Covered Ancillary Services

Consistent with the established ASC payment system policy (72 FR 42497), we are proposing to update the ASC list of covered ancillary services to reflect the payment status for the services under the CY 2020 OPPS. Maintaining consistency with the OPPS may result in proposed changes to ASC payment indicators for some covered ancillary services because of changes that are being proposed under the OPPS for CY 2020. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2019, but is proposed for packaged status under the CY 2020 OPPS, to maintain consistency with the OPPS, we would also propose to package the ancillary service under the ASC payment system for CY 2020. We are proposing to continue this reconciliation of packaged status for subsequent calendar years. Comment indicator ''CH'', which is discussed in section XIII.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 2020.

All ASC covered ancillary services and their proposed payment indicators for CY 2020 are included in Addendum BB to this proposed rule (which is available via the internet on the CMS website).

D. Proposed Update and Payment for ASC 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 only the service portion of the rate is subject to the ASC standard ratesetting methodology. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59028 through 59080), we updated the CY 2018 ASC payment rates for ASC covered surgical procedures with payment indicators of ''A2'', ''G2'', and ''J8'' using CY 2017 data, consistent with the CY 2019 OPPS update. We also updated payment rates for device-intensive procedures to incorporate the CY 2019 OPPS device offset percentages calculated under the standard APC ratesetting methodology, as discussed earlier in this section.

Payment rates for office-based procedures (payment indicators ''P2'', ''P3'', and ''R2'') are the lower of the PFS nonfacility PE RVU-based amount or the amount calculated using the ASC standard rate setting methodology for the procedure. In the CY 2018 OPPS/ASC final rule with comment period, we updated the payment amounts for office-based procedures (payment indicators ''P2'', ''P3'', and ''R2'') using the most recent available MPFS and OPPS data. We compared the estimated

CY 2018 rate for each of the office-based procedures, calculated according to the ASC standard rate setting methodology, to the PFS nonfacility PE RVU-based amount to determine which was lower and, therefore, would be the CY 2018 payment rate for the procedure under our final policy for the revised ASC payment system (§ 416.171(d)).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75081), we finalized our proposal to calculate the CY 2014 payment rates for ASC covered surgical procedures according to our established methodologies, with the exception of device removal procedures. For CY 2014, we finalized a policy to conditionally package payment for device removal procedures under the OPPS. Under the OPPS, a conditionally packaged procedure (status indicators ''Q1'' and ''Q2'') describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indicator ''N1'') under the ASC payment system. Under the OPPS, device removal procedures are conditionally packaged and, therefore, would be packaged under the ASC payment system. There would be no Medicare payment made when a device removal procedure is performed in an ASC without another surgical procedure included on the claim; therefore, no Medicare payment would be made if a device was removed but not replaced. To ensure that the ASC payment system provides separate payment for surgical procedures that only involve device removal—conditionally packaged in the OPPS (status indicator ''Q2'')—we continued to provide separate payment since CY 2014 and assigned the current ASC payment indicators associated with these procedures.

b. Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2020

We are proposing to update ASC payment rates for CY 2020 and subsequent years using the established rate calculation methodologies under § 416.171 and using our definition of device-intensive procedures, as discussed in section XII.C.1.b. of this proposed rule. Because the proposed OPPS relative payment weights are generally based on geometric mean costs, the ASC system would generally use geometric means to determine proposed relative payment weights under the ASC standard methodology. We 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 2020 OPPS device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. Payment for office-based procedures would be at the lesser of the proposed CY 2020 MPFS nonfacility PE RVU-based amount or the proposed CY 2020 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2019, for CY 2020, we 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.

c. Proposed Limit on ASC Payment Rates for Low Volume Device-Intensive Procedures

As stated in section XIII.D.1.b. of this proposed rule, the ASC payment system generally uses OPPS geometric mean costs under the standard methodology to determine proposed relative payment weights under the standard ASC ratesetting methodology. However, for low-volume device-intensive procedures, the proposed relative payment weights are based on median costs, rather than geometric mean costs, as discussed in section IV.B.5. of this proposed rule.

While we believe this policy generally helps to provide more appropriate payment for low-volume device intensive procedures, these procedures can still have data anomalies as a result of the limited data available for these procedures in our ratesetting process. For the Level 5 Intraocular APC, which includes only HCPCS code 0308T (insj ocular telescope prosth), based on the CY 2018 claims data available for this proposed rule, the geometric mean cost and median cost under the standard ASC ratesetting methodology is $67,946.51 and $111,019.30, respectively. As described in section IV.B.5. of this proposed rule, a device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures is considered ''low-volume'' and the cost of the procedure is based on calculations using the APC's median cost instead of the APC's geometric mean cost. Since this APC meets the criteria for low-volume device-intensive procedure designation, the ASC relative weight would be based on the median cost rather than the geometric mean cost. We note that this median cost for this APC is significantly higher than either the OPPS geometric mean cost or median cost based on the OPPS comprehensive ratesetting methodology, which are $28,122.51 and $19,269.55, respectively. This very large difference in cost calculations between these two settings is largely attributable to the APC's low claims volume and to the comprehensive methodology used under the OPPS which is not utilized in ratesetting under the ASC payment system. The cost calculation for this APC under the ASC payment system is primarily based on charges from one hospital with a significantly higher device cost center cost-to-charge ratio and significantly higher charges when compared to other hospitals providing the procedure.

If the ASC payment system were to base the CY 2020 payment rate for HCPCS code 0308T on the median cost of $111,019.30, the ASC payment rate would be several times greater than the OPPS payment rate for HCPCS code 0308T. We note that the median cost under the OPPS ratesetting methodology based on CY 2018 claims data is closer to the historical average for the median cost of HCPCS code 0308T (approximately $19,000). In addition, given that the outpatient hospital setting is generally considered to have higher costs than the ASC setting and that the payment rates for both settings are based on hospital outpatient cost data, we do not believe there should be a scenario where the payment rate for a low-volume device intensive procedure under the ASC payment system is significantly greater than payment under the OPPS.

Therefore, for CY 2020 and subsequent years, we are proposing to limit the ASC payment rate for low-volume device intensive procedure to a payment rate equal to the OPPS

payment rate for that procedure. Under this proposal, where the ASC payment rate based on the standard ASC ratesetting methodology for low volume device-intensive procedures would exceed the rate paid under the OPPS for the same procedure, we are proposing to establish an ASC payment rate for such procedures equal to the OPPS payment rate for the same procedure. In this CY 2020 proposed rule, our proposed policy would only affect HCPCS code 0308T, which has very low claims volume (7 claims used for ratesetting in the OPPS). We are proposing to amend 42 CFR 416.171(b) of the regulations to reflect the proposed new limit on ASC payment rates for low-volume device-intensive procedures. CMS' existing regulation at 42 CFR 416.171(b)(2) requires the payment of the device portion of a device-intensive procedure at an amount derived from the payment rate for the equivalent item under the OPPS using our standard ratesetting methodology. We are proposing to add paragraph (b)(4) to § 416.171 to require that, notwithstanding paragraph (b)(2), low volume device-intensive procedures where the otherwise applicable payment rate calculated based on the standard methodology for device-intensive procedures would exceed the payment rate for the same procedure set under the OPPS, the payment rate for the procedure under the ASC payment system would be equal to the payment rate for the same procedure under the OPPS.

Covered surgical procedures and their proposed payment rates for CY 2020 are listed in Addendum AA to this proposed rule (which is available via the internet on the CMS website).

2. Proposed Payment for Covered Ancillary Services

a. Background

Our payment policies under the ASC payment system for covered ancillary services generally vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators ''N'', ''Q1'', and ''Q2'') under the OPPS. In the CY 2013 OPPS/ASC rulemaking (77 FR 45169 and 77 FR 68457 through 68458), we further clarified our policy regarding the payment indicator assignment of procedures that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2''). Under the OPPS, a conditionally packaged procedure describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are generally packaged (payment indictor ''N1'') under the ASC payment system (except for device removal procedures, as discussed in section IV. of this proposed rule). Thus, our policy generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for those ancillary services also to be paid, ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies generally provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates and package payment for drugs and biologicals for which payment is packaged under the OPPS. However, as discussed in section XIII.D.3. of this proposed rule, below, for CY 2019 we finalized a policy to unpackage and pay separately at ASP + 6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting, even though payment for these drugs continues to be packaged under the OPPS. We generally pay for separately payable radiology services at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount (''Z3''), regardless of which is lower (42 CFR 416.171(d)(1)).

Similarly, we also finalized our policy to set the payment indicator to ''Z2'' for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight using the ASC standard ratesetting methodology and, therefore, will include the cost for the contrast agent (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 PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). We finalized that the diagnostic tests for which the payment is based on the ASC standard ratesetting methodology be assigned to payment indicator ''Z2'' and revised the definition of payment indicator ''Z2'' to include a reference to diagnostic services and those for which the payment is based on the PFS nonfacility PE RVU-based amount be assigned payment indicator ''Z3,'' and revised the definition of payment indicator ''Z3'' to include a reference to diagnostic services.

b. Proposed Payment for Covered Ancillary Services for CY 2020

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 2020 OPPS and ASC payment rates and subsequent year payment rates. We also are proposing to continue to set the CY 2020 ASC payment rates and subsequent year payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for CY 2020 and subsequent year payment rates.

We note that stakeholders requested that we propose to add CPT code 91040 (Esophageal balloon distension study, diagnostic, with provocation when performed) to the ASC Covered Procedures List (CPL) and ASC list of covered ancillary services as it is integral to the performance of covered surgical procedures such as CPT code 43235 (Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)) and 43239 (Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple). Based on available data and other information related to CPT code 91040, we do not believe this diagnostic test is integral to the covered surgical procedures of CPT codes 43235 or 43239. Therefore, we are not proposing to add CPT code 91040 as a covered ancillary service.

Covered ancillary services and their proposed payment indicators for CY 2020 are listed in Addendum BB 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 PFS proposed rates, the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the proposed PFS rates effective January 1, 2020. For a discussion of the PFS rates, we refer readers to the CY 2020 PFS proposed rule, which will be 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 2020 ASC Packaging Policy for Non-Opioid Pain Management Treatments

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59066 through 59072), we finalized the policy to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2019. We also finalized conforming changes to 42 CFR 416.164(a)(4) to exclude non-opioid pain management drugs that function as a supply when used in a surgical procedure from our policy to package payment for drugs and biologicals for which separate payment is not allowed under the OPPS into the ASC payment for the covered surgical procedure. We added a new 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 covered ancillary services that are integral to a covered surgical procedure. Finally, we finalized a change to 42 CFR 416.171(b)(1) to exclude non-opioid pain management drugs that function as a supply when used in a surgical procedure from our policy to pay for ASC covered ancillary services an amount derived from the payment rate for the equivalent item or service set under the OPPS.

In that final rule with comment period, we noted that we will continue to analyze the issue of access to non-opioid alternatives in the OPPS and ASC settings as we implement section 6082 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act) (Pub. L. 115–271), enacted on October 24, 2018. We also discussed our policy to unpackage and pay separately at ASP + 6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting in section II.A.3.b. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58854 through 58860). As required under Section 6082(b) of the SUPPORT Act, we will continue to review and revise ASC payments for non-opioid alternatives for pain management, as appropriate. For more information on our implementation of section 6082 of the SUPPORT for Patients and Communities Act and related proposals, we refer readers to section II.A.3.b. of 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 2020

We did not receive any requests for review to establish a new NTIOL class for CY 2020 by March 1, 2019, the due date published in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59072).

3. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we are not proposing to revise the payment adjustment amount for CY 2020.

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 CPL prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services, including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, or NTIOLs.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators included in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator ''NI'' is used in the OPPS/ASC final rule to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator ''NI'' also is assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, and the interim payment indicator assigned is subject to comment, as discussed in the CY2010 OPPS/ASC final rule with comment period (74 FR 60622).

The comment indicator ''NP'' is used in the OPPS/ASC proposed rule to indicate new codes for the next calendar year for which the proposed payment indicator assigned is subject to comment. The comment indicator ''NP'' also is assigned to existing codes with substantial revisions to their descriptors, such that we consider them to be describing new services, and the proposed payment indicator assigned is subject to comment, as discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70497).

The ''CH'' comment indicator is used in Addenda AA and BB to this proposed rule (which are available via the internet on the CMS website) to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and the next calendar year, for example if an active HCPCS code is newly recognized as payable in ASCs; or an active HCPCS code is discontinued at the end of the current calendar year. The ''CH'' comment indicators that are published in the final rule with comment period are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

2. Proposed ASC Payment and Comment Indicators for CY 2020

For CY 2020, 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 2019 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2020 compared to the CY 2019 descriptors 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 2020 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 2020 update.

G. Proposed Calculation of the ASC Payment Rates and the ASC Conversion Factor

1. Background

In the August 2, 2007 final rule (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and the OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY

2008 being equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007, as required under section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system budget neutral in subsequent calendar years (72 FR 42532 through 42533; 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.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252) and 2010 Census Bureau data. (A copy of this bulletin may be obtained at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2013/b13-01.pdf*). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963), we implemented the use of the CBSA delineations issued by OMB in OMB Bulletin 13–01 for the IPPS hospital wage index beginning in FY 2015.

OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. OMB Bulletin No. 15–01 made changes that are relevant to the IPPS and ASC wage index. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79750) for a discussion of these changes and our implementation of these revisions. (A copy of this bulletin may be obtained at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2015/15-01.pdf*).

On August 15, 2017, OMB issued OMB Bulletin No. 17–01, which provided updates to and superseded OMB Bulletin No. 15–01 that was issued on July 15, 2015. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58864 through 58865) for a discussion of these changes and our implementation of these revisions. (A copy of this bulletin may be obtained at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf*).

For CY 2020, the proposed CY 2020 ASC wage indexes fully reflect the OMB labor market area delineations (including the revisions to the OMB labor market delineations discussed above, as set forth in OMB Bulletin Nos. 15–01 and 17–01).

We note that, in certain instances, there might be urban or rural areas for which there is no IPPS hospital that has wage index data that could be used to set the wage index for that area. For these areas, our policy has been to use the average of the wage indexes for CBSAs (or metropolitan divisions as applicable) that are contiguous to the area that has no wage index (where ''contiguous'' is defined as sharing a border). For example, for CY 2014, we applied a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville-Fort Stewart, GA) and CBSA 08 (Rural Delaware).

When all of the areas contiguous to the urban CBSA of interest are rural and there is no IPPS hospital that has wage index data that could be used to set the wage index for that area, we determine the ASC wage index by calculating the average of all wage indexes for urban areas in the State (75 FR 72058 through 72059). (In other situations, where there are no IPPS hospitals located in a relevant labor market area, we continue our current policy of calculating an urban or rural area's wage index by

calculating the average of the wage indexes for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index.)

2. Proposed Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2020 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and PFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). Consistent with our established policy, we are proposing to scale the CY 2020 relative payment weights for ASCs according to the following method. Holding ASC utilization, the ASC conversion factor, and the mix of services constant from CY 2018, we are proposing to compare the total payment using the CY 2019 ASC relative payment weights with the total payment using the CY 2020 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2019 and CY 2020. We are proposing to use the ratio of CY 2019 to CY 2020 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2020. The proposed CY 2020 ASC weight scalar is 0.8452 and scaling would apply to the ASC relative payment weights of the covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes, which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.

Scaling would not apply in the case of ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services. The ASC payment weights for those services without predetermined national payment amounts (that is, those services with national payment amounts that would be based on OPPS relative payment weights) would be scaled to eliminate any difference in the total payment between the current year and the update year.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. At the time of this proposed rule, we had available 98 percent of CY 2018 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 2018 claims data. We used the supplier zip code reported on the claim to associate State, county, and CBSA with each ASC. This file, available to the public as a supporting data file for 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 2020, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2018 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2020 ASC wage indexes. Specifically, holding CY 2018 ASC utilization, service-mix, and the proposed CY 2020 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2019 ASC wage indexes and the total adjusted payment using the proposed CY 2020 ASC wage indexes. We used the 50-percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2019 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2020 ASC wage indexes and applied the resulting ratio of 1.0008 (the proposed CY 2020 ASC wage index budget neutrality adjustment) to the CY 2019 ASC conversion factor to calculate the proposed CY 2020 ASC conversion factor.

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated amounts established under the revised ASC payment system in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (CPI–U), U.S. city average, as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. The statute does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI–U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at 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 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59080), we finalized our proposal to apply the hospital market basket update to ASC payment system rates for an interim period of 5 years (CY 2019 through CY 2023), during which we will assess whether there is a migration of the performance of procedures from the hospital setting to the ASC setting as a result of the use of a hospital market basket update, as well as whether there are any unintended consequences, such as less than expected migration of the performance of procedures from the hospital setting to the ASC setting. In addition, we finalized our proposal to revise our regulations under 42 CFR 416.171(a)(2), which address the annual update to the ASC conversion factor. During this 5-year period, we intend to assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner and could propose a plan to collect such information. We refer readers to that final rule for a detailed discussion of the rationale for these policies.

For this proposed rule, the hospital market basket update for CY 2020 is projected to be 3.2 percent, as published in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19402), based on IHS Global Inc.'s (IGI's) 2018 fourth quarter forecast with historical data through the third quarter of 2018.

We finalized the methodology for calculating the MFP adjustment in the CY 2011 PFS final rule with comment period (75 FR 73394 through 73396) and revised it in the CY 2012 PFS final rule with comment period (76 FR 73300 through 73301) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70500 through 70501). For this proposed rule, the proposed MFP adjustment for CY 2020 is projected to be 0.5 percentage point, as published in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19402) based on IGI's 2018 fourth quarter forecast.

For CY 2020, we are proposing to utilize the hospital market basket update of 3.2 percent minus the MFP adjustment of 0.5 percentage point, resulting in an MFP-adjusted hospital market basket update factor of 2.7 percent for ASCs meeting the quality reporting requirements. Therefore, we are proposing to apply a 2.7 percent MFP-adjusted hospital market basket update factor to the CY 2019 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2020 ASC payment amounts. The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage point reduction to the update factor for ASCs that fail to meet the ASCQR Program requirements. We refer readers to section XIV.E. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 59138 through 59139) and section XIV.E. of this proposed rule for a detailed discussion of our policies regarding payment reduction for ASCs that fail to meet ASCQR Program requirements. We are proposing to utilize the hospital market basket update of 3.2 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then subtract the 0.5 percentage point MFP adjustment. Therefore, we are proposing to apply a 0.7 percent MFP-adjusted hospital market basket update factor to the CY 2019 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also 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 2020 ASC update for the final rule with comment period.

For CY 2020, we are proposing to adjust the CY 2019 ASC conversion factor ($46.532) by the proposed wage index budget neutrality factor of 1.0008 in addition to the MFP-adjusted hospital market basket update factor of 2.7 percent discussed above, which results in a proposed CY 2020 ASC conversion factor of $47.827 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we are proposing to adjust the CY 2019 ASC conversion factor ($46.532) by the proposed wage index budget neutrality factor of 1.0008 in addition to the quality reporting/MFP-adjusted hospital market basket update factor of 0.7 percent discussed above, which results in a proposed CY 2020 ASC conversion factor of $46.895.

3. Display of Proposed CY 2020 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 2020 for covered surgical procedures and covered ancillary services, respectively. For those covered surgical procedures and covered ancillary services where the payment rate is the lower of the proposed rates under the ASC standard ratesetting methodology and the MPFS proposed rates, the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the proposed PFS rates that would be effective January 1, 2020. For a discussion of the PFS rates, we refer readers to the CY 2020 PFS proposed rule that is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

The 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 2020 payment rates. Specifically, in Addendum AA, a ''Y'' in the column titled ''To be Subject to Multiple Procedure Discounting'' indicates that the surgical procedure would be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50-percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session.

Display of the comment indicator ''CH'' in the column titled ''Comment Indicator'' indicates a change in payment policy for the item or service, including identifying discontinued HCPCS codes, designating items or services newly payable under the ASC payment system, and identifying items or services with changes in the ASC payment indicator for CY 2020. Display of the comment indicator ''NI'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that comments will be accepted on the interim payment indicator for the new code. Display of the comment indicator ''NP'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that comments will be accepted on the ASC payment indicator for the new code.

The values displayed in the column titled ''Proposed CY 2020 Payment Weight'' are the proposed relative payment weights for each of the listed services for CY 2020. The proposed relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Therefore, scaling was not applied to the device portion of the device-intensive procedures, services that are paid at the MPFS nonfacility PE RVU-based amount, separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS, or services that are contractor-priced or paid at reasonable cost in ASCs. This includes separate payment for non-opioid pain management drugs.

To derive the proposed CY 2020 payment rate displayed in the ''Proposed CY 2020 Payment Rate'' column, each ASC payment weight in the ''Proposed CY 2020 Payment Weight'' column was multiplied by the proposed CY 2020 conversion factor of $47.827. 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 XIII.G.2.b. of this proposed rule).

In Addendum BB, there are no relative payment weights displayed in the ''Proposed CY 2020 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''Proposed CY 2020 Payment'' column displays the proposed CY 2020 national unadjusted ASC payment rates for all items and services. The proposed CY 2020 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on ASP data used

for payment in physicians' offices in April 2019.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are proposed to be excluded from payment in ASCs for CY 2020.

XIV. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

A. Background

1. Overview

CMS seeks to promote higher quality and more efficient healthcare for Medicare beneficiaries. Consistent with these goals, CMS has implemented quality reporting programs for multiple care settings including the quality reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (OQR) Program, formerly known as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP). The Hospital OQR Program is generally aligned with the quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (IQR) Program, formerly known as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program.

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58820 through 58822) and section I.A.2. of this proposed rule where we discuss our Meaningful Measures Initiative and our approach in evaluating quality program measures.

2. Statutory History of the Hospital OQR Program

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital OQR Program.

3. Regulatory History of the Hospital OQR Program

We refer readers to the CY 2008 through 2019 OPPS/ASC final rules with comment period (72 FR 66860 through 66875; 73 FR 68758 through 68779; 74 FR 60629 through 60656; 75 FR 72064 through 72110; 76 FR 74451 through 74492; 77 FR 68467 through 68492; 78 FR 75090 through 75120; 79 FR 66940 through 66966; 80 FR 70502 through 70526; 81 FR 79753 through 79797; 82 FR 59424 through 59445; and 83 FR 59080 through 59110) for the regulatory history of the Hospital OQR Program. We have codified certain requirements under the Hospital OQR Program at 42 CFR 419.46.

B. Hospital OQR Program Quality Measures

1. Considerations in the Selection of Hospital OQR Program Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74458 through 74460) for a detailed discussion of the priorities we consider for the Hospital OQR Program quality measure selection. We are not proposing any changes to these policies in this proposed rule.

2. Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

We previously adopted a policy to retain measures from a previous year's Hospital OQR Program measure set for subsequent years' measure sets in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68471) whereby quality measures adopted in a previous year's rulemaking are retained in the Hospital OQR Program for use in subsequent years unless otherwise specified. For more information regarding this policy, we refer readers to that final rule with comment period. We codified this policy at 42 CFR 419.46(h)(1) in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59082).

3. Removal of Quality Measures From the Hospital OQR Program Measure Set

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60635), we finalized a process to use the regular rulemaking process to remove a measure for circumstances for which we do not believe that continued use of a measure raises specific patient safety concerns.[70] We codified this policy at 42 CFR 419.46(h)(3) in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59082).

a. Considerations in Removing Quality Measures From the Hospital OQR Program

(1) Immediate Removal

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60634 through 60635), we finalized a process for immediate retirement, which we later termed ''removal,'' of Hospital OQR Program measures, based on evidence that the continued use of the measure as specified raises patient safety concerns.[71] We codified this policy at 42 CFR 419.46(h)(2) in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59082).

(2) Consideration Factors for Removing Measures

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59083 through 59085), we clarified, finalized, and codified at 42 CFR 419.46(h)(2) and (3) an updated set of factors[72] and policies for determining whether to remove measures from the Hospital OQR Program. We refer readers to that final rule with comment period for a detailed discussion of our policies regarding measure removal. The factors are:

- Factor 1. Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped out'' measures).
- Factor 2. Performance or improvement on a measure does not result in better patient outcomes.
- Factor 3. A measure does not align with current clinical guidelines or practice.
- Factor 4. The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic.
- Factor 5. The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.
- Factor 6. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.
- Factor 7. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.
- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

b. Proposed Removal of Quality Measure From the Hospital OQR Program Measure Set: OP–33: External Beam Radiotherapy (NQF# 1822)

In this proposed rule, we are proposing to remove one measure from the Hospital OQR Program for the CY 2022 payment determination as discussed below. Specifically, beginning with the CY 2022 payment

[70] 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.

[71] 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.

[72] 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.

determination, we are proposing to remove OP–33: External Beam Radiotherapy for Bone Metastases under removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70507 through 70510), where we adopted OP–33: External Beam Radiotherapy (NQF# 1822), beginning with the CY 2018 payment determination and for subsequent years. This measure assesses the ''percentage of patients (all-payer) with painful bone metastases and no history of previous radiation who receive EBRT with an acceptable dosing schedule.'' [73] We adopted this measure to address the performance gap in External Beam Radiotherapy (EBRT) treatment variation, ensure appropriate use of EBRT, and prevent the overuse of radiation therapy (80 FR 70508).

We believe that removing EBRT from the Hospital OQR Program is appropriate at this time because the costs associated with this measure outweigh the benefit of its continued use in the program (removal Factor 8). The Hospital OQR Program implemented the EBRT measure using ''radiation delivery'' Current Procedural Terminology (CPT) codes, which are appropriate for hospital-level measurement. We have identified issues with reporting this measure, finding that more questions are received about how to report the EBRT measure than about any other measure in the program. In addition, the measure steward has received feedback on data collection of the measure in the outpatient setting, and has indicated new and significant concerns regarding the ''radiation delivery'' CPT coding used to report the EBRT measure in the Hospital OQR Program including complicated measure exclusions, sampling concerns, and administrative burden.

''Radiation delivery'' CPT codes require complicated measure exclusions, and the use of ''radiation delivery'' CPT codes causes the administration of EBRT to different anatomic sites to be considered separate cases for this measure. The numerator for this measure includes all patients, regardless of age, with painful bone metastases, and no previous radiation to the same anatomic site who receive EBRT with any of the following recommended fractionation schemes: 30Gy/10fxns, 24Gy/6fxns, 20Gy/5fxns, 8Gy/1fxn. The denominator for this measure includes all patients with painful bone metastases and no previous radiation to the same anatomic site who receive EBRT.[74] As noted above, each anatomic site is considered a different case, and as a result it is necessary to determine when EBRT has been administered to different anatomic sites. This determination is not possible without completing a detailed manual review of the patient's record, creating burden and difficulty in determining which sites and instances of EBRT administration are considered cases and should be included in the denominator for the measure. These challenges in determining which cases are included in the denominator for the measure result in difficulty in determining if sample size requirements for the measure are being met.

Further, current information systems do not automatically calculate the total dose provided, so manual review of patient records by practice staff is also required in order to determine the total dose and fractionation scheme, which in turn is used to determine which cases fall into the numerator for this measure. This manual review of patient records is a labor-intensive process that contributes to burden and difficulty in reporting this measure. As a result, we believe that the complexity of reporting this measure places substantial administrative burden on facilities. This also reflects observations made by the measure steward that implementing the measure in the outpatient setting has proven to be very burdensome, given that facilities have noted confusion regarding when the administration of EBRT to different numbers and locations of bone metastases are considered separate cases. These issues identifying cases have led to questions about sampling and difficulty determining if sample size requirements are met. Additional burdens associated with this measure have come to our attention,—including complicated measure exclusions, sampling concerns, and administrative burden. These challenges cause difficulty in tracking and reporting data for this measure and additional administrative burden, as evidenced by numerous questions about how to report this measure received by CMS and its contractors.

This EBRT measure was also adopted into another CMS quality reporting program, the PCHQR Program (79 FR 50278 through 50279). That program initially used ''radiation planning'' CPT codes billable at the physician level, but beginning in March 2016, the PCHQR program updated the measure to enable the use of ''radiation delivery'' CPT codes.[75] In the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19502 through 19503), CMS proposed to remove the measure from the PCHQR Program because the burden associated with the measure outweighs the value of its inclusion in the PCHQR Program. Specifically, the PCHQR Program has proposed to remove the measure because it is overly burdensome and because the measure steward is no longer maintaining the measure. As such, the PCHQR Program stated it can no longer ensure that the measure is in line with clinical guidelines and standards (84 FR 19502 through 19503). We note that while the version of the measure using ''radiation planning'' CPT codes is less burdensome, Hospital Outpatient Departments (HOPDs) do not have access to physician billing data, and so it is not operationally feasible to use ''radiation planning'' CPT codes (as opposed to the current ''radiation delivery'' CPT codes) for the EBRT measure in the Hospital OQR Program.

This measure was originally adopted to address the performance gap in EBRT treatment variation, ensure appropriate use of EBRT, and prevent the overuse of radiation therapy. While we still believe that these goals are important, the benefits of this measure have diminished. Stakeholder feedback has shown that this measure is burdensome and difficult to report. Since the measure steward is no longer maintaining this measure,[76] we no longer believe that we can ensure that the measure is in line with clinical guidelines and standards. Thus, considering these circumstances, we believe the costs associated with this measure outweigh the benefit of its continued use in the program (removal Factor 8).

Therefore, we are proposing to remove the measure beginning with October 2020 encounters used in the CY 2022 payment determination and for subsequent years. We note that in crafting our proposal, we considered removing this measure beginning with the CY 2021 payment determination, but we decided on proposing to delay removal until the CY 2022 payment determination to be sensitive to facilities' planning and operational

[73] 80 FR 70508.

[74] National Quality Forum. NQF #1822 External Beam Radiotherapy for Bone Metastases. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=70374*.

[75] QualityNet. 2018 EBRT Measure Information Form. Available at: *https://www.qualitynet.org/dcs/ContentServer?cid=1228774479863&pagename=QnetPublic%2FPage%2FQnetTier4&c=Page*.

[76] See language about measure steward no longer maintaining this measure in the FY 2020 IPPS/LTCH PPS proposed rule at 84 FR 19502 through 19503.

procedures given that data collection for this measure begins during CY 2019 for the CY 2021 payment determination. We believe that this proposed removal date balances reporting burden, while recognizing that HOPDs must use resources to modify information systems and reporting processes to discontinue reporting the measure.

In summary, we are proposing to remove OP–33: External Beam Radiotherapy for Bone Metastases (NQF #1822) from the Hospital OQR Program beginning with the CY 2022 payment determination and for subsequent years under removal Factor 8.

4. Summary of Proposed Hospital OQR Program Measure Sets for the CY 2022 Payment Determination

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59099 through 59102) for a summary of the previously finalized Hospital OQR Program measure sets for the CY 2020 and CY 2021 payment determinations and subsequent years.

We are not proposing to add any measures and are proposing to remove one measure for the CY 2022 payment determination for the Hospital OQR Program. The Table 34 summarizes the proposed Hospital OQR Program measure set for the CY 2022 payment determination and subsequent years (including previously adopted measures and excluding one measure proposed for removal in this proposed rule).

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TABLE 34.--Proposed Hospital OQR Program Measure Set for the CY 2022 Payment Determination and Subsequent Years

NQF #	Measure Name
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
0514	OP-8: MRI Lumbar Spine for Low Back Pain†
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen†
0661	OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
1536	OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	OP-37a: OAS CAHPS – About Facilities and Staff**
None	OP-37b: OAS CAHPS – Communication About Procedure**
None	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery**
None	OP-37d: OAS CAHPS – Overall Rating of Facility**
None	OP-37e: OAS CAHPS – Recommendation of Facility**

† We note that NQF endorsement for this measure was removed.

* Measure voluntarily collected as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).

** Measure reporting delayed beginning with CY 2018 reporting and for subsequent years as discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433).

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5. Hospital OQR Program Measures and Topics for Future Consideration

We are requesting comment on the potential future adoption of four patient safety measures as well as future outcome measures generally.

a. Request for Comment on the Potential Future Adoption of Four Patient Safety Measures

We are seeking comment on the potential future adoption of four patient safety measures for the Hospital OQR Program that were previously adopted for the ASCQR Program: ASC–1: Patient Burn; ASC–2: Patient Fall; ASC–3: Wrong Site, Wrong Side, Wrong Procedure, Wrong Implant; and ASC–4: All-Cause Hospital Transfer/Admission.[77] We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74497 through 74499), where we adopted these measures (referred to as NQF #0263, NQF #0266, NQF #0267, and NQF #0265 at the time) in the ASCQR Program. We note that data collection for these measures was suspended in the ASCQR Program due to concerns with their data submission method using quality data codes (QDCs) in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59117 through 59123; 59134 through 59135); however, we refer readers to section XV.B.5. of this proposed rule, in which the ASCQR Program is requesting public comment on updating the submission method for these measures in the future. We are requesting public comment on potentially adding these measures with the updated submission method using a CMS online data submission tool, to the Hospital OQR Program in future rulemaking. These measures are currently specified for the ASC setting; we are considering having them specified for the hospital outpatient setting and would seek collaboration with the measure steward if we do so.

We believe these measures could be valuable to the Hospital OQR Program because they would allow us to monitor these types of events and prevent their occurrence to ensure that they remain rare, and because they provide critical data to beneficiaries and further transparency for care provided in the outpatient setting that could be useful in choosing a HOPD. In addition, these measures address an important Meaningful Measure Initiative quality priority, Making Care Safer by Reducing Harm Caused in the Delivery of Care.[78] There has been broad stakeholder support for these measures in the ASC setting; stakeholders believe these measures provide important data for facilities and patients because they are serious and the occurrence of these events should be zero (83 FR 59118). A few commenters noted in the CY 2019 OPPS/ASC final rule with comment period that it would be beneficial to also include these ASCQR Program measures in the Hospital OQR Program in order to provide patients with more meaningful data to compare sites of service (83 FR 59119). The future addition of these measures would further align the Hospital OQR and ASCQR Programs, which would benefit patients because these are two outpatient settings that patients may be interested in comparing, especially if they are able to choose in which of these two settings they receive care.

Although NQF endorsement for these ASC measures was removed (in February 2016 for the All-Cause Hospital Transfer/Admission measure; [79] in May 2016 for the Patient Burn [80] and the Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant [81] measures; and in June 2018 for the Patient Fall measure [82]), as one commenter pointed out in the CY 2019 OPPS/ASC final rule with comment period, the NQF endorsement of the ASC measures was removed as endorsement was allowed to lapse by the measure steward, not because they failed the endorsement maintenance process (83 FR 59119). If specified for the HOPD setting, we plan to coordinate with the measure steward to seek NQF endorsement for those measures. These measures are discussed in more detail below.

(1) Patient Burn

The ASCQR Patient Burn measure assesses the percentage of admissions experiencing a burn prior to discharge. The numerator for this measure is defined as ASC admissions experiencing a burn prior to discharge and the denominator is defined as all ASC admissions.[83] We believe this measure, if specified for the hospital outpatient setting, would allow HOPDs, Medicare beneficiaries, and other stakeholders to develop a better understanding of the incidence of these events. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74497 through 74498), we adopted this measure for the ASCQR Program because ASCs serve surgical patients who may face the risk of burns during ambulatory surgical procedures and we believe monitoring patient burns is valuable to patients and other stakeholders. HOPDs also serve surgical patients who may face the risk of burns during outpatient procedures, so we believe this measure would be valuable for the HOPD setting. Further, we have reviewed studies demonstrating the high impact of monitoring patient burns because patient burns are serious reportable events in healthcare [84] and because patient burns are preventable.[85] [86]

(2) Patient Fall

The ASCQR Program Patient Fall measure assesses the percentage of admissions experiencing a fall. The numerator for this measure is defined as ASC admissions experiencing a fall within the confines of the ASC and excludes ASC admissions experiencing a fall outside the ASC. The denominator is defined as all ASC admissions and excludes ASC admissions experiencing a fall outside the ASC.[87] We believe this measure, if specified for the hospital outpatient setting, would enable HOPDs to take steps to reduce the risk of falls. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74498), we adopted this measure for the ASCQR Program because falls, particularly in the elderly, can cause injury and loss of functional status; because the use of anxiolytics, sedatives, and anesthetic

[77] ASCQR Specifications Manual, discussing these measures, available at: *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754.*

[78] Centers for Medicare & Medicaid Services. Meaningful Measures Hub. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.*

[79] National Quality Forum. 0265 All-Cause Hospital Transfer/Admission. Available at: *http://www.qualityforum.org/QPS/0265.*

[80] National Quality Forum. 0263 Patient Burn. Available at: *http://www.qualityforum.org/QPS/0263.*

[81] National Quality Forum. 0267 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant. Available at: *http://www.qualityforum.org/QPS/0267.*

[82] National Quality Forum. 0266 Patient Fall. Available at: *http://www.qualityforum.org/QPS/0266.*

[83] ASC Quality Collaboration. Quality measures developed and tested by the ASC Quality Collaboration. Available at: *http://ascquality.org/documents/2019-Summary-ASC-QC-Measures.pdf.*

[84] National Quality Forum. Serious Reportable Events in Healthcare 2006 Update. Washington, DC: NQF, 2007. Available at: *https://www.qualityforum.org/Publications/2007/03/Serious_Reportable_Events_in_Healthcare%E2%80%932006_Update.aspx.*

[85] ECRI Institute. New clinical guide to surgical fire prevention. Health Devices 2009 Oct;38(10):314–32.

[86] 170. National Fire Protection Association (NFPA). NFPA 99: Standard for health care facilities. Quincy (MA): NFPA; 2005.

[87] ASC Quality Collaboration. Quality measures developed and tested by the ASC Quality Collaboration. Available at: *http://ascquality.org/documents/2019-Summary-ASC-QC-Measures.pdf.*

agents may put patients undergoing outpatient surgery at increased risk for falls; and because falls in healthcare settings can be prevented through the assessment of risk, care planning, and patient monitoring. These same risks for patient falls are a concern in the HOPD setting. Further, we have reviewed studies demonstrating the high impact of monitoring patient burns because patient falls are serious reportable events in healthcare [88] and because patient falls are preventable.[89]

(3) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

The ASCQR Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant measure assesses the percentage of admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant. The numerator for this measure is defined as ASC admissions experiencing a wrong site, a wrong side, a wrong patient, a wrong procedure, or a wrong implant, and the denominator is defined as all ASC admissions.[90] We believe this measure, if specified for the hospital outpatient setting, would provide important HOPD information about surgeries and procedures performed on the wrong site/side, and wrong patient. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74498 through 74499), we adopted this measure for the ASCQR Program because surgeries and procedures performed on the wrong site/side, and wrong patient can result in significant impact on patients, including complications, serious disability or death. We also stated that while the prevalence of such serious errors may be rare, such events are considered serious reportable events. These same significant impacts on patients apply for the HOPD setting. Further, we have reviewed studies demonstrating the high impact of monitoring wrong site, wrong side, wrong patient, wrong procedure, wrong implant procedures and surgeries because these types of errors are serious reportable events in healthcare [91] and because these errors are preventable.[92]

(4) All-Cause Hospital Transfer/ Admission

The All-Cause Hospital Transfer/ Admission measure assesses the rate of admissions requiring a hospital transfer or hospital admission upon discharge. The numerator for this measure is defined as ASC admissions requiring a hospital transfer or hospital admission upon discharge from the ASC and the denominator is defined as all ASC admissions.[93] We believe this measure, if specified for the hospital outpatient setting, would be valuable for HOPDs. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74499), we adopted this measure for ASCs because the transfer or admission of a surgical patient from an outpatient setting to an acute care setting can be an indication of a complication, serious medical error, or other unplanned negative patient outcome. We also stated that while acute intervention may be necessary in these circumstances, a high rate of such incidents may indicate suboptimal practices or patient selection criteria. These same potential negative patient outcomes apply to the HOPD setting. Further, we have reviewed studies demonstrating the high impact of monitoring patient transfers and admissions because facilities can take steps to prevent and reduce these types of events.[94] [95]

b. Future Outcome Measures

In this proposed rule, we are also requesting public comment on future measure topics for the Hospital OQR Program. Specifically, we are requesting public comment on any outcome measures that would be useful to add as well as feedback on any process measures that should be eliminated from the Hospital OQR Program to further our goal of developing a comprehensive set of quality measures for informed decision-making and quality improvement in HOPDs. We are moving towards greater use of outcome measures and away from use of clinical process measures across our Medicare quality reporting programs to better assess the results of care. The current measure set for the Hospital OQR Program includes measures that assess process of care, imaging efficiency patterns, care transitions, ED throughput efficiency, Health Information Technology (health IT) use, care coordination, and patient safety. Measures are of various types, including those of process, structure, outcome, and efficiency. Through future rulemaking, we intend to propose new measures that support our goal of achieving better health care and improved health for Medicare beneficiaries who receive health care in the HOPD setting, while aligning quality measures across the Medicare program to the extent possible.

6. Maintenance of Technical Specifications for Quality Measures

CMS maintains technical specifications for previously adopted Hospital OQR Program measures. These specifications are updated as we modify the Hospital OQR Program measure set. The manuals that contain specifications for the previously adopted measures can be found on the QualityNet website at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244*. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59104 through 59105), where we changed the frequency of the Hospital OQR Program Specifications Manual release beginning with CY 2019 and for subsequent years, such that we will release a manual once every 12 months and release addenda as necessary. We are not proposing any changes to these policies in this proposed rule.

7. Public Display of Quality Measures

We refer readers to the CY 2014 and CY 2017 OPPS/ASC final rules with comment period (78 FR 75092 and 81 FR 79791 respectively) for our previously finalized policies regarding public display of quality measures. In this proposed rule, we are not proposing any changes to our previously finalized public display policies.

[88] National Quality Forum. Serious Reportable Events in Healthcare—2006 Update: A Consensus Report. March 2007. Available at: *https://www.qualityforum.org/Publications/2007/03/Serious_Reportable_Events_in_Healthcare%E2%80%932006_Update.aspx.*

[89] Boushon B, Nielsen G, Quigley P, Rutherford P, Taylor J, Shannon D. Transforming Care at the Bedside How-to Guide: Reducing Patient Injuries from Falls. Cambridge, MA: Institute for Healthcare Improvement; 2008.

[90] ASC Quality Collaboration. Quality measures developed and tested by the ASC Quality Collaboration. Available at: *http://ascquality.org/documents/2019-Summary-ASC-QC-Measures.pdf.*

[91] National Quality Forum. Serious Reportable Events in Healthcare—2006 Update: A Consensus Report. March 2007. Available at: *https://www.qualityforum.org/Publications/2007/03/Serious_Reportable_Events_in_Healthcare%E2%80%932006_Update.aspx.*

[92] American College of Obstetricians and Gynecologists. ACOG committee opinion #464: patient safety in the surgical environment. Obstet Gynecol. 2010;116(3):786–790.

[93] ASC Quality Collaboration. Quality measures developed and tested by the ASC Quality Collaboration. Available at: *http://ascquality.org/documents/2019-Summary-ASC-QC-Measures.pdf.*

[94] Coley KC, Williams BA, DaPos SV, Chen C, Smith RB. Retrospective evaluation of unanticipated admissions and readmissions after same day surgery and associated costs. J Clin Anesth. 2002 Aug; 14(5):349–53.

[95] Junger A, Klasen J, Benson M, Sciuk G, Hartmann B, Sticher J, Hempelmann G. Factors determining length of stay of surgical day-case patients. Eur J Anaesthesiol. 2001 May;18(5):314–21.

C. Administrative Requirements

1. QualityNet Account and Security Administrator

The previously finalized QualityNet security administrator requirements, including setting up a QualityNet account and the associated timelines, are described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109). We codified these procedural requirements at 42 CFR 419.46(a) in that final rule with comment period. We are not proposing any changes to our requirements for the QualityNet account and security administrator in this proposed rule.

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519) and the CY 2019 OPPS/ASC final rule with comment period (83 FR 59103 through 59104) for requirements for participation and withdrawal from the Hospital OQR Program. We codified these procedural requirements regarding participation status at 42 CFR 419.46(a) and (b). We are not proposing any changes to our participation status policies in this proposed rule.

D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

1. Hospital OQR Program Annual Payment Determinations

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75110 through 75111) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519 through 70520), we specified our data submission deadlines. We codified these submission requirements at 42 CFR 419.46(c).

We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519 through 70520), where we finalized our proposal to shift the quarters upon which the Hospital OQR Program payment determinations are based beginning with the CY 2018 payment determination. The deadlines for the CY 2022 payment determination and subsequent years are illustrated in Table 35.

TABLE 35.--CY 2022 Payment Determination and Subsequent Years

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2020 (April 1 - June 30)	11/1/2020
Q3 2020 (July 1 – September 30)	2/1/2021
Q4 2020 (October 1 - December 31)	5/1/2021
Q1 2021 (January 1 - March 31)	8/1/2021

In the CY 2018 OPPS/ASC final rule with comment period, we finalized a policy to align the initial data submission timeline for all hospitals that did not participate in the previous year's Hospital OQR Program and made conforming revisions at 42 CFR 419.46(c)(3). We are not proposing any changes to these policies in this proposed rule.

2. Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS for the CY 2022 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68481 through 68484) for a discussion of the form, manner, and timing for data submission requirements of chart-abstracted measures for the CY 2014 payment determination and subsequent years. In this proposed rule, 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.

The following previously finalized Hospital OQR Program chart-abstracted measures will require patient-level data to be submitted for the CY 2022 payment determination and subsequent years:

- OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival (NQF #0288);
- OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention (NQF #0290);
- OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496); and
- OP–23: Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT Scan Interpretation Within 45 Minutes of ED Arrival (NQF #0661).

3. Claims-Based Measure Data Requirements for the CY 2022 Payment Determination and Subsequent Years

Currently, the following previously finalized Hospital OQR Program claims-based measures are required for the CY 2022 payment determination and subsequent years:

- OP–8: MRI Lumbar Spine for Low Back Pain (NQF #0514);
- OP–10: Abdomen CT—Use of Contrast Material;
- OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low Risk Surgery (NQF #0669);
- OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539);
- OP–35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy; and
- OP–36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687).

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59106 through 59107), where we established a three-year reporting period for OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy beginning with the CY 2020 payment determination and for subsequent years. In that final rule with comment period (83 FR 59136 through 59138), we established a similar policy under the ASCQR Program. In this proposed rule, we are not proposing any changes regarding the submission of claims-based measures.

4. Data Submission Requirements for the OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures for the CY 2022 Payment Determination and Subsequent Years

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79792 through 79794) for a discussion of the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measures. In addition, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433), where we finalized a policy to delay implementation of the OP–37a–e OAS CAHPS Survey-based measures beginning with the CY 2020 payment determination (2018 reporting period) until further action in future rulemaking. In this proposed rule, we are not proposing any changes to the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measures.

5. Data Submission Requirements for Measures for Data Submitted via a Web-Based Tool for the CY 2022 Payment Determination and Subsequent Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75112 through 75115) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70521) and the CMS QualityNet website (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1205442125082*) for a discussion of the requirements for measure data submitted via the CMS QualityNet website for the CY 2017 payment determination and subsequent years. In addition, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75097 through 75100) for a discussion of the requirements for measure data submitted via the CDC NHSN website. In this proposed rule, we are not proposing any changes to our policies regarding the submission of measure data submitted via a web-based tool. However, as discussed in section XIV.B.3.b. of this proposed rule, we are proposing to remove OP–33: External Beam Radiotherapy for Bone Metastases beginning with the CY 2022 payment determination and for subsequent years.

If our proposal to remove OP–33 is finalized, the following previously finalized quality measures will require data to be submitted via a web-based tool for the CY 2022 payment determination and subsequent years:

- OP–22: Left Without Being Seen (NQF #0499) (via CMS' QualityNet website);
- OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) (via CMS' QualityNet website); and
- OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) (via CMS' QualityNet website).

6. Population and Sampling Data Requirements for the CY 2021 Payment Determination and Subsequent Years

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72100 through 72103) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74482 through 74483) for discussions of our population and sampling requirements. We are not proposing any changes to our population and sampling requirements for chart-abstracted measures in this proposed rule.

7. Hospital OQR Program Validation Requirements

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484 through 68487), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 through 66965), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59443), and 42 CFR 419.46(e) for our policies regarding validation. We are not proposing any changes to these policies in this proposed rule.

8. Extraordinary Circumstances Exception (ECE) Process for the CY 2021 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75119 through 75120), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66966), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79795), the CY 2018 OPPS/ASC final rule with comment period (82 FR 59444), and 42 CFR 419.46(d) for a complete discussion of our extraordinary circumstances exception (ECE) process under the Hospital OQR Program. We are not proposing any changes to our ECE policy in this proposed rule.

9. Hospital OQR Program Reconsideration and Appeals Procedures for the CY 2021 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68487 through 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75118 through 75119), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79795), and 42 CFR 419.46(f) for our reconsideration and appeals procedures. We 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 2020 Payment Determination

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on measures selected by the Secretary, in the form and manner, and at a time, specified by the Secretary will incur a 2.0 percentage point reduction to their Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent year.

The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data in order to receive the full payment update factor and that fail to meet the Hospital OQR Program requirements. Hospitals that meet the reporting requirements receive the full OPPS payment update without the reduction. For a more detailed discussion of how this payment reduction was initially implemented, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative payment weight for the APC to which

the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to 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 2020

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 2020 annual payment update factor. For the CY 2020 OPPS, the proposed reporting ratio is 0.980, calculated by dividing the proposed reduced conversion factor of $79.770 by the proposed full conversion factor of $81.398. We are proposing to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2020 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.

XV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XIV.A.1. of this proposed rule for a general overview of our quality reporting programs and to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58820 through 58822) and section I.A.2. of this proposed rule where we discuss our Meaningful Measures Initiative and our approach in evaluating quality program measures.

2. Statutory History of the ASCQR Program

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74494) for a detailed discussion of the statutory history of the ASCQR Program.

3. Regulatory History of the ASCQR Program

We seek to promote higher quality and more efficient health care for beneficiaries. This effort is supported by the adoption of widely accepted quality of care measures. We have collaborated with relevant stakeholders to define such measures in most healthcare settings and currently measure some aspect of care for almost all settings of care available to Medicare beneficiaries. These measures assess structural aspects of care, clinical processes, patient experiences with care, and clinical outcomes. We have implemented quality measure reporting programs for multiple healthcare settings. To measure the quality of ASC services and to make such information publicly available, we implemented the ASCQR Program. We refer readers to the CYs 2014 through 2019 OPPS/ASC final rules with comment period (78 FR 75122; 79 FR 66966 through 66987; 80 FR 70526 through 70538; 81 FR 79797 through 79826; 82 FR 59445 through 59476; and 83 FR 59110 through 59139, respectively) for an overview of the regulatory history of the ASCQR Program. We have codified certain requirements under the ASCQR Program at 42 CFR part 16, subpart H (42 CFR 416.300 through 416.330).

B. ASCQR Program Quality Measures

1. Considerations in the Selection of ASCQR Program Quality Measures

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494) for a detailed discussion of the priorities we consider for ASCQR Program quality measure selection. We are not proposing any changes to these policies in this proposed rule.

2. Policies for Retention and Removal of Quality Measures From the ASCQR Program

a. Retention of Previously Adopted ASCQR Program Measures

We previously finalized a policy that quality measures adopted for an ASCQR Program measure set for a previous payment determination year be retained in the ASCQR Program for measure sets for subsequent payment determination years, except when they are removed, suspended, or replaced as indicated (76 FR 74494 and 74504; 77 FR 68494 through 68495; 78 FR 75122; and 79 FR 66967 through 66969). We are not proposing any changes to this policy in this proposed rule.

b. Removal Factors for ASCQR Program Measures

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59111 through 59115), we clarified, finalized and codified at 42 CFR 416.320 an updated set of factors [96] and the process for removing measures from the ASCQR Program. The factors are:

- Factor 1. Measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures).
- Factor 2. Performance or improvement on a measure does not result in better patient outcomes.
- Factor 3. A measure does not align with current clinical guidelines or practice.
- Factor 4. The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic.
- Factor 5. The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.
- Factor 6. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.
- Factor 7. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.
- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59111 through 59115) for a detailed discussion of our process regarding measure removal.

3. Proposed New Quality Measure for the ASCQR Program Measure Set: Proposal To Adopt ASC–19: Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357)

In this proposed rule, we are proposing one new quality measure for the ASCQR Program for the CY 2024 payment determination and subsequent years—ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357).

a. Background

Ambulatory surgery in the outpatient setting is common in the United States. Nearly 70 percent of all surgeries in the United States are performed in an outpatient setting with an expanding number and variety of procedures being performed at stand-alone ASCs.[97] [98] General surgery procedures are commonly performed at ASCs. Based on an analysis of Medicare fee-for-service (FFS) claims for patients aged 65 years and older, from January 1, 2015 through December 31, 2015, 3,251 ASCs performed 149,468 general surgery procedures. These procedures include abdominal, alimentary tract, breast, skin/soft tissue, wound, and varicose vein stripping procedures. Of the 3,251 ASCs that performed general surgery procedures, 1,157 (35.5 percent) performed at least 25 such procedures during this time period. Because of the large number of general surgery procedures that occur in the ambulatory setting, we believe that adopting ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers in the ASCQR Program will provide beneficiaries with transparent quality data that can be utilized in choosing healthcare facilities.

While ambulatory surgery is considered low risk for complications, there are well-described and potentially preventable adverse events that can occur after ambulatory surgery leading to unplanned care at a hospital, such as emergency department (ED) visits, observation stays, or hospital admissions. These events include uncontrolled pain, urinary retention, infection, bleeding, and venous thromboembolism.[99] [100]

[96] We note that we previously referred to these factors as ''criteria'' (for example, 79 FR 66967 through 66969); we now use the term ''factors'' in order to align the ASCQR Program terminology with the terminology we use in other CMS quality reporting and pay-for-performance (value-based purchasing) programs.

[97] Cullen KA, Hall MJ, Golosinskiy A, Statistics NCfH. *Ambulatory surgery in the United States, 2006.* US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics; 2009.

[98] Medicare Payment Advisory Committee. Report for the Congress: Medicare Payment Policy, March 2019. *http://medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec.pdf?sfvrsn=0.* Accessed May 24, 2019.

[99] Coley KC, Williams BA, DaPos SV, Chen C, Smith RB. Retrospective evaluation of unanticipated admissions and readmissions after same day surgery and associated costs. *Journal of clinical anesthesia.* 2002;14(5):349–353.

[100] Bain J, Kelly H, Snadden D, Staines H. Day surgery in Scotland: patient satisfaction and outcomes. *Quality in Health Care.* 1999;8(2):86–91.

Hospital visits following same-day surgery are an important and broadly accepted patient-centered outcome reported in the literature.[101] [102] [103] [104] [105] [106] [107] [108] National estimates of hospital visit rates following outpatient surgery vary from 0.5 to 9.0 percent, based on the type of surgery, outcome measured (admissions alone or admissions and ED visits), and length of time between the surgery and the hospital visit.[109] [110] [111] [112] [113] [114] [115] [116] [117] The frequency of such events also varies among ASCs, suggesting variation in quality of pre-surgical assessment, surgical care, post-surgical care, and the care and support provided to patients post-discharge.[118] [119] [120] [121] [122] [123] [124] [125]

We calculated the national unadjusted rate of hospital visits (ED visits, observation stays, or hospital admissions) following any general surgery procedure at an ASC. In a Medicare FFS dataset of claims for services during CY 2015 (January 1, 2015–December 31, 2015), the distribution of unadjusted outcome rates was skewed, suggesting variation in quality of care. Among 1,153 ASCs with at least 25 qualifying general surgery cases in the Medicare FFS CY 2015 dataset, the unadjusted rate of unplanned hospital visits ranged from 0.0 percent to 13.2 percent. These results suggest opportunity for ASCs to improve the quality of care for patients seeking general surgery procedures.

ASCs may be unaware of patients' subsequent unplanned hospital visits given that patients tend to present to the ED or to hospitals unaffiliated with the ASC. In addition, information on the rate of patients' subsequent unplanned hospital visits would provide transparent data to beneficiaries that could be utilized when choosing ambulatory surgery sites of care. Quality measurement of the number of unplanned hospital visits following general surgery procedures performed at ASCs, coupled with transparency through public reporting would make these outcomes more visible to both ASCs and beneficiaries. Therefore, we expect that this would encourage ASCs to incorporate quality improvement activities to reduce the number of unplanned hospital visits and track quality improvement over time.

Therefore, in this proposed rule, we are proposing to adopt ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357) (hereafter referred to as the proposed ASC–19 measure) into the ASCQR Program for the CY 2024 payment determination and subsequent years.

The proposed ASC–19 measure was developed in conjunction with two other measures adopted for the ASCQR Program beginning with the CY 2022 payment determination as finalized in the CY 2018 OPPS/ASC final rule with comment period: ASC–17: Hospital Visits After Orthopedic Ambulatory Surgical Center Procedures (82 FR 59455) and ASC–18: Hospital Visits After Urology Ambulatory Surgical Center Procedures (82 FR 59463). All three measures assess the same patient outcome for care provided in the ASC setting and use the same risk-adjustment methodology. These three measures differ in surgical procedures considered (orthopedic, urological, or general surgery), specific risk variables included, and reporting of the outcome, unplanned hospital visits. The proposed ASC–19 measure reports the outcome as a risk-standardized ratio because the diverse mix of procedures included in the proposed ASC–19 measure can have varying levels of risk of unplanned hospital visits; while the ASC–17 and ASC–18 measures report a risk-standardized rate that reflects clinically specific cohorts with fairly comparable mixes of procedures. We refer readers to section XV.B.3.d. of this proposed rule for a full discussion on the measure outcome calculation.

b. Overview of Measure

The proposed ASC–19 measure is a risk-adjusted outcome measure of acute, unplanned hospital visits within 7 days of a general surgery procedure performed at an ASC among Medicare FFS patients aged 65 years and older. We define an unplanned hospital visit as including an emergency department (ED) visit, observation stay, or unplanned inpatient admission. The measure aligns with the Admissions and Readmissions to Hospitals and Preventable Healthcare Harm Meaningful Measure areas of our

[101] Majholm BB. Is day surgery safe? A Danish multicentre study of morbidity after 57,709 day surgery procedures. Acta anaesthesiologica Scandinavica. 2012;56(3):323–331.

[102] Whippey A, Kostandoff G, Paul J, Ma J, Thabane L, Ma HK. Predictors of unanticipated admission following ambulatory surgery: a retrospective case-control study. *Canadian Journal of Anesthesia/Journal canadien d'anesthésie.* 2013;60(7):675–683.

[103] Fleisher LA, Pasternak LR, Herbert R, Anderson GF. Inpatient hospital admission and death after outpatient surgery in elderly patients: importance of patient and system characteristics and location of care. *Arch Surg.* 2004;139(1):67–72.

[104] Coley KC, Williams BA, DaPos SV, Chen C, Smith RB. Retrospective evaluation of unanticipated admissions and readmissions after same day surgery and associated costs. *Journal of clinical anesthesia.* 2002;14(5):349–353.

[105] Hollingsworth JMJM. Surgical quality among Medicare beneficiaries undergoing outpatient urological surgery. *The Journal of urology.* 2012;188(4):1274–1278.

[106] Bain J, Kelly H, Snadden D, Staines H. Day surgery in Scotland: patient satisfaction and outcomes. *Quality in Health Care.* 1999;8(2):86–91.

[107] Fortier J, Chung F, Su J. Unanticipated admission after ambulatory surgery—a prospective study. *Canadian journal of anaesthesia = Journal canadien d'anesthesie.* 1998;45(7):612–619.

[108] Aldwinckle R, Montgomery J. Unplanned admission rates and postdischarge complications in patients over the age of 70 following day case surgery. *Anaesthesia.* 2004;59(1):57–59.

[109] Coley KC, Williams BA, DaPos SV, Chen C, Smith RB. Retrospective evaluation of unanticipated admissions and readmissions after same day surgery and associated costs. *Journal of clinical anesthesia.* 2002;14(5):349–353.

[110] Hollingsworth JMJM. Surgical quality among Medicare beneficiaries undergoing outpatient urological surgery. *The Journal of urology.* 2012;188(4):1274–1278.

[111] Baugh RR. Safety of outpatient surgery for obstructive sleep apnea. *Otolaryngology—head and neck surgery.* 2013;148(5):867–872.

[112] Bhattacharyya N. Ambulatory sinus and nasal surgery in the United States: Demographics and perioperative outcomes. *The Laryngoscope.* 2010;120(3):635–638.

[113] Bhattacharyya NN. Unplanned revisits and readmissions after ambulatory sinonasal surgery. *The Laryngoscope.* 2014;124(9):1983–1987.

[114] Bhattacharyya NN. Revisits and postoperative hemorrhage after adult tonsillectomy. *The Laryngoscope.* 2014;124(7):1554–1556.

[115] Hansen DG, Abbott LE, Johnson RM, Fox JP. Variation in hospital-based acute care within 30 days of outpatient plastic surgery. *Plastic and reconstructive surgery (1963).* 2014;134(3):370e-378e.

[116] Mahboubi HH. Ambulatory laryngopharyngeal surgery: evaluation of the national survey of ambulatory surgery. *JAMA otolaryngology— head & neck surgery.* 2013;139(1):28–31.

[117] Orosco RKRK. Ambulatory thyroidectomy: a multistate study of revisits and complications. *Otolaryngology—head and neck surgery.* 2015;152(6):1017–1023.

[118] Baugh RR. Safety of outpatient surgery for obstructive sleep apnea. *Otolaryngology—head and neck surgery.* 2013;148(5):867–872.

[119] Bhattacharyya N. Ambulatory sinus and nasal surgery in the United States: Demographics and perioperative outcomes. *The Laryngoscope.* 2010;120(3):635–638.

[120] Bhattacharyya NN. Unplanned revisits and readmissions after ambulatory sinonasal surgery. *The Laryngoscope.* 2014;124(9):1983–1987.

[121] Bhattacharyya NN. Revisits and postoperative hemorrhage after adult tonsillectomy. *The Laryngoscope.* 2014;124(7):1554–1556.

[122] Hansen DG, Abbott LE, Johnson RM, Fox JP. Variation in hospital-based acute care within 30 days of outpatient plastic surgery. *Plastic and reconstructive surgery (1963).* 2014;134(3):370e–378e.

[123] Mahboubi HH. Ambulatory laryngopharyngeal surgery: evaluation of the national survey of ambulatory surgery. *JAMA otolaryngology— head & neck surgery.* 2013;139(1):28–31.

[124] Menachemi. Quality of care differs by patient characteristics: outcome disparities after ambulatory surgical procedures. *American journal of medical quality.* 2007;22(6):395–401.

[125] Orosco RKRK. Ambulatory thyroidectomy: a multistate study of revisits and complications. *Otolaryngology—head and neck surgery.* 2015;152(6):1017–1023.

Meaningful Measures Initiative.[126] This measure was developed with input from a national Technical Expert Panel (TEP) consisting of patients, surgeons, methodologists, researchers, and providers. We also held a three-week public comment period soliciting stakeholder input on the measure methodology, and publicly posted a summary of the comments received as well as our responses (available in the Downloads section at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods.html*).

During the measure development public comment period, we received public comment recommending the removal of two specific procedures (CPT 29893 endoscopic plantar and CPT 69222 clean out mastoid cavity) deemed outside the scope of general surgery and to review the cohort procedure list with general surgeons to ensure appropriateness. In response to this feedback, we reviewed the cohort of procedures incorporating feedback from general surgeons and removed 15 individual skin/soft tissue and wound procedure codes from the measure that are outside the scope of general surgery practice. These procedures include those specifically suggested for removal (that is, endoscopic plantar and clean out mastoid cavity) as well as chemical peels, dermabrasions, and nerve procedures.

Section 1890A of the Act requires the Secretary to establish a pre-rulemaking process with respect to the selection of certain categories of quality and efficiency measures. Under section 1890A(a)(2) of the Act, the Secretary must make available to the public by December 1 of each year a list of quality and efficiency measures that the Secretary is considering. The ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers measure was included on a publicly available document entitled ''List of Measures under Consideration for December 1, 2017.'' [127] The MAP reviewed this measure (MUC17–233) and provided conditional support for rulemaking, pending NQF review and endorsement, with the recognition that this measure assesses an important outcome for patients receiving care at ASCs.[128] The MAP had some concerns about the attribution model of the measure, noting that hospital visits after ASC procedures are relatively rare events and could disproportionately affect low-income or rural ASCs and that the measure may need risk adjustment for social risk factors. At the time of the MAP's review, this measure was still undergoing field testing.

Since the MAP's conditional support,[129] we completed testing for the proposed ASC–19 measure by estimating risk-standardized scores using two full years of Medicare FFS claims data (CYs 2014 and 2015) containing 286,999 procedures. The results showed score variation across ASCs, from a minimum risk-standardized ratio of 0.42 to a maximum of 2.13; the median was 0.97 and the 25th and 75th percentiles were 0.90 and 1.10, respectively. After adjusting for case and procedure mixes of ASCs, these results suggest there are underlying differences in the quality of care and opportunities for quality improvement. The reliability testing found an intraclass correlation coefficient (ICC) score of 0.530, indicating moderate measure score reliability.[130] We considered the face validity of the measure score among TEP members. Among the 14 TEP members, 12 agreed that the measure scores are valid and useful measures of ASC quality of care for general surgery procedures and will provide ASCs with information that can be used to improve their quality of care. Detailed testing results are available in the technical report for this measure, located at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

On June 6, 2018, the NQF's Consensus Standards Approval Committee endorsed ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357).[131] The proposed ASC–19 measure is consistent with the information submitted to the NQF and the MAP, supporting its scientific acceptability for use in quality reporting programs. We note that we have made minor annual coding updates to the measure to incorporate changes to the CPT and ICD–10 coding systems and to incorporate clinical input to remove select procedures outside the scope of general surgery as noted above, endoscopic plantar, clean out mastoid cavity, chemical peels, dermabrasions, and nerve procedures. For the current list of codes that define the proposed ASC–19 measure and a description of updates since development, we refer readers to the zip file labeled ''Version 1.0 Hospital Visits General Surgery ASC Procedures Measure Technical Report'' located at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

We believe this proposed measure reflects consensus among stakeholders because it was developed with stakeholder input from a TEP convened by a CMS contractor as well as from the measure development public comment period.[132] During the measure development processes and the MAP meeting, the majority of public commenters supported the measure's focus on assessing patient outcomes after general surgery procedures performed in ASC setting of care. Most commenters supported MAP's conditional support of the measure, noting it should be further developed and NQF-endorsed before implementation in the ASCQR Program. Importantly, the proposed ASC–19 measure addresses the MAP-identified priority measure area of addressing preventable healthcare harm, such as surgical complications, for the ASCQR Program.[133] Therefore, we believe it is appropriate to incorporate this proposed measure into the ASCQR Program measure set because collecting and publicly reporting these data would increase transparency, inform patients and ASCs, and foster quality improvement efforts.

c. Data Sources

The proposed ASC–19 measure is claims-based using Part A and Part B Medicare administrative claims and

[126] 83 FR 58820 through 58822.

[127] National Quality Forum. List of Measures under Consideration for December 1, 2017. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86526.*

[128] National Quality Forum. MAP 2018 Considerations for Implementing Measures: Hospitals—Final Report. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=87096.*

[129] Ibid.

[130] Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics.* 1977;33(1):159–174.

[131] National Quality Forum. Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers. Available at: *http://www.qualityforum.org/QPS/3357.*

[132] National Quality Forum. ''MAP 2018 Considerations for Implementing Measures in Federal Programs: Hospitals.'' Report. 2017. Available at: *http://www.qualityforum.org/map/* under ''Hospitals—Final Report.''

[133] The Centers for Medicare and Medicaid Services Center for Clinical Standards and Quality. ''2018 Measures under Consideration List: Program-Specific Measure Needs and Priorities''. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/2018-CMS-Measurement-Priorities-and-Needs.pdf.* Accessed February 28, 2019.

Medicare enrollment data to calculate the measure.

We are proposing that the data collection period for the proposed ASC–19 measure would be the 2 calendar years ending 2 years prior to the applicable payment determination year. For example, for the CY 2024 payment determination, the data collection period would be CYs 2021 to 2022. Because the measure data are collected via claims, ASCs will not need to submit any additional data directly to CMS. We refer readers to section XV.D.4. of this proposed rule for a more detailed discussion of the requirements for data submitted via claims.

d. Measure Calculation

The measure outcome is all-cause, unplanned hospital visits within 7 days of any general surgery procedure performed at an ASC. For the purposes of this measure, ''hospital visits'' include emergency department visits, observation stays, and unplanned inpatient admissions. The outcome of hospital visits is limited to 7 days since existing literature suggests that the vast majority of adverse events after outpatient surgery occur within the first 7 days following the surgery.[134] [135] When there are two or more qualifying surgical procedures within a 7-day period, the measure considers all procedures as index procedures; however, the timeframe for outcome assessment is defined as the interval between procedures (including the day of the next procedure) and then 7 days after the last procedure.

The facility-level score is a risk-standardized hospital visit ratio (RSHVR), an approach that accounts for the clustering of patients within ASCs and variation in sample size across ASCs. The proposed ASC–19 measure reports the outcome as a risk-standardized ratio because the diverse mix of procedures included in the proposed measure can have varying levels of risk of unplanned hospital visits. The RSHVR is calculated as the ratio of the predicted to the expected number of unplanned hospital visits among ASC patients. For each ASC, the numerator of the ratio is the number of hospital visits predicted for the ASC's patients accounting for its observed rate, the number of the general surgery procedures performed at the ASC, the case-mix, and the surgical complexity mix. The denominator of the ratio is the number of hospital visits expected nationally given the ASC's case-mix and surgical complexity mix. To calculate an ASC's predicted-to-expected (P/E) ratio, the measure uses a two-level hierarchical logistic regression model. The log-odds of the outcome for an index procedure is modeled as a function of the patient demographic, comorbidity, procedure characteristics, and a random ASC-specific intercept. A ratio of less than one indicates the ASC facility's patients were estimated as having fewer post-surgical visits than expected compared to ASCs with similar surgical complexity and patients; and a ratio of greater than one indicates the ASC facility's patients were estimated as having more visits than expected. This approach is analogous to an observed-to-expected ratio, but the method accounts for within-facility correlation of the observed outcome and sample size differences, accommodates the assumption that underlying differences in quality across ASCs lead to systematic differences in outcomes, and is tailored to and appropriate for a publicly reported outcome measure as articulated in published scientific guidelines.[136] [137] [138] For more information on measure calculations, we refer readers to: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

e. Cohort

The patient cohort for the proposed ASC–19 measure includes all Medicare beneficiaries ages 65 and older undergoing outpatient general surgery procedures at an ASC who have 12 prior months of Medicare FFS (Medicare Parts A and B) enrollment. The target group of procedures includes those that: (1) Are routinely performed at ASCs; (2) involve some increased risk of post-surgery hospital visits; and (3) are within the scope of general surgery training. These include the following types of procedures: Abdominal (for example, hernia repair), alimentary tract (for example, hemorrhoid procedures), breast (for example, mastectomies), skin/soft tissue (for example, skin grafting), wound (for example, incision and drainage of skin and subcutaneous tissue), and varicose vein stripping. The proposed ASC–19 measure does not include gastrointestinal endoscopy, endocrine, or vascular procedures, other than varicose vein procedures, because for these procedures, reasons for hospital visits are typically related to patients' underlying comorbidities.

The scope of general surgery overlaps with that of other specialties (for example, vascular surgery and plastic surgery). For this measure, we targeted surgeries that general surgeons are trained to perform with the understanding that other subspecialists may also be performing many of these surgeries at ASCs. Since the type of surgeon performing a particular procedure may vary across ASCs in ways that affect quality, the measure is neutral to surgeons' specialty training.

Procedures included in the measure cohort are on CMS' list of covered ASC procedures.[139] We developed this list to identify surgeries that have a low-to-moderate risk profile. Surgeries on the ASC list of covered procedures do not involve or require major or prolonged invasion of body cavities, extensive blood loss, major blood vessels, or care that is either urgent or life threatening. We annually review and update this list, which includes a transparent public comment submission and review process for addition and/or removal of procedures codes.[140] The current list is accessible in the Downloads section at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/11_addenda_updates.html.*

In addition, the measure includes only ''major'' and ''minor'' procedures, as indicated by the Medicare Physician Fee Schedule global surgery indicator (GSI) values of 090 and 010, respectively, to focus the measure only on the subset of surgeries on CMS' list of covered ASC procedures that impose a meaningful risk of post-procedure hospital visits. This list of GSI values is publicly available for CY 2015 at: *https://www.cms.gov/Medicare/*

[134] Fleisher LA, Pasternak LR, Herbert R, Anderson GF. Inpatient hospital admission and death after outpatient surgery in elderly patients: Importance of patient and system characteristics and location of care. *Arch Surg.* 2004;139(1):67–72.

[135] Mattila K, Toivonen J, Janhunen L, Rosenberg PH, Hynynen M. Postdischarge symptoms after ambulatory surgery: First-week incidence, intensity, and risk factors. *Anesthesia and analgesia.* 2005;101(6):1643–1650.

[136] Krumholz HM, Brindis RG, Brush JE, et al. Standards for Statistical Models Used for Public Reporting of Health Outcomes An American Heart Association Scientific Statement From the Quality of Care and Outcomes Research Interdisciplinary Writing Group: Cosponsored by the Council on Epidemiology and Prevention and the Stroke Council Endorsed by the American College of Cardiology Foundation. Circulation. 2006;113(3):456–462.

[137] Normand S–LT, Shahian DM. Statistical and clinical aspects of hospital outcomes profiling. Statistical Science. 2007;22(2):206–226.

[138] National Quality Forum. Measure Evaluation Criteria and Guidance for Evaluating Measures for Endorsement. 2015. Available at: *http://www.qualityforum.org/Measuring_Performance/Submitting_Standards/2015_Measure_Evaluation_Criteria.aspx.* Accessed July 26, 2016.

[139] Centers for Medicare and Medicaid Services. ''Ambulatory Surgical Center (ASC) Payment: Addenda Updates.'' Available at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/11_addenda_updates.html.*

[140] Ibid.

Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1612-FC.html (download PFS Addenda, Addendum B). Moreover, to identify the subset of ASC procedures within the scope of general surgery, we used the Clinical Classifications Software (CCS) developed by the Agency for Healthcare Research and Quality.[141] We identified and included CCS categories within the scope of general surgery, and only included individual procedures within the CCS categories at the procedure (CPT code) level if they were within the scope of general surgery practice. For more cohort details, we refer readers to the measure technical report located at: *https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

To ensure that all patients included under this measure have full data available for outcome assessment, the measure excludes patients who survived at least 7 days following general surgery procedures at an ASC, but were not continuously enrolled in Medicare FFS (Medicare Parts A and B) during the 7 days after surgery. There are no additional patient inclusion or exclusion criteria for the proposed ASC–19 measure. Additional methodology and measure development details are available at: *https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

f. Risk Adjustment

The statistical risk-adjustment model includes clinically relevant risk-adjustment variables that are strongly associated with risk of hospital visits within 7 days following ASC general surgery procedures. Accordingly, only comorbidities that convey information about the patient at that time or in the 12 months prior, and not complications that arise during the course of the index procedure, are included in the risk adjustment. The measure risk adjusts for age, 18 comorbidities, procedure type (abdomen vs. alimentary tract vs. breast vs. skin/soft tissue vs. wound vs. varicose vein), a variable for work Relative Value Units (RVUs) to adjust for surgical complexity, and an interaction term of procedure type and surgical complexity.[142]

To select the final set of variables for the risk-adjustment model, candidate risk variables were entered into logistic regression analyses [143] predicting the outcome of hospital visits within 7 days. To develop a parsimonious risk model, non-significant variables were iteratively removed from the model using a stepwise selection approach described by Hosmer and Lemeshow.[144] All variables significant at $p<0.05$ were retained in the final model. We also tested interaction terms and retained those that were both significant at $p<0.05$ and demonstrated a clinically plausible relationship to the outcome. Finally, after reviewing TEP and public comments, as well as the statistically selected variables for face validity, we settled upon the model variables. We retained one additional variable (opioid use) for the final risk model because experts advised it was an important risk predictor and expressed a strong preference for including it in the model even though it was not statistically selected. Additional details on risk model development and testing are available in the technical report at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

g. Public Reporting

We are proposing that if the proposed ASC–19 measure is adopted, we would publicly report results only for facilities with sufficient case numbers to meet moderate reliability standards.[145] We would determine the case size cutoff for meeting moderate reliability standards by calculating reliability at different case sizes using the ratio of true variance to observed variance during the measure dry run (discussed below).[146] We would provide confidential performance data directly to all facilities including those which do not meet the criteria for sufficient case numbers for reliability considerations so that all facilities can benefit from seeing their measure results and individual patient-level outcomes. We believe that the measure will provide beneficiaries with information about the quality of care for general surgery procedures in the ASC setting. In addition, we believe that these performance data may help ASCs track their patient outcomes and provide information on their cases that facilities can use to improve quality of care.

h. Provision of Facility-Specific Information Prior to Public Reporting

If this proposed measure is finalized, we intend to conduct a dry run before the official data collection period or any public reporting. A dry run is a period of confidential reporting and feedback during which ASCs may review their dry run measure results, and in addition, further familiarize themselves with the measure methodology and ask questions. For the dry run, we intend to use the most current 2-year set of complete claims (usually 12 months prior to the start date) available at the time of dry run. For example, if the dry run began in June 2020, the most current 2-year set of data available would likely be July 2017 to June 2019. Because we use paid, final action Medicare claims, ASCs would not need to submit any additional data for the dry run. The dry run would generate confidential feedback reports for ASCs, including patient-level data indicating whether the patient had a hospital visit and, if so, the type of visit (emergency department visit, observation stay, or unplanned inpatient admission), the admitting facility, and the principal discharge diagnosis. Further, the dry run would enable ASCs to see their dry run measure results prior to the measure being implemented. General information about the dry run as well as confidential facility-specific reports would be made available for ASCs to review on their accounts at: *http://www.qualitynet.org.* We plan to continue to generate these reports for ASCs after we implement the proposed measure if it is finalized so ASCs can use the information to identify performance gaps and develop quality improvement strategies.

These confidential dry run results are not publicly reported and do not affect payment. We expect the dry run to take approximately one month to conduct, during which facilities would be provided the confidential report and the opportunity to review their performance and provide feedback to us. After the dry run, measure results would have a payment impact and would be publicly reported as discussed above beginning with the CY 2024 payment determination and for subsequent years.

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[141] Healthcare Cost and Utilization Project. *Clinical Classifications Software for Services and Procedures.* Available at: *https://www.hcup-us.ahrq.gov/toolssoftware/ccs_svcsproc/ccssvcproc.jsp.*

[142] S. Coberly. The Basics; Relative Value Units (RVUs). National Health Policy Forum. January 12, 2015. Available at: *http://www.nhpf.org/library/the-basics/Basics_RVUs_01-12-15.pdf.*

[143] Hosmer DW, Lemeshow S. Introduction to the logistic regression model. *Applied Logistic Regression, Second Edition.* 2000:1–30.

[144] Hosmer DW, Lemeshow S. Introduction to the logistic regression model. *Applied Logistic Regression, Second Edition.* 2000:1–30.

[145] Ibid.

[146] Snijders TA, Bosker RJ. *Multilevel Analysis: An introduction to basic and advanced multilevel modeling.* SAGE Publications. 2000. London.

4. Summary of ASCQR Program Quality Measure Set Proposed for the CY 2024 Payment Determination and for Subsequent Years

As discussed above, we are proposing to add one measure beginning with the CY 2024 payment determination and for subsequent years to the ASCQR Program. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59129 through 59132) for previously finalized ASCQR Program measure sets.

Table 36 summarizes the proposed ASCQR Program measure set for the CY 2024 payment determination and subsequent years (including previously adopted measures).

TABLE 36.--Proposed ASCQR Program Measure Set for the CY 2024 Payment Determination and Subsequent Years

ASC #	NQF #	Measure Name
ASC-1	0263†	Patient Burn*
ASC-2	0266†	Patient Fall*
ASC-3	0267†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant*
ASC-4	0265†	All-Cause Hospital Transfer/Admission*
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-11	1536†	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery**
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-15a	None	OAS CAHPS – About Facilities and Staff***
ASC-15b	None	OAS CAHPS – Communication About Procedure***
ASC-15c	None	OAS CAHPS – Preparation for Discharge and Recovery***
ASC-15d	None	OAS CAHPS – Overall Rating of Facility***
ASC-15e	None	OAS CAHPS – Recommendation of Facility***
ASC-17	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers****

† NQF endorsement was removed.
* Measure finalized for suspension in reporting beginning with the CY 2021 payment determination (CY 2019 data collection) until further action in future rulemaking as discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59117 through 59123).
** Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).
***Measure finalized for delay in reporting beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking as discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451).
****Measure proposed for adoption in section XV.B.3. of this proposed rule beginning with the CY 2024 payment determination

5. ASCQR Program Measures and Topics for Future Consideration

In this proposed rule, we are considering one topic for future implementation: Updates to the submission method for ASC–1: Patient Burn, ASC–2: Patient Fall, ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant, and ASC–4: All-Cause Hospital Transfer/Admission measures.

ASC–1, ASC–2, ASC–3, and ASC–4 were adopted into the ASCQR Program in the CY 2012 OPPS/ASC final rule with comment period beginning with the CY 2014 payment determination (76 FR 74496 through 74500). These

measures were developed by the ASC Quality Collaboration (ASC QC). The ASC QC is a cooperative effort of organizations and companies formed in 2006 with a common interest in ensuring that ASC quality data is measured and reported in a meaningful way.[147] Stakeholders in the ASC QC include ASC corporations, ASC associations, professional societies and accrediting bodies that focus on ASC quality and safety.[148] The ASC QC initiated a process of standardizing ASC quality measure development through evaluation of existing nationally endorsed quality measures to determine which could be directly applied to the outpatient surgery facility setting.[149]

The ASC QC developed and pilot-tested ASC–1, ASC–2, ASC–3, and ASC–4 at the facility-level for feasibility and usability (76 FR 74496). These measures are calculated via quality data codes (QDCs), as described in section XV.D.1. of this proposed rule. ASCs were formerly required to submit the appropriate QDCs on individual Medicare FFS claims billed by the facility (78 FR 75135). In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53640 through 53641), we finalized our policy that the minimum threshold for successful reporting be that at least 50 percent of claims meeting measure specifications contain QDCs. At that time, we believed that 50 percent was a reasonable minimum threshold for the initial implementation years of the ASCQR Program, because ASCs were not yet familiar with how to report quality data under the ASCQR Program and because many ASCs are relatively small and may have needed more time to set up reporting systems (77 FR 53641). We stated in that final rule that we intended to propose to increase this percentage for subsequent years' payment determinations as ASCs become more familiar with reporting requirements for the ASCQR Program. We have assessed this reporting threshold annually and have found that over 78 percent of reporting ASCs report data for at least 90 percent of eligible claims.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59117 through 59123), we expressed concern that the data submission method for these measures may impact the completeness and accuracy of the data due to the inability of ASCs to correct errors in submitted QDCs that are used to calculate these measures. An ASC that identifies an erroneous or missing QDC is unable to correct or add a QDC if the claim has already been submitted to Medicare and been processed. We also stated that we believe that revising the data submission method for the measures, such as via QualityNet, would address this issue and allow ASCs to correct any data submissions errors, resulting in more complete and accurate data. In that final rule with comment period, we explained that we agree it is important to continue to monitor the types of events included in these measures considering the potential negative impacts to patients' morbidity and mortality, in order to continue to prevent their occurrence and ensure that they remain rare. We acknowledged that these measures provide critical data to beneficiaries and further transparency for care provided in the ASC setting that would be useful in choosing an ASC for care, and that these measures are valuable to the ASC community.

As such, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59117 through 59123; 59134 through 59135), we retained these measures in the ASCQR Program, but suspended their data submission until further action in rulemaking with the goal of updating their data submission method.

In this proposed rule, we are requesting comment about potential future updates to the data submission method for ASC–1: Patient Burn, ASC–2: Patient Fall, ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant, and ASC–4: All-Cause Hospital Transfer/Admission. Specifically, we have considered updating the data submission method to a CMS online data submission tool. We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59473) (and the previous rulemakings cited therein) and 42 CFR 416.310(c)(1) for our requirements regarding data submitted via a CMS online data submission tool. We are currently using the QualityNet website (*https://www.qualitynet.org*) as our CMS online data submission tool.

To submit measures via an online data submission tool to the QualityNet website, ASCs and any agents submitting data on an ASC's behalf would have to maintain a QualityNet account (42 CFR 416.310(c)(1)). A QualityNet security administrator would be necessary to set up such an account for the purpose of submitting this information (42 CFR 416.310(c)(1)). We believe that using a CMS online data collection tool would address our concern about the ability of ASCs to correct data submission errors because ASCs would simply report their data via the online tool. If data for these measures were submitted via QualityNet, ASCs would still submit claims for reimbursement to CMS, but would not be required to include QDCs. As specified at 42 CFR 416.310(c)(1)(ii), the data collection time period for quality measures for which data are submitted via a CMS online data submission tool is for services furnished during the calendar year 2 years prior to the payment determination year. ASCs would then submit their data for ASC–1, ASC–2, ASC–3, and ASC–4 via QualityNet during the data submission period, January 1 through May 15 in the year prior to the payment determination year. ASCs would be able to submit and modify their data throughout the data submission period and could correct any errors during this period. We are seeking comments on whether updating the data submission method for ASC–1, ASC–2, ASC–3, and ASC–4 to a CMS online data submission tool would be appropriate for these measures in the future.

We are committed to work with stakeholders to ensure the ASCQR Program measure set does not place an inappropriate amount of burden on facilities while addressing and providing information about these types of patient safety, adverse, rare events to patients and other consumers. We recognize that updating the data submission method to a CMS online data submission tool would add some burden to the ASCQR Program due to the additional time for submitting any of these four measures via QualityNet for each payment determination year. Thus, we are also seeking comment about the burden associated with potentially updating the data submission method for ASC–1, ASC–2, ASC–3, and ASC–4 to a CMS online data submission tool (for example, the QualityNet website) in future years.

6. Maintenance of Technical Specifications for Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74513 through 74514), where we finalized our proposal to follow the same process for updating the ASCQR Program measures that we adopted for the Hospital OQR Program measures, including the subregulatory process for updating adopted measures. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68496 through 68497), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75131), and the CY 2015 OPPS/ASC

[147] ASC Quality Collaboration. ASC Quality Measures Implementation Guide Version 6.1 March 2019. Available at: *http://ascquality.org/documents/ASC-QC-Implementation-Guide-6.1-March-2019.pdf.*

[148] Ibid.

[149] Ibid.

final rule with comment period (79 FR 66981), we provided additional clarification regarding the ASCQR Program policy in the context of the previously finalized Hospital OQR Program policy, including the processes for addressing nonsubstantive and substantive changes to adopted measures. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70531), we provided clarification regarding our decision to not display the technical specifications for the ASCQR Program on a CMS website, but stated that we will continue to display the technical specifications for the ASCQR Program on the QualityNet website. In addition, our policies regarding the maintenance of technical specifications for the ASCQR Program are codified at 42 CFR 416.325. In 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. We are not proposing any changes to our public reporting policies in this proposed rule.

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). We are not proposing any changes to these policies in this proposed rule.

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75133 through 75135) for a complete discussion of the participation status requirements for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70533 through 70534), we codified these requirements regarding participation status for the ASCQR Program at 42 CFR 416.305. We are not proposing any changes to these policies in this proposed rule.

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).

We are not proposing any changes to these requirements in this proposed rule. We note that data submission for the following claims-based measures using QDCs was suspended in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59117 through 59123; 59134 through 59135) until further action in rulemaking:

- ASC–1: Patient Burn;
- ASC–2: Patient Fall;
- ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and
- ASC–4: Hospital Transfer/Admission.

We also note that we are requesting comment on updating the submission method for the above measures in section XV.B.5. of this proposed rule.

These data processing and collection period requirements will remain in the ASCQR Program for application to any future claims-based measures using QDCs adopted by the ASCQR Program.

2. Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59472) (and the previous rulemakings cited therein), as well as 42 CFR 416.310(a)(3) and 42 CFR 416.305(c) for our policies about minimum threshold, minimum case volume, and data completeness for claims-based measures using QDCs. In 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*.

a. Requirements for Data Submitted via a Non-CMS Online Data Submission Tool

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75139 through 75140) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66985 through 66986) for our requirements regarding data submitted via a non-CMS online data submission tool (that is, the CDC NHSN website). We codified our existing policies regarding the data collection time periods for measures involving online data submission and

the deadline for data submission via a non-CMS online data submission tool at 42 CFR 416.310(c)(2).

As we noted in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59135), no measures submitted via a non-CMS online data submission tool remain in the ASCQR Program beginning with the CY 2020 payment determination. 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 ASCQR Program.

b. Requirements for Data Submitted via a CMS Online Data Submission Tool

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59473) (and the previous rulemakings cited therein) and 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 to host our CMS online data submission tool: *https://www.qualitynet.org*. We note that in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59473), we finalized expanded submission via the CMS online tool to also allow for batch data submission and made corresponding changes to 42 CFR 416.310(c)(1)(i).

In this proposed rule, we are not proposing any changes to this policy. 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–9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
- ASC–11: Cataracts: Improvement in Patients' Visual Function within 90 Days Following Cataract Surgery
- ASC–13: Normothermia Outcome
- ASC–14: Unplanned Anterior Vitrectomy

4. Requirements for Non-QDC Based, Claims-Based Measure Data

We are not proposing any changes to our requirements for non-QDC based, claims-based measures in this proposed rule. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59136 through 59138, where we established a 3-year reporting period for the previously adopted measure, ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. In that final rule with comment period (83 FR 59106 through 59107), we established a similar policy under the Hospital OQR Program.

We also note that we are proposing to adopt ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357) in section XV.B.3. of this proposed rule to which these requirements for non-QDC based, claims-based measures would apply if the proposed ASC–19 measure is finalized as proposed.

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 the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499) for a detailed discussion of the statutory background regarding payment reductions for ASCs that fail to meet the ASCQR Program requirements.

2. Policy Regarding Reduction to the ASC Payment Rates for ASCs That Fail To Meet the ASCQR Program Requirements for a Payment Determination Year

The national unadjusted payment rates for many services paid under the ASC payment system are equal to the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. For CY 2020, the 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 annual update for the ASC payment system for a 5-year period (CY 2019 through CY 2023). Under the ASCQR Program in accordance with section 1833(i)(7)(A) of the Act and as discussed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499), any annual increase shall be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction applied beginning with the CY 2014 payment rates (77 FR 68500). For a complete discussion of the calculation of the ASC conversion factor and our finalized proposal to update the ASC payment rates using the inpatient hospital market basket update for CYs 2019 through 2023, we refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59073 through 59080).

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), in order to implement

the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we finalized our proposal that we would calculate two conversion factors: A full update conversion factor and an ASCQR Program reduced update conversion factor. We finalized our proposal to calculate the reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination. We finalized our proposal that application of the 2.0 percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the MFP adjustment.

The ASC conversion factor is used to calculate the ASC payment rate for services with the following payment indicators (listed in Addenda AA and BB to the proposed rule, which are available via the internet on the CMS website): ''A2'', ''G2'', ''P2'', ''R2'' and ''Z2'', as well as the service portion of device-intensive procedures identified by ''J8'' (77 FR 68500). We finalized our proposal that payment for all services assigned the payment indicators listed above would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor (77 FR 68500).

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators ''A2'', ''G2'', ''J8'', ''P2'', ''R2'' and ''Z2.'' These services include separately payable drugs and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPS payment rates, and certain office-based procedures, radiology services and diagnostic tests where payment is based on the PFS nonfacility PE RVU-based amount, and a few other specific services that receive cost-based payment (77 FR 68500). As a result, we also finalized our proposal that the ASC payment rates for these services would not be reduced for failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, not affected by reductions to the annual update (77 FR 68500).

Office-based surgical procedures (generally those performed more than 50 percent of the time in physicians' offices) and separately paid radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents) are paid at the lesser of the PFS nonfacility PE RVU-based amounts or the amount calculated under the standard ASC ratesetting methodology. Similarly, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized our proposal that payment for certain diagnostic test codes within the medical range of CPT codes for which separate payment is allowed under the OPPS will be at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the standard ASC ratesetting methodology when provided integral to covered ASC surgical procedures. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the standard ASC ratesetting methodology for this type of comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to these procedures or services is consistent for each HCPCS code, regardless of whether payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we believe that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionately reduced coinsurance liability for beneficiaries (77 FR 68500). Therefore, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the Medicare beneficiary's national unadjusted coinsurance for a service to which a reduced national unadjusted payment rate applies will be based on the reduced national unadjusted payment rate.

In that final rule with comment period, we finalized our proposal that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program (77 FR 68500). For example, the following standard adjustments would apply to the reduced national unadjusted payment rates: The wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; and the adjustment for devices furnished with full or partial credit or without cost (77 FR 68500). We believe that these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR Program requirements (77 FR 68500).

In the CY 2015, CY 2016, CY 2017, CY 2018, and CY 2019 OPPS/ASC final rules with comment period (79 FR 66981 through 66982; 80 FR 70537 through 70538; 81 FR 79825 through 79826; 82 FR 59475 through 59476; and 83 FR 59138 through 59139, respectively), we did not make any other changes to these policies. We are not proposing any changes to these policies for CY 2020 in this proposed rule.

XVI. Proposed Requirements for Hospitals To Make Public a List of Their Standard Charges

A. Introduction and Overview

1. Statutory Basis and Current Guidance

Section 1001 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by section 10101 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), amended Title XXVII of the Public Health Service Act (the PHS Act), in part, by adding a new section 2718(e). Section 2718 of the PHS Act, entitled ''Bringing Down the Cost of Health Care Coverage,'' requires each hospital operating within the United States for each year to establish (and update) and make public a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the Social Security Act (the Act).

In the FY 2015 IPPS/LTCH PPS proposed and final rules (79 FR 28169 and 79 FR 50146, respectively), we reminded hospitals of their obligation to comply with the provisions of section 2718(e) of the PHS Act and provided guidelines for its implementation. At that time, we required hospitals to either make public a list of their standard charges or their policies for allowing the public to view a list of those charges in response to an inquiry. In addition, we stated that we expected hospitals to update the information at least annually, or more often as appropriate, to reflect current charges. We also encouraged hospitals to undertake efforts to engage in consumer-friendly communication of their charges to enable consumers to compare charges for similar services across hospitals and to help consumers understand what their potential financial liability might be for items and services they obtain at the hospital.

In the FY 2019 IPPS/LTCH PPS proposed rule and final rule (83 FR 20164 and 83 FR 41144, respectively), we again reminded hospitals of their obligation to comply with the provisions of section 2718(e) of the PHS Act and updated our guidelines for its implementation. The announced update to our guidelines became effective January 1, 2019, and took one step to further improve the public accessibility of standard charge information. Specifically, we updated 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. We subsequently published two sets of Frequently Asked Questions (FAQs) [150] that provided additional guidance to hospitals, including a FAQ clarifying that while hospitals could choose the format they would use to make public a list of their standard charges, the publicly posted information should represent their standard charges as reflected in the hospital's chargemaster. We also clarified that the requirement applies to all hospitals operating within the United States and to all items and services provided by the hospital.

2. Background

As health care costs continue to rise, health care affordability has become an area of intense focus. Health care spending is projected to consume 20 percent of the economy by 2026.[151] One reason for this upward trajectory in spending is the lack of transparency in health care pricing.[152] Additionally, numerous studies suggest that consumers want greater transparency. For example, a study of high deductible health plan enrollees found that respondents wanted additional health care price information so that they could make more informed decisions about where to seek care based on price.[153] Health economists and other experts state that significant cost containment cannot occur without widespread and sustained transparency in provider prices.[154] We believe there is a direct connection between transparency in hospital standard charge information and having more affordable health care and lower health care coverage costs. We believe health care markets could work more efficiently and provide consumers with higher-value health care if we promote policies that encourage choice and competition.[155] In short, as articulated by the CMS Administrator, we believe that transparency in health care pricing is ''critical to enabling patients to become active consumers so that they can lead the drive towards value.'' [156]

Many empirical studies have investigated the impact of price transparency on markets, with most research showing that price transparency leads to lower and more uniform prices, consistent with predictions of standard economic theory.[157] Traditional economic analysis suggests that if consumers have better pricing information for health care services, providers would face pressure to lower prices and provide better quality care.[158] Falling prices may, in turn, expand access to health care for consumers.[159]

Presently, however, the information that health care consumers need to make informed decisions based on the prices of health care services is not readily available. The Government Accountability Office (GAO) report (2011), ''Health Care Price Transparency: Meaningful Price Information is Difficult for Consumers to Obtain Prior to Receiving Care,'' [160] found that opacity in health care prices, coupled with the often wide pricing disparities for particular procedures within the same market, can make it difficult for consumers to understand health care prices and to effectively shop for value. The report references a number of barriers that make it difficult for consumers to obtain price estimates in advance for health care services. Such barriers include the difficulty of predicting health care service needs in advance, a complex billing structure resulting in bills from multiple providers, the variety of insurance benefit structures, and concerns related to the public disclosure of rates negotiated between providers and third party payers. The GAO report goes on to explore various price transparency initiatives, including tools that consumers could use to generate price estimates in advance of receiving a health care service. The report notes that pricing information displayed by tools varies across initiatives, in large part due to limits reported by the initiatives in their access or authority to collect certain necessary price data. According to the GAO report, transparency initiatives were best able to provide reasonable estimates of consumers' complete costs when they had access and integrated pricing data from both providers and insurers.

The concept of making health care provider charges and insurance benefit information available to consumers is not new; some States have required disclosure of pricing information by providers and payers for a number of years. More than half of the States have passed legislation establishing price transparency websites or mandating that health plans, hospitals, or physicians make price information available to consumers.[161] As of early 2012, there

[150] Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FAQs-Req-Hospital-Public-List-Standard-Charges.pdf* and *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProspMedicareFeeSvcPmtGen/Downloads/Additional-Frequently-Asked-Questions-Regarding-Requirements-for-Hospitals-To-Make-Public-a-List-of-Their-Standard-Charges-via-the-internet.pdf*.

[151] CMS. National Health Expenditures Projections, 2018–2027: Forecast Summary. Available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ForecastSummary.pdf*.

[152] Scheurer, D. Lack of Transparency Plagues U.S. Health Care System. *The Hospitalist.* 2013 May; 2013(5). Available at: *https://www.the-hospitalist.org/hospitalist/article/125866/health-policy/lack-transparency-plagues-us-health-care-system*. Bees, J. Survey Snapshot: Is Transparency the Answer to Rising Health Care Costs? *New England Journal of Medicine* Catalyst. March 20, 2019. Available at: *https://catalyst.nejm.org/health-care-cost-transparency-answer/*. Wetzell, S. Transparency: A Needed Step Towards Health Care Affordability. *American Health Policy Institute.* March, 2014. Available at: *http://www.americanhealthpolicy.org/Content/documents/resources/Transparency%20Study%201%20-%20The%20Need%20for%20Health%20Care%20Transparency.pdf*. Robert Wood Johnson Foundation. How Price Transparency Can Control the Cost of Health Care. March 1, 2016. Available at: *https://www.rwjf.org/en/library/research/2016/03/how-price-transparency-controls-health-care-cost.html*.

[153] Sinaiko, A.D., Mehrotra, A., & Sood, N. (2016). Cost-Sharing Obligations, High-Deductible Health Plan Growth, and Shopping for Health Care: Enrollees with Skin in the Game. JAMA internal medicine, 176(3), 395–397. doi:10.1001/jamainternmed.2015.7554.

[154] Boynton A, and Robinson, JC. Appropriate Use of Reference Pricing Can Increase Value. July 7, 2015. Available at: *https://www.healthaffairs.org/do/10.1377/hblog20150707.049155/full/*.

[155] Azar, A.M., Mnuchin, S.T., and Acosta, A. ''Reforming America's Healthcare System Through Choice and Competition.'' December 3, 2018. Available at: *https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf*.

[156] Bresnick J. Verma: Price Transparency Rule a ''First Step'' for Consumerism. January 11, 2019. Available at: *https://healthpayerintelligence.com/news/verma-price-transparency-rule-a-first-step-for-consumerism*.

[157] Congressional Research Service Report to Congress: Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Healthcare Sector, July 24, 2007.

[158] Ibid.

[159] Ibid.

[160] Available at: *https://www.gao.gov/products/GAO-11-791*.

[161] Desai S, Hatfield LA, Hicks AL, et al. Association Between Availability of a Price Transparency Tool and Outpatient Spending. *JAMA*. 2016;315(17):1874–1881. Available at:

were 62 consumer-oriented, State-based health care price comparison websites.[162] Half of these websites were launched after 2006, and most were developed and funded by a State government agency (46.8 percent) or hospital association (38.7 percent).[163] Most websites report prices of inpatient care for medical conditions (72.6 percent) or surgeries (71.0 percent). Information about prices of outpatient services such as diagnostic or screening procedures (37.1 percent), radiology studies (22.6 percent), prescription drugs (14.5 percent), or laboratory tests (9.7 percent) are reported less often.[164]

Since the early 2000s, California-licensed hospitals have been required to submit annually to the State for public posting on a State website: The charge description master (CDM, also known as a ''chargemaster''); a list of the hospital's average charges for at least 25 common outpatient procedures, including ancillary services; and the estimated percentage increase in gross revenue due to price changes.[165] The information is required to be submitted in plain language using easily understood terminology.[166] In 2012, Massachusetts began requiring insurers to provide, upon request, the estimated amount insured patients will be responsible to pay for proposed admissions, procedures, or services based upon the information available to the insurer at the time, and also began requiring providers to disclose the charge for the admission, procedure, or service upon request by the patient within 2 working days.[167] Since 2015, Oregon has offered pricing data for the top 100 common hospital outpatient procedures and top 50 common inpatient procedures on its *OregonHospitalGuide.org* website, which displays the median negotiated amount of the procedure by hospital and includes patient paid amounts such as deductibles and copayments. The data are derived from State-mandated annual hospital claims collection by the State's all payer claims database (APCD) and represent the service package cost for each of the procedures, including ancillary services and elements related to the procedure, with the exception of professional fees which are billed separately.[168] More recently, in 2018, Colorado began requiring hospitals to post the prices of the 50 most used diagnosis-related group (DRG) codes, and the 25 most used outpatient Current Procedural Terminology (CPT) codes or health care services procedure codes with a ''plain-English description'' of the service, which must be updated at least annually.[169]

Not only have States taken an interest in price transparency, but insurers and self-funded employers have also moved in this direction. For example, some self-funded employers are using price transparency tools to incentivize their employees to make cost-conscious decisions when purchasing health care services. Most large insurers have embedded cost estimation tools into their member websites, and some provide their members with comparative cost and value information, which includes rates that the insurers have negotiated with in-network providers and suppliers.

Research suggests that making such consumer-friendly pricing information available to the public can reduce health care costs for consumers. Specifically, recent research evaluating the impact of New Hampshire's price transparency efforts reveals that providing insured patients with information about prices can have an impact on the out-of-pocket costs paid by consumers for medical imaging procedures, not only by helping users of New Hampshire's website choose lower-cost options, but also by leading to lower prices that benefited all patients, including those in the State that did not use the website.[170]

Despite the growing consumer demand and awareness of the need for health care pricing data, there continues to be a gap in easily accessible pricing information for consumers to use for health care shopping purposes. Specifically, there is inconsistent (and many times nonexistent) availability of provider charge information. We believe this information gap can, in part, be filled by the proposals in this proposed rule which seek to further price transparency by proposing to adopt new requirements under section 2718(e) of the PHS Act, as described below. We believe that ensuring public access to hospital standard charge data will promote and support current and future price transparency efforts. We believe that this, in turn, will enable health care consumers to make more informed decisions, increase market competition, and ultimately drive down the cost of health care services, making them more affordable for all patients.

3. Summary of Stakeholder Engagement

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20548 and 20549) and other Requests for Information (RFIs) published during 2018 (which we will refer to as the 2018 RFIs),[171] we remarked that challenges continue to exist for consumers because of insufficient transparency in pricing information. Therefore, we sought public comment on a variety of questions related to our price transparency efforts, including:

- 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 help third parties create patient-friendly interfaces with these data?
- Should health care 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? What changes would be needed to support greater transparency around patient obligations for their out-of-pocket costs? What can be done to better inform patients of these obligations? Should health care providers and suppliers play any role in helping to inform patients of what their out-of-pocket obligations will be?

Most of the commenters who responded to the 2018 RFIs supported furthering price transparency efforts, although a few stakeholders opposed efforts to make hospital pricing information available to the public. Reasons stakeholders cited in opposition included, for example: That hospital chargemasters are highly technical documents that frequently

https://jamanetwork.com/journals/jama/fullarticle/2518264.

[162] Kullgren JT, Duey KA, Werner RM. A census of state health care price transparency websites. *JAMA.* 2013;309(23):2437–2438. Available at: *https://jamanetwork.com/journals/jama/fullarticle/1697957.*

[163] Ibid.

[164] Ibid.

[165] Available at: *https://oshpd.ca.gov/data-and-reports/cost-transparency/hospital-chargemasters/2018-chargemasters/.*

[166] Jenkins K. *CMS Price Transparency Push Trails State Initiatives.* The National Law Review. February 8, 2019. Available at: *https://www.natlawreview.com/article/cms-price-transparency-push-trails-state-initiatives.*

[167] Ibid.

[168] Available at: *http://oregonhospitalguide.org/* and *http://oregonhospitalguide.org/understanding-the-data/procedure-costs.html.*

[169] Jenkins K. *CMS Price Transparency Push Trails State Initiatives.* The National Law Review. February 8, 2019. Available at: *https://www.natlawreview.com/article/cms-price-transparency-push-trails-state-initiatives.*

[170] Brown, ZY. What would happen if hospitals openly shared their prices? *The Conversation.* January 30, 3019. Available at: *https://theconversation.com/what-would-happen-if-hospitals-openly-shared-their-prices-110352.* And *http://www-personal.umich.edu/~zachb/zbrown_empirical_model_price_transparency.pdf.*

[171] FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20164); CY 2019 Home Health proposed rule (83 FR 32473); CY 2020 ESRD PPS proposed rule (83 FR 34394); CY 2020 PFS proposed rule (83 FR 36009); and CY 2019 OPPS/ASC proposed rule (83 FR 37211).

identify items and services by the complex payment codes used by hospitals for purposes of billing, instead of terms that consumers can understand; concern that hospital charge data as found in the hospital chargemaster may not be helpful to consumers for determining what they are likely to pay for a service or facility encounter because most consumers have health insurance; concern that some pricing information might be commercially sensitive; and that posting price information without corresponding educational tools might increase patient confusion.

In addition to seeking public input on price transparency issues through the 2018 RFIs, we hosted a series of five listening sessions in the summer and fall of 2018 that were attended by a wide representation of stakeholders, including hospitals, clinicians, payers, tool developers, and consumer and patient advocacy groups. During the listening sessions, several stakeholders applauded our efforts to release public use files on a quarterly basis and stated that they use the information in those files to supplement their algorithms to provide Medicare fee-for-service patients with out-of-pocket pricing information. Price transparency tool developers asserted that machine-readable chargemaster release would provide promising opportunities and support existing efforts for user-friendly tool development, including the development of out-of-pocket comparison cost estimates for self-pay and commercially insured health care consumers. Some stakeholders noted that the most useful pricing information for consumers is information that displays a patient's expected out-of-pocket costs for nonurgent health care services that can be scheduled in advance, also referred to as ''shoppable'' services.

We appreciate the many detailed comments and suggestions stakeholders have provided us during the past year. In this proposed rule, after taking into consideration our past pricing transparency efforts and stakeholder feedback and our policy objective to make price information more readily available, we are proposing to codify a set of requirements that further implement section 2718(e) of the PHS Act. We believe that the public posting of hospital standard charge information will be useful to health care consumers who need to obtain items and services from a hospital, health care consumers who wish to view hospital prices prior to selecting a hospital, clinicians who use the data at the point of care when making referrals, and other members of the public who may develop consumer-friendly price transparency tools. These proposed requirements represent an important step towards putting health care consumers at the center of their health care and ensuring they have access to the hospital standard charge information they need.

4. Summary of Proposals

Health care consumers continue to lack the meaningful pricing information they need to choose the healthcare services they want and need despite prior requirements for hospitals to publicly post their chargemaster rates online. Therefore, in response to stakeholders and in accordance with President's Executive Order on ''Improving Price and Quality Transparency in American Healthcare to Put Patients First'' (June 24, 2019), we are proposing an expansion of hospital charge display requirements to include charges and information based on negotiated rates and for common shoppable items and services, in a manner that is consumer-friendly. We believe this will meaningfully inform patients' decision making and allow consumers to compare prices across hospitals. We are also proposing to establish a mechanism for monitoring and the application of penalties for noncompliance.

Specifically, we are proposing to add a new Part 180—Hospital Price Transparency to title 45 of the Code of Federal Regulations (CFR) which would contain our regulations on price transparency for purposes of section 2718(e) of the PHS Act. In our discussions in the sections that follow, we make proposals related to: (1) A definition of ''hospital''; (2) different reporting requirements that would apply to certain hospitals; (3) definitions for two types of ''standard charges'' (specifically, gross charges and payer-specific negotiated charges) that hospitals would be required to make public, and a request for public comment on other types of standard charges that hospitals should be required to make public; (4) a definition of hospital ''items and services'' that would include all items and services (both itemized and packaged) provided by the hospital to a patient in connection with an inpatient admission or an outpatient department visit; (5) requirements for making public a machine-readable file that contains a hospital's gross charges and payer-specific negotiated charges for all items and services provided by the hospital; (6) requirements for making public payer-specific negotiated charges for select hospital-provided items and services that are ''shoppable'' and that are displayed and packaged in a consumer-friendly manner; (7) monitoring for hospital noncompliance with public disclosure requirements to make public standard charges; (8) actions that would address hospital noncompliance, which include issuing a written warning notice, requesting a corrective action plan, and imposing civil monetary penalties (CMPs) on noncompliant hospitals and publicizing these penalties on a CMS website; and (9) appeals of CMPs.

We believe that these proposals requiring public release of hospital standard charge information are a necessary and important first step in ensuring transparency in health care prices for consumers, although we recognize that the release of hospital standard charge information is not sufficient by itself to achieve our ultimate goals for price transparency. For example, we know through our stakeholder engagement and research conducted over the past year that consumers of health care services simply want to know where they can get a needed health care service and what that service will cost them out-of-pocket. There are many barriers to achieving this simple desire to make price comparisons for health care services, including that the data necessary for such an analysis are not available to the general public. Necessary data to make price comparisons depends on an individual's circumstances. For example, a self-pay individual may simply want to know the amount a health care provider will accept in cash (or cash equivalent) as payment in full, while an individual with health insurance may want to know the charge negotiated between the health care provider and payer, along with additional individual benefit-specific information such as the amount of cost-sharing, the network status of the health care provider, how much of a deductible has been paid to date, and other information. The proposals in this proposed rule seek to address the barriers related to lack of hospital data by standardizing the release of two types of hospital standard charge information—gross charges and payer-specific negotiated charges.

We believe these proposed policies are an important first step in our efforts to achieve price transparency in health care, and believe our proposed policies should be viewed in the context of the broader price transparency initiative. We are continuing to explore other authorities that the Department can use to further advance our goal of getting

patients the information they need to make informed health care decisions.

B. Proposed Definition of ''Hospital'' and Proposed Special Requirements That Would Apply to Certain Types of Hospitals

1. Proposed Definition of ''Hospital''

Section 2718(e) of the PHS Act does not define ''hospital.'' Initially, we considered proposing to adopt a definition of ''hospital'' that is used either in other sections of the PHS Act or in the Social Security Act, but we found that no single or combined definition was suitable because those other definitions were applicable to specific programs or Medicare participation and therefore had program-specific requirements that made them too narrow for our purposes. For example, we considered referencing the definition of ''hospital'' at section 1861(e) of the Social Security Act because that definition is well understood by institutions that participate as hospitals for purposes of Medicare. However, we were concerned that doing so could have had the unintentional effect of limiting the institutions we believe should be covered by section 2718(e) of the PHS Act. Even so, we believe that the licensing requirement described at section 1861(e)(7) of the Social Security Act captures the institutions that we believe should be characterized as hospitals for purposes of this section.

Accordingly, we are proposing to define a ''hospital'' as an institution in any State in which State or applicable local law provides for the licensing of hospitals, (1) is licensed as a hospital pursuant to such law or (2) is approved, by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing (which we propose to codify in new 45 CFR 180.20).

We believe this proposed definition is the best way to ensure that section 2718(e) of the PHS Act applies to each hospital operating within the United States. First, in addition to applying to all Medicare-enrolled hospitals (that, by definition, must be licensed by a State as a hospital, or otherwise approved by the State or local licensing agency as meeting hospital licensing standards), the proposed definition would also capture any institutions that are, in fact, operating as hospitals under State or local law, but might not be considered hospitals for purposes of Medicare participation. As discussed in section XVI.A.2. of this proposed rule, many States have promoted price transparency initiatives and some require institutions they license as hospitals to make certain charges public as a part of those initiatives. Therefore, defining a hospital by its licensure (or by its approval by the State or locality as meeting licensing standards) may carry the advantage of aligning the application of Federal and State price transparency initiatives to the same institutions.

We also are proposing that, for purposes of the definition of ''hospital,'' a State includes each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands. This proposed definition of State would be consistent with how that term is defined under section 2791(d)(14) of the PHS Act. We believe that adopting this definition of ''State'' for purposes of section 2718(e) of the PHS Act is appropriate because, unlike the other provisions in section 2718 which apply to health insurance issuers, section 2718(e) applies to hospitals. Therefore, it is distinguishable from the approach outlined in the July 2014 letters [172] to the Territories regarding the PHS Act health insurance requirements established or amended by Public Law 111–148 and Public Law 111–152.

Our proposed definition focuses on whether or not the institution is licensed by the State or under applicable local law as a hospital, or is approved, by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing. As such, a ''hospital'' would include each institution that satisfies the definition, regardless of whether that institution is enrolled in Medicare or, if enrolled, regardless of how Medicare designates the institution for its purposes. Thus, the proposed definition would include critical access hospitals (CAHs), inpatient psychiatric facilities (IPFs), sole community hospitals (SCHs), and inpatient rehabilitation facilities (IRFs), which we previously identified in our guidelines as being hospitals for the purposes of section 2718(e),[173] as well as any other type of institution, so long as such institutions are licensed as a hospital (or otherwise approved) as meeting hospital licensing standards.

Finally, we note that the proposed definition of ''hospital'' would not include entities such as ambulatory surgical centers (ASCs) or other non-hospital sites-of-care from which consumers may seek health care items and services. For example, nonhospital sites may offer ambulatory surgical services, laboratory or imaging services, or other services that are similar or identical to the services offered by hospital outpatient departments. In the interest of increasing opportunities for health care consumers to compare prices for similar services and promoting widespread transparency in health care prices, we encourage non-hospital sites-of-care to make public their lists of standard charges in alignment with these proposed requirements so that consumers can make effective pricing comparisons.

We invite public comments on our proposed definition of ''hospital,'' which we are proposing to codify at 45 CFR 180.20.

2. Proposed Special Requirements That Would Apply to Certain Hospitals

In sections XVI.E. and XVI.F of this proposed rule, we propose the requirements that most institutions meeting our definition of ''hospital'' would have to meet in order to comply with section 2718(e) of the PHS Act. However, we are proposing that these requirements would not apply to federally-owned or operated hospitals, including Indian Health Service (IHS) facilities (including Tribally-owned and operated facilities), Veterans Affairs (VA) facilities, and Department of Defense Military Treatment Facilities (MTFs), because, with the exception of some emergency services, these facilities do not provide services to the general public and the established payment rates for services are not subject to negotiation. Instead, each of these facility types is authorized to provide services only to patients who meet specific eligibility criteria. For example, individuals must meet the requirements enumerated at 42 CFR 136.22 through 136.23 to be eligible to receive services from IHS and Tribal facilities. Similarly, under 38 CFR 17.43 through 17.46, Veterans Affairs hospitals provide hospital, domiciliary, and nursing home services to individuals with prior authorization who are discharged or retiring members of the Armed Forces and, upon authorization, beneficiaries of the Public Health Service, Office of Workers' Compensation Programs, and other Federal agencies (38 CFR 17.43). In addition, federally-owned or operated hospitals such as IHS and Tribal

[172] The July 2014 letters are available at: *https://www.cms.gov/CCIIO/Resources/Letters/index.html#Health%20Market%20Reforms.*

[173] Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProspMedicareFeeSvcPmtGen/Downloads/Additional-Frequently-Asked-Questions-Regarding-Requirements-for-Hospitals-To-Make-Public-a-List-of-Their-Standard-Charges-via-the-internet.pdf.*

facilities [174] impose no cost-sharing, or, in the case of VA hospitals [175] and Department of Defense MTFs,[176] little cost-sharing. With respect to such facilities where there is cost-sharing, the charges are publicized through the **Federal Register**, Federal websites, or direct communication and therefore known to the populations served by such facilities in advance of receiving health care services. Only emergency services at federally-owned or operated facilities are available to non-eligible individuals. Because these hospitals do not treat the general public, their rates are not subject to negotiation, and the cost sharing obligations for hospital provided services are known to their patients in advance, we believe it is appropriate to establish different requirements that apply to these hospitals. Specifically, we are proposing to deem federally owned or operated hospitals that do not treat the general public (except for emergency services) and whose rates are not subject to negotiation, meet the requirements of section 2718(e) of the PHS Act when their charges for hospital provided services are publicized to their patients in advance (for example, through the **Federal Register**) (proposed new 45 CFR 180.30(b)).

In addition, as a result of public comments received in response to the 2018 RFIs suggesting that certain hospitals be exempted from having to make public their standard charges, we considered whether it was appropriate to establish different requirements for hospitals located in a rural areas, critical access hospitals (CAHs), or hospitals that are not federally owned or operated but that serve special populations (such as children's hospitals and State psychiatric hospitals). However, because such hospitals are open to the general public, and their charges are generally not made available to the public, we continue to believe there is value in such hospitals making public their standard charges. For example, hospitals may gain market share and enjoy increased patient satisfaction as a result of being transparent with their prices.[177] Moreover, we believe that the proposed requirements are not overly burdensome because hospitals already have these data readily available. Therefore, at this time, we are not proposing different requirements for hospitals located in rural areas, CAHs or hospitals that are not federally owned or operated but that treat special populations. However, we are requesting public comments on whether exceptions to our proposed requirements might be warranted for hospitals (for example, hospitals located in rural areas, CAHs, or hospitals that treat special populations) that are not federally owned or operated, while also ensuring that charges for the services provided by such hospitals are available to the public. Specifically, we recognize that many hospitals are going above and beyond these proposed requirements, for example, by offering patient-friendly price transparency tools that calculate individualized out-of-pocket cost estimates. We seek comment on whether offering such tools could qualify a hospital to be excepted from some of the proposed requirements, for example, the consumer-friendly display requirements discussed in section XVI.F.

C. Proposed Definition of ''Items and Services'' Provided by Hospitals

Section 2718(e) of the PHS Act requires that hospitals make public a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis related groups (DRGs). We are proposing that, for purposes of section 2718(e), ''items and services'' provided by the hospital are all items and services, including individual items and services and service packages, that could be provided by a hospital to a patient in connection with an inpatient admission or an outpatient department visit for which the hospital has established a standard charge. Examples of these items and services include, but are not limited to, supplies, procedures, room and board, use of the facility and other items (generally described as facility fees), services of employed physicians and non-physician practitioners (generally reflected as professional charges), and any other items or services for which a hospital has established a charge.

Our proposed definition includes both individual items and services as well as ''service packages'' for which a hospital has established a charge. Every hospital maintains a file system known as the chargemaster (or Charge Description Master ''CDM''), which contains all billable procedure codes performed at the hospital, along with descriptions of those codes and the hospitals' own list prices. The format and contents of the chargemaster vary from one hospital to the next, although the source codes are derived from common billing code systems (such as the AMA's CPT system). Chargemasters can include tens of thousands of line items, depending on the type of facility, and can be maintained in spreadsheet or database formats.[178] For purposes of section 2718(e) of the PHS Act, we are proposing to define ''chargemaster'' to mean the list of all individual items and services maintained by a hospital for which the hospital has established a standard charge (at proposed new 45 CFR 180.20). Each individual item or service found on the hospital chargemaster has a corresponding ''gross'' charge (discussed in more detail in section XVI.D.2). Each individual item or service may also have a corresponding negotiated discount because some hospitals negotiate with third party payers to establish a flat percent discounted rate off the gross charge for each individual item and service listed on the chargemaster; for example, a hospital may negotiate a 50 percent discount off all chargemaster gross rates with a third party payer.

In contrast to the chargemaster or so-called ''fee-for-service'' price list, hospitals also routinely negotiate rates with third party payers for bundles of services or ''service packages'' in lieu of charging for each and every imaging study, laboratory test, or alcohol swab found on the chargemaster.[179] Such service packages may have charges established on, for example, the basis of a common procedure or patient characteristic, or may have an established per diem rate that includes all individual items and services furnished during an inpatient stay. Some hospitals present ''self-pay package pricing'' for prompt same-day payment from health care consumers. The hospital's billing and accounting systems maintain the negotiated charges for service packages which are commonly identified in the hospital's billing system by recognized industry standards and codes. For example, a diagnosis-related group (DRG) system may be used to define a hospital product based on the characteristics of patients receiving similar sets of

[174] Section 1680r(b) of the Indian Health Care Improvement Act (25 U.S.C. 1680r).

[175] VA cost-sharing information available at: *https://www.va.gov/HEALTHBENEFITS/cost/copays.asp*.

[176] MTF cost-sharing information available at: *https://tricare.mil/Costs/Compare* and *https://comptroller.defense.gov/Portals/45/documents/rates/fy2019/2019_ia.pdf*.

[177] Hammer, David C. ''Adapting customer service to consumer-directed health care: by implementing new tools that provide greater transparency in billing, hospitals can decrease collection costs while improving consumer satisfaction.'' *Healthcare Financial Management,* Sept. 2006, p. 118+. *Academic OneFile,* Accessed 8 July 2019. *https://www.mckesson.com/documents/providers/hfma---adapting-customer-service-to-consumer-directed-health-care/*.

[178] *https://www.healthaffairs.org/doi/10.1377/hlthaff.25.1.45*.

[179] *https://www.healthaffairs.org/doi/10.1377/hlthaff.25.1.81*.

[itemized] services.[180] Medicare and some commercial insurers have adopted DRG classifications as a method of inpatient hospital payment. Other codes (for example, payer specific codes, CPT or HCPCS codes) are used by hospitals and payers to identify service packages based on procedures.

For purposes of section 2718(e) of the PHS Act, we are proposing to define a ''service package'' to mean an aggregation of individual items and services into a single service with a single charge (proposed new 45 CFR 180.20). We believe this is appropriate and consistent with section 2718(e) of the PHS Act because we believe its inclusion of DRGs as an item or service in section 2718(e) recognizes that hospital services can be provided and charged for based on the service's individual component parts or as a more inclusive packaged service. While section 2718(e) of the PHS Act specifically includes items and services grouped into DRGs as an example of the items and services for which hospitals must list their standard charges, we believe that our definition of ''items and services'' should include not just all DRGs (as established under 1886(d)(4) of the Social Security Act) but also all other service packages provided by the hospital, including, for example, service packages the hospital provides in an outpatient setting for which a hospital may have established a standard charge. Therefore, our proposed definition of ''items and services'' includes both individual items and services and service packages.

We would also include in our proposed definition of ''items and services'' provided by the hospital the services furnished by physicians and non-physician practitioners who are employed by the hospital. We believe the services the hospital provides through its employed physicians (and non-physician practitioners) are items and services provided by the hospital, because such physicians (and non-physician practitioners) are employed by the hospital specifically so that the hospital can offer such services to the hospital's patients. In addition, the hospital establishes and negotiates the charges for the employed physician and non-physician services. The hospital bills and retains the payment for the professional services of employed physician and non-physician practitioners. We therefore believe it is appropriate for these services to be included in our proposed definition of hospital items and services provided by the hospital under Section 2718(e), and for hospitals to make public the charges for the services of their employed physician and non-physician practitioners.

We also considered including in our proposed definition of items and services the services provided by physicians and non-physician practitioners who are not employed by the hospitals, but who provide services at a hospital location. For example, a procedure performed in a hospital setting may involve anesthesiology services provided by a non-employed physician who has established his or her own charge for the service he or she is providing at a hospital location. These physicians and non-physician practitioners may send a bill that is separate from the hospital bill, or, they may elect to reassign their billing rights to the hospital that will send a single bill that includes both hospital charges and professional service charges. Often, health care consumers are not expecting an additional charge or are otherwise surprised when they receive bills from entities other than the hospital, or when charges for non-employed physicians and non-physician practitioners are higher than expected (for example, when a non-employed physician is out-of-network and the consumer's third party payer declines payment for those services for that reason). We believe that the provision of such additional charge information would be exceptionally valuable to give consumers a more complete picture of the total amount they might be charged in connection with an inpatient admission or an outpatient department visit at a hospital location, potentially helping to address the widely recognized ''surprise billing'' issue. However, because physicians and non-physician practitioners who are not employed by the hospital are practicing independently, establish their own charges for services, and receive the payment for their services, we do not believe their charges for their services fall within the scope of section 2718(e) as they are not services ''provided by the hospital.''

We welcome comment on these proposals.

D. Proposed Definitions for Types of ''Standard Charges''

1. Overview and Background

Under our current guidelines regarding section 2718(e) of the PHS Act (as discussed in the FY 2019 IPPS/LTCH PPS proposed rule and final rule (83 FR 20164 and 41144, respectively)), a hospital may choose the format it uses to make public a list of its standard charges, so long as the information represents the hospital's current standard charges as reflected in its chargemaster.

In response to the 2018 RFIs, several commenters, including hospitals and patient advocacy organizations, commented that gross charges as reflected in hospital chargemasters may only apply to a small subset of consumers; for example, those who are self-pay or who are being asked to pay the chargemaster rate because the hospital is not included in the patient's insurance network. Many commenters also noted that the charges listed in a hospital's chargemaster are typically not the amounts that hospitals actually charge to consumers who have health insurance because, for the insured population, hospitals charge amounts reflect discounts to the chargemaster rates that the hospital has negotiated with third party payers. Further, with respect to patients who qualify for financial assistance or who pay in cash, commenters pointed out that some hospitals will charge lower amounts than the rates that appear on the chargemaster. Adding to the complexity, some commenters noted that hospitals often package items and services and charge a single discounted negotiated amount for the packaged service. For example, as discussed in XVI.C. of this proposed rule, instead of itemizing and charging for each individual hospital item or service found on the chargemaster, a hospital may identify a primary common condition or procedure and charge a single negotiated or ''cash'' amount for the primary common condition or procedure that includes all associated items and services that are necessary for treatment of the common condition or to perform the procedures. We believe that these comments illustrate a fundamental challenge of making health care prices transparent in general, and specifically with respect to the issue of how we should best implement section 2718(e) of the PHS Act; simply put, hospitals do not offer all consumers a single ''standard charge'' for the items and services they furnish. Rather, the ''standard charge'' for an item or service (including service packages) varies depending on the circumstances particular to the consumer.

Therefore, we sought public comment through the RFIs issued in 2018[181] on

[180] *https://repository.library.georgetown.edu/handle/10822/556896.*

[181] FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20164); CY 2019 Home Health proposed rule (83 FR 32473); CY 2020 ESRD PPS proposed rule (83 FR 34394); CY 2020 PFS proposed rule (83 FR 36009); and CY 2019 OPPS/ASC proposed rule (83 FR 37211).

a definition of ''standard charges.'' Specifically, we requested information on the following:

- Should ''standard charges'' be defined to mean: Average or median rates for the items in the chargemaster; average or median rates for groups of services commonly billed together (such as for an MS–DRG), as determined by the hospital based on its billing patterns; or the average discount off the chargemaster amount across all payers, either for each item on the chargemaster 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 [rate]? Or is the best measure of a hospital's standard charges its chargemaster [rate]?

Commenters responded with a number of suggestions for defining ''standard charges'' including the following:

- Chargemaster rates.
- Average discount off the chargemaster amount across all payers (for example, an average negotiated rate).
- Actual, estimated, or average out-of-pocket costs to individuals.
- The amount the hospital will accept as payment in full for items and services (without complications) by non-governmental payers and individuals (for example, a negotiated rate).
- Usual and customary charges as defined by the National Council of Insurance Legislators (NCIL). Specifically, the NCIL defines usual and customary as the 80th percentile of physician charges in a geographic region based on an independent unbiased benchmarking charge database.
- Median or average charges for groups of services routinely billed together, such as at the DRG or APC level, or other layman-termed groupings.
- Average median payment rate or average out-of-pocket charges for shoppable services (that is, nonemergent or elective procedures that patients will most likely use).
- Net negotiated charges for health insurance plan networks.

We appreciate the many comments and suggestions on this issue offered by stakeholders. We believe the variety of suggested definitions reflects our assessment that hospitals can have different standard charges for various groups of individuals. In general, for purposes of 2718(e), we believe a standard charge can be identified as a charge that is the regular rate established by the hospital for the items and services provided to a specific group of paying patients. Therefore, we considered what types of standard charges may reflect certain common and identifiable groups of paying patients. After considering the feedback noted above and the various types of standard charges that may exist, we are proposing to define standard charges to mean ''gross charges'' and ''payer-specific negotiated charges,'' and to codify this definition in proposed new 45 CFR 180.20. ''Gross charges'' and ''payer-specific negotiated charges'' are further defined in sections XVI.D.2. and XVI.D.3., respectively, of this proposed rule. We believe the proposal to define standard charges as gross charges and payer-specific negotiated charges reflects the fact that a hospital's standard charge for an item or service is not typically a single fixed amount, but, rather, depends on factors such as who is being charged for the item or service, and particular circumstances that apply to an identifiable group of people, including, for example, health care consumers that are insured members of third party insurance products and plans that have negotiated a rate on its members' behalf.

We are proposing to define standard charges as ''gross charges'' and ''payer-specific negotiated charges'' based on our research and prior stakeholder input. Hospitals would be required to make public these two types of standard charges in the form and manner proposed in sections XVI.E and F. As explained in section XVI.C. of this proposed rule, gross charges found in the chargemaster as well as negotiated charges are both informative and necessary for consumers to understand their potential out-of-pocket cost obligations, but such information is not readily available to consumers. We believe these two specific types of standard charges have the potential to inform two large identifiable groups of health care consumers who do not currently have ready access to hospital charge information, specifically those who have limited power to negotiate charges (for example, self-pay individuals) and those who rely on third party payers to negotiate charges on their behalf. We also believe that these two specific types of standard charges present a limited burden for hospitals to make publicly available, because these charges are already available, maintained, and in use in hospital billing systems. Moreover, we believe these two specific types of standard charges are necessary basic information needed to begin to ensure that consumers have the ability to shop for and compare pricing for health care services. We believe these proposals will help provide information to consumers to help make health care more affordable and drive down the cost of health care coverage.

We acknowledge that the proposed definition of hospital ''standard charges'' is limited to only two of the many possibilities that exist for defining types of hospital ''standard charges,'' and we discuss below other potential definitions that we considered, but decided not to propose at this time. We are seeking public input and comment on the alternatives and additional types of standard charges that may be useful to consumers.

2. Proposed Definition of ''Gross Charges'' as a Type of Standard Charge

As previously noted, in general, for purposes of 2718(e), we believe a standard charge can be identified as a charge that is the regular rate established by the hospital for the items and services provided to a specific group of paying patients. We are proposing that, for purposes of the first type of ''standard charge,'' a ''gross charge'' would be defined as the charge for an individual item or service that is reflected on a hospital's chargemaster, absent any discounts (at proposed new 45 CFR 180.20). As we explain in section XVI.C. of this proposed rule, the hospital chargemaster contains a list of all individual items and services the hospital provides. The gross charges reflected in the chargemaster often apply to a specific group of individuals who are self-pay, but do not reflect charges negotiated by third party payers. We also note that the chargemaster does not include charges that the hospital may have negotiated for service packages, such as per diem rates, DRGs or other common payer service packages, and therefore this type of standard charge would not include standard charges for service packages.

We are proposing to require hospitals to make public their gross charges because, in addition to applying to a specific group of individuals, based on research and stakeholder input, we believe gross charges are useful to the general public, necessary to promote price transparency, and necessary to drive down premium and out-of-pocket costs for consumers of health care. For example, studies suggest that the gross charge plays an important role in the negotiation of third party insurance products that are subsequently sold to consumers.[182] Specifically, as hospital

[182] Bai G and Anderson GF. Market Power: Price Variation Among Commercial Insurers for Hospital Services. *Health Affairs.* Oct 2018; 37(10): 1615–

executives and others familiar with hospital billing cycles often note, hospitals routinely use gross charges as a starting point for negotiating discounted rates with third party payers, and higher gross charges have been found to be associated with both higher negotiated rates and, in turn, higher premiums and out-of-pocket costs for insured individuals.[183] [184] As such, gross charges are relevant to all consumers, including those with insurance coverage. We believe that requiring transparency of hospital gross charges may drive competition, which might, in turn, have the effect of not only lowering hospital charges for the most vulnerable consumers and those with the least market power to negotiate prices, but also for consumers who have access to charges negotiated on their behalf by a third party payer.

In addition, as a result of stakeholder feedback, we learned that third party developers of consumer price transparency tools can use gross charges in conjunction with additional information (such as an individual's specific insurance and benefit information and quality data) to develop and make available consumer-friendly out-of-pocket cost estimates that allow consumers to compare health care service prices across hospitals and other nonhospital settings of care. Moreover, as previously noted in section XVI.A.2., research suggests that making such consumer-friendly information available to the public has been demonstrated to reduce consumer health care costs. As such, we believe that public access to hospital gross charges is critical to inform all patients (both self-pay and insured) of their choices and drive transparency in prices.

We are proposing to codify the proposed definition of ''gross charges'' at proposed new 45 CFR 180.20. We are inviting public comments on our proposal to define a type of ''standard charge'' as a ''gross charge'' and on our proposed definition of ''gross charge.''

3. Proposed Definition of ''Payer-Specific Negotiated Charge'' as a Type of Standard Charge

As noted in section XVI.D.1, in general, for purposes of 2718(e), we believe a standard charge can be identified based on the regular rate established by the hospital for the items and services provided to a specific group of paying patients. We are proposing that, for purposes of the second type of ''standard charge,'' a ''payer-specific negotiated charge'' would be defined as the charge that the hospital has negotiated with a third party payer for an item or service. We are further proposing to define ''third party payer'' for purposes of section 2718(e) of the PHS Act as an entity that is, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service and to codify this definition at proposed new 45 CFR 180.20. As the reference to ''third party'' suggests, this definition excludes an individual who pays for a health care item or service that he or she receives (such as self-pay patients).

We are proposing to focus on a second type of ''standard charge'' related to negotiated rates because most consumers (over 90 percent [185]) rely on a third party payer to cover a portion or all of the cost of health care items and services, including a portion or all of the cost of items and services provided by hospitals (in accordance with the terms and conditions of the third party payer's contract agreement with that consumer). Some third party payers (for example, Medicare fee-for-service or Medicaid fee-for-service) currently make public the maximum rate they pay for a hospital item or service. However, many third party payers do not reveal their negotiated rates, even to individuals on behalf of whom they pay. Additionally, many contracts between third party payers and hospitals contain so-called ''gag clauses'' that prohibit hospitals from disclosing the rates they have negotiated with third party payers.[186] Because consumers are not generally part of the negotiations or privy to the resulting negotiated rates, consumers often find it difficult to learn in advance of receiving a health care service the rate their third party payers may pay. Having insight into the charges that have been negotiated on one's behalf, however, is necessary for insured health care consumers to determine their potential out-of-pocket obligations prior to receipt of a health care service. For example, if a health care consumer knows that he or she will be responsible for 20 percent of the charges for a hospital service, her or she can compare the charges that the third party negotiated with hospital A and hospital B and, from that, the consumer can determine his or her expected out-of-pocket costs at hospital A versus hospital B.

Knowing a negotiated charge is also important because a growing number of insured health care consumers are finding that some services are more affordable if the consumer chooses to forego insurance and pay out-of-pocket. For example, stakeholders and reports indicate that an increasing number of consumers are discovering that sometimes the providers' cash discount can mean paying lower out-of-pocket costs than paying the out-of-pocket costs calculated after taking a third party payer's higher negotiated rate into account.[187] [188] [189] [190] However, consumers cannot make such determinations without knowing the rate their third party payer has negotiated.

For the reasons discussed above, we agree with commenters that gross charges (as a type of standard charge) are largely applicable to one identifiable group of consumers (for example, self-pay) and are not enough for another large and identifiable group of consumers (for example, those with third party insurance) to know their charges for hospital items. Thus, we are proposing that a type of 'standard charge' is the ''payer-specific negotiated charge'' that would be defined as all charges that the hospital has negotiated with third party payers for an item or service. We decided to focus on negotiated rates rather than all payer rates because charges that are not negotiated (for example, Medicare fee-for-service or Medicaid fee-for-service rates) are often already publicly available.

We recognize that the impact resulting from the release of negotiated rates is largely unknown. While it is

1622. Available at: *https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.0567.*

[183] Bai G and Anderson GF. Extreme Markup: The Fifty US Hospitals With The Highest Charge-To-Cost Ratios. *Health Affairs.* Jun 2015; 34(6): 922–928. Available at: *https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1414.*

[184] Batty M and Ippolito B. Mystery of The Chargemaster: Examining The Role Of Hospital List Prices in What Patients Actually Pay. *Health Affairs.* April 2017; 36(4): 689–696. Available at: *https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0986.*

[185] *https://www.census.gov/content/dam/Census/library/publications/2018/demo/p60-264.pdf.*

[186] *https://pdfs.semanticscholar.org/f604/1a0484c65c593525d0c07e040cf655697f2d.pdf.*

[187] Beck, M. How to Cut Your Health-Care Bill: Pay Cash. *The Wall Street Journal.* February 15, 2016. Available at: *https://www.wsj.com/articles/how-to-cut-your-health-care-bill-pay-cash-1455592277.*

[188] Rosato, D. How Paying Your Doctor in Cash Could Save You Money. *Consumer Reports.* May 4, 2018. Available at: *https://www.consumerreports.org/healthcare-costs/how-paying-your-doctor-in-cash-could-save-you-money/.*

[189] Terhune, C. Many hospitals, doctors offer cash discount for medical bills. *Los Angeles Times.* March 27, 2012. Available at: *https://www.latimes.com/business/healthcare/la-fi-medical-prices-20120527-story.html.*

[190] *https://khn.org/news/an-arm-and-a-leg-can-you-shop-around-for-a-lower-priced-mri/.*

clear that such data is necessary for consumers to be able to determine their potential out-of-pocket costs in advance, and we believe the release of such data will help drive down health care costs (as discussed above), some stakeholders have expressed concern with the public display of de-identified negotiated rates which may have the unintended consequence of increasing health care costs of hospital services in highly concentrated markets or as a result of anticompetitive behaviors without additional legislative or regulatory efforts.[191]

Moreover, we recognize that requiring release of all payer-specific negotiated charges for all hospital items and services (both individual items and services as well as service packages) would mean releasing a large amount of data. To get a sense for the number of potential negotiated rates a hospital may have, we conducted an internal analysis of plans in the regulated individual and small group insurance markets under the Patient Protection and Affordable Care Act. Our analysis indicates that the number of products or lines of service per rating area ranges from approximately 1 to 200 in the individual market (averaging nearly 20 products or lines of service in each rating area), while in the small market group, the number ranges from 1 to 400 (averaging nearly 40 products or lines of service in each rating area). Most (if not all) hospitals maintain such data electronically because these data are used routinely for billing, and therefore we believe it presents little burden for a hospital to electronically pull and display these data online in a machine-readable format (as discussed in more detail in section XVI.E). However, we recognize that ensuring display of such a large amount of data in a consumer-friendly manner may pose greater challenges that we address in section (XVI.F).

We note that, in displaying the payer-specific negotiated charges, hospitals would display all negotiated charges, including, for example, charges negotiated with Medicare Advantage (MA) plans because such rates are negotiated. Conversely, hospitals would not include payment rates that are not negotiated, such as rates set by certain health care programs that are directly government-financed, for example, those set by CMS for Medicare fee-for-service. We believe, however, that the display of a non-negotiated rate, for example, display of a Medicare and Medicaid fee-for-service rate for an item or service, in conjunction with the gross charge and the payer-specific negotiated charges for the same item or service could be informative for the public and that nothing in this proposed rule would preclude hospitals from displaying them.

We are proposing to codify the definition of ''payer-specific negotiated charge'' and ''third party payer'' at proposed new 45 CFR 180.20. We invite public comments on our proposal to define a type of ''standard charge'' as a ''payer-specific negotiated charge''. Given concerns raised by stakeholders related to release of identifiable negotiated charges, we are seeking public comment on whether and how the release of such specific charge information could result in unintended consequences. We also seek comment on whether and how there may be different methods for making such information available to individuals who seek to understand what their out-of-pocket cost obligations may be in advance of receiving a health care service.

4. Request for Comment on Alternative Definitions for Types of Standard Charges Under Consideration

Although we propose above that two types of charges would be standard charges for purposes of section 2718(e), we are seeking public comments on whether we should instead, or additionally, require the disclosure of other types of charges discussed below as standard charges. We considered alternatives for types of standard charges related to groups of individuals with third party payer coverage and also for types of standard charges that could be useful to groups of individuals who are self-pay.

a. Alternative Types of ''Standard Charges'' Related to Groups of Individuals With Third Party Payer Coverage

Access to the rate one's third party payer has negotiated on one's behalf can be a challenge. As discussed earlier, we believe that disclosure of negotiated charges will help many consumers with health care coverage know the charge hospitals have negotiated with their third party payers for items and services. However, we understand that the ''payer-specific negotiated charge'' represents a type of standard charge for some, but not all, groups of individuals with health care coverage; for example, individuals who have third party payer coverage for charges that are not negotiated. Additionally, we recognize concerns that may exist related to the unintended consequence of increased healthcare costs in some geographic regions as a result of disclosure of all negotiated charges. For this reason, we considered several additional or alternative types of ''standard charges'' that hospitals could be required to make public that would provide estimated or additional information for individuals with health care coverage. Specifically, we considered the following types of ''standard charges'':

- *Volume driven negotiated charge.* As a variant of the definition of the ''payer-specific negotiated charge,'' we considered defining a type of ''standard charge'' based on the volume of patients to whom the hospital applies the standard charge. Specifically, we considered defining a type of ''standard charge'' as the ''modal negotiated charge.'' The mode of a distribution represents the number that occurs most frequently in a set of numbers. Here, we considered defining ''modal negotiated charge'' as the most frequently charged rate across all rates the hospital has negotiated with third party payers for an item or service. We believe that this definition could provide a useful and reasonable proxy for payer-specific negotiated charges and decrease burden for the amount of data the hospital would have to make public and display in a consumer-friendly format. While we are not proposing this definition at this time, we are seeking public comment on whether the modal negotiated charge would be as informative to consumers with insurance and whether it should be required as an alternative or in addition to the payer-specific negotiated charges.
- *Minimum, median and maximum negotiated charge.* We also considered defining a type of ''standard charge'' as the minimum, median, and maximum negotiated charge. Under this definition, the hospital would be required to make public the lowest, median, and highest charges of the distribution of all negotiated charges across all third party payer plans and products. This information could provide health care consumers with an estimate of what a hospital may charge, because it conveys the range of charges negotiated by all third party payers. Such a definition may also limit the amount of data a hospital would have to make public and package in a consumer-friendly manner which may reduce some burden. It may also relieve some concerns by stakeholders related to the potential for increased healthcare costs in some markets as a result of the disclosure of third party payer negotiated charges.
- *All Allowed Charges.* We also considered defining a type of ''standard charge'' as the charges for all items and

[191] *https://pdfs.semanticscholar.org/f604/1a0484c65c593525d0c07e040cf655697f2d.pdf.*

services for all third party payer plans and products, including charges that are non-negotiated (such as FFS Medicare rates), which we would call ''all allowed charges.'' This option would require hospitals to provide the broadest set of charge information for all individuals with health insurance coverage because it would have the advantage of including all identified third party payer charges (including third party payer rates that are not negotiated). Additionally, every consumer would have access to charge information specific to their insurance plan. We considered, but are not proposing, this alternative because we believe consumers with non-negotiated health care coverage already have adequate and centralized access to non-negotiated charges for hospital items and services and are largely protected from out-of-pocket costs which may make them less sensitive to price shopping. However, we seek public comment on whether increasing the data hospital would be required to make public would pose a burden, particularly for smaller or rural hospitals that may not keep such data electronically available.

b. Alternative Types of ''Standard Charges'' Considered for Groups of Individuals That Are Self-Pay

As discussed earlier, hospital gross charge information may be most directly relevant to a large group of self-pay consumers who do not have third party payer insurance coverage or who seek care out-of-network. Such consumers would not need information in additional to hospital gross charges in order to determine their potential out-of-pocket cost obligations. However, stakeholders have indicated that hospitals often offer discounts off the gross charge or make other concessions to individuals who are self-pay. Thus, we considered additional definitions of hospital standard charges that may be relevant to certain subgroups of individuals who are self-pay.

• *Discounted Cash Price.* We considered defining a type of ''standard charge'' as the ''discounted cash price,'' defined as the price the hospital would charge individuals who pay cash (or cash equivalent) for an individual item or service or service package. We considered this alternative definition because there are many consumers who pay in cash (or cash equivalent) for hospital items and services.

The first subgroup of self-pay consumers that could benefit from knowing the discount cash price would be those who are uninsured. The number of uninsured individuals in the United States rose to 27.4 million in 2017.[192] These individuals' need for transparency in hospital charges differs from patients with insurance who generally are otherwise shielded from the full cost of hospitalization and hospital items and services. Uninsured individuals do not have the advantage of having access to a discounted group rate that has been negotiated by a third party payer. Therefore, individuals without insurance may face higher out-of-pocket costs for health care services.

The second subgroup of self-pay consumers who may benefit from knowing the discounted cash price are those who may have some health care coverage but who still bear the full cost of at least certain health care services. For example, these may be individuals who: Have insurance but who go out of network; have exceeded their insurance coverage limits; have high deductible plans but have not yet met their deductible; prefer to pay through a health savings account (HSA) or similar vehicle; or seek noncovered and/or elective items or services.

Many hospitals offer discounts to these groups of individuals, either as a flat percentage discount off the chargemaster rate or the insurer's negotiated rate, while some hospitals offer consumers a cash discount if they pay in full on the day of the service.[193] Other hospitals have developed and offer standardized cash prices for service packages for certain segments of the population who traditionally pay in cash for health care services. Currently, it is difficult for most consumers to determine in advance of receiving a service what discount(s) the hospital may offer an individual because cash and financial need discounts and policies can vary widely among hospitals.

Under this option, we specifically considered an option that would require hospitals to make public the cash discount that would apply for shoppable service packages that would include all ancillary services, similar to our proposals in XVI.F for consumer-friendly display of payer-specific negotiated charges. In this case, the discounted cash price would represent the amount a hospital would accept as payment in full for the shoppable service package from an individual. Such charges could be lower than the rate the hospital negotiates with third party payers because it would not require many of the administrative functions that exist for hospitals to seek payment from third party payers (for example, prior authorization and billing functions). However, we recognize, that many hospitals have not determined or maintain a standard cash discount that would apply uniformly to all self-pay consumers for each of the items and services provided by the hospital or for services packages, unlike they do for negotiated charges. We are seeking comment on this option, specifically, how many shoppable services for which it would be reasonable to require hospitals to develop and maintain and make public a discounted cash price.

• *Median Cash Price.* Similar to rates hospitals negotiate with third party payers, a hospital may offer a range of cash (or cash equivalent) discounts to various certain groups of self-pay consumers. For example, in addition to other cash discount prices mentioned earlier, many hospitals offer cash discounts on a sliding scale according to financial need. In such instances, as noted above, it may be difficult for a hospital to establish and make public a single standardized cash rate for such groups of consumers. For this reason, we also considered a definition that would take sliding scale cash discounts into account by defining a standard charge as the median cash price. The median cash price would be the midpoint of all cash discounts offered to consumers, including prices for self-pay patients and those qualifying for financial assistance. For uninsured patients who may qualify for financial assistance, the value of making a median cash price public could raise awareness of their available options, including the ability to apply for financial assistance. At this time, we are not proposing to require hospitals to make public their median cash price because we believe such a rate would be less useful to the public than a single standard cash price that the hospital would accept as payment in full as discussed above. However, we continue to consider it and seek public comments on whether this definition would be useful and whether it would enhance our policy goals for improving consumer health care affordability.

E. Proposed Requirements for Public Disclosure of All Hospital Standard Charges for All Items and Services

1. Overview

Section 2718(e) of the PHS Act requires hospitals to make their

[192] Kaiser Family Foundation. Available at: *https://www.kff.org/uninsured/press-release/the-number-of-uninsured-people-rose-in-2017-reversing-some-of-the-coverage-gains-under-the-affordable-care-act/.*

[193] Beck, M. How to Cut Your Health-Care Bill: Pay Cash. *The Wall Street Journal.* February 15, 2016. Available at: *https://www.wsj.com/articles/how-to-cut-your-health-care-bill-pay-cash-1455592277.*

standard charges public in accordance with guidelines developed by the Secretary. Therefore, in the following sections we make proposals for hospitals to make public their standard charges in two ways: (1) A comprehensive machine-readable file that makes public all standard charge information for all hospital items and services (XVI.E), and (2) a consumer-friendly display of common ''shoppable'' services derived from the machine-readable file (XVI.F). We believe that these two different methods of making hospital standard charges public is necessary to ensure such data is available to consumers where and when it is needed (for example, via integration into price transparency tools, EHRs, and consumer apps), and also directly available and useful to consumers that search for hospital-specific charge information without use of a developed price transparency tool.

In this section, we make proposals for requirements for hospitals to make public online in a machine-readable file the standard charges (both gross charges and payer-specific negotiated charges) for all items and services (both individual items and services as well as service packages) provided by the hospital. For display of these standard charge data, we are proposing requirements for the file format, the content of the data in the file, and how to ensure the public can easily access and find the file. We believe these data could be of most use to health care consumers indirectly; that is, such data could be used by the public in price transparency tools or integrated into EHRs for purposes of clinical decision-making and referrals.

In section XVI.F. of this proposed rule, we propose requirements for hospitals to make public a limited amount of standard charge data for a limited set of the items and services the hospital provides online in a form and manner that is more user-friendly. Specifically, we are proposing to require hospitals to make public their payer-specific negotiated rates for certain ''shoppable'' services online in a consumer-friendly format. To do so, we are proposing that the hospital would disply their payer-specific negotiated charges for the primary shoppable service side-by-side with payer-specific negotiated charges for all ancillary items and services the hospital customarily as part of or in conjunction with the primary service. We make additional proposals related to consumer-friendly form, content, and manner of public display of these data. We believe these proposed requirements are responsive to stakeholder feedback and will assist health care consumers by making hospital standard charge information more directly useful and understandable to the public without the use of a developed price transparency tool.

2. Proposed Standardized Data Elements

As discussed in more detail in section XVI.E.3. of this proposed rule, we are proposing that hospitals disclose their list of standard charges for all items and services online in a single digital file that is machine-readable. Without specifying a minimum reporting standard for the machine-readable file, the standard charges data made publicly available by each hospital could vary, making it difficult for consumers to compare items and services. For example, some hospitals currently post a single column of gross charges without any associations to CPT or HCPCS codes or other identifying descriptions of the items and services to which the gross charge applies. A similar example would be a hospital that displays a list of gross charges that is correlated with a list of item numbers that are meaningful to the hospital billing personnel, but a not understandable to the general public. By contrast, some hospitals list their gross charges along with a brief description of the item or service to which each gross charge applies and the corresponding standardized identifying codes (typically HCPCS or CPT codes).

We are concerned that the lack of uniformity leaves the public unable to meaningfully use, understand, and compare standard charge information across hospitals. Therefore, for the first way we are proposing hospital make public their standard charges, which would contain gross charges and payer-specific negotiated charges for all hospital items and services, we are making a proposal to ensure uniformity of the data made publicly available by each hospital. To inform this proposal, we considered what data elements are typically included in a hospital's billing system and which of those elements would result in hospital standard charge data being most transparent, identifiable, meaningful, and comparable.

Based on a review of current State requirements and a sampling of hospitals that are currently making public their charges, we are proposing that hospitals make public a list of each item or service the hospital provides and that the list include the following corresponding information, as applicable, for each item or service:

- Description of each item or service (including both individual items and services and service packages).
- The corresponding gross charge that applies to each individual item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.
- The corresponding payer-specific negotiated charge that applies to each item or service (including charges for both individual items and services as well as service packages) when provided in, as applicable, the hospital inpatient setting and outpatient department setting. Each list of payer-specific charges must be clearly associated with the name of the third party payer.
- Any code used by the hospital for purposes of accounting or billing for the item or service, including, but not limited to, the Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS) code, Diagnosis-Related Group (DRG), National Drug Code (NDC), or other common payer identifier.
- Revenue code, as applicable.

We are proposing to codify these requirements at proposed new 45 CFR 180.50(b). We believe that these elements are necessary to ensure that the public can compare standard charges for similar or the same items and services provided by different hospitals.

We are proposing that hospitals associate each standard charge with a CPT or HCPCS code, DRG, NDC, or other common payer identifier, as applicable, because hospitals uniformly understand them and commonly use them for billing items and services (including both individual items and services and service packages). We also are proposing that hospitals include item descriptions for each item or service. In the case of items and services that are associated with common billing codes (such as the HCPCS codes), the hospital could use the code's associated short text description.

In addition, based on stakeholder feedback suggesting hospital charge information should include revenue codes to be comparable, we are proposing to require that the hospital include a revenue code where applicable and appropriate. Hospitals use revenue codes to associate items and services to various hospital departments. When a hospital charges differently for the same item or service in a different department, we are proposing that the hospital associate the charge with the department represented by the revenue code, providing the public some additional detail about the charges they may expect for hospital services provided in different hospital departments.

In developing this proposal, we also considered whether the following data elements, which are commonly included in hospital billing systems, might be useful to the public:

- Numeric designation for hospital department.
- General ledger number for accounting purposes.
- Long text description.
- Other identifying elements.

However, we determined that, for various reasons, these data elements may not be as useful as the data elements that we are proposing to require hospitals to make public. For example, data elements such as general ledger numbers are generally relevant to the hospital for accounting purposes but may not add value for the public, while data elements such as alternative code sets (such as ICD–10 codes) or long text descriptions associated with CPT codes, while useful, might be difficult to associate with a single item or service or be otherwise difficult to display in a file that is intended mainly for further computer processing. Because of this, while long text descriptions might benefit health care consumers and be appropriate for the consumer-friendly display of shoppable services (discussed in XVI.F), we believe it may add unnecessary burden for hospitals when such descriptions are not readily electronically available, or when the display of such data is not easily formatted into a machine-readable file. Therefore, we are not proposing to require these additional elements for the machine-readable data file that contains a list of all standard charges for all hospital items and services. We invite public comments on the proposed data elements for standard charge data that hospitals would be required to make public. We also seek public comments on the other data elements that, as we detail above, we considered but are not proposing to require, and on any other standard charge data elements that CMS should consider requiring hospitals to make public.

3. Proposed File Format Requirements

To make public their list of all gross charges and all payer-specific negotiated charges for all hospital items and services, we are proposing to require that hospitals post the charge information in a single digital file that is in a machine-readable format. We are proposing to define a machine-readable format as a digital representation of data or information in a file that can be imported or read into a computer system for further processing. Examples of machine-readable formats include, but are not limited to, .XML, JSON and .CSV formats. A PDF would not meet this definition because the data contained within the PDF file cannot be easily extracted without further processing or formatting. We are proposing to codify these format requirements at proposed new 45 CFR 180.50(c) and the definition of machine-readable at proposed new 45 CFR 180.20. We believe that making public such data in a machine-readable format poses little burden on hospitals because many (if not all) hospitals already keep these data in electronic format in their accounting systems for purposes of, for example, ensuring accurate billing. However, we seek comment on this assumption and the burden associated with transferring hospital charge data into a machine-readable format.

As an alternative, we considered proposing to require that hospitals post their list of all standard charges for all items and services using a single standardized file format, specifically.XML only, because this format is generally easily downloadable and readable for many health care consumers, and it could simplify the ability of price transparency tool developers to access the data. However, we did not want to be overly prescriptive in our requirements for formatting. We are seeking public comments on whether we should require that hospitals use a specific machine-readable format, and if so, which format(s). Specifically, we are seeking public comment on whether we should require hospitals to make all standard charge data for all items and services available as an .XML file only.

In addition, we considered formats that could allow direct public access to hospital standard charge information. For example, through the HHS' outreach on innovation,[194] we have heard ideas from stakeholders about processes involving standards and technologies that could allow public access to hospital standard charge data in real time. Such a process could have a number of benefits for the public and hospitals. Specifically, such a process could ensure the public has access to the most up-to-date standard charge information, rather than waiting for the hospital to update data that is publicly posted in a static digital file. Such technology may require or involve a type of portal or standard(s) in which entities have access to certain nonsensitive data elements or files within the hospital IT system environment, such as the chargemaster, but that otherwise restricts access to sensitive, personal identifying information (PII) commercial, protected health information (PHI), and/or confidential information.

Therefore, we seek public comment from all stakeholders, particularly hospitals and innovative information technology vendors, regarding such technologies or standards that could facilitate public access to real-time updates in a format to make it easier for information to be available when and where consumers want to use it, for example, into applications used by health care consumers or into electronic medical records for point-of-care decision-making and referral opportunities by clinicians. For example, application programming interface (API) standards could be used to facilitate public access to real-time hospital charge information. An API can be thought of as a set of commands, functions, protocols, or tools published by one software developer (''A'') that enable other software developers to create programs (applications or ''apps'') that can interact with A's software without needing to know the internal workings of A's software, all while maintaining consumer privacy data standards. This is how API technology enables the seamless user experiences associated with applications familiar from other aspects of many consumers' daily lives, such as travel and personal finance. Standardized, transparent, and procompetitive API technology can similarly benefit consumers of health care services. In the case of ''open'' APIs, technical and other information required for a third-party application to connect is openly published. More information on API certification criteria and how APIs can be used by patients and health care providers and other entities to exchange electronic information can be found on the website at: *https://www.healthit.gov/api-education-module/story_content/external_files/hhs_transcript_module.pdf*.

We are specifically seeking public comment on adopting a requirement that hospitals make public their standard charges through an ''openly published'' (or simply ''open'') API through which they would disclose the standard charges and associated data elements discussed in XVI.E.2. of this proposed rule. Being able to access these data through open APIs would allow the health care consumers to use the application of their choice to obtain personalized, actionable health care service price estimates.

An ''open API,'' for purposes of this comment solicitation, would simply be one for which the technical and other

[194] *https://www.hhs.gov/cto/initiatives/index.html.*

information required for a third-party application to connect to it is openly published. Open API does not imply that any and all applications or application developers would have unfettered access to sensitive information. Rather, an open API's published technical and other information specifically includes what an application developer would need to know to connect to and obtain the data required to be disclosed under this proposed rule. For example, hospitals could use the CMS open source implementation which would facilitate adoption.[195] We also seek public comment on the additional burden that may be associated with a requirement that hospitals make public their standard charges through an open API.

4. Proposed Location and Accessibility Requirements

We have reviewed how hospitals are currently implementing our updated guidelines, which took effect on January 1, 2019, and we are concerned that some charge information made public by hospitals may be difficult for the public to locate. For example, information may be difficult to locate if the public is required to click down several levels in order to find the information. We also are concerned about barriers that could inhibit the public's ability to access the information once located. For example, we are aware that some hospitals require consumers to set up a username and password, or require consumers to submit various types of other information, including, but not limited to, their email address, in order to access the data. We are concerned that these requirements might deter the public from accessing hospital charge information.

Accordingly, we are proposing that a hospital would have discretion to choose the internet location it uses to post its file containing the list of standard charges so long as the file is displayed on a publicly-available web page, it is displayed prominently and clearly identifies the hospital location with which the standard charges information is associated, and the standard charge data are easily accessible, without barriers, and the data can be digitally searched. For purposes of these proposed requirements: (1) ''displayed prominently'' would mean that the value and purpose of the web page[196] and its content[197] is clearly communicated, there is no reliance on breadcrumbs[198] to help with navigation, and the link to the standard charge file is visually distinguished on the web page;[199] (2) ''easily accessible'' would mean that standard charge data are presented in a single machine-readable file that is searchable and that the standard charges file posted on a website can be accessed with the fewest number of clicks;[200] and (3) ''without barriers'' would mean the data can be accessed free of charge, users would not have to input information (such as their name, email address, or other PII) or register to access or use the standard charge data file. We are proposing to codify this requirement at proposed new 45 CFR 180.50(d).

We encourage hospitals to review the HHS Web Standards and Usability Guidelines (available at: *https://webstandards.hhs.gov/*), which are research-based and are intended to provide best practices over a broad range of web design and digital communications issues.

We also are requesting public comments on an alternative we considered, which would require hospitals to submit a link to the standard charges file to a CMS-specified central website, or submit a link to the standard charge file to CMS that would be made public on a CMS web page. Such a method could allow the public to access standard charge information for their purposes in one centralized location. We believe this could reduce potential confusion about where to find standard charge information and potentially allow standard charge information to be posted alongside CMS hospital quality information. It could also assist in the assessment of hospital compliance with section 2718(e) of the PHS Act. In spite of these possible benefits, we are not now proposing to require hospitals to submit or upload a link to their standard charge information to a CMS-specified centralized website because we believe such an effort could be unnecessarily duplicative of ongoing State and private sector efforts to centralize hospital pricing information and potentially confuse consumers who may reasonably look to a hospital website directly for charge information. However, because we appreciate the advantages of having all data available through a single site, we are considering this alternative and seek public comments. We seek comment on this alternative option, specifically, whether the burden outweighs the advantages.

Finally, we seek public comments on potential additional requirements, including easily-searchable file naming conventions and whether we should specify the website location for posting rather than our current proposal that would permit hospitals some flexibility in choosing an appropriate website. Current instances of machine-readable charge files posted on hospital websites contain variable file types, file names, and locations on each website. Standardizing file name or website location information could provide consumers with a standard pathway to find the information and would provide uniformity, making it easier for potential software to review information on each website. Specific requirements for file naming conventions and locations for posting on websites could also facilitate the monitoring and enforcement of the requirement. Therefore, we are seeking public comments on whether we should propose to adopt these additional requirements or other requirements related to these issues.

5. Proposed Frequency of Updates

The statute requires hospitals to establish, update, and make public their standard charges for each year. Therefore, we are proposing to require hospitals to make public and update their file containing the list of all standard charges for all items and services at least once annually (proposed new 45 CFR 180.50(e)). We recognize that hospital charges may change more frequently and therefore we encourage (but are not requiring) hospitals to update this file more often, as appropriate, so that the public may have access to the most up-to-date charge information. We also recognize that hospitals update their charges at different times during the year and may also have various State price transparency reporting requirements that require updates. For purposes of these requirements, we believe that updates that occur at least once in a 12-month period will satisfy our proposed requirement to update at least once annually and reduce reporting burden for hospitals. In other words, the hospital could make public and update its list of standard charges at any point in time during the year, so long as the update to the charge data occurs no more than 12 months after posting.

We also are proposing to require hospitals to clearly indicate the date of the last update they have made to the standard charge data, with some

[195] *https://developer.cms.gov/*.

[196] *https://webstandards.hhs.gov/guidelines/49*.

[197] Nielsen, J. (2003, November 10). The ten most violated homepage design guidelines. Alertbox. Available at: *http://www.useit.com/alertbox/20031110.html*.

[198] *https://webstandards.hhs.gov/guidelines/78*.

[199] *https://webstandards.hhs.gov/guidelines/88*.

[200] *https://webstandards.hhs.gov/guidelines/181*.

discretion as to where the date of late update is indicated. For example, if a hospital chooses to make public its list of standard charges in .XML format, the first row of the spreadsheet could indicate the date the file was last updated. The hospital could also indicate the date the file was last updated in text associated with the file on the web page on which it is posted, or could indicate the date in some other way, as long as that date is clearly indicated and associated with the file or location containing the standard charge information.

6. Proposed Requirements for Making Public Separate Files for Different Hospital Locations

We recognize that some hospitals may have different locations operating under a consolidated or single State license, and that different hospital locations may offer different services that have different associated standard charges. To address this circumstance, we are proposing at proposed new 45 CFR 180.50(a)(2) that the proposed requirements for making public the file containing all standard charges for all items and services in this section of this proposed rule would separately apply to each hospital location such that each hospital location would be required to make public a separate identifiable list of standard charges.

F. Proposed Requirements for Consumer-Friendly Display of the Payer-Specific Negotiated Charges for Selected Shoppable Services

1. Background and Overview

We believe that our proposal in section XVI.E. of this proposed rule requiring hospitals to post on the internet a machine-readable file containing a list of all standard charges (both gross charges and payer-specific negotiated charges) for all items and services (both individual items and services and service packages) is a good first step for driving transparency in health care pricing. As noted earlier, we also believe our proposed policy for making these data available in a machine-readable format will help make these data accessible to health care consumers when and where it is needed to make decisions, for example, via integration in price transparency tools or into electronic health record systems. However, as noted by many stakeholders in the 2018 RFIs and listening sessions, such long lists of charges in a file posted online in a machine-readable format may not be immediately or directly useful for many health care consumers, because the amount of data could be overwhelming or not easily understood by consumers. Because of this, we considered ways of requiring or encouraging hospitals to make public standard charges for frequently provided services in a form and manner that is more directly accessible and consumer friendly. In addition to including all their payer-specific negotiated charges for all items and services in the machine-readable file (as described in section XVI.E. of this proposed rule), in the following sections we propose that hospitals must make public their payer-specific negotiated charges for common services for which consumers may have the opportunity to shop.

First, we propose requirements for hospitals to display a list of payer-specific negotiated charges for a set of 'shoppable' services. We believe doing so will enable consumers to make comparisons across hospital sites of care. Second, we make proposals intended to ensure the charge information for 'shoppable' services are presented in a way that is consumer-friendly. To be consumer-friendly, we believe that the information should be displayed in a way that is understandable to patient (for example, by including plain-language descriptions of the services), that the shoppable service charge is displayed along with charges for ancillary services the hospital customarily provides with the primary shoppable service, and that the consumer can easily search for and find charges for the shoppable services based on the service description, by the code associated with the shoppable service, or by payer.

We believe the proposals related to consumer-friendly display of hospital charge information align with and enhance many ongoing State and hospital efforts. We seek comment from hospitals regarding the extent to which our proposals are duplicative of such ongoing efforts, and how best to ensure consistency of consumer-friendly data display across hospital settings. We further seek comment from consumers regarding their potential engagement with a list of 'shoppable' hospital items and services, including whether our proposals provide for a useful amount of data and data elements that allow for actionable comparisons of 'shoppable' hospital provided items and services.

2. Proposed Definition of ''Shoppable Service''

For purposes of this requirement, a ''shoppable service'' would be defined as a service package that can be scheduled by a health care consumer in advance. Shoppable services are typically those that are routinely provided in non-urgent situations that do not require immediate action or attention to the patient, thus allowing patients to price shop and schedule a service at a time that is convenient for them. We are proposing this definition because it is consistent with definitions proposed by policy experts or used by researchers who identify a service as 'shoppable' if a patient is able to determine where and when they will receive services and can compare charges for multiple providers.[201] Since hospitals may not have insight into whether a particular service is available across multiple providers or where a consumer will ultimately determine where they want to receive a particular services, we have focused our proposed definition on the first aspect, that is, whether or not a service offered by the hospital could be scheduled by the consumer in advance.

Additionally, we are proposing that the charges for such services be displayed as a grouping of related services, meaning that the charge for the shoppable service is displayed along with charges for ancillary items and services the hospital customarily provides as part of or in addition to the primary shoppable service. We are proposing that hospital make public the payer-specific negotiated charge for a shoppable service that is grouped together with charges for associated ancillary services because we believe charge information displayed in such a way is consumer-friendly and patient-focused. In other words, we believe that consumers want to see and shop for healthcare services in the way they experience the service. We are proposing to define an ''ancillary service'' as an item or service a hospital customarily provides as part of or in conjunction with a shoppable primary service (proposed new 45 CFR 180.20). Ancillary items and services may include laboratory, radiology, drugs, delivery room (including maternity labor room), operating room (including post-anesthesia and postoperative recovery rooms), therapy services (physical, speech, occupational), hospital fees, room and board charges, and charges for employed professional services. Ancillary services may also include other special items and services for which charges are customarily made in addition to a routine service charge. For example, an outpatient procedure

[201] White, Chapin and Eguchi, Megan. Reference Pricing: A Small Piece of the Health Care Price and Quality Puzzle. *National Institute for Health Care Reform* Research Brief Number 18 (2014). *https://nihcr.org/wp-content/uploads/2016/07/Research_Brief_No._18.pdf.*

may include many services that are provided by the hospital, for example, local and/or global anesthesia, services of employed professionals, supplies, facility and/or ancillary facility fees, imaging services, lab services and pre- and post-op follow up. To the extent that a hospital customarily provides (and bills for) such services as a part of or in conjunction with the primary service, the hospital should group the service charge along with the other payer-specific negotiated charges that are displayed for the shoppable service. We believe such a practice is consumer-friendly by presenting charge information in a way that reflects how the patient experiences the service.

Examples of shoppable services may include certain imaging and laboratory services, medical and surgical procedures, and outpatient clinic visits. The emphasis on shoppable services aligns with various State price transparency efforts and is consistent with stakeholder feedback. We also believe that this emphasis is consistent with research demonstrating that improving price transparency for shoppable services can have an impact on driving down the cost of health care (we refer readers to section XVI.A.2. of this proposed rule). We are proposing to add this definition to our regulations at proposed new 45 CFR 180.20.

3. Proposed Selected Shoppable Services

We are proposing to require hospitals to make public a list of their payer-specific negotiated charges for as many of the 70 shoppable services that we identify in Table 37 below that are provided by the hospital, and as many additional shoppable services selected by the hospital as is necessary for a combined total of at least 300 shoppable services (new § 180.60(a)).

In a study of 2011 claims by autoworkers, researchers identified a set of 350 frequently billed healthcare services that consumers could schedule in advance and for which there was variation in charges across providers.[202] Hospitals that are early adopters of price transparency have suggested that it is possible to initially identify and display good-faith individualized price estimates for at least 350 shoppable health care services identified by primary billing codes (including prices for ancillary services) with more sophisticated price transparency tool developers creating and being able to display individualized pricing estimates for at least 1000 shoppable services. In contrast, most States that require hospital posting of shoppable services range in requiring 25–50 shoppable services, with California being the only State that requires the corresponding charge information to include ancillary services. Since these proposed regulations will apply to all hospitals operating in the United States, some of which may not have any experience in displaying charges for shoppable services, we believe it is reasonable to propose a starting point of at least 300 shoppable services for which hospitals would be required to display payer-specific negotiated charges. We anticipate we would increase this number over time as hospitals become accustomed to displaying charge information to consumers as a grouping of related charges and as such data is more routinely used by consumers.

Moreover, we believe it is reasonable to require a portion of the 300 shoppable services to be CMS-selected in order to ensure standardization that would provide consumers with the ability to compare prices across hospital settings. We further believe it would be prudent to permit hospitals to select a portion of the shoppable services themselves, recognizing that some hospitals may specialize in certain services (for example, specialized procedures) or may serve populations that utilize other shoppable services with more frequency or are more relevant than the ones we have identified for purposes of the CMS-selected services.

The proposed 70 CMS-specified shoppable services are identified by a primary HCPCS, CPT, or DRG code and are in Table 37.

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[202] *https://nihcr.org/wp-content/uploads/2016/07/Research_Brief_No._18.pdf.*

TABLE 37.—PROPOSED LIST OF 70 CMS-SPECIFIED SHOPPABLE SERVICES

Evaluation & Management Services	2020 CPT/HCPCS Primary Code
Psychotherapy, 30 min	90832
Psychotherapy, 45 min	90834
Psychotherapy, 60 min	90837
Family psychotherapy, not including patient, 50 min	90846
Family psychotherapy, including patient, 50 min	90847
Group psychotherapy	90853
New patient office or other outpatient visit, typically 30 min	99203
New patient office of other outpatient visit, typically 45 min	99204
New patient office of other outpatient visit, typically 60 min	99205
Patient office consultation, typically 40 min	99243
Patient office consultation, typically 60 min	99244
Initial new patient preventive medicine evaluation (18-39 years)	99385
Initial new patient preventive medicine evaluation (40-64 years)	99386
Laboratory & Pathology Services	**2020 CPT/HCPCS Primary Code**
Basic metabolic panel	80048
Blood test, comprehensive group of blood chemicals	80053
Obstetric blood test panel	80055
Blood test, lipids (cholesterol and triglycerides)	80061
Kidney function panel test	80069
Liver function blood test panel	80076
Manual urinalysis test with examination using microscope	81000 or 81001
Automated urinalysis test	81002 or 81003
PSA (prostate specific antigen)	84153-84154
Blood test, thyroid stimulating hormone (TSH)	84443
Complete blood cell count, with differential white blood cells, automated	85025
Complete blood count, automated	85027
Blood test, clotting time	85610
Coagulation assessment blood test	85730
Radiology Services	**2020 CPT/HCPCS Primary Code**
CT scan, head or brain, without contrast	70450
MRI scan of brain before and after contrast	70553
X-Ray, lower back, minimum four views	72110

MRI scan of lower spinal canal	72148
CT scan, pelvis, with contrast	72193
MRI scan of leg joint	73721
CT scan of abdomen and pelvis with contrast	74177
Ultrasound of abdomen	76700
Abdominal ultrasound of pregnant uterus (greater or equal to 14 weeks 0 days) single or first fetus	76805
Ultrasouind pelvis through vagina	76830
Mammography of one breast	77065
Mammography of both breasts	77066
Mammography, screening, bilateral	77067
Medicine and Surgery Services	**2020 CPT/HCPCS/DRG Primary Code**
Cardiac valve and other major cardiothoracic procedures with cardiac catheterization with major complications or comorbidities	216
Spinal fusion except cervical without major comorbid conditions or complications (MCC)	460
Major joint replacement or reattachment of lower extremity without major comorbid conditions or complications (MCC).	470
Cervical spinal fusion without comorbid conditions (CC) or major comorbid conditions or complications (MCC).	473
Uterine and adnexa procedures for non-malignancy without comorbid conditions (CC) or major comorbid conditions or complications (MCC)	743
Removal of 1 or more breast growth, open procedure	19120
Shaving of shoulder bone using an endoscope	29826
Removal of one knee cartilage using an endoscope	29881
Removal of tonsils and adenoid glands patient younger than age 12	42820
Diagnostic examination of esophagus, stomach, and/or upper small bowel using an endoscope	43235
Biopsy of the esophagus, stomach, and/or upper small bowel using an endoscope	43239
Diagnostic examination of large bowel using an endoscope	45378
Biopsy of large bowel using an endoscope	45380
Removal of polyps or growths of large bowel using an endoscope	45385
Ultrasound examination of lower large bowel using an endoscope	45391
Removal of gallbladder using an endoscope	47562
Repair of groin hernia patient age 5 years or older	49505
Biopsy of prostate gland	55700
Surgical removal of prostate and surrounding lymph nodes using an endoscope	55866
Routine obstetric care for vaginal delivery, including pre-and post-delivery care	59400

Routine obstetric care for cesarean delivery, including pre-and post-delivery care	59510
Routine obstetric care for vaginal delivery after prior cesarean delivery including pre-and post-delivery care	59610
Injection of substance into spinal canal of lower back or sacrum using imaging guidance	62322-62323
Injections of anesthetic and/or steroid drug into lower or sacral spine nerve root using imaging guidance	64483
Removal of recurring cataract in lens capsule using laser	66821
Removal of cataract with insertion of lens	66984
Electrocardiogram, routine, with interpretation and report	93000
Insertion of catheter into left heart for diagnosis	93452
Sleep study	95810
Physical therapy, therapeutic exercise	97110

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These 70 shoppable services were selected based on an analysis of shoppable services that are currently made public under State price transparency requirements, a review of services that frequently appear in web-based price transparency tools, an analysis of high volume services and high cost procedures derived from External Data Gathering Environment (EDGE) server data [203]), and a review by CMS medical officers. In other words, we used a combination of quantitative analysis of the EDGE server claims data, a qualitative review of commonly selected services for State and hospital price transparency initiatives and tools, and clinician review to ensure such services could be scheduled in advance in order to identify our list of 70 CMS-selected shoppable services.

In addition to the 70 CMS-selected shoppable services proposed above, we also are proposing that each hospital would select, at minimum, 230 additional shoppable services, identified by a primary HCPCS, CPT, DRG, or other widely used industry code, as applicable, and make publicly available a list of its payer-specific negotiated charges for each of those shoppable services, including the payer-specific negotiated charges for the shoppable service in both the inpatient setting and the outpatient setting, if different. We further propose that hospitals select such services based on the utilization or billing rate of the services in the past year. We believe that enabling hospitals to select most of the shoppable services for which they make their payer-specific negotiated charges available will permit them to tailor their list of shoppable services to their specific patient populations and area of expertise. For example, a children's hospital could select additional shoppable services that are predominantly provided to children.

Although we believe that most hospitals provide the 70 CMS-selected shoppable services which are very common and frequently billed by hospitals, it is possible that some hospitals may not offer all of them (for example, specialty hospitals). Therefore, we are propose that hospitals make public a list of their payer-specific negotiated charges for as many of the 70 shoppable services that we identify in Table 36 that are provided by the hospital, plus as many additional shoppable services as is necessary to reach a total of at least 300 shoppable services.

An alternative option would be for us to propose a larger set of shoppable services and allow hospitals to select up to 70 CMS-selected shoppable services from the larger list for which it would make its payer-specific negotiated charges publicly available. The hospital would then select an additional 230 shoppable services for a total of 300 shoppable services. However, we are not proposing this because we believe most hospitals provide the 70 CMS selected shoppable services and because we have concerns that more discretion will erode our desire to ensure consumers can get hospital charge information for a minimum standardized set of services.

We seek public comments on the 70 CMS-selected shoppable services we identify in Table 36. We are particularly interested in feedback regarding the specific services we have identified as shoppable services and whether other services should be included because they are more common, more shoppable or both. We also are interested in feedback on whether we should require more or less than a total of 300 shoppable services. Specifically, we seek comment from hospitals and consumers on whether a list of 100 shoppable services (or less) is a reasonable starting point. We also are seeking public comment on whether we should identify more specific requirements related to hospital-selected shoppable services; for example, requiring hospitals to select their most frequently billed shoppable services (that are not included in the CMS-specified list).

4. Proposed Required Corresponding Data Elements

We are proposing that the consumer-friendly charge information the hospital makes available to the public online for the CMS and hospital-selected shoppable services must include certain corresponding data elements in order to ensure that consumers understand the hospital's payer-specific negotiated charge for each shoppable service and can use that information to make comparisons across hospitals. Specifically, we are proposing that the consumer-friendly display of payer-specific negotiated charge information contain the following corresponding information for each of the 70 CMS-selected and at least 230 hospital-selected shoppable services:

- A plain-language description of each shoppable service. For example,

[203] Consistent with 45 CFR 153.700, in States where HHS is operating the risk adjustment program, issuers must submit enrollment, claims, and encounter data for risk adjustment-covered plans in the individual and small group markets through the External Data Gathering Environment (EDGE) servers. Issuers upload enrollee, pharmaceutical claim, medical claim, and supplemental diagnosis information from their systems to an issuer-owned and controlled EDGE server.

hospitals would not be required but are invited to review and use the Federal plain language guidelines.[204]

- The payer-specific negotiated charge that applies to each shoppable service. If the hospital does not provide one or more of the CMS-selected shoppable services, the hospital may indicate ''N/A'' for the corresponding charge or otherwise make it clear that the service is not provided by the hospital. Each payer-specific charge must be clearly associated with the name of the third party payer.
- A list of all the associated ancillary items and services that the hospital provides with the shoppable service, including the payer-specific negotiated charge for each ancillary item or service.
- The location at which each shoppable service is provided by the hospital (for example, Smithville Campus or XYZ Clinic), including whether the payer-specific negotiated charge for the shoppable service applies at that location to the provision of that shoppable service in the inpatient setting or the outpatient department setting or both. If the payer-specific negotiated charge for the shoppable service varies based upon location or whether the hospital provides the shoppable service in the inpatient setting versus the outpatient setting, the hospital would be required to identify each payer-specific negotiated charge.
- Any primary code used by the hospital for purposes of accounting or billing for the shoppable service, including, but not limited to, the Current Procedural Terminology (CPT) code, the Healthcare Common Procedure Coding System (HCPCS) code, the Diagnosis-Related Group (DRG), or other commonly used service billing code.

As discussed in more detail in section XVI.F, we are proposing that hospital make public the payer-specific negotiated charge for a shoppable service in a manner that groups the payer-specific negotiated charge for the primary shoppable service along with charges for associated ancillary services because we believe charge information displayed in such a way is consumer-friendly and patient-focused. In other words, we believe that consumers want to see and shop for healthcare services in the way they experience the service. We recognize that not all hospitals will customarily provide exactly the same ancillary items or services with a primary shoppable service and therefore we believe it is important for hospitals to display a list of which ancillary services are included in conjunction with or as part of the primary shoppable service.

We are proposing to codify these proposed required data elements at proposed new 45 CFR 180.60(b). We are seeking public comments on these data elements and whether there are additional data elements that should be displayed to the public in a consumer-friendly manner. We emphasize that nothing in this proposed rule is meant to inhibit or restrict hospitals from including additional data elements that would improve the ability of health care consumers to understand the hospital's charges for shoppable services, for example, a hospital could choose to display the cash price the hospital would accept as payment in full for the shoppable service from a consumer.

5. Proposals for Format of Display of Consumer-Friendly Information

We are aware that many hospitals are already making public various types of standard charges for shoppable services available online in various formats. For example, some hospitals offer searchable price transparency tools on their website that offer estimated charges (averages or individualized out-of-pocket costs) or may display charges for shoppable services in brochures (both online and offline) that contain self-pay discounted prices for a service package. Because there are a variety of consumer-friendly ways to display charges for hospital services and because we do not want to restrict hospitals from innovating or from having to duplicate efforts, we are not proposing a specific format for making such data public online in a consumer-friendly manner. Specifically, unlike our proposals for the machine-readable list of standard charges for all items and services (discussed in section XVI.E), we are not proposing to require that hospitals make payer-specific charge data public in a single digital file posted online. Instead, we are proposing that hospitals retain flexibility on how best to display the payer-specific negotiated charge data and proposed associated data elements to the public online, so long as the website is easily accessible to the public. We believe this approach would permit some flexibility for hospitals to, for example, post one or more files online with a list of payer-specific charges for the shoppable services and associated data elements, or, for example, to integrate such data into existing price estimate tools.

Additionally, we note that we are not proposing, but are considering, an option that would require hospitals to make these data available in API format. As explained in more detail in section XVI.E.3. of this proposed rule, an API enabled format could allow consumers to access the data by searching for it directly when they do not have a computer by, for example, putting a CPT code in the URL path of the hospital to render in one's mobile phone browser the gross or payer-specific negotiated charge for the service. For example, a consumer searching for the price of a blood test for cholesterol (CPT code 80061) at fictional hospital ABC could look it up by inserting the URL path *https://hospitalABC.com/api/80061*.

We further recognize not all consumers have access to the internet. Therefore, we are proposing to require hospitals make the data elements proposed in section XVI.F.4. of this proposed rule available in a consumer-friendly manner offline. Specifically, we are proposing that the hospital must provide a paper copy (for example, a brochure or booklet) of the information is available to consumers upon request within 72 hours of the request. We are proposing to codify this provision at proposed new 45 CFR 180.60(c).

6. Proposed Location and Accessibility Requirements

Additionally, we are proposing that hospitals make the data elements proposed in section XVI.F.4. of this proposed rule online in such a way that the payer-specific negotiated charge and associated data elements can be located and accessed easily by consumers.

First, we propose that a hospital would have discretion to select an appropriate internet location it uses to post the standard charge information required under this section (that is, the payer-specific charges for shoppable services and associated data elements). We further propose that the website location be publicly available, that the data be displayed prominently and clearly identifies the hospital location with which the standard charge information is associated, and the standard charge data are easily accessible, without barriers, and the data can be digitally searched. For purposes of these proposed requirements: (1) ''displayed prominently'' would mean that the value and purpose of the web page [205] and its content [206] is clearly communicated, there is no reliance on breadcrumbs [207] to help with navigation, and the link to the standard charge

[204] found here: *https://plainlanguage.gov/guidelines/*.

[205] *https://webstandards.hhs.gov/guidelines/49*.

[206] Nielsen, J. (2003, November 10). The ten most violated homepage design guidelines. Alertbox. Available at: *http://www.useit.com/alertbox/20031110.html*.

[207] *https://webstandards.hhs.gov/guidelines/78*.

information is visually distinguished on the web page; [208] (2) ''easily accessible'' would mean that standard charge data are presented in format that is searchable by service description, billing code, and payer, and that the standard charge data posted on the website can be accessed with the fewest number of clicks; [209] and (3) ''without barriers'' would mean the data can be accessed free of charge, users would not have to input information (such as their name, email address, or other PII) or register to access or use the standard charge data. We are proposing to codify this requirement at proposed new 45 CFR 180.50(d).

We encourage hospitals to review the HHS Web Standards and Usability Guidelines (available at: *https://webstandards.hhs.gov/*), which are research-based and are intended to provide best practices over a broad range of web design and digital communications issues.

We seek comment on these proposed location and accessibility requirements and specifically regarding whether there are additional requirements that should be considered to ensure public access to payer-specific negotiated charges for shoppable services.

7. Proposed Frequency of Updates

The statute requires hospitals to establish, update, and make public their standard charges for each year. Therefore, we are proposing to require hospitals to make public and update the standard charge information proposed in section XVI.F.2 at least once annually (proposed new 45 CFR 180.60(e)). We recognize that hospital charges may change more frequently and therefore we encourage (but are not requiring) hospitals to update this file more often, as appropriate, so that the public may have access to the most up-to-date charge information. We also recognize that hospitals update their charges at different times during the year and may also have various State price transparency reporting requirements that require updates. For purposes of these requirements, we believe that updates that occur at least once in a 12-month period will satisfy our proposed requirement to update at least once annually and reduce reporting burden for hospitals. In other words, the hospital could make public and update its list of standard charges at any point in time during the year, so long as the update to the charge data occurs no more than 12 months after posting.

We also are proposing to require hospitals to clearly indicate the date of the last update they have made to the standard charge data, with some discretion as to where the date of late update is indicated.

G. Proposed Monitoring and Enforcement of Requirements for Making Standard Charges Public

1. Background

Section 2718(b)(3) of the PHS Act requires the Secretary to promulgate regulations to enforce the provisions of section 2718 of the PHS Act, and in so doing, the Secretary may provide for appropriate penalties. As such, we are proposing that we may impose penalties on hospitals that fail to make their standard charges public in accordance with the requirements we finalize under section 2718(e) of the PHS Act. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20549), we sought public comments on a variety of issues related to enforcement of the requirement that hospitals make public their standard charges and noted our intent to address enforcement and other actions to ensure compliance in future rulemaking.

We specifically sought comments on the following:

- What is the most appropriate mechanism for CMS to enforce price transparency requirements?
- Should CMS require hospitals to attest to meeting requirements in the provider agreement or elsewhere?
- How should CMS assess hospital compliance?
- Should CMS publicize complaints regarding access to price information or review hospital compliance and post results? What is the most effective way for CMS to publicize information regarding hospitals that fail to comply?
- Should CMS impose civil monetary penalties (CMPs) on hospitals that fail to make standard charges publicly available as required by section 2718(e) of the PHS Act?
- Should CMS use a framework similar to the Federal civil penalties under 45 CFR 158.601 through 158.615, that apply to issuers that fail to report information and pay rebates related to medical loss ratios, as required by sections 2718(a) and (b) of the PHS Act, or would a different framework be more appropriate?

We received a number of comments in response to this RFI. Many commenters agreed that enforcing this requirement under section 2718(e) of the PHS Act would send an important signal that CMS values transparency and ensure that the public has access to hospital charge information. Some commenters suggested that CMS model enforcement after various quality reporting programs, such as the Hospital Inpatient and Outpatient Quality Reporting Programs or the LTCH Quality Reporting Program. Some commenters recommended publicizing noncompliant hospitals or providing a mechanism for the public to file complaints against noncompliant hospitals. Some commenters suggested that CMS propose to make the publication of standard charges a Medicare condition of participation or provider enrollment. However, one commenter indicated that revoking a provider agreement over lack of a website disclosure would be unnecessarily punitive. Other commenters warned that subjecting hospitals violating pricing transparency provisions to compliance actions could pose a challenge, particularly for smaller hospitals, and recommended limiting or deferring compliance actions to a later date. Some commenters agreed that imposing monetary penalties on noncompliant hospitals was appropriate, while other commenters believed that CMS does not have authority to enforce section 2718(e) of the PHS Act and, for that reason, should not adopt penalties for noncompliance.

We agree with commenters who noted that an enforcement regime signals the value we place on price transparency and assurance of public access to hospital standard charges. We interpret section 2718(b)(3) of the PHS Act as authorizing us to enforce the provisions of section 2718(e). Therefore, in this proposed rule, we are proposing to adopt mechanisms to monitor and enforce our requirements for making standard charges public.

2. Proposed Monitoring Methods

Section 2718(e) of the PHS Act requires hospitals to make public their list of standard charges and authorizes the Secretary to promulgate additional criteria that hospitals must satisfy in order to make such charges public. The statute does not prescribe monitoring procedures or the factors we should consider in imposing penalties on hospitals for noncompliance. Based on our experience with the Medicare program and health care marketplace plans, we believe it is important for the public to be informed, and, therefore, for CMS to ensure compliance with this statutory requirement. Therefore, we are proposing to employ methods to monitor and assess hospital compliance with section 2718(e) of the PHS Act, and specifically proposed new 45 CFR 180.40, 180.50, and 180.60.

In general, we are proposing that CMS may use methods to monitor hospital

[208] *https://webstandards.hhs.gov/guidelines/88.*

[209] *https://webstandards.hhs.gov/guidelines/181.*

compliance with the requirements under proposed 45 CFR part 180. We anticipate relying predominantly on complaints made to CMS by individuals or entities regarding a hospital's potential noncompliance. Therefore, we are proposing that our monitoring methods may include, but are not limited to, the following, as appropriate:

- CMS' evaluation of complaints made by individuals or entities to CMS.
- CMS review of individuals' or entities' analysis of noncompliance.

As we gain experience with monitoring compliance with the requirements for proposed 45 CFR part 180, based on reports of potential noncompliance, we may consider self-initiating audits of hospitals' websites as a monitoring method. Therefore, we are proposing that our monitoring methods may include CMS audit of hospitals' websites.

We are proposing to set forth these monitoring methods in the regulations at proposed new 45 CFR 180.70.

3. Proposed Actions To Address Hospital Noncompliance With Requirements To Make Public Standard Charges

We are proposing that hospitals that CMS identifies as noncompliant would be notified of their deficiencies and given an opportunity to take corrective action to come into compliance. As discussed in section XVI.G.4. of this proposed rule, for hospitals determined by CMS to be noncompliant with section 2718(e) of the PHS Act that fail to respond to CMS' requests to submit a corrective action plan (CAP) or comply with the requirements of a CAP, we are proposing that we may impose CMPs on hospitals and publicize these penalties on a CMS website.

Should we conclude, based upon the proposed monitoring activities previously described, that a hospital is noncompliant with section 2718(e) of the PHS Act and the requirements of proposed 45 CFR part 180, we are proposing that CMS may take any of the following actions, which generally, but not necessarily, would occur in this order:

- We may provide a written warning notice to the hospital of the specific violation(s).
- We would request a CAP from the hospital if its noncompliance constitutes a material violation of one or more requirements.
- If the hospital fails to respond to CMS' request to submit a CAP or comply with the requirements of a CAP, CMS may impose a CMP on the hospital and publicize the penalty on a CMS website as discussed in section XVI.G.4. of this proposed rule.

Prior to requesting a CAP, or in the case of violations that are deemed nonmaterial violations warranting a CAP, CMS anticipates warning, via written notice, a hospital of noncompliance with one or more of the requirements to make public standard charges (according to section 2718(e) of the PHS Act and the requirements of proposed 45 CFR part 180), and of the need for voluntary corrective action. We would then reevaluate the hospital's compliance with the statutory and proposed regulatory requirements. Should we determine the hospital remains noncompliant and that the noncompliance constitutes a material violation of one or more requirements, we anticipate requiring that the hospital submit a CAP, and there would be increasing consequences for failure to remedy noncompliance.

We are proposing that a material violation may include, but is not limited to, the following:

- A hospital's failure to make public its standard charges required by proposed new 45 CFR 180.40.
- A hospital's failure to make public its standard charges in the form and manner required under to proposed new 45 CFR 180.50 and 180.60.

We are proposing that CMS may request that a hospital submit a CAP, specified in a notice of violation issued by CMS to a hospital. A hospital required to submit a CAP must do so, in the form and manner, and by the deadline, specified in the notice of violation issued by CMS to the hospital and must comply with the requirements of the CAP.

We are proposing that a hospital's CAP must specify elements including, but not limited to, the deficiency or deficiencies that caused noncompliance to occur, the corrective actions or processes the hospital will take to come into compliance with the requirements of 45 CFR part 180, and the timeframe by which the hospital will complete the corrective action. We are proposing that a CAP would be subject to CMS review and approval. We are proposing that after CMS' review and approval of a hospital's CAP, CMS may monitor and evaluate the hospital's compliance with the corrective actions.

We are proposing that a hospital's failure to respond to CMS' request to submit a CAP includes failure to submit a CAP in the form, manner, or by the deadline, specified in a notice of violation issued by CMS to the hospital. We are proposing that a hospital's failure to comply with the requirements of a CAP includes failure to correct violation(s) within the specified timeframes.

We are proposing to set forth in the regulations at proposed new 45 CFR 180.70 the actions CMS may take to address a hospital's noncompliance with the requirements to make public standard charges, and to set forth in proposed new 45 CFR 180.80 the requirements for a CAP, as discussed in this section of this proposed rule.

4. Proposal To Impose Civil Monetary Penalties

We are proposing that we may impose a CMP on a hospital that we identify as noncompliant with the requirements of proposed 45 CFR part 180, and that fails to respond to CMS' request to submit a CAP or comply with the requirements of a CAP as we describe earlier.

We are proposing that we may impose a CMP upon a hospital for a violation of each requirement of proposed 45 CFR part 180. The maximum daily dollar amount for a CMP to which a hospital may be subject would be $300. We are proposing that even if a hospital is in violation of multiple discrete requirements of proposed 45 CFR part 180, the maximum total sum that a single hospital may be assessed per day is $300.

Further, we are proposing to adjust the CMP amount annually by applying the cost-of-living adjustment multiplier determined by OMB for adjusting applicable CMP amounts pursuant to the *Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.* This multiplier, based on the Consumer Price Index for All Urban Consumers (CPI–U), not seasonally adjusted, is applied to the CMPs in 45 CFR 102.3. For instance, the cost-of-living adjustment multiplier for 2018, based on the CPI–U for the month of October 2017, not seasonally adjusted, was 1.02041 (83 FR 51369).

Given the importance of compliance with the price transparency policies, we believe this proposed CMP amount strikes a balance between penalties that are sufficiently harsh to incentivize compliance but not so severe as to be punitive. We reviewed CMP amounts for other CMS programs that require reporting information and we believe our proposed $300 maximum daily dollar amount for a CMP is commensurate with the level of severity of the potential violation, taking into consideration that nondisclosure of standard charges does not rise to the level of harm to the public as other violations (such as safety and quality issues) for which CMS imposes CMPs and, therefore, should remain at a relatively lower level.

We considered applying lower and higher maximum dollar amounts for a CMP for noncompliance with the requirements of proposed 45 CFR part 180. For example, we considered that CMS has imposed $100 per day penalty amounts with respect to other compliance matters, such as where health insurers fail to comply with premium revenue reporting and rebate requirements found at 45 CFR 158.606. The basis for the CMPs under 45 CFR 158.606 is the number of individuals affected. With respect to the disclosure requirements under proposed 45 CFR part 180, where the lack of information could affect an unknown number of consumers and in myriad ways (for example, not just individuals who paid more for items and services), we do not believe it is feasible to utilize a ''per person'' type basis. We also considered proposing higher maximum daily dollar amounts, such as $400 per day, $500 per day or more.

Further, we considered establishing a cumulative annual total limit for the CMP to which a hospital is subject for noncompliance with proposed 45 CFR part 180. For example, we considered applying a cumulative annual total limit of $100,000 per hospital for each calendar year. However, we are concerned that such an approach could, for example, mitigate the amount of penalty imposed on hospitals that remain noncompliant for multiple years.

If CMS imposes a penalty in accordance with the requirements of proposed 45 CFR part 180, we are proposing that CMS provides a written notice of imposition of a CMP to the hospital via certified mail or another form of traceable carrier. This notice may include, but would not be limited to, the following:

- The basis for the hospital's noncompliance, including, but not limited to, the following: CMS' determination as to which requirement(s) the hospital violated; and the hospital's failure to respond to CMS' request to submit a CAP or comply with the requirements of a CAP.
- CMS' determination as to the effective date for the violation(s). This date would be the latest date of the following:

++ The first day the hospital is required to meet the requirements of proposed 45 CFR part 180.

++ If a hospital previously met the requirements of this part but did not update the information annually as required, the date 12 months after the date of the last annual update specified in information posted by the hospital.

++ A date determined by CMS, such as one resulting from monitoring activities specified in proposed new 45 CFR 180.70, or development of a CAP as specified in proposed new 45 CFR 180.80.

- The amount of the penalty as of the date of the notice.
- A statement that a CMP may continue to be imposed for continuing violation(s).
- Payment instructions.
- Intent to publicize the hospital's noncompliance and CMS' determination to impose a CMP on the hospital for noncompliance with the requirements of proposed 45 CFR part 180 by posting the notice of imposition of a CMP on a CMS website.
- A statement of the hospital's right to a hearing (as described in section XVI.H. of this proposed rule).
- A statement that the hospital's failure to request a hearing within 30 calendar days of the issuance of the notice permits the imposition of the penalty, and any subsequent penalties pursuant to continuing violations, without right of appeal.

Further, in the event that a hospital elects to appeal the penalty, and if the CMP is upheld, in part, by a final and binding decision, we propose that CMS would issue a modified notice of imposition of a CMP.

We are proposing that a hospital must pay a CMP in full within 60 calendar days after the date of the notice of imposition of a CMP from CMS. In the event a hospital requests a hearing (as described in section XVI.H. of this proposed rule), we are proposing that the hospital must pay the amount in full within 60 calendar days after the date of a final and binding decision to uphold, in whole or in part, the CMP. We are also proposing that if the 60th calendar day is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

We also are proposing to publicize, by posting on a CMS website, our notice of imposition of a CMP on a hospital for noncompliance with these requirements, and any subsequently issued notice of imposition of a CMP for continuing violations. In the event that a hospital requests a hearing (as described in section XVI.H. of this proposed rule), we are proposing that CMS would indicate in its posting that the CMP is under review. If the CMP amount is upheld, in whole, by a final and binding decision, we would maintain the posting of the notice of imposition of a CMP on a CMS website. If the CMP is upheld, in part, by a final and binding decision, we would issue a modified notice of imposition of a CMP, and would make this modified notice public on a CMS website. If the CMP is overturned in full by a final and binding decision, we would remove the notice of imposition of a CMP from a CMS website.

In addition, we are proposing that CMS may issue subsequent notice(s) of imposition of a CMP, as described in this section of this proposed rule, that result from the same instance(s) of noncompliance.

We are proposing to set forth in proposed new 45 CFR 180.90 the proposed CMPs for hospitals determined by CMS to be noncompliant with requirements for making standard charges public.

We seek comment on whether the proposed amount of a CMP, in combination with making public on a CMS website our notice of imposition of a CMP, are reasonable and sufficient to ensure hospitals' compliance with the proposed requirements to make public standard charges. We are interested in public comments on our proposed $300 maximum daily dollar amount for a CMP for noncompliance with section 2718(e) of the PHS Act and proposed 45 CFR part 180. In particular, we seek comment on whether we should impose stronger penalties for noncompliance, or whether we should further limit the maximum amount of penalty we would impose on a hospital for a calendar year and the methodology for creating such a limit (for instance through limiting the maximum daily penalty amount, by establishing a cumulative annual total limit on the penalty amount, or both). We seek comment on unintended consequences of the proposed penalties for noncompliance. We also seek commenters' suggestions on whether other penalties should be applied for noncompliance with section 2718(e) of the PHS Act.

H. Proposed Appeals Process

Under section 2718(b)(3) of the PHS Act, we are proposing to impose penalties on hospitals that fail to make their standard charges public in accordance with the requirements we finalize under section 2718(e). We believe it is important to establish a fair administrative process by which a hospital may appeal CMS' decisions to impose penalties under section 2718(b)(3) regarding the hospital's noncompliance with the requirements of section 2718(e) of the PHS Act and the requirements of proposed 45 CFR part 180. Through various Medicare programs, we have gained experience with administrative hearings and other processes to review CMS' determinations.

We are proposing to align the procedures for the appeals process with

the procedures established under section 2718(b)(3) of the PHS Act for an issuer to appeal a CMP imposed by HHS for its failure to report information and pay rebates related to medical loss ratios, as required by sections 2718(a) and (b) of the PHS Act, and according to 45 CFR parts 158 and 150. Therefore, we are proposing that a hospital upon which CMS has imposed a penalty under proposed 45 CFR part 180 may appeal that penalty in accordance with 45 CFR part 150, subpart D, except as we have proposed otherwise.

Generally, under this proposed approach, a hospital upon which CMS has imposed a penalty may request a hearing before an Administrative Law Judge (ALJ) of that penalty. The Administrator of CMS, at his or her discretion, may review in whole or in part the ALJ's decision. A hospital against which a final order imposing a CMP is entered may obtain judicial review.

For purposes of applying the appeals procedures at 45 CFR part 150 to appeals of CMPs under proposed 45 CFR part 180, we are proposing the following exceptions to the provisions of 45 CFR part 150:

- Civil money penalty means a civil monetary penalty according to proposed new 45 CFR 180.90.
- Respondent means a hospital that received a notice of imposition of a CMP according to proposed new 45 CFR 180.90(b).
- References to a notice of assessment or proposed assessment, or notice of proposed determination of CMPs, are considered to be references to the notice of imposition of a CMP specified in proposed new 45 CFR 180.90(b).
- Under 45 CFR 150.417(b), in deciding whether the amount of a civil money penalty is reasonable, the ALJ may only consider evidence of record relating to the following:

++ The hospital's posting(s) of its standard charges, if available.

++ Material the hospital timely previously submitted to CMS (including with respect to corrective actions and CAPs).

++ Material CMS used to monitor and assess the hospital's compliance according to proposed new 45 CFR 180.70(a)(2).

- The ALJ's consideration of evidence of acts other than those at issue in the instant case under 45 CFR 150.445(g) does not apply.

We are proposing to set forth in proposed new 45 CFR 180.100 the proposed procedures for a hospital to appeal the CMP imposed by CMS for its noncompliance with the requirements of proposed 45 CFR part 180.

We also are proposing to set forth in proposed new 45 CFR 180.110 the consequences for failure of a hospital to request a hearing. If a hospital does not request a hearing within 30 calendar days of the issuance of the notice of imposition of a CMP described in proposed new 45 CFR 180.90(b), we are proposing that CMS may impose the CMP indicated in such notice and may impose additional penalties pursuant to continuing violations according to proposed new 45 CFR 180.90(f) without right of appeal. We propose that if the 30th calendar day is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day. We also are proposing that the hospital has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with 45 CFR 150.405, unless the hospital can show good cause, as determined at 45 CFR 150.405(b), for failing to timely exercise its right to a hearing.

Alternatively, we considered and are seeking public comment on following a process for appealing CMPs similar to the approach specified in 42 CFR part 498, subparts D through F. There are differences between the appeals procedures at 42 CFR part 498 compared to 45 CFR part 150. Under the regulations at 42 CFR part 498, for example, either party dissatisfied with a hearing decision by the ALJ may request Departmental Appeals Board review of the ALJ's decision.

XVII. Request for Information (RFI): Quality Measurement Relating to Price Transparency for Improving Beneficiary Access to Provider and Supplier Charge Information

A. Introduction

Last year, we published Requests for Information (RFIs) on price transparency in several Medicare payment rules,[210] including the CY 2019 OPPS/ASC proposed rule (83 FR 37211 and 37212). In the RFIs, we sought public comments on a variety of issues related to making provider and supplier charges for health care services furnished in hospitals more transparent. In general, we encouraged 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 plan to obtain, and to enable patients to compare charges for similar services. We encouraged providers and suppliers of health services to update this information at least annually, or more often as appropriate, to reflect current charges. We expressed concern that challenges continue to exist for patients due to insufficient price transparency. We also indicated that we are considering potential actions that would be appropriate to further our objective of having providers and suppliers of health care services 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 them, 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 hospital outpatient department or an ambulatory surgical center.

In response to the RFIs, stakeholders consistently indicated support for our efforts to improve transparency in health care pricing. Stakeholders noted that out-of-pocket costs are the most relevant and beneficial information for patients and that such pricing information should be shared with patients along with associated quality of care and outcome data. Some stakeholders suggested that educational efforts would help to increase health care pricing literacy. Stakeholders believed that pricing and quality of care information should be shared with patients in a user-friendly format and be comparable across services and providers, which would allow patients to ''shop'' for the best value of health care. Multiple stakeholders commented that quality of care and outcome data should be paired with price information to allow patients to make informed decisions about where they could receive their care and to help ensure that consumers do not assume that the high cost of services necessarily equates to higher quality of care. Respondents to the RFIs suggested that quality information could be displayed by health care entities (such as hospitals) in conjunction with the posting of hospital standard charges, integrated electronically with cost and coverage data in electronic health records (EHRs) or regional health information exchanges (HIEs) for use in shared decision making at the point of care, or incorporated into public facing websites and price transparency tools.

Over the years, CMS has made much progress in improving health care quality measurement and making such quality information publicly available

[210] FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20164); CY 2019 Home Health proposed rule (83 FR 32473); CY 2020 ESRD PPS proposed rule (83 FR 34394); CY 2020 PFS proposed rule (83 FR 36009); and CY 2019 OPPS/ASC proposed rule (83 FR 37211).

through various mechanisms, including public use files (PUFs) on the CMS website. In addition, CMS makes quality of health care information publicly available on the website at *https://data.Medicare.gov* for a number of different health care providers and suppliers, including hospitals, nursing homes, and physicians. Such data are available for the public and could be used by providers and suppliers of health care and pricing tool developers and integrated into EHRs in the manner identified by respondents to the RFI in the CY 2019 OPPS/ASC proposed rule. In addition, CMS has adopted Medicare quality measures that encourage patient engagement, improve patient experience of care, and create incentives for health care providers and suppliers to help patients understand their treatment choices and the financial implications. For example, starting in 2019, Merit-Based Incentive Payment System eligible clinicians participating in the Quality Payment Program will have the opportunity to receive points in the Improvement Activities performance category for helping patients or their caregivers understand the costs of care and explore different payment options by providing financial counseling (83 FR 60289).

B. Request for Information

To enhance our future efforts to improve policies related to transparency in health care charges, we are interested in stakeholder input on a number of related quality of health care issues, including the following:

1. Improving availability and access to existing quality of health care information for third parties and health care entities to use when developing price transparency tools and when communicating charges for health care services. Stakeholders are invited to submit specific suggestions and comments on the following:

- What type of existing quality of health care information would be most beneficial to patients, and how can health care providers and suppliers best enable patients to use quality of health care information in conjunction with information on charges in their decision making before or at the time a service is sought? For example, would it be feasible to use health care quality information from the Medicare Quality Payment Program (QPP) or the Quality Measures Inventory (QMI)? Could quality of health care information from state-mandated quality reporting initiatives or quality reporting initiatives by nationally recognized accrediting entities, such as the National Committee for Quality Assurance, URAC, the Joint Commission, and the National Quality Forum, be engaged to help patients meaningfully assess quality information at the time care is sought?
- How can CMS help providers, suppliers, and third parties create patient-friendly interfaces with this information? What steps should be taken to ensure that quality outcome and experience of care measure data can be used by providers, suppliers, third party pricing tool developers, and consumers when and where health care decisions are being made? Are there potential strategies CMS should consider to create standardized quality data? We are also interested in comments on the timing of information delivery relative to the referral or event, the form of delivery of the information, and the channels (for instance, verbally by the referring doctor, via a mobile application, and on a website, among others) through which the information could best be delivered.
- Is there value in displaying volume and complications of procedures side by side with charge information for patients? If so, should this information be best displayed at the individual physician level, the group practice level, or the facility level and why?
- Should health care providers and suppliers integrate quality information when informing patients of how much their out-of-pocket costs for services will be before patients are furnished services? How would providers that are not included in certain hospital-based quality initiatives, such as critical access hospitals, integrate quality information? What can be done better to inform patients of quality outcomes and patient experience with various providers and suppliers?

2. Improving incentives and assessing the ability of health care providers and suppliers to communicate and share charge information with patients. Stakeholders are invited to submit specific suggestions and comments on the following:

- Should CMS develop Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) questions to assess how well hospitals and other providers and suppliers communicate and discuss the cost of care with their patients? Example questions could be: ''How well did your doctor communicate the expected out-of-pocket cost for your health care services in advance?'' ''Were you surprised by the amount of out-of-pocket costs you had for a given procedure or hospital stay?''
- Are there existing measures or measure concepts to develop that can help patients when assessing the accuracy of charges that providers and suppliers communicate in advance of a service, including the accuracy of expected out-of-pocket cost information? What indices should be used to assess how well a provider or supplier aggregates charge and quality information for public display?
- Are there Medicare value-based purchasing initiatives that could be improved by developing or implementing additional assessments of how well Medicare providers and suppliers engage and respond to patient inquiries related to cost of care, or how Medicare providers and suppliers engage in shared decision making for future care, including discussions of both charges and quality of referral services?

XVIII. Organ Procurement Organizations (OPOs) Conditions for Coverage (CfCs): Proposed Revision of the Definition of ''Expected Donation Rate''

A. Background

1. Organ Procurement Organizations (OPOs)

Organ procurement organizations (OPOs) are vital partners in the procurement, distribution, and transplantation of human organs in a safe and equitable manner for all potential transplant recipients. The role of OPOs is critical to ensuring that the maximum possible number of transplantable human organs is available to seriously ill patients who are on a waiting list for an organ transplant. OPOs are responsible for identifying eligible donors, recovering organs from deceased donors, and complying with all CMS outcome and process performance measures. OPOs also must be a member of, participate in, and abide by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN) that have been approved by the Secretary. The OPTN is a membership organization that links all professionals in the United States organ donation and transplantation system and whose board establishes and maintains transplant policies (which are available on the OPTN website at: *https://optn.transplant.hrsa.gov/governance/about-the-optn/*). Currently, the United Network for Organ Sharing (UNOS) serves as the OPTN under contract. OPOs are required to report specific information to the OPTN, including the data used to calculate the outcome measures for OPOs.

2. Statutory and Regulatory Provisions

To be an OPO, an entity must meet the applicable requirements of both the Act and the Public Health Service Act (the PHS Act). Section 1138(b) of the Act provides the statutory qualifications and requirements that an OPO must meet in order for organ procurement costs to be paid under the Medicare program or the Medicaid program. Section 1138(b)(1)(A) of the Act specifies that an OPO must operate under a grant made under section 371(a) of the PHS Act or must be certified or recertified by the Secretary as meeting the standards to be a qualified OPO within a certain time period. Congress has provided that payment may be made for organ procurement cost ''only if'' the OPO meets the performance-related standards prescribed by the Secretary. To receive payment under the Medicare program or the Medicaid program for organ procurement costs, the entity must have an agreement with, or be designated by, the Secretary (section 1138(b)(1)(F) of the Act and 42 CFR 486.304).

Pursuant to section 371(b)(1)(D)(ii)(II) of the PHS Act, the Secretary is required to establish outcome and process performance measures for OPOs to meet based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of the qualified OPO. An OPO also must be a member of and abide by the rules and requirements of the OPTN that have been approved by the Secretary (section 1138(b)(1)(D) of the Act). We established Conditions for Coverage (CfCs) for OPOs to be able to receive payments from the Medicare and Medicaid programs at 42 CFR part 486, subpart G, to implement the statutory requirements. These regulations set forth the certification and recertification processes, outcome requirements, and process performance measures for OPOs and were effective on July 31, 2006 (71 FR 30982).

3. HHS Initiatives Related to OPO Services

In 2000, the Secretary's Advisory Committee on Organ Transplantation (ACOT) was established under the general authority of section 222 of the PHS Act, as amended, and implementing regulations under 42 CFR 121.12. A 2012 recommendation by ACOT stated: ''The ACOT recognizes that the current CMS and HRSA/OPTN structure creates unnecessary burdens and inconsistent requirements on transplant centers (TCs) and OPOs and that the current system lacks responsiveness to advances in TC and OPO performance metrics. The ACOT recommends that the Secretary direct CMS and HRSA to confer with the OPTN, [Scientific Registry of Transplant Recipients] SRTR, the OPO community, and TC representatives to conduct a comprehensive review of regulatory and other requirements, and to promulgate regulatory and policy changes to requirements for OPOs and TCs that unify mutual goals of increasing organ donation, improving recipient outcomes, and reducing organ wastage and administrative burden on TCs and OPOs. These revisions should include, but not be limited to, improved risk adjustment methodologies for TCs and a statistically sound method for yield measures for OPOs. . . .'' [211] We believe that our proposal to harmonize the definitions of ''expected donation rate'' as discussed below would address this ACOT recommendation. We also believe that the proposal demonstrates responsiveness to advances in OPO metrics and resolves an inconsistency in the OPO requirements for how OPO measures are being determined.

B. Proposed Revision of the Definition of ''Expected Donation Rate''

As set forth in 42 CFR 486.328, which specifies the condition for reporting of data, transplant hospitals and OPOs must report data to the OPTN and those data are transmitted on a monthly basis to the SRTR contractor. The OPTN members, including OPOs, are required to submit certain data to the OPTN or SRTR. The OPTN and SRTR collect and analyze the data pursuant to the HRSA mission to increase organ donation and transplantation. Periodically, the data that OPOs must report to the OPTN or the SRTR is revised based on methodologies and clinical practice improvements that enable them to draw more accurate conclusions about donor and organ suitability for transplantation.

The CfCs for OPOs regulations at 42 CFR 486.318(a) and (b) require that an OPO must meet two of the three following outcome measures:

- The OPOs donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below the mean national donation rate of eligible donors as a percentage of eligible deaths, averaged over the 4 years of the re-certification cycle. Both the numerator and denominator of an individual OPO's donation rate ratio are adjusted by adding a 1 for each donation after cardiac death donor and each donor over the age of 70;
- The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re-recertification, as calculated by SRTR;
- The OPO data reports, averaged over the 4 years of the re-certification cycle, must meet the rules and requirements of the most current OPTN aggregate donor yield measure.

The expected donation rate used in the second outcome measure is calculated by the SRTR. The CfCs for OPOs at 42 CFR 486.302 defines ''expected donation rate'' as the donation rate expected for an OPO based on the national experience for OPOs serving similar hospitals and donation service areas (DSAs). This rate is adjusted for the following hospital characteristics: Level I or Level II trauma center; Metropolitan Statistical Area (MSA) size; Metropolitan Statistical (MS) case-mix index; total bed size; number of intensive care unit (ICU) beds; primary service; presence of a neurosurgery unit; and hospital control/ownership.

In 2009, the SRTR modified the definition of ''expected donation rate'' we used for this outcome measure. The updated SRTR's definition states: ''[t]he expected donation rate per 100 eligible deaths is the rate expected for an OPO based on the national experience for OPOs serving similar eligible donor populations and DSAs. This rate is adjusted for the distributions of age, sex, race, and cause of death among eligible deaths.'' [212]

To determine the expected donation rate, the SRTR believed that it was important to adjust for characteristics that would allow for isolation of the effects that OPOs' practices were having on donation in that DSA. The SRTR determined that basing the expected donation rate for an OPO on the national experience for OPOs serving similar hospitals and DSAs and then adjusting for hospital characteristics did not take into consideration the eligible donor population in the DSA. The SRTR found that the eligible donor population varies from DSA to DSA across the country and such variations do have an impact on donation rates. Therefore, the SRTR determined that a more precise method to calculate an OPO's expected donation rate would be to base it on the national experience for OPOs serving similar eligible donor populations and DSAs and then adjust for patient characteristics, that is age, sex, race, and cause of death among eligible deaths.

[211] Available at: *https://www.organdonor.gov/about-dot/acot/acotrecs55.html*.

[212] Available at: *https://www.srtr.org/about-the-data/technical-methods-for-the-opo-specific-reports/*.

Due to an oversight, CMS did not make a corresponding change to the definition in the CfCs for OPOs at the time that the SRTR made its change. In order to address this issue, we are proposing to change our requirements so that we are consistent with the SRTR's definition for the second outcome measure. Therefore, in this proposed rule, we are proposing to make a change to harmonize the CMS definition with the SRTR definition. We are proposing to make this change at this time in order to clarify the regulatory standard so that we may properly enforce the second outcome measure, eliminate any provider confusion, and further support our goals of accurately and reliably measuring OPO performance.

Specifically, we are proposing to revise the definition to state that the expected donation rate per 100 eligible deaths is the rate expected for an OPO based on the national experience for OPOs serving similar eligible donor populations and DSAs. We are proposing that this rate would be adjusted for the distributions of age, sex, race, and cause of death among eligible deaths.

If we finalize this proposal, this change would take effect on the effective date of the final rule with comment period, which would occur during the 2022 recertification cycle. Because the final regulation change would not be retroactive and, in order to give OPOs adequate time to comply with the change to the definition for ''expected donation rate,'' we are proposing to change the time period for the observed donation rate for the second outcome measure for the 2022 recertification cycle only. As a result, we also are proposing to revise § 486.318(a)(2), (b)(2), and (c)(1) to reduce the time period for this outcome measure. We are proposing to calculate the expected donation rate using 12 of the 24 months of data following the effective date of the final rule with comment period (using data from January 1, 2020 through December 31, 2020). After the 2022 recertification cycle, and if there are no other changes to the OPO outcome measures, we would assess OPO performance based on 36 months of data.

C. Request for Information Regarding Potential Changes to the Organ Procurement Organization and Transplant Center Regulations

Since the OPO and the transplant center regulations were finalized, we have received substantial feedback from the organ procurement and transplant communities recommending modifications to the current requirements. Therefore, we are considering a comprehensive proposal to update the CfCs for OPOs and possibly the CoPs for transplant centers. We are including transplant centers in this request for information due to the inextricable connection between transplant centers and OPOs. We are seeking public input regarding what revisions may be appropriate for the current CfCs for OPOs that are set forth at 42 CFR 486.301 through 486.360 and the current CoPs for transplant centers that are set forth at 42 CFR 482.68 through 482.104. The CfCs for OPOs set forth the requirements each OPO must meet to be eligible for payment under the Medicare and Medicaid programs. The CoPs for transplant centers set forth the requirements each transplant center must meet to be eligible for payment under the Medicare. In addition, more information on how data regarding OPOs as well as transplant centers are identified and used can be found on the website at: *https://www.srtr.org/*.

The following are key areas on which we are seeking public input:

- Do the current OPO outcome measures that are set forth at 42 CFR 486.318 accurately and reliably reflect an OPO's performance? If not, please explain.
- What are the impacts or consequences of the current outcome measures on: (1) An OPO's performance; and (2) the availability of transplantable organs?
- What impact, if any, do the certification and decertification processes for OPOs have on organ procurement and transplantation?
- Are there any potential, empirically based outcome measures, other than those currently at § 486.318, that could be used either in addition to, or instead of, the current outcome measures for OPOs? If recommending another outcome measure, what is the empirical evidence for that recommended measure?
- In addition to the outcome measures, are there other indicators of quality that could be used for OPOs in the CfCs? If recommending another quality indicator, why should that indicator be used in the OPOs CfCs and what is the supporting evidence for this indicator?
- Are there any transplant center CoPs that conflict with or should be harmonized with the OPOs CfCs? If yes, identify the specific requirements and how they would harmonize or otherwise modify the requirements.

We also are soliciting public comment on whether the following two potential OPO outcome measures would be valid measures and would be consistent with statutory requirements. We are especially interested in public comments about the validity and reliability of these possible measures.

The first potential measure would be the actual deceased donors as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation. The data on inpatient deaths, including additional related demographic data, would be derived from the CDC Detailed Mortality File and the National Center for Health Statistic's National Vital Statistics Report. We believe that the consistency and quality of this measure could be a significant improvement over the current measures because it relies on independent data to measure true organ donation potential. While this donation rate might include potential donors in the denominator who would never clinically qualify as organ donors, it does so consistently across all OPOs, which provides a reliable comparative performance measure across all OPO DSAs. This outcome measure also would account for: (1) Geographic differences in the manner of deaths across the United States (for example, trauma deaths); (2) geographic differences in the age distribution of deaths; and (3) geographic differences in in-hospital versus out-of-hospital deaths. This measure would reward efforts to maximize total organ procurement and efforts to improve placements of all procured organs.

The second potential measure is the actual organs transplanted as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation. This measure also would reward efforts to maximize total organ procurement and efforts to improve placements of all procured organs.

In addition to public comments on both of these potential outcome measures, we are interested in public comments on appropriate parameters for these measures. How should we determine what percentage indicates that an OPO's performance is acceptable or successful? If commenters cannot recommend a specific percentage, how should we determine what the parameters for the outcome measures should be? We are requesting that commenters explain and include any evidence or data they have to support their comments. We are interested in any comments about what commenters believe would be the benefit or consequences, or perhaps unintended consequences, of using these measures and the potential impact on OPOs,

transplant centers, organ donation, and transplant recipients. We are also interested in comments on potential additional compliance burdens on OPOs and transplant centers. Finally, we are seeking comments that demonstrate how revising the OPO outcome measures would benefit or negatively impact patient outcomes, access, and quality of life.

For additional information on these potential outcome measures, we refer readers to the document, *Changing Metrics of Organ Procurement Organization Performance in Order to Increase Organ Donation Rates in the United States,* published in the American Journal for Transplantations.[213]

We will consider the public comments that we receive from this request for information for future rulemaking and potential revisions to the CfCs for OPOs and the CoPs for transplant centers.

XIX. Clinical Laboratory Fee Schedule: Potential Revisions to the Laboratory Date of Service Policy

A. Background on the Medicare Part B Laboratory Date of Service Policy

The date of service (DOS) is a required data field on all Medicare claims for laboratory services. However, a laboratory service may take place over a period of time—the date the laboratory test is ordered, the date the specimen is collected from the patient, the date the laboratory accesses the specimen, the date the laboratory performs the test, and the date results are produced may occur on different dates. In the final rule on coverage and administrative policies for clinical diagnostic laboratory services published in the **Federal Register** on November 23, 2001 (66 FR 58791 through 58792), we adopted a policy under which the DOS for clinical diagnostic laboratory services generally is the date the specimen is collected. In that final rule, we also established a policy that the DOS for laboratory tests that use an archived specimen is the date the specimen was obtained from storage (66 FR 58792).

In 2002, we issued Program Memorandum AB–02–134, which permitted contractors discretion in making determinations regarding the length of time a specimen must be stored to be considered ''archived.'' In response to comments requesting that we issue a national standard to clarify when a stored specimen can be considered ''archived,'' in the Procedures for Maintaining Code Lists in the Negotiated National Coverage Determinations for Clinical Diagnostic Laboratory Services final notice, published in the **Federal Register** on February 25, 2005 (70 FR 9357), we defined an ''archived'' specimen as a specimen that is stored for more than 30 calendar days before testing. Specimens stored for 30 days or less continued to have a DOS of the date the specimen was collected.

B. Medicare DOS Policy and the ''14-Day Rule''

In the final rule with comment period entitled, in relevant part, ''Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B'' published in the **Federal Register** on December 1, 2006 (December 1, 2006 MPFS final rule) (71 FR 69705 through 69706), we added a new § 414.510 in title 42 of the CFR regarding the clinical laboratory DOS requirements and revised our DOS policy for stored specimens. We explained in that MPFS final rule that the DOS of a test may affect payment for the test, especially in situations in which a specimen that is collected while the patient is being treated in a hospital setting (for example, during a surgical procedure) is later used for testing after the patient has been discharged from the hospital. We noted that payment for the test is usually bundled with payment for the hospital service, even when the results of the test did not guide treatment during the hospital stay. To address concerns raised for tests related to cancer recurrence and therapeutic interventions, we finalized modifications to the DOS policy in § 414.510(b)(2)(i) for a test performed on a specimen stored less than or equal to 30 calendar days from the date it was collected (a non-archived specimen), so that the DOS is the date the test was performed (instead of the date of collection) if the following conditions are met:

- The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;
- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test do not guide treatment provided during the hospital stay; and
- The test was reasonable and medically necessary for the treatment of an illness.

As we stated in the December 1, 2006 MPFS final rule, we established these five criteria, which we refer to as the ''14-day rule,'' to distinguish laboratory tests performed as part of posthospital care from the care a beneficiary receives in the hospital. When the 14-day rule applies, laboratory tests are not bundled into the hospital stay, but are instead paid separately under Medicare Part B (as explained in more detail below).

We also revised the DOS requirements for a chemotherapy sensitivity test performed on live tissue. As discussed in the December 1, 2006 MPFS final rule (71 FR 69706), we agreed with commenters that these tests, which are primarily used to determine posthospital chemotherapy care for patients who also require hospital treatment for tumor removal or resection, appear to be unrelated to the hospital treatment in cases where it would be medically inappropriate to collect a test specimen other than at the time of surgery, especially when the specific drugs to be tested are ordered at least 14 days following hospital discharge. As a result, we revised the DOS policy for chemotherapy sensitivity tests, based on our understanding that the results of these tests, even if they were available immediately, would not typically affect the treatment regimen at the hospital. Specifically, we modified the DOS for chemotherapy sensitivity tests performed on live tissue in § 414.510(b)(3) so that the DOS is the date the test was performed if the following conditions are met:

- The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;
- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test do not guide treatment provided during the hospital stay; and
- The test was reasonable and medically necessary for the treatment of an illness.

We explained in the December 1, 2006 MPFS final rule that, for chemotherapy sensitivity tests that meet this DOS policy, Medicare would allow separate payment under Medicare Part

[213] Changing Metrics of Organ Procurement Organization Performance in order to Increase Organ Donation Rates in the United States, *Am J Transplant,* 2017 Dec; 17(12): 3183–3192. doi: 10.1111/ajt. 14391. Epub 2017 Jul20.

B; that is, separate from the payment for hospital services.

C. Billing and Payment for Laboratory Services Under the OPPS

The DOS requirements at 42 CFR 414.510 are used to determine whether a hospital bills Medicare for a clinical diagnostic laboratory test (CDLT) or whether the laboratory performing the test bills Medicare directly. Separate regulations at 42 CFR 410.42(a) and 411.15(m) generally provide that Medicare will not pay for a service furnished to a hospital patient during an encounter by an entity other than the hospital unless the hospital has an arrangement (as defined in 42 CFR 409.3) with that entity to furnish that particular service to its patients, with certain exceptions and exclusions. These regulations, which we refer to as the ''under arrangements'' provisions in this discussion, require that if the DOS falls during an inpatient or outpatient stay, payment for the laboratory test is usually bundled with the hospital service.

Under our current rules, if a test meets all DOS requirements in § 414.510(b)(2)(i), (b)(3), or (b)(5) (an additional exception finalized in the CY 2018 OPPS/ASC final rule with comment period that we describe later in this section), the DOS is the date the test was performed. In this situation, the laboratory would bill Medicare directly for the test and would be paid under the Clinical Laboratory Fee Schedule (CLFS) directly by Medicare. However, if the test does not meet the DOS requirements in § 414.510(b)(2)(i), (b)(3), or (b)(5), the DOS would be the date the specimen was collected from the patient. In that case, the hospital would bill Medicare for the test and then would pay the laboratory that performed the test, if the laboratory provided the test under arrangement.

In recent rulemakings, we have reviewed appropriate payment under the OPPS for certain diagnostic tests that are not commonly performed by hospitals. In CY 2014, we finalized a policy to package certain CDLTs under the OPPS (78 FR 74939 through 74942 and 42 CFR 419.2(b)(17) and 419.22(l)). In CYs 2016 and 2017, we made some modifications to this policy (80 FR 70348 through 70350; 81 FR 79592 through 79594). Under our current policy, certain CDLTs that are listed on the CLFS are packaged as integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the hospital outpatient setting during the same outpatient encounter and billed on the same claim. Specifically, we conditionally package most CDLTs and only pay separately for a laboratory test when it is: (1) The only service provided to a beneficiary on a claim; (2) considered a preventive service; (3) a molecular pathology test; or (4) an advanced diagnostic laboratory test (ADLT) that meets the criteria of section 1834A(d)(5)(A) of the Act (78 FR 74939 through 74942; 80 FR 70348 through 70350; and 81 FR 79592 through 79594). In the CY 2016 OPPS/ASC final rule with comment period, we excluded all molecular pathology laboratory tests from packaging because we believed these relatively new tests may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged.

For similar reasons, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79592 through 79594), we extended the exclusion to also apply to all ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act, which we describe below. We stated that we will assign status indicator ''A'' (Separate payment under the CLFS) to ADLTs once a laboratory test is designated an ADLT under the CLFS. Laboratory tests that are separately payable and are listed on the CLFS are paid at the CLFS payment rates outside the OPPS.

D. ADLTs Under the New Private Payor Rate-Based CLFS

Section 1834A of the Act, as established by section 216(a) of Public Law 113–93, the Protecting Access to Medicare Act of 2014 (PAMA), requires significant changes to how Medicare pays for CDLTs under the CLFS. Section 216(a) of PAMA also establishes a new subcategory of CDLTs known as ADLTs, with separate reporting and payment requirements under section 1834A of the Act. In the CLFS final rule published in the **Federal Register** on June 23, 2016, entitled ''Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule'' (81 FR 41036), we implemented the requirements of section 1834A of the Act.

As defined in § 414.502, an ADLT is a CDLT covered under Medicare Part B that is offered and furnished only by a single laboratory, and cannot be sold for use by a laboratory other than the single laboratory that designed the test or a successor owner. Also, an ADLT must meet either Criterion (A), which implements section 1834A(d)(5)(A) of the Act, or Criterion (B), which implements section 1834A(d)(5)(B) of the Act, as follows:

- *Criterion (A):* The test is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins; when combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies); provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and may include other assays.

Or:

- *Criterion (B):* The test is cleared or approved by the Food and Drug Administration.

Generally, under the revised CLFS, ADLTs are paid using the same methodology based on the weighted median of private payor rates as other CDLTs. However, updates to ADLT payment rates occur annually instead of every 3 years. The payment methodology for ADLTs is detailed in the June 23, 2016 CLFS final rule (81 FR 41076 through 41083). For additional information regarding ADLTs, we refer readers to the CMS website: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.html*.

E. Additional Laboratory DOS Policy Exception for the Hospital Outpatient Setting

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59393 through 59400), we established an additional exception at § 414.510(b)(5) for the hospital outpatient setting so that the DOS for molecular pathology tests and certain ADLTs that are excluded from the OPPS packaging policy is the date the test was performed (instead of the date of specimen collection) if certain conditions are met. Under the exception that we finalized at § 414.510(b)(5), in the case of a molecular pathology test or a test designated by CMS as an ADLT under paragraph (1) of the definition of an ADLT in § 414.502, the DOS of the test must be the date the test was performed only if:

- The test was performed following a hospital outpatient's discharge from the hospital outpatient department;
- The specimen was collected from a hospital outpatient during an encounter (as both are defined in 42 CFR 410.2);
- It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;

- The results of the test do not guide treatment provided during the hospital outpatient encounter; and
- The test was reasonable and medically necessary for the treatment of an illness.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59397), we explained that we believed the laboratory DOS policy in effect prior to CY 2018 created administrative complexities for hospitals and laboratories with regard to molecular pathology tests and laboratory tests expected to be designated by CMS as ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act. We noted that under the laboratory DOS policy in effect prior to CY 2018, if the tests were ordered less than 14 days following a hospital outpatient's discharge from the hospital outpatient department, laboratories generally could not bill Medicare directly for the molecular pathology test or ADLT. In those circumstances, the hospital had to bill Medicare for the test, and the laboratory had to seek payment from the hospital. We noted that commenters informed us that because ADLTs are performed by only a single laboratory and molecular pathology tests are often performed by only a few laboratories, and because hospitals may not have the technical ability to perform these complex tests, the hospital may be reluctant to bill Medicare for a test it would not typically (or never) perform. The commenters also stated that as a result, the hospital might delay ordering the test until at least 14 days after the patient is discharged from the hospital outpatient department, or even cancel the order to avoid the DOS policy, which may restrict a patient's timely access to these tests. In addition, we noted that we had heard from commenters that the laboratory DOS policy in effect prior to CY 2018 may have disproportionately limited access for Medicare beneficiaries under Medicare Parts A and B, because Medicare Advantage plans under Medicare Part C and other private payors allow laboratories to bill directly for tests they perform.

We also recognized that greater consistency between the laboratory DOS rules and the current OPPS packaging policy would be beneficial and would address some of the administrative and billing issues created by the DOS policy in effect prior to CY 2018. We noted that we exclude all molecular pathology tests and ADLTs under section 1834A(d)(5)(A) of the Act from the OPPS packaging policy because we believe these tests may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged, and we had already established exceptions to the DOS policy that permit the DOS to be the date of performance for certain tests that we believe are not related to the hospital treatment and are used to determine posthospital care. We stated that we believed a similar exception is justified for the molecular pathology tests and ADLTs excluded from the OPPS packaging policy, which we understood are used to guide and manage the patient's care after the patient is discharged from the hospital outpatient department. We noted that we believed that, like the other tests currently subject to DOS exceptions, these tests can legitimately be distinguished from the care the patient receives in the hospital, and thus we would not be unbundling services that are appropriately associated with hospital treatment. Moreover, we reiterated that these tests are already paid separately outside of the OPPS at CLFS payment rates. Therefore, we agreed with the commenters that the laboratory performing the test should be permitted to bill Medicare directly for these tests, instead of relying on the hospital to bill Medicare on behalf of the laboratory under arrangements.

A list of the specific laboratory tests currently subject to the laboratory DOS exception at § 414.510(b)(5) is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy.html*.

Following publication of the CY 2018 OPPS/ASC final rule with comment period, we issued Change Request (CR) 10419, Transmittal 4000, the claims processing instruction implementing the laboratory DOS exception at § 414.510(b)(5), with an effective date of January 1, 2018 and an implementation date of July 2, 2018. After issuing CR 10419, we heard from stakeholders that many hospitals and laboratories were having administrative difficulties implementing the DOS exception set forth at § 414.510(b)(5). On July 3, 2018, we announced that, for a 6-month period, we would exercise enforcement discretion with respect to the laboratory DOS exception at § 414.510(b)(5). We explained that stakeholder feedback suggested many providers and suppliers would not be able to implement the laboratory DOS exception by the July 2, 2018 implementation date established by CR 10419, and that such entities required additional time to develop the systems changes necessary to enable the performing laboratory to bill for tests subject to the exception. We noted that this enforcement discretion applies to all providers and suppliers with regard to ADLTs and molecular pathology tests subject to the laboratory DOS exception policy, and that during the enforcement discretion period, hospitals may continue to bill for these tests that would otherwise be subject to the laboratory DOS exception.

We then extended the enforcement discretion period for two additional, consecutive 6-month periods, after learning through communications with representatives of providers and suppliers affected by the policy that there are still many entities who will not be able to implement the laboratory DOS exception and will need additional time to come into compliance. The enforcement discretion period is currently in effect until January 2, 2020. The latest enforcement discretion announcement as well as CR 10419, Transmittal 4000 is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy.html.*

During this time, we have continued to gage the industry's readiness to implement the laboratory DOS exception at § 414.510(b)(5). Stakeholders, including representatives of hospitals, have informed us that hospitals, in particular, are having difficulty with developing the systems changes necessary to provide the performing laboratory with the patient's hospital outpatient status, beneficiary demographic information, and insurance information, such as whether the beneficiary is enrolled in original fee-for-service Medicare or a specific Medicare Advantage plan. According to stakeholders, the performing laboratory requires this information so that it can bill Medicare directly for the test instead of seeking payment from the hospital.

In addition, stakeholders, including representatives of laboratories, have noted that some entities performing molecular pathology testing subject to the laboratory DOS exception, such as blood banks and blood centers, may not be enrolled in the Medicare program and may not have established a mechanism to bill Medicare directly. According to these stakeholders, blood banks and blood centers that are not currently enrolled in the Medicare program would need to establish a billing mechanism so that they can bill Medicare directly when the requirements of § 414.510(b)(5) are met. Stakeholders have asserted that establishing a billing mechanism is

labor intensive and that blood banks and blood centers currently lack the financial resources and expertise to take on this task.

We also note that protein-based Multianalyte Assays with Algorithmic Analysis (MAAAs) that are not considered molecular pathology tests and are not designated as ADLTs under paragraph (1) of the definition of ADLT in § 414.502, are also conditionally packaged under the OPPS at this time. Several stakeholders have suggested that they believe that the pattern of clinical use of some of these protein-based MAAAs make them relatively unconnected to the primary hospital outpatient service, though they do not currently qualify for the DOS exception at § 414.510(b)(5) solely because they are MAAAs. We note that a protein-based MAAA that is designated by CMS as an ADLT under paragraph (1) of the definition of an ADLT in § 414.502 would be eligible for the DOS exception at § 414.510(b)(5), and we intend to consider policies regarding MAAAs for future rulemaking.

F. Potential Revisions to Laboratory DOS Policy and Request for Public Comments

In response to the implementation concerns raised by stakeholders, we are considering making additional changes to the laboratory DOS policy.

As discussed previously, under the exception that we finalized at § 414.510(b)(5), a molecular pathology test or a test designated by CMS as an ADLT under paragraph (1) of the definition of an ADLT in § 414.502, the DOS of the test must be the date the test was performed only if: (i) The test was performed following a hospital outpatient's discharge from the hospital outpatient department; (ii) the specimen was collected from a hospital outpatient during an encounter (as both are defined in 42 CFR 410.2); (iii) it was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter; (iv) the results of the test do not guide treatment provided during the hospital outpatient encounter; and (v) the test was reasonable and medically necessary for the treatment of an illness. When all conditions under the laboratory DOS exception at § 414.510(b)(5) are met, the DOS is the date of test performance, instead of the date of specimen collection, which effectively unbundles the test from the hospital outpatient encounter. As such, the test is not considered a hospital outpatient service for which the hospital must bill Medicare and for which the performing laboratory must seek payment from the hospital, but rather a laboratory test under the CLFS for which the performing laboratory must bill Medicare directly. We are considering three options for potential changes to the laboratory DOS exception at § 414.510(b)(5), and we seek comment on these changes. Specifically, we are seeking comment on:

1. Changing the Test Results Requirement at 42 CFR 414.510(b)(5)(iv);

2. Limiting the Laboratory DOS Exception at 42 CFR 414.510(b)(5) to ADLTs; and/or

3. Excluding Blood Banks and Blood Centers from the Laboratory DOS Exception at 42 CFR 414.510(b)(5).

These potential revisions are discussed below.

1. Changing the Test Results Requirement at 42 CFR 414.510(b)(5)(iv)

Since finalizing the laboratory DOS exception at § 414.510(b)(5), we have continued to review and analyze the factors we use to determine whether a molecular pathology test or Criterion (A) ADLT is unrelated to the hospital treatment and used to determine posthospital care, and therefore should have a DOS that is the date of performance rather than the date of specimen collection. One such factor, in § 414.510(b)(5)(iv), is that the results of the test must not guide treatment provided during the hospital outpatient encounter—meaning, the encounter in which the specimen was collected. We are no longer convinced that the determination as to whether a molecular pathology test or ADLT is separable from a hospital service should be based on whether the test results guide treatment during the specific hospital outpatient encounter in which the specimen was collected. We believe that a molecular pathology test or an ADLT that is performed on a specimen collected during a hospital outpatient encounter, in which the results of the test are intended to guide treatment during a future hospital outpatient encounter, is a hospital service, and therefore should be billed by the hospital that collected the specimen under arrangements, just like if the test does not meet one of the other prongs of § 414.510(b)(5). In contrast, if the results of the test are not intended to guide treatment during a hospital outpatient encounter, and if all other requirements in § 414.510(b)(5) are met, the test is separable from a hospital service and therefore, should be considered a laboratory service and the performing laboratory should bill for the test.

We believe that a test's relationship to a hospital outpatient encounter depends on many factors, including the patient's current diagnosis (or lack of a current diagnosis), the procedure(s) being considered for the patient, the patient's current and previous medical history, and other factors and that the ordering physician would be aware of these beneficiary characteristics. As such, we believe that it should be the role of the ordering physician to determine whether the results of a molecular pathology test or ADLT are or are not intended to guide treatment during a hospital outpatient encounter.

Therefore, we are considering a revision to our current laboratory DOS policy at § 414.510(b)(5)(iv) to specify that the ordering physician would determine whether the results of the ADLT or molecular pathology test are intended to guide treatment provided during a hospital outpatient encounter, if the other four requirements under § 414.510(b)(5) are met. Under this approach, the test would be considered a hospital service unless the ordering physician determines that the test does not guide treatment during a hospital outpatient encounter. If the ordering physician determines that the test results are not intended to guide treatment during the hospital outpatient encounter from which the specimen was collected or during a future hospital outpatient encounter, for purposes of the laboratory DOS exception at § 414.510(b)(5), the DOS service of the test would be the date of test performance. In this situation, the test would not be considered a hospital service and the performing laboratory would be required to bill for the test.

Conversely, if the other four requirements under § 414.510(b)(5) are met, but the ordering physician determines that the results of the laboratory test are intended to guide treatment during a hospital outpatient encounter, the DOS would be the date of specimen collection. As a result, the hospital that collected the specimen would bill for the laboratory test under arrangements and the laboratory would seek payment from the hospital for the test. This potential revision to the laboratory DOS exception at § 414.510(b)(5) would be consistent with our belief that a molecular pathology test or a Criterion (A) ADLT is a hospital service when the results of the test are intended to guide treatment during a hospital outpatient encounter.

We are requesting comments from hospitals, laboratories, physicians and non-physician practitioners, and other interested stakeholders regarding this potential revision to the laboratory DOS

exception at § 414.510(b)(5). We are particularly interested in comments regarding our position that when the results of molecular pathology testing and Criterion (A) ADLTs are intended to guide treatment during a future hospital outpatient encounter, the test is a hospital service. We also are interested in receiving public comments regarding the administrative aspects of requiring the ordering physician to determine when the test results are not intended to guide the treatment during a hospital outpatient encounter, as well as the process for the ordering physician to document this decision and provide notification to the hospital that collected the specimen for billing purposes. We note that we would consider finalizing this potential revision to the laboratory DOS policy as a result of our review of the comments received on this topic.

We note that at this time, we are only soliciting comments on potential changes to the laboratory DOS exception at § 414.510(b)(5), and not the 14-day rule DOS exception at § 414.510(b)(2) and the chemotherapy sensitivity test DOS exception at § 414.510(b)(3). These exceptions would continue to include the requirement that the results of the test do not guide treatment provided during the hospital stay, meaning the hospital stay in which the specimen was collected. Although we recognize that the considerations about how a hospital service is determined under § 414.510(b)(5) discussed previously may also be applicable to the 14-day rule DOS exception and chemotherapy sensitivity test DOS exception, we are only considering revisions to the laboratory DOS exception at § 414.510(b)(5) at this time. Because of the administrative issues raised by stakeholders regarding the implementation of the laboratory DOS exception at § 414.510(b)(5), we believe a cautious and incremental approach to making changes to laboratory DOS policy is warranted. As such, any potential changes to the 14-day rule DOS exception at § 414.510(b)(2) and the chemotherapy sensitivity test DOS exception at § 414.510(b)(3) would be addressed in future rulemaking.

2. Limiting the Laboratory DOS Exception at 42 CFR 414.510(b)(5) to ADLTs

As discussed previously in this section, we established a laboratory DOS policy exception for the hospital outpatient setting at § 414.510(b)(5), in part, because of stakeholder concerns that the laboratory DOS policy in effect prior to CY 2018 created beneficiary access issues with regard to molecular pathology tests and laboratory tests expected to be designated by CMS as ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act. In the CY 2018 OPPS/ASC proposed rule (82 FR 33653), we considered revising the DOS rule to create an exception only for ADLTs that meet the criteria in section 1834A(d)(5)(A) of the Act because ADLTs are offered and furnished only by a single laboratory (as defined in 42 CFR 414.502). We noted that a hospital, or another laboratory that is not the single laboratory (as defined in 42 CFR 414.502), cannot furnish the ADLT, and there may be additional beneficiary concerns for these ADLTs that may not apply to the molecular pathology tests. For example, a hospital may not have an arrangement with the single laboratory that furnishes a particular ADLT, which could lead the hospital to delay the order for the ADLT until 14 days after the patient's discharge to avoid financial risk and thus potentially delay medically necessary care for the beneficiary. We solicited comments as to whether molecular pathology tests present the same concerns of delayed access to medically necessary care as ADLTs, noting that molecular pathology tests are not required to be furnished by a single laboratory and that there may be ''kits'' for certain molecular pathology tests that a hospital can purchase, allowing the hospital to perform the test. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59399) we agreed with commenters that limiting the new laboratory DOS exception to include only ADLTs (and not molecular pathology tests) would be inconsistent with the OPPS packaging policy and that relatively few laboratories may perform certain molecular pathology testing. We also acknowledged that hospitals may not currently have the technical expertise or certification requirements necessary to perform molecular pathology testing and therefore must rely on independent laboratories to perform the test. Therefore, we concluded that similar beneficiary access concerns that apply to ADLTs may also apply to molecular pathology tests, and we decided not to limit the exception at 42 CFR 414.510(b)(5) to ADLTs only.

However, after further review of this issue, we no longer believe the same beneficiary access concerns that apply to ADLTs also apply to molecular pathology tests. In particular, unlike ADLTs, molecular pathology tests are not required by statute to be furnished by a single laboratory, so hospital laboratories and independent laboratories are not prevented from performing molecular pathology testing. In addition, we understand that a number of kits have recently been developed and approved by FDA that would allow a hospital to more easily perform some of these molecular pathology tests. As such, we are no longer convinced that molecular pathology tests present the same concerns of delayed access to medically necessary care as ADLTs, which must be performed by a single laboratory. We believe a hospital's laboratory can develop the expertise to perform a molecular pathology test or establish an arrangement with an independent laboratory to perform the test. Therefore, we believe that any incentives that may exist to delay ordering until at least 14 days following a patient's discharge from the hospital outpatient department do not apply to molecular pathology tests.

We recognize that limiting the laboratory DOS exception to ADLTs is not consistent with OPPS packaging policy. As discussed previously in this section of the proposed rule, we exclude all molecular pathology laboratory tests from OPPS packaging because we believe these tests may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged (80 FR 70348 through 70350). However, consistency with the OPPS packaging policy only formed part of the basis for the laboratory DOS exception at § 414.510(b)(5). We note that beneficiary access concerns were the primary reason for establishing this laboratory DOS exception and we no longer believe the access concerns are sufficiently compelling for the molecular pathology tests. In light of the billing and enrollment concerns raised by the blood banks and blood centers and administrative issues raised by other stakeholders, CMS believes the policy reasons for removing these tests from the laboratory DOS exception at § 414.510(b)(5) outweigh the difference it creates with the OPPS packaging policy.

Therefore, we are considering a potential revision that would limit the laboratory DOS provisions of § 414.510(b)(5) to tests designated by CMS as an ADLT under paragraph (1) of the definition of an ADLT in § 414.502. Molecular pathology tests would be removed from the provisions of § 414.510(b)(5). However, we note that molecular pathology tests would still be subject to the laboratory DOS provisions of § 414.510(b)(2) and (3).

We are requesting comments on potentially limiting the laboratory DOS exception policy at § 414.510(b)(5) to Criterion (A) ADLTs that have been granted ADLT status by CMS. We note that we would consider finalizing this approach as a result of the public comments received.

3. Excluding Blood Banks and Blood Centers From the Laboratory DOS Exception at 42 CFR 414.510(b)(5)

Following publication of the CY 2018 OPPS/ASC final rule with comment period, stakeholders informed us that blood banks and blood centers perform some of the molecular pathology test codes that are subject to the laboratory DOS exception policy at § 414.510(b)(5). Based on information from stakeholders, it is our understanding that blood banks and centers are entities whose primary function is the collection, storage and dissemination of blood products and are typically accredited by the AABB (formally known as the American Association of Blood Banks). Representatives of blood banks and centers contend that while these entities may perform the same molecular pathology tests that are performed and billed by other laboratories that are not blood banks and centers, the blood banks and centers perform these tests for different reasons. Specifically, they assert that the blood banks and centers perform molecular pathology testing primarily to identify the most compatible blood product for a patient, whereas other laboratories typically provide molecular pathology testing for diagnostic purposes. According to these stakeholders, the patient has already been diagnosed with a specific disease or condition before the blood sample is provided to the blood bank or center, who are then tasked with providing compatible blood products and assessing risks of incompatibility for hospitals. In other words, blood banks and centers perform molecular pathology testing for patients to enable hospitals to prevent adverse conditions associated with blood transfusions, rather than perform molecular pathology testing for diagnostic purposes. Examples of molecular pathology testing performed by blood banks and centers include red blood cell phenotyping, as described by HCPCS code 81403, red blood cell antigen testing as described by HCPCS code 0001U, and platelet antigen testing as described by HCPCS code 81105.

As discussed previously, when a test meets all of the conditions in the current laboratory DOS exception at § 414.510(b)(5), the DOS of the test must be the date the test was performed, and the laboratory that performed the test must bill Medicare directly for the test. This would include circumstances when a laboratory that is a blood bank or blood center performs the test. However, given the different purpose of molecular pathology testing performed by the blood banks and centers, that is, blood compatibility testing, we question whether the molecular pathology testing performed by blood banks and centers is appropriately separable from the hospital stay, given that it typically informs the same patient's treatment during a future hospital stay. We are concerned that our current policy may unbundle molecular testing performed by a blood bank or center for a hospital patient. As such, we believe that molecular pathology testing, when performed by blood banks or centers, is inherently tied to a hospital service because hospitals receive payment for and/or use the blood and/or blood products provided by blood banks and blood centers to treat patients in the hospital setting. Accordingly, we believe that such testing is so connected to the treatment furnished to the patient in the hospital that it must be considered a hospital service and that hospitals should be permitted to bill and receive payment for such testing performed on these blood and/or blood-related products.

Based on our concern and the comments we have received from stakeholders, we are considering a regulatory change that would exclude blood banks and centers from the laboratory DOS exception at § 414.510(b)(5). Under this potential revision, the DOS for laboratory testing performed by blood banks and centers on specimens collected from a hospital outpatient during a hospital outpatient encounter would, depending on the underlying service, be the date of specimen collection. As a result, the hospital would bill for the laboratory test under arrangements and the blood bank or center performing the test would seek payment from the hospital. In addition, for purposes of excluding blood banks and centers from the provisions of § 414.510(b)(5), we would define a blood bank and center as an entity whose primary function is the collection, storage and dissemination of blood products. We believe this potential definition of a blood bank and center describes the primary responsibility of all blood banks and centers, which distinguishes these entities from other laboratory types. In developing a definition of blood banks and centers we are distinguishing blood banks and blood centers from non-blood bank and blood center laboratories that perform the same molecular pathology test codes but for different reasons, that is, for diagnostic purposes rather than for blood compatibility testing.

We are requesting comments from hospitals, blood banks and centers, and other interested stakeholders regarding a potential revision to laboratory DOS policy that would exclude blood banks and centers from the laboratory DOS exception policy at § 414.510(b)(5). We also are requesting specific comments as to how a blood bank and blood center may be defined in the context of this provision, and particularly how to distinguish blood banks and centers from other laboratories. We note that we would consider finalizing a revision to the laboratory DOS policy that excludes blood banks and centers from the provisions of § 414.510(b)(5) as a result of comments received on this topic.

XX. Proposed Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services

A. Background

As part of its responsibility to protect the Medicare Trust Funds, CMS routinely analyzes data associated with all facets of the Medicare program. This responsibility includes monitoring the total amount or types of claims submitted by providers and suppliers; analyzing the claims data to assess the growth in the number of claims submitted over time (for example, monthly and annually, among other intervals); and conducting comparisons of the data with other relevant data, such as the total number of Medicare beneficiaries served by providers to help ensure the continued appropriateness of payment for services furnished in the hospital outpatient department (OPD).

In line with this responsibility, CMS recently completed an analysis of the volume of covered OPD services furnished and determined that CMS has experienced significant increases in the utilization volume of some of these services. As an initial effort to focus our analysis, we chose to target services that represent procedures that are likely to be cosmetic surgical procedures and/or are directly related to cosmetic surgical procedures that are not covered by Medicare, but may be combined with or masquerading as therapeutic services.[214] However, we also recognized the need to establish baseline measures for comparison purposes, including, but not limited to, the yearly rate-of-increase in the number of OPD claims submitted

[214] Medicare Benefit Policy Manual. Internet Only. Publication 100–02, Chapter 16, § 120.

and the average annual rate-of-increase in Medicare allowed amounts. Our analysis included the review of over 1.1 billion claims related to OPD services during the 11-year period from 2007 through 2017.[215] We note that we determined that the overall rate of OPD claims submitted for payment to the Medicare program increased each year by an average rate of 3.2 percent. This equated to an increase from approximately 90 million OPD claims submitted for payment in 2007 to approximately 118 million claims submitted for payment in 2017. Our analysis also showed an average annual rate-of-increase in the Medicare allowed amount (the amount that Medicare would pay for services regardless of external variables, such as beneficiary plan differences, deductibles, and appeals) of 8.2 percent. We found that the total Medicare allowed amount for the OPD services claims processed in 2007 was approximately $31 billion and increased to $65 billion in 2017, while during this same 11-year period, the average annual increase in the number of Medicare beneficiaries per year was only 1.1 percent. The 8.2 percent increase exceeds the average annual increase of 5.8 percent per year in overall health care spending during that same time period (2007–2017), according to the analysis of the U.S. Bureau of Labor and Statistics Consumer Price Index for medical care.[216]

Upon reviewing specific OPD categories of services in comparison to these figures, we found higher than expected volume increases for several services. Many of these services fall within the following five general categories of services: (1) Blepharoplasty; (2) botulinum toxin injections; (3) panniculectomy; (4) rhinoplasty; and (5) vein ablation.

As discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015), and addressed again in section X.D. of this proposed rule, we have developed many payment policies with the goal in mind of managing the growth in Medicare spending for OPD services, and most recently, to control unnecessary increases in the volume of OPD services using our authority under section 1833(t)(2)(F) of the Act. Section 1833(t)(2)(F) of the Act authorizes CMS to develop a method for controlling unnecessary increases in the volume of covered OPD services. We believe the increases in volume associated with certain covered OPD services described earlier in this section are unnecessary because the data show that the volume of utilization of these services far exceeds what would be expected in light of the average rate-of-increase in the number of Medicare beneficiaries; these procedures are often considered cosmetic and, in those instances, would not be covered by Medicare; and we are unaware of other factors that might contribute to clinically valid increases in volume. Therefore, these above-average increases in volume suggest an increase in unnecessary utilization. As discussed in detail below, we are proposing to use the authority under section 1833(t)(2)(F) of the Act to require prior authorization for certain covered OPD services as a condition of Medicare payment.

B. Proposal for a Prior Authorization Process for Certain OPD Services

We believe a prior authorization process for certain OPD services would ensure that Medicare beneficiaries continue to receive medically necessary care while protecting the Medicare Trust Funds from improper payments, and at the same time keeping the medical necessity documentation requirements unchanged for providers. We believe prior authorization for these services will be an effective method for controlling increases in the volume of these services because we expect that it will reduce the instances in which Medicare pays for these services when they are merely cosmetic and not medically necessary. As a method for controlling unnecessary increases in the volume of certain covered OPD services, we are proposing to use our authority under section 1833(t)(2)(F) of the Act to establish a process through which providers would submit a prior authorization request for a provisional affirmation of coverage before a covered OPD service is furnished to the beneficiary and before the claim is submitted for processing. We are proposing to establish a new subpart I under 42 CFR part 419 to codify the conditions and requirements for the proposed prior authorization for certain covered OPD services to help control unnecessary increases in the volume of covered OPD services. This subpart would establish the conditions of payment for OPD services that require prior authorization; establish the submission requirements for prior authorization requests, including methods for expedited review of prior authorization requests; and provide for suspension of the prior authorization process generally, or for particular services. In order to allow time for providers to better understand this proposed prior authorization process, for CMS to ensure sufficient time is allowed for outreach and education to affected stakeholders, and for contractor operational updates to be in place, we are proposing that this requirement would begin for dates of service on or after July 1, 2020. We note that we are proposing to pattern some of the provisions for prior authorization for covered OPD services after the prior authorization program that we have already established for certain durable medical equipment, prosthetics, and supplies (DMEPOS) under 42 CFR 414.234.

As we noted, CMS routinely analyzes data as part of its oversight of the Medicare program, and our analysis was used as a basis for this proposed rule. Moreover, the Medicare program is continuing to incorporate advancements in health information technology (health IT) into its program operations. This includes improvements in interoperability, the secure electronic transmission of clinical data, and the potential incorporation of artificial intelligence into the claims review process. As these advancements in health IT continue, we are committed to ensuring that these efficiencies and enhancements will be considered, whenever possible, to reduce the burden placed on providers.

As stated earlier, we are proposing to establish a new subpart I under part 419 (containing §§ 419.80 through 419.89 (§§ 419.84 through 419.89 would be reserved)) to codify the following proposed policies for prior authorization for certain covered OPD services.

1. Basis, Scope, and Definitions for Proposed New Subpart I Under Part 419

We are proposing to specify the basis and scope of the proposed subpart under proposed new § 419.80, using section 1833(t)(2)(F) of the Act as our authority to establish the prior authorization process and requirements.

We are proposing to define key terms associated with the proposed prior authorization process for certain covered OPD services under proposed new § 419.81. We are proposing to define ''prior authorization'' to mean a

[215] The data reviewed are maintained in the CMS Integrated Data Repository (IDR). The IDR is a high-volume data warehouse integrating Medicare Parts A, B, C, and D, and DME claims, beneficiary and provider data sources, along with ancillary data such as contract information and risk scores. Additional information is available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/IDR/index.html*.

[216] The 5.8 percent average increase per year in overall health care spending was arrived at using data publicly available on the Bureau of Labor and Statistics web page, located at: *https://www.bls.gov/cpi/factsheets/medical-care.htm*.

process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the service is provided to the beneficiary and before the claim is submitted. We are proposing to define ''provisional affirmation'' to mean a preliminary finding that a future claim for the service will meet Medicare's coverage, coding, and payment rules. As previously mentioned, we patterned these proposed definitions after the prior authorization process for certain DMEPOS under 42 CFR 414.234. Lastly, we are proposing to define the ''list of hospital outpatient department services requiring prior authorization'' as the list of outpatient department services CMS publishes in accordance with proposed new § 419.83(a) that require prior authorization as a condition of payment.

2. Prior Authorization as a Method for Controlling Unnecessary Increases in the Volume of Covered Outpatient Services (Proposed New § 419.82)

In proposed new § 419.82(a), we are proposing that, as a condition of Medicare payment, a provider must submit a prior authorization request for services on the list of hospital outpatient department services requiring prior authorization to CMS that meets the requirements of the proposed new § 419.82(c); namely, that the prior authorization request includes all documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules, and that the request be submitted before the service is furnished to the beneficiary and before the claim is submitted. We are proposing that claims submitted for services that require prior authorization that have not received a provisional affirmation of coverage from CMS or its contractors would be denied, unless the provider is exempt under § 419.83(c) (proposed new in § 419.82(b)(1)). This would include the denial of any claims associated with the denial of a service listed in proposed § 419.83(a)(1), including services such as anesthesiology services, physician services, and/or facility services. Moreover, we are proposing that even when a provisional affirmation has been received, a claim for services may be denied based on either technical requirements that can only be evaluated after the claim has been submitted for formal processing or information not available at the time the prior authorization request is received (proposed new § 419.82(b)(2)(i) and (ii)).

We are proposing that a provider must submit a prior authorization request for any service on the list of outpatient department services requiring prior authorization that would be published by CMS (proposed new § 419.82(c)). As noted earlier, we are proposing that, in submitting a prior authorization request, the provider must include all relevant documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules and that the request be submitted before the service is provided to the beneficiary and before the claim is submitted (proposed new § 419.82(c)(1)(i) and (ii)). We also are proposing that providers have an opportunity to submit prior authorization requests for expedited review when a delay could seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (proposed new § 419.82(c)(2). Documentation that the beneficiary's life, health, or ability to regain maximum function is in serious jeopardy must be submitted with this request.

We are proposing that CMS or its contractor will review a prior authorization request for compliance with applicable Medicare coverage, coding, and payment rules (proposed new § 419.82(d)). If the request meets the applicable Medicare coverage, coding, and payment rules, CMS or its contractor would issue a provisional affirmation to the requesting provider (proposed new § 419.82(d)(1)(i)). If the request does not meet the applicable Medicare coverage, coding, and payment rules, CMS or its contractor would issue a non-affirmation decision to the requesting provider (proposed new § 419.82(d)(1)(ii)). In proposed new § 419.82(d)(iii), we are proposing that CMS or its contractor would issue a decision (affirmative or non-affirmative) within 10 business days.

We are proposing that, if the provider receives a non-affirmation decision, we would allow the provider to resubmit a prior authorization request with any applicable additional relevant documentation. This would include the resubmission of requests for expedited reviews (proposed new § 419.82(e)(1) and (2)).

We are proposing that CMS or its contractor would initiate an expedited review of a prior authorization request when requested by a provider and where CMS or its contractor determines that a delay could seriously jeopardize the beneficiary's life, health or ability to regain maximum function (proposed new § 419.82(d)(2)). Upon making this determination, we are proposing that CMS or its contractor would issue a provisional affirmation or non-affirmation in accordance with proposed new § 419.82(d)(1) using an expedited timeframe of 2 business days.

As part of the requirements for the DMEPOS prior authorization process,[217] under 42 CFR 405.926(t), we specified that a prior authorization request that is non-affirmed is not an initial determination on a claim for payment for services provided and, therefore, would not be appealable. We are proposing to apply this same provision to the OPD services prior authorization process. Therefore, we are proposing to revise § 405.926(t) so that OPD prior authorization requests that are determined non-affirmed also would not be considered an initial determination and, therefore, would not be appealable. However, the provider will still have the opportunity to resubmit a prior authorization request under proposed new § 419.82(e) provided the claim has not yet been submitted and denied.

If a claim is submitted for the services listed in proposed new § 419.83(a)(1) without a provisional affirmation, it will be denied. The claim denial is an initial determination and a redetermination request may be submitted in accordance with 42 CFR 405.940. Consistent with current policy, we also are proposing in proposed new § 419.82(b)(3) that any claims associated with or related to a service listed in proposed new § 419.83(a)(1) for which a claim denial is issued will be denied as well since these services would be unnecessary if the service listed in proposed new § 419.83(a)((1) had not been provided. These associated services include, but are not limited to, services such as anesthesiology services, physician services, and/or facility services. The associated claims would be denied whether a non-affirmation was received for a service listed in proposed new § 419.83(a)(1) or the provider did not request a prior authorization request. A contractor is not required to request medical documentation from the provider who billed the associated claims before making such a denial. We are requesting public comments on whether the requirement in proposed new § 419.82(b)(3) should remain in 42 CFR part 419 or be co-located with the regulatory provisions governing initial determinations located in 42 CFR part 405.

3. Proposed List of Outpatient Department Services That Would Require Prior Authorization (Proposed New § 419.83)

We are proposing that the list of covered OPD services that would require prior authorization are those

[217] 80 FR 81674 (December 30, 2015).

identified by the CPT codes in Table 38. For ease of review, we are only including the five categories of services within which these CPT codes fall in proposed new § 419.83(a)(1). The five categories of services would be: Blepharoplasty; botulinum toxin injections; panniculectomy; rhinoplasty; and vein ablation. In proposed new § 419.83(a)(2), we are proposing that technical updates, such as corrections or conforming changes to the names of the services or CPT codes, may be made on the CMS web page.

Also, we are proposing that CMS may elect to exempt a provider from the prior authorization process in proposed new § 419.82 upon a provider's demonstration of compliance with Medicare coverage, coding, and payment rules and that this exemption would remain in effect until CMS elects to withdraw the exemption (proposed new § 419.83(c)). We would exempt providers that achieve a prior authorization provisional affirmation threshold of at least 90 percent during a semiannual assessment. We anticipate that an exemption will take approximately 90 calendar days to effectuate. We believe that, by achieving this percentage, the provider would be demonstrating an understanding of the requirements for submitting accurate claims. We do not believe it is necessary for a provider to achieve 100 percent compliance to qualify for an exemption because innocent and sporadic errors could occur that are not deliberate or systematic attempts to submit claims that are not payable. In addition, we propose that we might withdraw an exemption if evidence becomes available based on a review of claims that the provider has begun to submit claims that are not payable based on Medicare's billing, coding or payment requirements. If the rate of nonpayable claims submitted becomes higher than 10 percent during a biannual assessment, we will consider withdrawing exemption. Again, we anticipate that withdrawing the exemption may take approximately 90 calendar days to effectuate.

Moreover, we are proposing that CMS may suspend the outpatient department services prior authorization process requirements generally or for a particular service(s) at any time by issuing notification on CMS' web page (proposed new § 419.83(d)). While we believe this is unlikely to occur, we nonetheless believe it is necessary for us to retain this flexibility in the event of certain circumstances, such as where the cost of the prior authorization program exceeds the savings it generates.

C. Proposed List of Outpatient Department Services Requiring Prior Authorization

As mentioned earlier, we have identified a list of specific services (Table 38) that, based on review and analysis of claims data for the 11-year period from 2007 through 2017, show higher than expected, and therefore, we believe, unnecessary, increases in the volume of service utilization. These services fall within the following five categories: blepharoplasty; botulinum toxin injections; panniculectomy; rhinoplasty; and vein ablation. In making the decision to propose to include the specific services in the proposed list of hospital outpatient department services requiring prior authorization as shown in Table 38, we first considered that these services are most often considered cosmetic and, therefore, are only covered by Medicare in very rare circumstances. We then viewed the current volume of utilization of these services and determined that the utilization far exceeds what would be expected in light of the average rate-of-increase in the number of Medicare beneficiaries. We note that we are unaware of other factors that might contribute to increases in volume of services that indicate that the services are increasingly medically necessary, such as clinical advancements or expanded coverage criteria that would have led to the increases. Below we describe what we believe are the unnecessary increases in volume of each of the categories of services for which we are proposing to require prior authorization:

- *Botulinum Toxin Injections:* In reviewing CMS data available through the Integrated Data Repository (IDR), we determined that destruction of nerves to muscles of the face via botulinum toxin injections had an overall average annual increase in the number of unique claims of approximately 19.3 percent from 2007 through 2017, with an average annual increase in financial expense to the Medicare program as a result of allowed amounts in service costs and payments of approximately 27.8 percent and an average annual increase in the number of unique patients of approximately 17.9 percent. Based on analysis and comparisons of claims data, these increases in service utilization volume, financial expense, and the number of Medicare patients far exceed the typical baseline rates or trends we identified.
- *Panniculectomy:* Our analysis of IDR data showed that panniculectomy had an average annual increase in the number of unique claims of approximately 9.2 percent from 2007 through 2017, with an average annual increase in financial expense to the Medicare program as a result of allowed amounts in service costs and payments of approximately 13.9 percent and an average annual increase in the number of unique patients of approximately 9.2 percent. Based on analysis and comparisons of claims data, these increases in service utilization volume, financial expense to the Medicare program, and the number of Medicare patients also far exceed the typical baseline rates or trends we identified (that is, the 9.2 percent average annual increase in the rate of Medicare beneficiaries receiving a panniculectomy is significantly higher than the 1.1 percent average annual increase in the Medicare beneficiaries who received outpatient services over that eleven-year period). Additionally, some panniculectomy services were reported on claims by providers in combination with procedures performed on the patient's chest region, in addition to abdominal procedures.
- *Vein Ablation:* In reviewing the available data from the IDR, vein ablation had an average annual increase in the number of unique claims of approximately 11.1 percent from 2007 through 2017, with an average annual increase in financial expense to the Medicare program as a result of allowed amounts in service costs and payments of approximately 11.5 percent and an average annual increase in the number of unique patients of approximately 9.5 percent. Based on analysis and comparisons of claims data, these increases in service utilization volume, financial expense to the Medicare program, and the number of Medicare patients also far exceed the typical baseline rates or trends we identified (that is, the 9.5 percent average annual increase in the rate of Medicare beneficiaries receiving vein ablation is significantly higher than the 1.1 percent average annual increase in the Medicare beneficiaries who received outpatient services over that eleven-year period).
- *Rhinoplasty:* In reviewing available IDR data, rhinoplasty had an average annual increase in the number of unique patients of approximately 1.9 percent. This represents a 64.1 percent increase in comparison to the 1.1 percent rate of increase for unique patients for all OPPS services for that same time period. Even though this category of services includes some procedures that had annual increases in service utilization volume far exceeding what we would expect based on the typical rate, this was not true for all services within the category. One example that did exceed the

expected rate was the number of unique claims for the procedure of widening of the nasal passage. This rate increased significantly more than the expected rate and was as much as 34.8 percent from 2016 through 2017.

• *Blepharoplasty:* In reviewing the IDR data, blepharoplasty, like rhinoplasty, had overall statistics that were similar to the rate increases expected for outpatient services. However, some procedures had annual increases in service utilization volume that far exceeded these expected rates. As an example, the number of unique claims for the procedure of repairing of the upper eyelid muscle to correct drooping or paralysis increased as high as 48.9 percent from 2011 through 2012, which far exceeds the rate we would expect for such a service.

Table 38 lists the specific procedures within the five categories of services that we are proposing for the proposed list of hospital outpatient department services requiring prior authorization.

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TABLE 38.--PROPOSED LIST OF OUTPATIENT SERVICES THAT WOULD REQUIRE PRIOR AUTHORIZATION

Code	(i) Blepharoplasty, Eyelid Surgery, Brow Lift, and Related Services
15820	Removal of excessive skin of lower eyelid
15821	Removal of excessive skin of lower eyelid and fat around eye
15822	Removal of excessive skin of upper eyelid
15823	Removal of excessive skin and fat of upper eyelid
67900	Repair of brow paralysis
67901	Repair of upper eyelid muscle to correct drooping or paralysis
67902	Repair of upper eyelid muscle to correct drooping or paralysis
67903	Shortening or advancement of upper eyelid muscle to correct drooping or paralysis
67904	Repair of tendon of upper eyelid
67906	Suspension of upper eyelid muscle to correct drooping or paralysis
67908	Removal of tissue, muscle, and membrane to correct eyelid drooping or paralysis
67911	Correction of widely-opened upper eyelid
Code	**(ii) Botulinum Toxin Injection**
64612	Injection of chemical for destruction of nerve muscles on one side of face
64615	Injection of chemical for destruction of facial and neck nerve muscles on both sides of face
J0585	Injection, onabotulinumtoxina, 1 unit
J0587	Injection, rimabotulinumtoxinb, 100 units
Code	**(iii) Panniculectomy, Excision of Excess Skin and Subcutaneous Tissue (Including Lipectomy), and Related Services**
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (eg, abdominoplasty) (includes umbilical transposition and fascial plication) (list separately in addition to code for primary procedure)
15877	Suction assisted removal of fat from trunk
Code	**(iv) Rhinoplasty, and Related Services**
20912	Nasal cartilage graft
21210	Repair of nasal or cheek bone with bone graft
21235	Obtaining ear cartilage for grafting
30400	Reshaping of tip of nose
30410	Reshaping of bone, cartilage, or tip of nose

30420	Reshaping of bony cartilage dividing nasal passages
30430	Revision to reshape nose or tip of nose after previous repair
30435	Revision to reshape nasal bones after previous repair
30450	Revision to reshape nasal bones and tip of nose after previous repair
30460	Repair of congenital nasal defect to lengthen tip of nose
30462	Repair of congenital nasal defect with lengthening of tip of nose
30465	Widening of nasal passage
30520	Reshaping of nasal cartilage
Code	**(v) Vein Ablation and Related Services**
36473	Mechanochemical destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36474	Mechanochemical destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36475	Destruction of insufficient vein of arm or leg, accessed through the skin
36476	Radiofrequency destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36478	Laser destruction of incompetent vein of arm or leg using imaging guidance, accessed through the skin
36479	Laser destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36482	Chemical destruction of incompetent vein of arm or leg, accessed through the skin using imaging guidance
36483	Chemical destruction of incompetent vein of arm or leg, accessed through the skin using imaging guidance

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XXI. Comment Solicitation on Cost Reporting, Maintenance of Hospital Chargemasters, and Related Medicare Payment Issues

The Department is examining the relationship of hospital chargemasters to the Medicare cost report and its use in setting Medicare payment for hospital services in connection with the Department's effort to increase innovation in its programs. For this cause, the Department is seeking public comments, including comments from hospitals and revenue cycle management experts, cost report experts, accounting firms, or others who understand hospital cash flows, on innovative and streamlined methods for establishing hospital payment to the extent permitted by law.

Medicare-certified institutional providers are required to submit an annual cost report to CMS which is used to set prospective payment rates for institutions. The cost report contains provider information such as facility characteristics, utilization data, cost and charges by cost center (in total and for Medicare), Medicare settlement data, and financial statement data.[218] The reported charges are generally those that are derived from the hospital chargemaster. We are seeking public comments on the continued value of the chargemaster charges in setting hospital payment and to other stakeholders, as well as the costs associated with maintaining the chargemaster for purposes of Medicare cost reporting and payment. Further, we are seeking public comments on whether it would be possible to modernize or streamline the Medicare cost reporting process, for example, by replacing it with other processes or if it could be modified in content, methodology, or approach. We also recognize that hospital charge data are used in calculating a number of payments CMS makes to hospitals (for example, in recalibrating relative weights, the calculation of outlier payments, critical access hospital payments, new technology add-on payments, and pretransplant cost reimbursement) and that these charge data may reflect the charges found on the hospital's chargemaster. We are seeking public comments on whether and how the replacement or modification of the chargemaster might affect the submission of data used by CMS to calculate these payments, as well as alternative sources that could be used for the information necessary to calculate these payments. We also are seeking public comments on the decision process, and why the chargemaster might be updated more frequently than on an annual basis and how this more frequent updating could affect costs for patients.

[218] *https://www.cms.gov/research-statistics-data-and-systems/downloadable-public-use-files/cost-reports/.*

XXII. Proposed Changes to Requirements for Grandfathered Children's Hospitals-Within-Hospitals (HwHs)

Existing regulations at § 412.22(e) define a hospital-within-a-hospital (HwH) as a hospital that occupies space in the same building as another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital.

Existing § 412.22(f) provides for the grandfathering of HwHs that were in existence on or before September 30, 1995, so long as the HwH continues to operate under the same terms and conditions, including the number of beds. Sections 412.22(h) and 412.25(e), relating to satellites of hospitals and hospital units, respectively, excluded from the IPPS, define a satellite facility as a part of a hospital or unit that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital. Sections 412.22(h)(3) and 412.25(e)(3) provide for the grandfathering of excluded hospitals and units that were structured as satellite facilities on September 30, 1999, to the extent that they operate under the same terms and conditions in effect on that date. While these rules initially only applied to LTCHs, in 1997, CMS expanded the scope of these rules to all hospitals excluded from the IPPS (including children's hospitals) because the underlying policy concern of hospitals creating new entities that were separate in name only (essentially operating as units of the hospital) in order to increase Medicare revenue was not unique to LTCHs. For example, we have expressed our concerns that an HwH's ''configuration could result in patient admission, treatment, and discharge patterns that are guided more by attempts to maximize Medicare payments than by patient welfare'' and that ''the unregulated linking of an IPPS hospital and a hospital excluded from the IPPS could lead to two Medicare payments for what was essentially one episode of patient care'' (69 FR 48916 and 49191).

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38292 through 38294), we finalized a change to our HwH regulations at § 412.22(e) to only require, as of October 1, 2017, that IPPS-excluded HwHs that are co-located with IPPS hospitals comply with the separateness and control requirements in those regulations. We adopted this change because we believe that the policy concerns that underlay the previous HwH regulations are sufficiently moderated in situations where IPPS-excluded hospitals are co-located with each other, in large part due to changes that have been made to the way most types of IPPS-excluded hospitals are paid under Medicare. As part of our ongoing efforts to reduce regulatory burdens, we have continued to examine areas in which the rules for co-located entities are no longer necessary. As a result of this examination, we believe that there is no Medicare payment policy rationale for prohibiting grandfathered children's HwHs from increasing their number of beds. Given the low number of Medicare claims submitted by these children's hospitals, which results in a minimal level of Medicare reimbursement to them relative to the payments they receive from other payers, we believe that such a regulatory change would allow these hospitals to address changing community needs for services without any increased incentive for inappropriate patient shifting to maximize Medicare payments. Additionally, we do not believe that allowing grandfathered children's HwHs to increase their bed size would impart an economic advantage to these hospitals relative to other hospitals; however, we invite comment on this area. We are proposing to revise § 412.22(f)(1) and (2) of the regulations to allow a grandfathered children's HwH to increase its number of beds without resulting in the loss of grandfathered status. We are seeking public comment on this proposal. Additionally, we are seeking public comment on whether this proposal could create unintended or inadvertent consequences.

XXIII. Files Available to the Public via the Internet

The Addenda to the OPPS/ASC proposed rules and the final rules with comment period are published and available via the internet on the CMS website. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59154), for CY 2019, we changed the format of the OPPS Addenda A, B, and C, by adding a column entitled ''Copayment Capped at the Inpatient Deductible of $1,364.00'' where we flag, through use of an asterisk, those items and services with a copayment that is equal to or greater than the inpatient hospital deductible amount for any given year (the copayment amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year). For CY 2020, we are proposing to retain these columns, updated to reflect the amount of the 2020 inpatient deductible.

To view the Addenda to this proposed rule pertaining to CY 2020 payments under the OPPS, we refer readers to the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*; select ''1717–P'' from the list of regulations. All OPPS Addenda to this proposed rule are contained in the zipped folder entitled ''2020 NPRM OPPS Addenda'' at the bottom of the page. To view the Addenda to this proposed rule pertaining to CY 2020 payments under the ASC payment system, we refer readers to the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html*; select ''1717–P'' from the list of regulations. All ASC Addenda to this proposed rule are contained in a zipped folder entitled ''Addendum AA, BB, DD1, DD2, and EE.''

XXIV. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In 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 2019 OPPS/ASC final rules with comment periods (75 FR 72111 through 72114; 76 FR 74549 through 74554; 77 FR 68527 through 68532; 78 FR 75170 through 75172; 79 FR 67012 through 67015; 80 FR 70580 through 70582; 81 FR 79862 through 79863; 82 FR 59476 through 59479; and 83 FR 59155 through 59156, respectively) for detailed discussions of

Hospital OQR Program information collection requirements we have previously finalized. The information collection requirements associated with the Hospital OQR Program are currently approved under OMB control number 0938–1109 which expires on March 31, 2021. Below we discuss only the changes in burden that would result from the proposed policies in this proposed rule with comment period, if finalized.

In section XIV.B.3.b. of this proposed rule, we are proposing to remove one measure from the Hospital OQR Program for the CY 2022 payment determination; OP–33: External Beam Radiotherapy for Bone Metastases. The reduction in burden associated with this proposal is discussed below.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59477), we finalized a proposal to utilize the median hourly wage rate, in accordance with the Bureau of Labor Statistics (BLS), to calculate our burden estimates for the Hospital OQR Program. The BLS describes Medical Records and Health Information Technicians as those responsible for organizing and managing health information data; therefore, we believe it is reasonable to assume that these individuals will be tasked with abstracting clinical data for submission for the Hospital OQR Program. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59156), we utilized a median hourly wage of $18.29 per hour. We note that since then, more recent wage data have become available, and we are updating the wage rate used in these calculations. The more recent data (May 2018) from the Bureau of Labor Statistics reflects a median hourly wage of $19.40 [219] per hour for a Medical Records and Health Information Technician professional. We have finalized a policy to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage (82 FR 59477). This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($19.40 × 2 = $38.80) to estimate total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs. This approach is consistent with our previously finalized burden calculation methodology (82 FR 59477). Accordingly, we calculate cost burden to facilities using a wage plus benefits estimate of $38.80 per hour throughout the discussion below for the Hospital OQR Program.

2. Proposed Removal of OP–33 for the CY 2022 Payment Determination and Subsequent Years

In section XIV.B.3.b. of this proposed rule, we are proposing to remove one measure submitted via a web-based tool beginning with the CY 2022 payment determination and for subsequent years: OP–33: External Beam Radiotherapy for Bone Metastases. 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–33 for the CY 2022 payment determination would reduce burden by 0.167 hours per hospital, resulting in a burden reduction of 551 hours (0.167 hours × 3,300 hospitals) and $21,379 (551 hours × $38.80) across 3,300 hospitals.

C. ICRs for the ASCQR Program

1. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74554), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53672), and the CY 2013, CY 2014, CY 2015, CY 2016, CY 2017, CY 2018, and CY 2019 OPPS/ASC final rules with comment period (77 FR 68532 through 68533; 78 FR 75172 through 75174; 79 FR 67015 through 67016; 80 FR 70582 through 70584; 81 FR 79863 through 79865; 82 FR 59479 through 59481; and 83 FR 59156 through 59157, respectively) for detailed discussions of the ASCQR Program information collection requirements we have previously finalized. The information collection requirements associated with the ASCQR Program are currently approved under OMB control number 0938–1270 which expires on January 31, 2022. As discussed below, there are only nominal changes in burden that would result from the proposed policies in this proposed rule.

2. Proposal To Adopt ASC–19: Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357)

In section XV.B.3. of this this proposed rule, we are proposing, beginning with the CY 2024 payment determination and for subsequent years, to adopt one measure collected via Medicare claims: ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357). Data used to calculate scores for this measure are collected via Medicare Part A and Part B administrative claims and Medicare enrollment data; therefore, ASCs would not be required to report any additional data. Because this measure does not require ASCs to submit any additional data, we believe there would be only a nominal change in other costs experienced by ASCs associated with this proposal due to having to review and track confidential feedback and reports related to the proposed ASC–19 measure.

D. ICR for Proposal on Hospital Price Transparency

In section XVI. of this proposed rule, we seek to promote price transparency in hospital standard charges so that consumers can be empowered to make more informed decisions about their health care. If finalized, we believe these proposed requirements would represent an important step towards putting consumers at the center of their health care and ensuring they have access to needed information.

We note that hospitals in the United States maintain chargemasters, a list of their gross charges for all individual items and services as part of their standard billing and business practices.[220] Additionally, hospitals maintain electronic data on charges they negotiate with third party payers for hospital items and services as well as service packages. As such, we believe that the burden for making this information publicly available is minimal and estimate only a small burden for each hospital to extract, review, and conform the posting of gross charges and payer-specific negotiated charges for all hospital items and services in the machine-readable format as specified in this proposed rule. In addition, we estimate some burden associated with hospitals making public their payer-specific negotiated charges for a set of at least 300 (70 CMS-specified and at least 230 hospital-selected) shoppable services in a consumer-friendly manner, with flexibility for hospitals to determine the most consumer-friendly format, as

[219] Occupational Employment and Wages, May 2018. Available at: *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.* Accessed May 7, 2019.

[220] Batty, M., & Ippolito, B. (2017). Mystery of the chargemaster: Examining the role of hospital list prices in what patients actually pay. *Health Affairs, 36*(4), 689–696. Available at: *https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0986.*

discussed in section XVI.F.5. of this proposed rule.

We estimate that this proposed rule applies to 6,002 hospitals operating within the United States under the definition of ''hospital'' discussed in section XVI.B.1. of this proposed rule. To estimate this number, we subtract 208 federally-owned hospitals from the total number of U.S. hospitals, 6,210 hospitals [221] (6,210 total hospitals—208 federally-owned hospitals).

We estimate the hourly cost for each labor category used in this analysis by referencing Bureau of Labor Statistics report on Occupational Employment and Wages (May 2018 [222]) in the Table 39. There are many professions involved in any business's processes. Therefore, we use the wages of General and Operations Managers as a proxy for management staff, the wages of Lawyers as a proxy for legal staff, the wages of Network and Computer Systems Administrators as a proxy for information technology (IT) staff, and the wage of Business Operations Specialists as a proxy for other business staff throughout this analysis. Obtaining data on overhead costs is challenging. Overhead costs vary greatly across industries and facility sizes. In addition, the precise cost elements assigned as ''indirect'' or ''overhead'' costs, as opposed to direct costs or employee wages, are subject to some interpretation at the facility level. Therefore, we calculate the cost of overhead at 100 percent of the mean hourly wage in line with the Hospital Inpatient Quality Reporting Program and the Hospital Outpatient Quality Reporting Program (81 FR 57260 and 82 FR 59477, respectively).

TABLE 39.--OCCUPATION TITLES AND WAGE RATES

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Lawyers	23-1011	$69.34	$69.34	$138.68
General and Operations Managers	11-1021	$59.56	$59.56	$119.12
Business Operations Specialists	13-1199	$37.00	$37.00	$74.00
Network and Computer Systems Administrators	15-1142	$41.86	$41.86	$83.72

In order to comply with regulatory updates proposed in this proposed rule, affected hospitals would first need to review the rule. We estimate that this task would take a lawyer on average 1 hour (at $138.68 per hour, which is based on the Bureau of Labor Statistics (BLS) wage for Lawyers (23–1011) [223]) to perform the initial review, and a general operations manager on average 1 hour (at $119.12 per hour, which is based on the Bureau of Labor Statistics (BLS) wage for General and Operations Managers (11–1021) [224]) to review and determine compliance requirements. Therefore, we estimate 2 hours per hospital, with a total of 12,004 hours (2 hours × 6,002 hospitals). The cost is $257.80 per hospital (1 hour × $138.68 + 1 hour × $119.12), with a total cost of $1,547,316 ($257.80 × 6,002 hospitals).

After reviewing the rule, hospitals would need to review their policies and business practices in the context of the defined terms and requirements for information collection then determine how to comply. We believe this will require minimal changes for affected hospitals because the standard charge information to be collected is already compiled and maintained as part of hospitals' management practices and electronic accounting and billing systems. Moreover, we are proposing requirements to make payer-specific negotiated rates public for a total of 300 shoppable services (70 CMS-specified and 230 hospital-selected) in a consumer-friendly manner, including listing the charges for associated ancillary services provided by the hospital so that the hospital charge information is more accessible and easier to digest for consumers seeking to obtain pricing information for making decisions about their treatment. We are proposing several definitions and requirements for making data publicly available pertaining to gross charges, negotiated charges and shoppable services at proposed 45 CFR part 180. We estimate it would take a business operations specialist, on average, 8 hours (at $74.00 per hour, which is based on the Bureau of Labor Statistics (BLS) wage for Business Operations Specialists, All Other (13–1199) [225]) to complete necessary processes and procedures to gather and compile required information and post it to the web in the form and manner specified by this proposed rule. We estimate 8 hours per hospital. The total burden hours are 48,016 hours (8 hours × 6,002 hospitals). The cost is $592.00 per hospital (8 hours × $74.00), with a total cost of $3,553,184 (48,016 hours × $74.00).

We also are proposing several requirements for posting required information at proposed 45 CFR 180.50 and 180.60. These requirements impose form and manner standards for the hospitals as defined in this proposed rule. We estimate that a network and computer system administrator would spend on average 2 hours (at $83.72 per hour, which is based on the Bureau of Labor Statistics (BLS) wage for Network and Computer Systems Administrators (15–1142) [226]) to meet requirements specified by this proposed rule. Therefore, we estimate 2 hours per hospital. The total burden hours are 12,004 hours (2 hours × 6,002 hospitals). The cost is $167.44 per hospital (2 hours

[221] American Hospital Association. Fast Facts on U.S. Hospitals, 2019. Available at: *https://www.aha.org/statistics/fast-facts-us-hospitals.*

[222] Bureau of Labor Statistics. National Occupational Employment and Wage Estimates, May 2018. Available at: *http://www.bls.gov/oes/2018/may/oes__nat.htm.*

[223] Bureau of Labor Statistics. Occupational Employment and Wage Estimates, May 2018: 23–1011 Lawyers. Available at: *https://www.bls.gov/oes/current/oes231011.htm.*

[224] Bureau of Labor Statistics. Occupational Employment and Wage Estimates, May 2018: 11–1021 General and Operations Managers. Available at: *https://www.bls.gov/oes/current/oes111021.htm.*

[225] Bureau of Labor Statistics. Occupational Employment and Wages, May 2018: 13–1199 Business Operations Specialist, All Other. Available at: *https://www.bls.gov/oes/current/oes131199.htm.*

[226] Bureau of Labor Statistics. Occupational Employment and Wages, May 2018: 15–1142 Network and Computer System Administrators. Available at: *https://www.bls.gov/oes/current/oes151142.htm.*

× $83.72), with a total cost of $1,004,975 (12,004 hours × $83.72).

We conclude that the annual burden per hospital should be calculated with all activities performed by four professions combined. We estimate an annual burden assessment to be 12 hours (2 hours + 8 hours + 2 hours) per hospital with a cost of $1,017.24 ($257.80 + $592.00 + $167.44) per hospital. We also estimate a total national burden of 72,024 hours (12 hours × 6,002 hospitals) and total cost of $6,105,474 ($1,017.24 × 6,002 hospitals). (See Table 40.)

TABLE 40.--SUMMARY OF INFORMATION OF COLLECTION BURDENS

Regulation Section(s)	OMB Control No.	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Total Labor Cost of Reporting ($)
§180	0938-NEW	6,002	6,002	12	72,024	$6,105,474

E. ICRs for Proposed Revision of the Definition of ''Expected Donation Rate'' for Organ Procurement Organizations

As described in section XVIII. of this proposed rule, we are proposing to revise the definition of ''expected donation rate'' in the OPO CfCs. This change would allow OPOs to receive payment for organ donor costs under the Medicare and Medicaid programs using a definition that is consistent with the definition used by the Scientific Registry of Transplant Recipients (SRTR). Because we will be using data from the OPTN and the SRTR in assessing whether OPOs have satisfied the outcome measures of 42 CFR 486.318(b), we are proposing to adopt the definition currently used by the OPTN and SRTR in their statistical evaluation of OPO performance. This proposal would not change the data that are already collected by the OPTN and SRTR, and therefore it will not affect the information collection burden on OPOs.

F. ICR for Proposed Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services

In section XX. of this proposed rule, we are proposing to establish a prior authorization process for certain hospital outpatient services as a condition for Medicare payment. We are proposing to use our authority under section 1833(t)(2)(F) of the Act, which authorizes CMS to develop a method for controlling unnecessary increases in the volume of covered OPD services, to establish the prior authorization process. We believe a prior authorization process for OPD services would ensure beneficiaries receive medically necessary care while minimizing the risk of improper payments without changing the documentation requirements for providers and, therefore, protect the Medicare Trust fund.

We are proposing that providers would be required to obtain prior authorization from CMS for five groups of services and their related services before the services are provided to Medicare beneficiaries and before the provider could submit claims for payment under Medicare for these services. The five groups of services proposed are: Blepharoplasty, Botulinum Toxin Injections, Panniculectomy, Rhinoplasty, and Vein Ablation. The information collection requirements associated with prior authorization requests for these covered outpatient department services would be the required documentation submitted by providers. We are proposing that a prior authorization request must include all relevant documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules and that the request be submitted before the service is provided to the beneficiary and before the claim is submitted for processing. The burden associated with this proposed process is the time and effort necessary for the submitter to locate and obtain the relevant supporting documentation to show that the service meets applicable coverage, coding, and payment rules, and to forward the information to CMS or its contractor (MAC) for review and determination of a provisional affirmation. We expect that this information will generally be maintained by providers within the normal course of business and that this information will be readily available. We estimate that the average time for office clerical activities associated with this task to be 30 minutes, which is equivalent to that for normal prepayment or postpayment medical review. We anticipate that most prior authorization requests would be sent by means other than mail. However, we estimate a cost of $5 per request for mailing medical records. Due to a July start date, the first year of the prior authorization will only include 6 months. Based on calendar year 2017 data, we estimate that for those first 6 months at a minimum there will be 23,309 initial requests mailed during a year. In addition, we estimate there will be 7,650 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total mailing cost is estimated to be $154,799. Based on calendar year 2017 data, we estimate that annually at a minimum there will be 46,618 initial requests mailed during a year. In addition, we estimate there will be 15,299 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total mailing cost is estimated to be $309,584. We also estimate that an additional 3 hours would be required for attending educational meetings and reviewing training documents. While there may be an associated burden on beneficiaries while they wait for the prior authorization decision, we are unable to quantify that burden.

The average labor costs (including 100 percent fringe benefits) used to estimate the costs were calculated using data available from the Bureau of Labor Statistics. Based on the Bureau of Labor Statistics information, we estimate an average hourly rate of $16.63 with a loaded rate of $33.26. Therefore, we estimate that the total burden for the first year (6 months), allotted across all providers, would be 73,647 hours (.5 hours × 103,199 submisions plus 3 hours × 7,349 providers for education). The burden cost for the first year (6 months) is $2,604,281 (73,647 hours × $33.26 plus $154,799 for mailing costs). In addition, we estimate that the total annual burden hours, allotted across all providers, would be 125,242 hours (.5 hours × 206,389 submissions plus 3 hours × 7,349 providers for education). The annual burden cost would be $4,475,116 (125,242 hours × $33.26 plus $309,584 for mailing costs). For the total

burden and associated costs, we estimate the annualized burden to be 108,044 hours and $3,851,504 million. The annualized burden is based on an average of 3 years, that is, 1 year at the 6-month burden and 2 years at the 12-month burden. The information collection request is under development and will be submitted to OMB for approval.

G. Potential Revision to Laboratory Date of Service (DOS) Policy

In section XIX. of this proposed rule, we are soliciting comments regarding potential revisions to the laboratory date of service (DOS) provisions at § 414.510(b)(5) for a molecular pathology test or a test designated by CMS as an ADLT under paragraph (1) of the definition of an ''advanced diagnostic laboratory test'' in § 414.502. The laboratory DOS service policy does not impose any information collection requirements. Consequently, review by the Office of Management and Budget under the authority of the PRA is not required.

H. Total Reduction in Burden Hours and in Costs

The chart below reflects the total burden and associated costs for the provisions included in this proposed rule.

Information Collection Requests	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
Hospital Outpatient Quality Reporting Program	- 551	- $21,379
Ambulatory Surgical Center Quality Reporting Program	0	0
Proposal Relating to Hospital Price Transparency	+ 72,024	+ $6,105,474
Proposed Revised Definition of "Expected Donation Rate" for OPOS	0	0
Proposed Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services**	+ 108,044	+ $3,851,504
Potential Revisions to Laboratory Date of Service (DOS) Policy	0	0
Total	+ 96,218	$6,324,484

* Numbers rounded.

** Based on an average of three years - one year at the 6-month burden and two years at the 12-month burden.

XXV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XXVI. Economic Analyses

A. Statement of Need

This 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 2020. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We are proposing to revise the APC relative payment weights using claims data for services furnished on and after January 1, 2018, through and including December 31, 2018, and processed through December 31, 2018, and updated cost report information.

We note that we are completing the phase-in of our method, as described below, to control unnecessary increases in the volume of covered outpatient department services by paying for clinic visits furnished at off-campus PBDs at an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate). The site-specific PFS payment rate for clinic visits furnished in excepted off-campus PBDs is the OPPS rate reduced to the amount paid for clinic visits furnished by nonexcepted off-campus PBDs under the PFS, which is 40 percent of the OPPS rate. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013 through 59014), we implemented this policy with a 2-year phase-in. In CY 2019, the payment reduction is transitioned by applying 50 percent of the total reduction in payment that would apply if these off-campus PBDs were paid the site-specific PFS payment rate for the clinic visit service. In other words, these excepted off-campus PBDs are paid 70 percent of the OPPS rate for the clinic visit service

in CY 2019. In CY 2020, we will complete the transition to paying the PFS-equivalent amount for clinic visits furnished in excepted off-campus PBDs. In other words, these excepted off-campus PBDs will be paid the full reduced payment, or 40 percent of the OPPS rate for the clinic visit service in CY 2020.

This proposed rule also is necessary to make updates to the ASC payment rates for CY 2020, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in an ASC in CY 2020. Because ASC payment rates are based on the OPPS relative payment weights for most of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative payment weights. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC, not less frequently than every 2 years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59079), we finalized a policy to update the ASC payment system rates using the hospital market basket update instead of the CPI–U for CY 2019 through 2023. We believe that this policy will help stabilize the differential between OPPS payments and ASC payments, given that the CPI–U has been generally lower than the hospital market basket, and encourage the migration of services to lower cost settings as clinically appropriate.

B. Overall Impact for Provisions of This 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 for CY 2020.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This 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 the provisions 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 2020, compared to CY 2019, due only to the proposed changes to the OPPS in this proposed rule, would be approximately $940 million. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2020, we estimate that the OPPS expenditures, including beneficiary cost-sharing, for CY 2020 would be approximately $79.2 billion, which is approximately $6.2 billion higher than estimated OPPS expenditures in CY 2019. We note that these spending estimates include the CY 2020 completion of the phase-in, finalized in CY 2019, to control for unnecessary increases in the volume of covered outpatient department services by paying for clinic visits furnished at excepted off-campus PBDs in CY 2020 at a rate that will be 40 percent of the OPPS rate for a clinic visit service. Because the 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 38 of this proposed rule displays the distributional impact of the proposed CY 2020 changes in OPPS payment to various groups of hospitals and for CMHCs.

As noted in section V.B.5 of this proposed rule, we are proposing for CY 2020 to pay for separately payable drugs and biological products that do not have pass-through payment status and are not acquired under the 340B program at WAC+3 percent instead of WAC+6 percent, if ASP data are unavailable for payment purposes. If WAC data are not available for a drug or biological product, we are proposing to continue our policy to pay separately payable drugs and biological products at 95 percent of the AWP. We note that under our proposed CY 2020 policy, drugs and biologicals that are acquired under the 340B Program would continue to be paid at ASP minus 22.5 percent, WAC minus 22.5 percent, or 69.46 percent of AWP, as applicable.

We note that in the impact tables as displayed in this impact analysis, we have modeled current and prospective payments as if separately payable drugs acquired under the 340B program from hospitals not excepted from the policy are paid in CY 2020 under the OPPS at ASP–22.5 percent. As discussed in more detail in section V.B.6. of this proposed rule, there is ongoing litigation involving our payment policy for 340B-acquired drugs. We are soliciting public comments on the appropriate OPPS payment rate for 340B-acquired drugs, including whether a rate of ASP+3 percent could be an appropriate payment amount for these drugs, both for CY 2020 and for purposes of determining the remedy for CYs 2018 and 2019 in the event of an adverse decision on appeal in that litigation. In addition to comments on the appropriate payment amount for calculating the remedy for CYs 2018 and 2019 and for use for CY 2020, we also seek public comment on how to structure the remedy for CYs 2018 and 2019.

We note that a policy to pay for 340B-acquired drugs and biologicals under the CY 2020 OPPS at an amount of ASP+3 percent would necessitate an accompanying budget neutrality adjustment to the OPPS conversion factor to account for that payment differential. Based on alternative modeling we expect that a policy to pay for 340B-acquired drugs at ASP+3 percent would result in an additional adjustment of 0.9710 to the OPPS conversion factor, with an alternative conversion factor of $79.029, which would result in a reduction of approximately $1.4 billion in payments for non-drug items and services for CY 2020.

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 2020, and the completion of the phase-in to control for unnecessary increases in the volume of covered outpatient department services described in section X.D. of this proposed rule) would increase total OPPS payments by 2.0 percent in CY 2020. 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 2019 and CY 2020, 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 completion of the phase-in to control unnecessary increases in the volume of outpatient services as described in section X.D. 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 increase total estimated OPPS payments by 2.8 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 2020 compared to CY 2019, to be approximately $200 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 42 and 43 of this proposed rule display the redistributive impact of the proposed CY 2020 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

C. Detailed Economic Analyses

1. Estimated Effects of 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 2020 policy changes on various hospital groups. We post on the CMS website our hospital-specific estimated payments for CY 2020 with the other supporting documentation for this 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–1717–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 41. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. of this 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, but any policy that changes payment could have a behavioral response. In addition, we have not made adjustments for future changes in variables, such as service volume, service-mix, or number of encounters.

b. Estimated Effects of the CY 2020 Completion of Phase-In To Control for Unnecessary Increases in the Volume of Outpatient Services

In section X.D. of this proposed rule, we discuss the CY 2020 completion of the phase-in of our CY 2019 finalized method to control for unnecessary increases in the volume of outpatient department services by paying for clinic visits furnished at an off-campus PBD at an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate). Specifically, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013 through 59014), we finalized our proposal to pay for HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) when billed with modifier ''PO'' at an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate), with a 2-year transition period. For a discussion of the PFS payment amount for outpatient clinic visits furnished at nonexcepted off-campus PBDs, we refer readers to the CY 2018 PFS final rule with comment period discussion (82 FR 53023 through 53024), as well as the CY 2019 PFS final rule and the CY 2020 PFS proposed rule.

To develop an estimated impact of this policy, we began with CY 2018 outpatient claims data used in ratesetting for the CY 2020 OPPS. We then flagged all claim lines for HCPCS code G0463 that contained modifier ''PO'' because the presence of this modifier indicates that such claims were billed for services furnished by an off-campus department of a hospital paid under the OPPS. Next, we excluded those that were billed as a component of C–APC 8011 (Comprehensive Observation Services) or packaged into another C–APC because, in those instances, OPPS payment is made for a broader package of services. We then simulated payment for the remaining claim lines as if they were paid at the PFS-equivalent rate. An estimate of the policy that includes the effects of estimated changes in enrollment, utilization, and case-mix based on the FY 2020 President's budget approximates the estimated decrease in total payment under the OPPS at $810 million, with Medicare OPPS payments decreasing by $650 million and beneficiary copayments decreasing by $160 million in CY 2020. This estimate is utilized for the accounting statement displayed in Table 42 of this proposed rule because the impact of this CY 2020 policy, which is not budget neutral, is combined with the impact of the OPD update, which is also not budget neutral, to estimate changes in Medicare spending under the OPPS as a result of the changes proposed in this proposed rule.

We note that our estimates may differ from the actual effect of the proposed policy due to offsetting factors, such as changes in provider behavior. We note that, by removing this payment differential that may influence site-of-service decision-making, we anticipate an associated decrease in the volume of clinic visits provided in the excepted off-campus PBD setting. We note that

this estimate could change in the final rule with comment period based on factors such as the availability of updated data.

c. Estimated Effects of Proposed OPPS Changes on Hospitals

Table 41 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 41, and we discuss them separately below, because CMHCs are paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In CY 2020, we are 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 2020 is 3.2 percent. Section 1833(t)(3)(F)(i) of the Act reduces that 3.2 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is proposed to be 0.5 percentage point for FY 2020 (which is also the proposed MFP adjustment for FY 2020 in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19411)), resulting in the proposed OPD fee schedule increase factor of 2.7 percent. We are using the proposed OPD fee schedule increase factor of 2.7 percent in the calculation of the proposed CY 2020 OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.0000. The amounts attributable to this frontier State wage index adjustment are incorporated in the CY 2020 estimates in Table 41 of this proposed rule.

To illustrate the impact of the proposed CY 2020 changes, our analysis begins with a baseline simulation model that uses the CY 2019 relative payment weights, the FY 2019 final IPPS wage indexes that include reclassifications, and the final CY 2019 conversion factor. Table 41 shows the estimated redistribution of the proposed increase or decrease in payments for CY 2020 over CY 2019 payments to hospitals and CMHCs as a result of the following factors: The impact of the APC reconfiguration and recalibration changes between CY 2019 and CY 2020 (Column 2); the wage indexes and the provider adjustments (Column 3); the combined impact of all of the proposed changes described in the preceding columns plus the proposed 2.7 percent OPD fee schedule increase factor update to the conversion factor (Column 4); the proposed off-campus PBD clinic visits payment policy (Column 5), and the estimated impact taking into account all proposed payments for CY 2020 relative to all payments for CY 2019, including the impact of proposed changes in estimated outlier payments, 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 2020. 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 2020 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services will change), and the impact of the proposed wage index changes on the hospital. However, total payments made under this system and the extent to which this proposed rule will redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2019 and CY 2020 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the proposed rates for CY 2020 would increase Medicare OPPS payments by an estimated 2.0 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in an estimated 2.0 percent increase 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 41 shows the total number of facilities (3,734), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2018 hospital outpatient and CMHC claims data to model CY 2019 and CY 2020 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2019 or CY 2020 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this 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 (3,627), excluding the hold-harmless cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their ''pre-BBA amount'' as specified under the terms of the statute, and therefore, we removed them from our impact analyses. We show the isolated impact on the 41 CMHCs at the bottom of the impact table (Table 41) and discuss that impact separately below.

Column 2: APC Recalibration—All 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 a 0.1 percent increase, with the impact ranging from an increase of 0.5 percent to no increase, depending on the number of beds. Rural hospitals would experience a decrease of up to 0.8 percent depending on the number of beds. Major teaching hospitals would experience a 0.1 percent decrease.

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 2020 IPPS post-reclassification wage indexes; the proposed rural adjustment; the proposed frontier 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 2019 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

Column 3 reflects the independent effects of the proposed updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis, as well as the CY 2020 proposed changes in wage index policy discussed in section II.C. of this proposed rule. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we are continuing the rural payment adjustment of 7.1 percent to rural SCHs for CY 2020, as described in section II.E. of this proposed rule. We also modeled a budget neutrality adjustment for the cancer hospital payment adjustment because we are using a proposed payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2020 of .90, which is higher than the ratio that was reported for the CY 2019 OPPS/ASC final rule with comment period (83 FR 58873). We note that, in accordance with section 16002 of the 21st Century Cures Act, we are proposing to apply a budget neutrality factor calculated as if the cancer hospital adjustment target payment-to-cost ratio was 0.90, not the 0.89 target payment-to-cost ratio we are applying in section II.F. of this 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 2020 scaled weights and a CY 2019 conversion factor that included a budget neutrality adjustment for the effect of the proposed changes to the wage indexes between CY 2019 and CY 2020.

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 2.7 percent. Overall, these proposed changes would increase payments to urban hospitals by 2.8 percent and to rural hospitals by 3.0 percent. Urban hospitals would receive an increase in line with the 2.8 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 3.1 percent increase and other rural hospitals receiving an increase of 3.0 percent.

Column 5: Off-Campus PBD Visits Payment Policy

Column 5 displays the estimated effect of our CY 2020 volume control method, finalized in CY 2019, to pay for clinic visit HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) when billed with modifier ''PO'' by an excepted off-campus PBD at a rate that will be 40 percent of the OPPS rate for a clinic visit service for CY 2020. We note that the numbers provided in this column isolate the estimated effect of this policy adjustment relative to the numerator of Column 4. Therefore, the numbers reported in Column 5 show how much of the difference between the estimates in Column 4 and the estimates in Column 6 are a result of the off-campus PBD visits policy for CY 2020, as finalized in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013 through 59014).

Column 6: All Proposed Changes for CY 2020

Column 6 depicts the full impact of the proposed CY 2020 policies on each hospital group by including the effect of all proposed changes for CY 2020 and comparing them to all estimated payments in CY 2019. Column 6 shows the combined budget neutral effects of Columns 2 through 3; the proposed OPD fee schedule increase; the effect of the CY 2020 off-campus PBD visits policy finalized in CY 2019, the impact of estimated OPPS outlier payments, as discussed in section II.G. of this 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 XIV. 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 2019 update (and assumed, for modeling purposes, to be the same number for CY 2020), we included 23 hospitals in our model because they had both CY 2018 claims data and recent cost report data. We estimate that the cumulative effect of all proposed changes for CY 2020 would increase payments to all facilities by 2.0 percent for CY 2020. We modeled the independent effect of all proposed changes in Column 6 using the final relative payment weights for CY 2019 and the proposed relative payment weights for CY 2020. We used the final conversion factor for CY 2019 of $79.490 and the proposed CY 2020 conversion factor of $81.398 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 2020 IPPS/LTCH PPS proposed rule (84 FR 19596) of 5.4 percent (1.05446) to increase individual costs on the CY 2018 claims, and we used the most recent overall CCR in the April 2019 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2019. Using the CY 2018 claims and a 5.4 percent charge inflation factor, we currently estimate that outlier payments for CY 2019, using a multiple threshold of 1.75 and a fixed-dollar threshold of $4,825, would be approximately 1.03 percent of total payments. The estimated current outlier payments of 1.03 percent are incorporated in the comparison in Column 6. We used the same set of claims and a charge inflation factor of 11.2 percent (1.11189) and the CCRs in the April 2019 OPSF, with an adjustment of 0.975167, to reflect relative changes in cost and charge inflation between CY 2018 and CY 2020, to model the proposed CY 2020 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of

$4,950. The charge inflation and CCR inflation factors are discussed in detail in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19596 through 19597).

Overall, we estimate that facilities would experience an increase of 2.0 percent under this proposed rule in CY 2020 relative to total spending in CY 2019. This projected increase (shown in Column 6) of Table 38 reflects the proposed 2.7 percent OPD fee schedule increase factor, minus 0.6 percent for the off-campus PBD visits policy, minus 0.2 percent for the proposed change in the pass-through payment estimate between CY 2019 and CY 2020, plus a proposed decrease of 0.03 percent for the difference in estimated outlier payments between CY 2019 (1.03 percent) and CY 2020 (proposed 1.0 percent). We estimate that the combined effect of all proposed changes for CY 2020 would increase payments to urban hospitals by 2.0 percent. Overall, we estimate that rural hospitals would experience a 1.9 percent increase as a result of the combined effects of all the proposed changes for CY 2020.

Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all proposed changes would include an increase of 1.3 percent for major teaching hospitals and an increase of 2.3 percent for nonteaching hospitals. Minor teaching hospitals would experience an estimated increase of 2.1 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals would experience an increase of 1.8 percent, proprietary hospitals would experience an increase of 3.0 percent, and governmental hospitals would experience an increase of 1.9 percent.

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TABLE 41—ESTIMATED IMPACT OF THE PROPOSED CY 2020 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

		(1)	(2)	(3)	(4)	(5)	(6)
		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**	**Existing Off-Campus Provider-Based Department Visits Policy**	**All Proposed Changes**
ALL FACILITIES *		3,734	0.0	0.1	2.8	-0.6	2.0
ALL HOSPITALS		3,627	0.0	0.1	2.9	-0.6	2.0
(excludes hospitals permanently held harmless and CMHCs)							
URBAN HOSPITALS		2,845	0.1	0.0	2.8	-0.6	2.0
	LARGE URBAN	1,481	0.0	-0.3	2.5	-0.4	1.9
	(GT 1 MILL.)						
	OTHER URBAN	1,364	0.2	0.2	3.1	-0.6	2.1
	(LE 1 MILL.)						
RURAL HOSPITALS		782	-0.4	0.8	3.0	-0.6	1.9
	SOLE COMMUNITY	367	-0.4	0.8	3.1	-0.7	1.8
	OTHER RURAL	415	-0.5	0.8	3.0	-0.5	2.2
BEDS (URBAN)							
	0 - 99 BEDS	950	0.5	0.1	3.3	-0.4	2.6
	100-199 BEDS	834	0.0	0.0	2.8	-0.5	2.0
	200-299 BEDS	451	0.1	-0.1	2.8	-0.4	2.0
	300-499 BEDS	395	0.2	0.3	3.1	-0.5	2.2
	500 + BEDS	215	0.0	-0.2	2.5	-0.7	1.6
BEDS (RURAL)							
	0 - 49 BEDS	329	-0.8	1.5	3.4	-0.2	2.6
	50- 100 BEDS	283	-0.5	0.9	3.1	-0.7	1.8
	101- 149 BEDS	90	-0.5	0.9	3.0	-0.6	2.0
	150- 199 BEDS	42	-0.2	0.8	3.4	-1.0	1.9
	200 + BEDS	38	-0.1	-0.3	2.3	-0.5	1.7
REGION (URBAN)							
	NEW ENGLAND	135	-0.3	-1.9	0.5	-1.0	-0.5

		(1)	(2)	(3)	(4)	(5)	(6)
		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**	**Existing Off-Campus Provider-Based Department Visits Policy**	**All Proposed Changes**
	MIDDLE ATLANTIC	330	0.0	-0.3	2.4	-0.4	1.8
	SOUTH ATLANTIC	460	0.1	0.0	2.8	-0.5	2.1
	EAST NORTH CENT.	457	-0.1	0.0	2.6	-0.8	1.6
	EAST SOUTH CENT.	167	0.2	0.9	3.8	-0.2	3.4
	WEST NORTH CENT.	177	0.2	1.4	4.4	-0.6	2.5
	WEST SOUTH CENT.	489	0.4	0.3	3.5	-0.5	2.8
	MOUNTAIN	206	0.0	-0.1	2.7	-0.5	1.5
	PACIFIC	375	0.3	0.0	3.1	-0.5	2.4
	PUERTO RICO	49	1.2	17.9	22.5	0.0	22.1
REGION (RURAL)							
	NEW ENGLAND	21	-0.6	-1.3	0.8	-1.9	-1.1
	MIDDLE ATLANTIC	53	-0.5	0.0	2.2	-1.0	1.0
	SOUTH ATLANTIC	119	-0.7	0.7	2.7	-0.2	2.3
	EAST NORTH CENT.	120	-0.3	0.0	2.4	-0.7	1.5
	EAST SOUTH CENT.	151	-0.4	1.4	3.7	-0.2	3.3
	WEST NORTH CENT.	96	-0.2	1.7	4.2	-0.8	2.1
	WEST SOUTH CENT.	150	-0.5	1.2	3.5	-0.3	3.0
	MOUNTAIN	49	-0.3	2.6	5.1	-0.3	2.0
	PACIFIC	23	-0.6	0.1	2.2	-1.0	1.1
TEACHING STATUS							
	NON-TEACHING	2,491	0.1	0.3	3.0	-0.4	2.3
	MINOR	777	0.1	0.3	3.1	-0.6	2.1
	MAJOR	359	-0.1	-0.3	2.3	-0.8	1.3

		(1)	(2)	(3)	(4)	(5)	(6)
		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**	**Existing Off-Campus Provider-Based Department Visits Policy**	**All Proposed Changes**
DSH PATIENT PERCENT							
	0	13	3.1	1.4	7.4	0.0	6.6
	GT 0 - 0.10	269	1.1	0.0	3.9	-0.4	3.0
	0.10 - 0.16	260	0.2	0.0	2.9	-0.4	2.1
	0.16 - 0.23	558	0.2	0.1	3.0	-0.4	2.3
	0.23 - 0.35	1,115	0.0	0.2	2.9	-0.7	1.9
	GE 0.35	933	-0.2	0.0	2.6	-0.6	1.8
	DSH NOT AVAILABLE **	479	0.1	0.5	3.4	-0.4	2.8
URBAN TEACHING/DSH							
	TEACHING & DSH	1,019	0.0	0.0	2.7	-0.7	1.8
	NO TEACHING/DSH	1,359	0.2	0.1	3.0	-0.3	2.4
	NO TEACHING/NO DSH	11	3.2	1.4	7.5	0.0	7.1
	DSH NOT AVAILABLE**	456	0.1	0.2	3.0	-0.3	2.5
TYPE OF OWNERSHIP							
	VOLUNTARY	1,972	0.0	0.1	2.7	-0.6	1.8
	PROPRIETARY	1,194	0.6	0.2	3.6	-0.2	3.0
	GOVERNMENT	461	-0.2	0.2	2.8	-0.7	1.9
CMHCs		41	0.9	0.4	4.1	0.0	3.9

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all proposed CY 2020 OPPS policies and compares those to the CY 2019 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2020 hospital inpatient wage index and the non-budget neutral frontier adjustment. The rural SCH adjustment continues our policy of 7.1 percent so the budget neutrality factor is 1. The proposed budget neutrality adjustment for the cancer hospital adjustment is 0.9997 because in CY 2020 the target payment-to-cost ratio is higher than CY 2019 PCR target (0.89).

		(1)	(2)	(3)	(4)	(5)	(6)
		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**	**Existing Off-Campus Provider-Based Department Visits Policy**	**All Proposed Changes**
Column (4) shows the impact of all budget neutrality adjustments and the addition of the proposed 2.7 percent OPD fee schedule update factor (3.2 percent reduced by 0.5 percentage point for the productivity adjustment).							
Column (5) shows the additional impact of the policy to pay clinic visits for nonexcepted providers under the otherwise applicable payment system. We note that we are completing the 2-year phase-in so the amount of the reduction will be the full difference in CY 2020 (or payment at 40 percent of the OPPS rate).							
Column (6) shows the additional proposed adjustments to the conversion factor resulting from a change in the pass-through estimate, and adding estimated outlier payments. Note that previous years included the frontier adjustment in this column, but we have moved the frontier adjustment to Column 3 in this table.							
* These 3,734 providers include children's and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.							
**Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.							

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d. Estimated Effects of Proposed OPPS Changes on CMHCs

The last line of Table 41 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2019, CMHCs are paid under APC 5853 (Partial Hospitalization (3 or more services) for CMHCs). We modeled the impact of this APC policy assuming CMHCs will continue to provide the same number of days of PHP care as seen in the CY 2018 claims used for ratesetting in 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 3.9 percent increase in payments from CY 2019 (shown in Column 6). We note that this includes the trimming methodology as well as the proposed CY 2020 floor on geometric mean costs used for developing the PHP payment rates described in section VIII.B. of this proposed rule. The CY 2020 proposal to establish a floor based on geometric mean costs, rather than based on a predetermined payment rate, makes the OPPS budget neutrality adjustments for both the weight scaler and the conversion factor applicable.

Column 3 shows that the estimated impact of adopting the proposed FY 2020 wage index values would result in an increase of 0.4 percent to CMHCs. Column 4 shows that combining this proposed OPD fee schedule increase factor, along with proposed changes in APC policy for CY 2020 and the proposed FY 2020 wage index updates, would result in an estimated increase of 4.1 percent. Column 5 shows that the off-campus PBD clinic visits payment policy has no estimated effect on CMHCs. Column 6 shows that adding the proposed changes in outlier and pass-through payments would result in a total 3.9 percent increase in payment for CMHCs. This reflects all proposed changes for CMHCs for CY 2020.

e. 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 18.2 percent for all services paid under the OPPS in CY 2020. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the proposed CY 2020 comprehensive APC payment policy discussed in section II.A.2.b. of this proposed rule.

f. 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 XIII 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.

g. 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 $940 million in program payments for OPPS services furnished in CY 2020. The effect on the Medicaid program is expected to be limited to copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We estimate that

the proposed changes in this proposed rule would increase these Medicaid beneficiary payments by approximately $45 million in CY 2020. Currently, there are approximately 10 million dual-eligible beneficiaries, which represents approximately one third of Medicare Part B fee-for-service beneficiaries. The impact on Medicaid was determined by taking one-third of the beneficiary cost-sharing impact. The national average split of Medicaid payments is 57 percent Federal payments and 43 percent State payments. Therefore, for the estimated $45 million Medicaid increase, approximately $25 million would be from the Federal Government and $20 million would be from State government.

h. Alternative OPPS Policies Considered

Alternatives to the OPPS changes we are proposing 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.7. of this proposed rule for a discussion of our policy to assign any skin substitute product that was assigned to the high cost group in CY 2019 to the high cost group in CY 2020, regardless of whether the product's mean unit cost (MUC) or the product's per day cost (PDC) exceeds or falls below the overall CY 2020 MUC or PDC threshold. We will continue to assign products that exceed either the overall CY 2020 MUC or PDC threshold to the high cost group. We also considered, but are not proposing, reinstating our methodology from CY 2017 and assigning skin substitutes to the high cost group based on whether an individual product's MUC or PDC exceeded the overall CY 2020 MUC or PDC threshold based on calculations done for either the proposed rule or the final rule with comment period.

- Alternatives Considered for the Methodology for Payment for Non-Opioid Pain Management Treatments

We refer readers to sections II.A.3.b. and XIII.D.3. of this proposed rule and the CY 2019 OPPS/ASC final rule with comment period (83 FR 58860) for a discussion of our change in the packaging policy for certain drugs when administered in the ASC setting and policy of providing separate payment for non-opioid pain management drugs that function as a supply when used in a surgical procedure when the procedure is performed in an ASC. In those sections of the CY 2019 OPPS/ASC final rule with comment period, we discuss the comments we received on whether we should pay separately for other non-opioid treatments for pain under the OPPS and the ASC payment system. In the CY 2019 OPPS/ASC final rule with comment period, we also discuss the comments we received 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 under the OPPS 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, when furnished in the hospital outpatient setting.

- Alternatives Considered for the Proposed Changes in the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals (CAHs)

We refer readers to section X.A. of this proposed rule for a discussion of our proposal to change the minimum required default level of supervision from direct supervision to general supervision for all hospital outpatient therapeutic services provided by all hospitals and CAHs. We also considered, but are not proposing, reevaluation of the level of physician supervision for cardiac rehabilitation services to determine whether we should propose to change the supervision level from direct supervision to general supervision. Under this alternative, direct supervision would remain the minimum required default level for most hospital outpatient therapeutic services with the exception of those services that have been evaluated by the HOP Panel and received a change in supervision level based on those recommendations.

2. Estimated Effects of Proposed CY 2020 ASC Payment System Changes

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XIII. of this proposed rule, we are proposing to set the CY 2020 ASC relative payment weights by scaling the proposed CY 2020 OPPS relative payment weights by the proposed ASC scalar of 0.8452. The estimated effects of the proposed updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 39 and 40 below.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which we are proposing will be the hospital market basket for CY 2020) after application of any quality reporting reduction be reduced by a productivity adjustment. The Affordable Care Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period, ending with the applicable fiscal year, year, cost reporting period, or other annual period). For ASCs that fail to meet their quality reporting requirements, the CY 2020 payment determinations will be based on the application of a 2.0 percentage point reduction to the annual update factor, which we are proposing will be the hospital market basket for CY 2020. We calculated the proposed CY 2020 ASC conversion factor by adjusting the CY 2019 ASC conversion factor by 1.0008 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2019 and CY 2020 and by applying the proposed CY 2020 MFP-adjusted hospital market basket update factor of 2.7 percent (projected hospital market basket update of 3.2 percent minus a projected productivity adjustment proposed to be 0.5 percentage point). The proposed CY 2020 ASC conversion factor is $47.827 for ASCs that successfully meet the quality reporting requirements.

a. Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2020 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2018 and CY 2020 with precision. We believe the net effect on Medicare expenditures resulting from the proposed CY 2020 changes 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 2020 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 2020 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services, as reflected in our CY 2018 claims data. Table 39 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2019 payments to estimated proposed CY 2020 payments, and Table 40 shows a comparison of estimated CY 2019 payments to estimated proposed CY 2020 payments for procedures that we estimate would receive the most Medicare payment in CY 2019.

In Table 39, 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 42.

- Column 1—Surgical Specialty or Ancillary Items and Services Group indicates the surgical specialty into which ASC procedures are grouped and the ancillary items and services group which includes all HCPCS codes for covered ancillary items and services. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes, as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.
- Column 2—Estimated CY 2019 ASC Payments were calculated using CY 2018 ASC utilization data (the most recent full year of ASC utilization) and CY 2019 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2019 ASC payments.
- Column 3—Estimated CY 2020 Percent Change is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty or ancillary items and services group that is attributable to proposed updates to ASC payment rates for CY 2020 compared to CY 2019.

As shown in Table 39, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the proposed update to ASC payment rates for CY 2020 would result in a 3-percent increase in aggregate payment amounts for eye and ocular adnexa procedures, a 3-percent increase in aggregate payment amounts for nervous system procedures, 1-percent increase in aggregate payment amounts for digestive system procedures, a 2-percent increase in aggregate payment amounts for musculoskeletal system procedures, a 2-percent increase in aggregate payment amounts for genitourinary system procedures, and a 5-percent increase in aggregate payment amounts for cardiovascular system procedures. We note that these changes can be a result of different factors, including updated data, payment weight changes, and proposed changes in policy. In general, spending in each of these categories of services is increasing due to the 2.7 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 2.7-percent increase, depending on if payment weights in the OPPS APCs that correspond to the applicable services increased or decreased or if the most recent data show an increase or a decrease in the volume of services performed in an ASC for a category. For example, we estimate a 3-percent increase in proposed aggregate eye and ocular adnexa procedure payments due to an increase in hospital reported costs for the primary payment grouping for this category under the OPPS. This increases the payment weights for eye and ocular adnexa procedure payments and, overall, is further increased by the proposed 2.7 percent ASC rate update for these procedures. For estimated changes for selected procedures, we refer readers to Table 40 provided later in this section.

Also displayed in Table 42 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 5 percent for CY 2020. This is largely attributed to the drug packaging policies adopted under the OPPS and ASC payment system.

TABLE 42.—ESTIMATED IMPACT OF THE PROPOSED CY 2020 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2020 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2019 ASC Payments (in Millions) (2)	Estimated CY 2020 Percent Change (3)
Total	$5,043	3
Eye and ocular adnexa	$1,743	3
Nervous system	$1,106	3
Digestive system	$893	1
Musculoskeletal system	$608	2
Genitourinary system	$194	2
Cardiovascular system	$184	5
Ancillary items and services	$99	5

Table 43 shows the estimated impact of the proposed updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2020. The table displays 30 of the procedures receiving the greatest estimated CY 2019 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2019 program payment.

- Column 1—CPT/HCPCS code.
- Column 2—Short Descriptor of the HCPCS code.
- Column 3—Estimated CY 2019 ASC Payments were calculated using CY 2018 ASC utilization (the most recent full year of ASC utilization) and the CY 2019 ASC payment rates. The estimated CY 2019 payments are expressed in millions of dollars.
- Column 4—Estimated CY 2020 Percent Change reflects the percent differences between the estimated ASC payment for CY 2019 and the estimated payment for CY 2020 based on the proposed update.

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TABLE 43.--ESTIMATED IMPACT OF THE PROPOSED CY 2020 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2019 ASC Payment (in millions) (3)	Estimated CY 2020 Percent Change (4)
66984	Xcapsl ctrc rmvl w/o ecp	$1,210	3
63685	Insrt/redo spine n generator	$259	4
45385	Colonoscopy w/lesion removal	$200	0
45380	Colonoscopy and biopsy	$184	1
63650	Implant neuroelectrodes	$183	4
43239	Egd biopsy single/multiple	$177	1
64483	Inj foramen epidural l/s	$114	2
0191T	Insert ant segment drain int	$96	1
66982	Xcapsl ctrc rmvl cplx wo ecp	$91	3
64635	Destroy lumb/sac facet jnt	$79	1
64493	Inj paravert f jnt l/s 1 lev	$73	2
66821	After cataract laser surgery	$69	1
62323	Njx interlaminar lmbr/sac	$55	1
G0105	Colorectal scrn; hi risk ind	$54	0
64590	Insrt/redo pn/gastr stimul	$53	2
29827	Arthroscop rotator cuff repr	$49	2
45378	Diagnostic colonoscopy	$45	0
G0121	Colon ca scrn not hi rsk ind	$44	0
C9740	Cysto impl 4 or more	$42	8
36902	Intro cath dialysis circuit	$42	6
22869	Insj stablj dev w/o dcmprn	$34	-22
15823	Revision of upper eyelid	$34	2
64721	Carpal tunnel surgery	$33	1
63655	Implant neuroelectrodes	$30	2
29881	Knee arthroscopy/surgery	$29	2
64561	Implant neuroelectrodes	$28	5
26055	Incise finger tendon sheath	$26	1
G0260	Inj for sacroiliac jt anesth	$26	1
67042	Vit for macular hole	$25	3
64490	Inj paravert f jnt c/t 1 lev	$25	2

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c. Estimated Effects of Proposed ASC Payment System Policies on Beneficiaries

We estimate that the proposed CY 2020 update to the ASC payment system would be generally positive (that is, result in lower cost-sharing) 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 2020. For example, using 2018 utilization data and proposed CY 2020 OPPS and ASC payment rates, we estimate that if 5 percent of coronary intervention procedures migrate from the hospital outpatient setting to the ASC setting as a result of this proposed policy, Medicare payments would be reduced by approximately $15 million in CY 2020 and total beneficiary copayments would decline by approximately $3 million in CY 2020. First, other than certain preventive services where coinsurance and the Part

B deductible is waived to comply with sections 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs under the OPPS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment (other than for certain preventive services), although the majority of HOPD procedures have a 20-percent copayment. Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC payment system will almost always be less than the OPPS copayment amount for the same services. (The only exceptions would be if the ASC coinsurance amount exceeds the hospital inpatient deductible. The statute requires that copayment amounts under the OPPS not exceed the hospital inpatient deductible.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the ASC payment system, depending on the particular service and the relative payment amounts under the MPFS compared to the ASC. While the ASC payment system bases most of its payment rates on hospital cost data used to set OPPS relative payment weights, services that are performed a majority of the time in a physician office are generally paid the lesser of the ASC amount according to the standard ASC ratesetting methodology or at the nonfacility practice expense based amount payable under the PFS. For those additional procedures that we are proposing to designate as office-based in CY 2020, 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).

3. Accounting Statements and Tables

As required by OMB Circular A–4 (available on the Office of Management and Budget website at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/circulars/a004/a-4.html*), we have prepared accounting statements to illustrate the impacts of the proposed OPPS and ASC changes in this proposed rule. The first accounting statement, Table 44, illustrates the classification of expenditures for the CY 2020 estimated hospital OPPS incurred benefit impacts associated with the proposed CY 2020 OPD fee schedule increase. This $940 million in additional Medicare spending estimate includes the $1.6 billion in additional Medicare spending associated with updating the CY 2019 OPPS payment rates by the hospital market basket update for CY 2020, offset by the $650 million in Medicare savings associated with the CY 2020 completion of phase-in finalized in CY 2019 to pay for clinic visits furnished at off-campus PBDs at a PFS-equivalent rate. In addition, we estimate that 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 $45 million in CY 2020. The second accounting statement, Table 45, illustrates the classification of expenditures associated with the proposed 2.7 percent CY 2020 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. The estimated costs of ICR Burden and Regulatory Familiarization are included in Table 46.

TABLE 44.--ACCOUNTING STATEMENT: CY 2020 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2019 TO CY 2020 ASSOCIATED WITH THE PROPOSED CY 2020 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$940 million
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS
Total	$940 million

TABLE 45.--ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2019 TO CY 2020 AS A RESULT OF THE PROPOSED CY 2020 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$100 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	$100 million

TABLE 46.—ESTIMATED COSTS in CY 2020

CATEGORY	Costs
ICR Burden	$8.5 million*
Regulatory Familiarization	$2.6 million**

*The annual estimates are in 2018 year dollars which includes the impact of hospital outpatient QRP, hospital price transparency, and prior authorization process and requirements for certain OPD services.
** 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 2019 payment determination, we determined that 14 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor. In this proposed rule, we are not proposing to add any quality measures to the Hospital OQR Program measure set for the CY 2021 or CY 2022 payment determinations. However, we are proposing to remove one measure from the program measure set, as discussed in section XIV.B.3.b. of this proposed rule. We do not believe that this proposed policy would increase the number of hospitals that do not receive a full annual payment update for the CY 2021 or CY 2022 payment determinations.

b. Estimated Effects of Proposed Removal of OP–33 for the CY 2022 Payment Determination and Subsequent Years

In section XIV.B.3.b. of this proposed rule, we are proposing to remove OP–33: External Beam Radiotherapy for Bone Metastases beginning with the CY 2022 payment determination and for subsequent years. As discussed in section XXVI.B.2. of this proposed rule, we anticipate a burden reduction of 551 hours and $21,379 associated with the removal of OP–33 for the CY 2022 payment determination. In addition to burden associated with information collection however, we also anticipate that hospitals would experience a general burden and cost reduction associated with this proposal stemming from no longer having to implement, review, track, and maintain program requirements associated with this measure.

5. Effects of Proposed Requirements for the ASCQR Program

a. Background

In section XV. of this proposed rule, we discuss our proposed policies affecting the ASCQR Program. For the CY 2019 payment determination, of the 6,393 ASCs that met eligibility requirements for the ASCQR Program, 203 ASCs did not meet the requirements to receive the full annual payment update. In section XV.B.3. of this proposed rule, we are proposing to adopt ASC–19: Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at Ambulatory Surgical Centers to the ASCQR Program measure set for the CY 2024 payment determination and subsequent years. We do not believe that adoption of the proposed ASC–19 measure would cause any ASCs to fail to meet the ASCQR Program requirements. Therefore, we do not believe that our proposal would increase the number of ASCs that do not receive a full annual payment update for the CY 2024 payment determination. Below we discuss only the effects that would result from the provisions proposed in this proposed rule.

b. Estimated Effects of the Proposal To Adopt ASC–19: Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357)

In section XV.B.3. of this proposed rule, we are proposing, beginning with the CY 2024 payment determination and for subsequent years, to adopt one measure: ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357). As discussed in section XXVI.C.2. of this proposed rule, data used to calculate scores for this proposed measure are collected via Medicare Part A and Part B administrative claims and Medicare enrollment data. Therefore, ASCs would not be required to report any additional data. Because this change does not affect ASCQR Program participation requirements or data reporting requirements, we do not expect this proposed measure to change the information collection burden and would only nominally affect other costs

experienced by ASCs due to having to review and track confidential feedback and reports related to the proposed ASC–19 measure.

D. Effects of the Proposals Relating to Price Transparency in Hospital Standard Charges

1. Background

In section XVI. of this proposed rule, we are proposing to adopt requirements that would implement section 2718(e) of the Public Health Service Act, which 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 established under section 1886(d)(4) of the Act.

In the FY 2015 IPPS/LTCH PPS proposed and final rules (79 FR 28169 and 79 FR 50146, respectively), we reminded hospitals of their obligation to comply with the provisions of section 2718(e) of the PHS Act and provided guidelines for its implementation. At that time, we required hospitals to either make public a list of their standard charges or their policies for allowing the public to view a list of those charges in response to an inquiry. In addition, we stated that we expected hospitals to update the information at least annually, or more often as appropriate, to reflect current charges. We also encouraged hospitals to undertake efforts to engage in consumer-friendly communication of their charges to enable consumers to compare charges for similar services across hospitals and to help consumers understand what their potential financial liability might be for items and services they obtain at the hospital.

In the FY 2019 IPPS/LTCH PPS proposed rule and final rule (83 FR 20164 and 83 FR 41144, respectively), we again reminded hospitals of their obligation to comply with the provisions of section 2718(e) of the PHS Act and updated our guidelines for its implementation. The announced update to our guidelines became effective January 1, 2019, and took one step to further improve the public accessibility of standard charge information. Specifically, we updated 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.

However, we continue to have concerns that health care consumers lack the meaningful pricing information they need to choose the healthcare services they want and need. Therefore, in response to stakeholders and in accordance with Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First (June 24, 2019), we are proposing that hospitals make public their standard charges in two ways: (1) By publicly posting standard charge information, including gross charges and payer-specific negotiated rates and for all items and services, online in a machine-readable format, and (2) by making make public payer-specific negotiated rates for at least 300 shoppable services in a manner that is consumer-friendly that will meaningfully inform patients' decision making and allow consumers to compare prices across hospitals. To be consumer-friendly, the charge information for shoppable services must be displayed along with the charge information for all associated ancillary services, and the data must be easily accessible by the consumer and searchable. We are also proposing to establish a mechanism for monitoring and the application of penalties for noncompliance.

2. Estimated Burden on Hospitals

We estimate the total annual burden for hospitals to review and make public all gross and payer-specific negotiated charges for all items and services in a machine-readable format, and payer-specific negotiated charges for at least 300 shoppable services in a consumer-friendly format, to be 12 hours per hospital at $1,017.24 per hospital for a total burden of 72,024 hours (12 hours × 6,002 hospitals) and total cost of $6,105,474 ($1,017.24 × 6,002 hospitals).

We believe the burden is minimal for several reasons. First, this proposed rule is based on existing statutory requirements for hospitals to make public a list of standard charges (specifically, gross charges), which we stated in the FY 2019 IPPS/LTCH PPS final rule must be displayed in a machine readable format beginning January 1, 2019. Second, most (if not all) hospitals actively review, update, and maintain all gross charges and payer-specific negotiated charges in electronic format in hospital billing systems. Third, we have sampled hospital and state websites to see how hospitals are responding to current chargemaster posting guidance and we find that hospitals appear to be easily complying. Additionally, hospital executives and hospital finance experts have indicated that pulling already electronically available data out of hospital accounting and billing systems is very low burden. For all these reasons, we anticipate little additional burden for hospitals to meet the proposed requirement for making public gross charges and payer-specific negotiated charges online in a machine-readable format, other than the time accounted for below to review these proposed rules to ensure compliance.

As a result, the bulk of this burden estimate (8 hours) applies to the newly proposed requirements related to making public payer-specific negotiated charges in a consumer-friendly format for at least 300 shoppable items and services. In this estimate, we have accounted for activities associated with identifying hospital-selected shoppable services and for displaying payer-specific negotiated charges grouped along with the payer-specific charges for associated ancillary items and services the hospital customarily provides as part of or in conjunction with the primary service. We believe that hospitals will require this time to analyze their claims data to generate a list of hospital-selected shoppable services, to analyze claims data to determine the ancillary services that should be grouped with each shoppable service, and to display standard charges in a consumer-friendly manner in accordance with the proposed requirements at section XIV.F.2 of this proposed rule. We note that we have proposed that hospitals have flexibility to determine the format for making charges for shoppable services available to the public, recognizing that many hospitals may already be doing so in consumer-friendly online price estimator tools. We further note that most of the impact would likely occur in the first year and that updating such data annually would become more routine and automated over time.

As noted above, we believe this is an accurate estimate of burden because maintaining a set of negotiated charge data is part of normal operations for hospitals in order to work with payers and bill patients, and hospitals can readily access billing records to determine which services are commonly billed together to develop a total cost for the service package. Extracting from this data set should be a simple statistical command or formula in either MS Office applications or various database software, and it imposes minimal burden for hospitals' operations staff. We believe that our proposed accessibility requirements will ensure the hospital data can be easily found by consumers and therefore have not

included any burden estimates for additional public outreach and education, but seek public comment on whether to further consider a burden for this factor.

We believe that adding to or shifting the number of CMS-specific vs the number of hospital selected shoppable items and services would not alter this burden estimate. In total, we believe that additional burden for our proposals to make public the hospital's standard charges in the form and manner proposed would be, on average, 12 hours per hospital at $1,017.24 per hospital for hospitals in the United States.

3. Limitations of Our Analysis

It would be difficult for us to conduct a detailed quantitative analysis given the lack of studies at the national level on the regulatory impact of making price transparency information publicly available. Since we cannot produce a detailed quantitative analysis, we have developed a qualitative discussion for this regulatory impact analysis, drawing from the experiences of States that have enacted price transparency legislation and the use of price transparency tools in the private health care market. We have taken an approach that assesses potential directional impact of these proposed requirements (that is, increasing versus decreasing health care costs, increasing or decreasing likelihood of certain consumer or insurer behaviors) rather than attempting more specific estimates due to the lack of empirical data. We believe there are many benefits with this regulation, particularly for consumers who have the right to know the hospital services before they commit to them, and to be able to shop for the best value. We also discuss potential unintended consequences as a result of these proposals.

4. Estimated Effects on Private Sector

We believe that by requiring hospitals to make public their standard changes (both gross charges and payer-specific negotiated rates) for all hospital items and services (including individual items and services and service packages), our proposals will release data necessary to better understand how the level of price dispersion in various health care markets impacts health care spending and consumer out-of-pocket costs. As noted in section XVI. of this proposed rule, the negotiated charges for various procedures vary widely within and across geographic regions in the United States.[227] Some factors associated with the level of hospital price dispersion in a geographic area are the hospital's size, health care demand, labor costs, and technology, although it was the hospital's market power (level of competition) that was most positively associated with high price dispersion.[228] [229] Cooper found that variation in prices across hospital referral regions is the primary driver of variation in spending per enrollee for those privately insured, while the quantity of care provided across hospital referral regions is the primary driver of variation in spending per beneficiary for Medicare.[230] One major barrier to fully understanding health care price variation (and understanding the impact of transparency of health care pricing in general) is the lack of availability of negotiated charges to researchers and the public.[231] Our proposals would make hospital charge information available which would generate a better understanding of (1) hospital price dispersion, and (2) the relationship between hospital price dispersion and health care spending. Additionally, we believe understanding these relationships through release of pricing data could lead to downward price pressure on hospitals and reductions in overall spending.

We recognize the potential concern that hospitals may attempt to present a more favorable or discounted view of their payer-specific negotiated rates for the limited set of shoppable services, while potentially increasing charges for other items and services (for example, non-shoppable services). However, we believe that this risk will be mitigated by the requirement to post gross charges and the payer-specific negotiated charges for all items and services (including individual items and services and service packages) in a machine-readable format.

In addition to this possibility, we acknowledge there could be an impact in the commercial insurance market. A few studies have examined insurer competition in relation to negotiated hospital prices,[232] or price transparency and markups in health care.[233] We also realize that it takes time for markets to react to public disclosure of payer-specific negotiated rates, and its dynamic could vary state by state. We invite comments on the potential impact of disclosure of payer-specific negotiated charges on commercial insurers.

We believe that price transparency initiatives may reduce overall costs and price dispersion. In their comprehensive analysis of the impact of regulations across more than 30 States requiring public access to the prices of hospital procedures, Christensen et al. found that regulations lowered the price of shoppable procedures such as hip replacements by approximately five percent overall compared to prices for non-shoppable procedures such as appendectomies. They further found that half of the observed price reduction in charges was due to hospitals lowering their prices to remain competitive. This was particularly true for high priced hospitals and for hospitals in competitive urban areas.[234] Research has also indicated that price transparency initiatives can decrease prices paid by consumers and insurers. One study found that following the introduction of a State-run website providing out-of-pocket costs for a subset of shoppable outpatient services reduced the charges for these procedures by approximately 5 percent for consumers, in part by shifting demand to lower cost providers.[235] In addition, the study found that insurers over time experienced a 4-percent reduction in administrative costs for imaging services, following the introduction of the site.

[227] Kennedy K., et al. Health Care Cost Institute. Past the Price Index: Exploring Actual Prices Paid for Specific Services by Metro Area. Healthy Marketplace Index. April 30, 2019. Available at: *https://www.healthcostinstitute.org/blog/entry/hmi-2019-service-prices.*

[228] Cooper Z., et al. The Price Ain't Right? Hospital Prices and Health Spending on the Privately Insured. *The Quarterly Journal of Economics.* December 2015. Available at: *https://pdfs.semanticscholar.org/cb9c/f90786cc39ddac6d88f3ba1074a7c2d5f0a5.pdf.*

[229] Bai, G., & Anderson, G.F. (2018). Market Power: Price Variation Among Commercial Insurers For Hospital Services. *Health Affairs,* 37(10), 1615–1622. Available at: *https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.0567.*

[230] Cooper Z., et al. The Price Ain't Right? Hospital Prices and Health Spending on the Privately Insured. *The Quarterly Journal of Economics.* December 2015. Available at: *https://pdfs.semanticscholar.org/cb9c/f90786cc39ddac6d88f3ba1074a7c2d5f0a5.pdf.*

[231] Ibid.

[232] Ho K. & Lee R.S. Insurer Competition and Negotiated Hospital Prices. August 2013. *https://pdfs.semanticscholar.org/b6e9/11d7e171d3074b473439f93d377f4a4202bf.pdf*

[233] Brown Z.Y. An Empirical Model of Price Transparency and Markups in Health Care. August 2018. *http://www-personal.umich.edu/~zachb/zbrown_empirical_model_price_transparency.pdf.*

[234] Christensen H.B., Floyd E., and Maffett M. ''The Effects of Price Transparency Regulation on Prices in the Healthcare Industry.'' Available at: *https://www.bakerinstitute.org/media/files/event/01ce2e80/HPF-paper-AHEC-Floyd.pdf.*

[235] Brown Z.Y. 2018. ''Equilibrium Effects of Health Care Price Information,'' *Review of Economics and Statistics.* Available at: *https://www.mitpressjournals.org/doi/abs/10.1162/rest_a_00765.*

Based on our analysis of comments from stakeholders on the 2018 RFIs, we do not believe the economic effects will vary significantly between rural and critical access markets and larger or consolidated health care markets. However, we seek comment on whether there could be unforeseen effects of the proposals that may differentially impact markets with small, rural, or CAH hospitals.

Another possibility is that transparency in payer-specific negotiated charges may narrow the dispersion of prices in a market, meaning that knowledge of payer-specific charges may not only result in lowering prices for payers currently paying rates above the median, but could also increase prices for payers that are currently paying rates below the median. Making payer-specific negotiated prices public could risk disrupting the ability for certain payers to extract aggressive discounts in the future, especially from providers in markets with limited competition. For example, a hospital providing an aggressive discount to a particular payer may become motivated to withdraw such discount to avoid divulging such information to other payers with whom they contract.

Several studies of mandated price transparency in non-healthcare commodity markets have shown suppliers can use the information to their advantage in maximizing the prices they can charge in markets with limited competition or where commodities are not easily transferable across geographies. Although there are no definitive conclusions on the effects of price transparency on markets one study found that it can either increase or decrease prices depending on the strength of the bargainers and the size of the market.[236] While price transparency gives buyers and sellers important information about the value of items and services, the effect may result in price increases by changing the incentives for buyers and sellers may also enable traders to observe deviations from collusive practices. Allowing weaker bargainers to see prices negotiated by stronger bargainers will change incentives facing buyers and sellers, and can lead to price increases. We seek comment from stakeholders and the public as to whether they believe these types of potential drawbacks are legitimate risks in their market and, if so, whether the potential benefits of making transparent all negotiated prices outweigh the risks outlined above. If commenters believe these are risks, we further request input on what policies could mitigate these risks. If commenters believe the risks are not worth the benefits, we request further input on whether publishing only the minimum, median, and maximum negotiated rates (an alternative considered in this proposed rule) would improve the benefit-risk profile.

In the absence of a national model, we looked to two States that have previously enacted price transparency laws, California and New Hampshire. California enacted a requirement for hospitals to post their charge description master in 2004, and in 2003, New Hampshire created an all-payer claims database, later publishing the data in 2007 in a statewide, web-based price transparency comparison tool.

Studies assessing the impact of the New Hampshire State law have found that the efforts focused on the wide variation of provider prices, which in turn created opportunities for new benefit design that incentivized consumer choice of lower costs providers and sites of service.[237]

In California, the link between hospital chargemaster data and patient cost was validated through a 10-year study of the chargemaster data which found that each dollar in a hospital's list price was associated with an additional 15 cents in payment to a hospital for privately insured patients (versus publicly insured patients).[238]

This effort to improve the availability of charge data can open up the possibility to States to further regulate hospital charges—examples seen in both California and New Hampshire that took further legislative action to reduce price dispersion, reduce surprise billing and to place limits on charges for the uninsured and for out-of-network providers.

As noted earlier, we lack data to quantify the effects of our proposals along these dimensions, and we are seeking public comments on these impacts. In addition, we acknowledge that we may not have considered all areas in which the proposed rule may have effects, and we are seeking public comments on impacts of the proposals in areas we have not discussed here.

5. Estimated Effects on Consumers

In addition to economic effects described above, consumers may feel more satisfied with their care when they are empowered to make decisions about their treatment. A recent survey [239] indicated a strong desire for price transparency and openness. Eighty-eight percent of the population polled, demanded improved transparency with their total financial responsibility, including copays and deductibles. Another study suggests that improving a patient's financial experience served as the biggest area to improve overall customer satisfaction.[240] According to a 2011 GAO report, transparent health care price information may help consumers anticipate their health care costs, reduce the possibility of unexpected expenses, and make more informed choices about their care, including for both shoppable services as defined in this rule and other hospital items and services in both outpatient and inpatient settings.[241] We considered the likelihood of patients would shifting from seeking services from lower cost non-hospital sites such as ASCs, advanced radiology centers, or stand-alone labs as a result of this proposed rule and seek public comment on this potential effect.

A large part of the literature on consumer use of price information comes from studies of price transparency tools, particularly those offered by third party payers and for shoppable services. Some studies of consumer use of price information through web-based tools, such as those offered by self-insured employers or plans, indicate that they may help consumers save money on shoppable services. One study examined consumer use of an employer-sponsored, private price transparency tool and its impact on claims payments for three common medical services: laboratory tests;

[236] Congressional Research Service Report for Congress: Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Health Sector. July 24, 2007. Available at: *https://fas.org/sgp/crs/secrecy/RL34101.pdf.*

[237] Tu H, and Gourevitch R. California HealthCare Foundation and Robert Wood Johnson Foundation. Moving Markets, Lessons from the New Hampshire Price Transparency Experiment. April 2014. Available at: *https://www.chcf.org/wp-content/uploads/2017/12/PDF-MovingMarketsNewHampshire.pdf.*

[238] Barry M, and Ippolito B. Mystery Of The Chargemaster: Examining The Role Of Hospital List Prices In What Patients Actually Pay. *Health Affairs.* April, 2017. Available at: *https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0986.*

[239] See Gruessner V. Consumer Satisfaction Dips When Payers Lack Price Transparency. *Private Payers New*s (October 3, 2016). Available at: *https://healthpayerintelligence.com/news/consumer-satisfaction-dips-when-payers-lack-price-transparency.*

[240] Experian Health, Improve the healthcare financial journey. *Patient Engagement* (June 21, 2018). Available at: *https://www.experian.com/blogs/healthcare/2018/06/healthcare-financial-journey/.*

[241] Government Accountability Office. September 2011. Health Care Price Transparency: Meaningful Price Information Is Difficult for Consumers to Obtain Prior to Receiving Care. Available at: *https://www.gao.gov/assets/590/585400.pdf.*

advanced imaging services; and clinician office visits. [242] That study found that those who used the tool had lower claims payments by approximately 14 percent for laboratory tests; 13 percent for advanced imaging services; and approximately 1 percent for office visits compared to those who did not use the tool. Another study found that those employed by a large corporation who used a price transparency tool were able to reduce their costs by 10 to 17 percent compared to nonusers.[243] Those using the tool mainly searched for information on shoppable services and also tended to have more limited insurance coverage. However, one study of the use of price transparency tools by consumers with an employer-based, high deductible health plan found that consumers' likely perception that higher price is a proxy for higher quality care may lead them to select higher-cost options.[244] This study found a spending drop between 11.8 and 13.8 percent occurring across the spectrum of health care service categories at the health plan level; the majority of spending reductions were due to consumer quantity reductions across a broad range of services, including both high and low value care. Another study of the use of price transparency tools by consumers found that only 10 percent of consumers who were offered a tool with price information utilized it, and that there was a slight relative increase in their out-of-pocket health spending on outpatient services respective to the patient group that was not offered the tool.[245]

Although we do not propose to require that hospitals develop a price comparison tool, we encourage innovation in this area by making standard charges available in a machine-readable format to third-party tool developers as well as the general public. The use of a third-party tool would enhance public access to pricing data, but we do not believe the absence of one would cause confusion among consumers on how to use the available standard charge data made public by the hospital because we are also proposing requirements for hospitals to make public their payer-specific charges for a set of shoppable services in a consumer-friendly manner. A large part of consumer buy-in may depend on providers' willingness and ability to make public, and to have conversations with consumers about, their standard charge data to allow for price comparison and decisions about upcoming medical treatment. As consumers' health care costs continue to rise, clinicians are in a unique position to discuss the financial impacts of health care decisions with their patients. A paper by Chernew et al. found that patients will often choose services based on clinician referral rather than consideration of cost.[246] We believe that if the requirements of this proposed rule are finalized, the pricing information made available would help ensure that clinicians have relevant pricing data to counsel patients on financial options. A systematic review found that clinicians and their patients believe communication about health care costs is important and that they have the potential to influence health and financial outcomes, but that discussions between clinicians and patients about costs are not common.[247] We did find evidence that physicians were open to having these conversations, and that they were occurring more frequently, but providers have also identified the need for price information as a barrier to discussing costs with patients.[248] [249] In addition, a literature review of 18 studies measuring the effects of charge display on cost and practice patterns found that having prospective access to prices for radiology and laboratory services changed physician's ordering behavior, and in 7 of the 9 studies on cost reported statistically significant cost reduction when charges were displayed.[250]

6. Alternatives Considered

This proposed rule aims to make price information more readily available to the public in a manner that is consumer friendly. We considered a number of alternative approaches to maximize the value and accessibility of these data to consumers. For example, proposals to require release of hospital standard charge data in an API format, as discussed in section XVI.E.3. We also considered other types of ''standard charges'' that could be useful to consumers in section XVI.D.4. For example, in addition to or instead of the requirement to disclose gross charges and payer-specific charges, we sought comment on whether we should consider a definition of 'standard charge' to be a volume-driven negotiated charge, the minimum/median/maximum negotiated charge, all allowed charges. Such charges could be relevant to specific groups of individuals, particularly those with health insurance coverage. We also seek comment on a definition of 'standard charge' that might be relevant to subgroups of individuals who are self-pay, specifically, types of standard charges representing the discounted cash price for a service package, or the median cash price.

Under these alternative definitions of 'standard charges', hospitals would employ statistical command or formulas to sort, extract or calculate the rates for all items and services and the list of shoppable services or service packages. We do not believe the burden associated with these alternative requirements would vary significantly, other than to account for extra analysis and statistical steps involved to calculate or extract the rates from the hospital's electronic accounting and billing system. Ultimately, however, we determined that most of these options would simply limit the usefulness of hospital charge data for consumers and that our current proposals for the disclosure of gross charges and payer-specific negotiated charges provide greater transparency and better encourage innovation from third party vendors.

[242] Whaley C., et al. ''Association Between Availability of Health Service Prices and Payments for These Services.'' *JAMA.* 2014;312(16):1670–1676. Available at *https://jamanetwork.com/journals/jama/fullarticle/1917438.*

[243] Lieber EMJ. ''Does It Pay to Know Prices in Health Care?'' *American Economic Journal.* 2017, 9(1): 154–179. Available at: *https://pubs.aeaweb.org/doi/pdfplus/10.1257/pol.20150124.*

[244] Brot-Goldberg ZC, et al. What Does a Deductible Do? The Impact of Cost-Sharing on Health Care Prices, Quantities, and Spending Dynamics. Cambridge, MA: National Bureau of Economic Research; Working Paper, October 2015. Available at: *https://www.nber.org/papers/w21632.pdf.*

[245] Desai S, et al. Association between availability of a price transparency tool and outpatient spending. *JAMA.* 2016;315(17):1874–1881. doi:10.1001/jama.2016.4288.

[246] Chernew M, et al. ''Are Health Care Services Shoppable? Evidence from the Consumption of Lower-Limb MRI Scans''. National Bureau of Economic Research, Working Paper No. 24869. Issued July 2018, revised January 2019. Available at: *https://www.nber.org/papers/w24869.*

[247] Meluch AL, & Oglesby WH. (2015). Physician–patient communication regarding patients' healthcare costs in the US: A systematic review of the literature. *Journal of Communication in Healthcare,* 8(2), 151–160. Available at: *https://www.tandfonline.com/doi/full/10.1179/1753807615Y.0000000010?scroll=top&needAccess=true.*

[248] Schiavoni KH, et al. How Primary Care Physicians Integrate Price Information into Clinical Decision-Making, *J Gen Intern Medicine.* 2017 January; 32(1): 81–87. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5215149/.*

[249] Alexander GC, et al. Barriers to Patient-physician Communication About Out-of-pocket Costs, *J Gen Intern Med.* 2004 August; 19(8): 856–860. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1492500/.*

[250] Goetz C, et al. The effect of charge display on cost of care and physician practice behaviors: A systematic review, *Journal Gen Intern Med.* 2015 Jun; 30(6):835–42. Available at: *https://www.ncbi.nlm.nih.gov/pubmed/25691240.*

We also considered, but are not proposing, hospitals would display a set of at least 100 shoppable services with their payer-specific negotiated rates (instead of at least 300 shoppable services as currently proposed). As we discussed in section XVI.F.3, some states require hospitals to make public shoppable service packages that include ancillary service. Other hospitals have developed price estimators that take ancillary services into account. We understand that developing consumer-friendly shoppable service packages can be a challenge. With that in mind, we believe that reducing the number of required shoppable services would have a small impact on hospitals' burden, mainly due to a reduced number an analyses that would have to be performed as described in more detail above. We estimate that the burden for hospitals to display payer-specific negotiated charges for 30 selected shoppable services rather than 230 would result in a reduction of 2 hours of operations. However, we assess that this decrease of 2 hours in burden does not outweigh the decrease in benefit of price transparency for consumers.

E. Effects of Proposed Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services

1. Overall Impact

As discussed in section XX. of this proposed rule, we are proposing to developing a new prior authorization process and requirements for certain hospital outpatient department (OPD) services. This proposal would use our authority in section 1833(t)(2)(f) of the Act to require provisional affirmation of coverage as a condition of Medicare payment unless the provider is exempt. This proposed new requirement for prior authorization of certain covered OPD services aims to reduce the unnecessary increases in volume of certain covered hospital outpatient department services.

We believe there are a number of factors that may contribute to the potential growth assumed in the estimate presented below. For example, as the provider community acclimates to using prior authorization as part of their billing practice, there may be greater systemic or other processing efficiencies to allow more extensive implementation.

The overall economic impact of this proposal on the health care sector is dependent on the number of claims affected. Table 47, Overall Economic Impact to the Health Sector, lists an estimate for the overall economic impact to the health sector for the services combined. The values populating this table were obtained from the cost reflected in Table 48, Annual Private Sector Costs, and Table 49, Estimated Annual Medicare Costs. Together, Tables 48 and 49 combine to convey the overall economic impact to the health sector, which is illustrated in Table 47. It should be noted that due to a July start date, year one will include only 6 months of prior authorization requests.

Based on the estimate, the overall economic impact of this proposal is approximately $8.4 million in the first year based on 6 months. The 5-year impact is approximately $71.8 million, and the 10-year impact is approximately $152 million. The 5 and 10 year impacts account for year one including only 6 months. Additional administrative paperwork costs to private sector providers and an increase in Medicare spending to conduct reviews combine to create the financial impact. However, this impact is offset by some savings. We believe there are likely to be other benefits and cost savings that result from the proposed OPD service prior authorization requirement. However, many of those benefits are difficult to quantify. For instance, we expect to see savings in the form of reduced unnecessary utilization, fraud, waste, and abuse, including a reduction in improper Medicare fee-for-service payments (we note that not all improper payments are fraudulent). We are soliciting public comments on the potential increased costs and benefits associated with this proposed provision.

TABLE 47.--OVERALL ECONOMIC IMPACT TO THE HEALTH SECTOR

	Year 1	5 Years	10 Years
Private Sector Costs	$2,604,281	$19,771,299	$42,146,879
Medicare Costs	$5,787,055	$52,068,840	$109,924,735
Total Economic Impact to Health Sector	$8,391,336	$71,840,139	$152,071,614

The definition of small entity in the RFA includes nonprofit organizations. According to the RFA's use of the term, most suppliers and providers are small entities. Likewise, the vast majority of physician and nurse practitioner (NP) practices are considered small businesses according to the SBA's size standards total revenues of $10 million or less in any 1 year. While the economic costs and benefits of this proposal are substantial in the aggregate, the economic impact on individual entities would be relatively small. We estimate that 90 to 95 percent of providers who provide these services are small entities under the RFA definition. The rationale behind requiring prior authorization is to control unnecessary increases in the volume of covered OPD services. The impact on these providers could be significant; if finalized, the proposal would change the billing practices of providers. We believe that the purpose of the statute and this proposal is to avoid unnecessary utilization of OPD services. Therefore, we do not view decreased revenues from OPD services subject to unnecessary utilization by providers to be a condition that we must mitigate. We believe that the effect would be minimal on providers who are compliant with Medicare coverage and payment rules and requirements. This proposal would offer an additional protection to a provider's cash flow as the provider would know in advance if the Medicare requirements are met.

2. Anticipated Specific Cost Effects

a. Private Sector Costs

We do not believe that this proposal would significantly affect the number of legitimate claims submitted for these services. However, we do expect a decrease in the overall amount paid for OPD services resulting from a reduction in unnecessary utilization of the services requiring prior authorization.

As described previously in this proposed rule, we have identified a list of specific services that, based on review and analysis of claims data, show higher than expected, and therefore we believe unnecessary, increases in the volume of service utilization. In making the decision to propose to include the specific services in the proposed list of hospital outpatient department services requiring prior authorization, we first considered that these services are considered cosmetic and, therefore, are only covered by Medicare in very rare circumstances. We then viewed the current volume of utilization of these services and determined that the utilization far exceeded what would be expected.

We have developed a proposed list of potential OPD services categories for inclusion in the OPD services prior authorization process—blepharoplasty; botulin toxin injections; panniculectomy; rhinoplasty; vein ablation, and their related services. The list includes services from each of five categories that have demonstrated an unnecessary increase in volume and can serve some cosmetic purpose and/or are being claimed as therapeutic services.

We estimate that the private sector's per-case time burden attributed to submitting documentation and associated clerical activities in support of a prior authorization request is equivalent to that of submitting documentation and clerical activities associated for prepayment review, which is 0.5 hours. We apply this time burden estimate to initial submissions and resubmissions.

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TABLE 48.--Year 1 (6 Month) PRIVATE SECTOR COSTS

Activity	Responses Per Year (i.e. number of reviewed claims)	Time Per Response (hours) or Dollar Cost	Total Burden Per Year (hours)	Total Burden Costs Per Year Using Loaded Rate
Fax and Electronic Submitted Requests-Submissions	54,389	0.5	27,194	$904,482
Fax and Electronic Submitted Requests-Resubmissions	17,851	0.5	8,925	$296,857
Mailed in Requests-Submissions	23,309	0.5	11,655	$ 387,635
Mailed in Requests-Resubmissions	7,650	0.5	3,825	$127,224
Mailing Costs-Total Submissions	30,960	$5		$154,799
Provider Demonstration-Education	Providers 7,349	3	22,047	$733,283
Total			73,647	$2,604,281

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b. Medicare Costs

Medicare would incur additional costs associated with processing the proposed prior authorization requests. We use the range of potentially affected cases (submissions and resubmissions) and multiply it by $50, the estimated cost to review each request. The cost also includes other elements such as appeals, education and outreach, and system changes.

TABLE 49.--Year 1 (6 Month) ESTIMATED ANNUAL MEDICARE COSTS

Blepharoplasty	Panniculectomy	Vein Ablation	Rhinoplasty	Botulin Toxin Injections	Combined
$808,934	$117,718	$599,260	$671,134	$3,590,011	$5,787,055

c. Estimated Beneficiary Costs

We expect a reduction in the utilization of Medicare OPD services when such utilization does not comply with one or more of Medicare's coverage, coding, and payment rules. While there may be an associated burden on beneficiaries while they wait for the prior authorization decision, we are unable to quantify that burden. Although the proposal is designed to permit utilization that is medically necessary, OPD services that are not medically necessary may still provide convenience or usefulness for beneficiaries; any rule-induced loss of such convenience or usefulness constitutes a cost of the rule that we lack data to quantify. Additionally, beneficiaries may have out-of-pocket costs for those services that are determined not to comply with Medicare requirements and thus, are not eligible for Medicare payment. We lack the data to quantify these costs as well.

3. Estimated Benefits

There would be quantifiable benefits for this proposal because we expect a reduction in the unnecessary utilization of those Medicare OPD services subject to prior authorization. It is difficult to project the decrease in unnecessary utilization. However, we would closely monitor utilization and billing practices. The expected benefits would include a changed billing practice that also enhances the coordination of care for the beneficiary. For example, requiring prior authorization for certain OPD services ensures that the primary care practitioner recommending the service and the facility collaborate more closely to provide the most appropriate OPD services to meet the needs of the beneficiary. The practitioner recommending the service evaluates the beneficiary to determine his or her condition and what services are needed and medically necessary. This requires the facility to collaborate closely with the practitioner early on in the process to ensure the services are truly necessary and met all requirements and the documentation is complete and correct. Improper payments made because the practitioner did not evaluate the patient or the patient does not meet the Medicare requirements, would likely be reduced by the requirement that a provider submit clinical documentation created by as part of its prior authorization request.

F. Effects of Proposal Relating to Changes in the Definition of Expected Donation Rate for Organ Procurement Organizations

In section XVIII. of this proposed rule, we are proposing to revise the definition of ''expected donation rate'' in the CfCs for OPOs. This proposed change would allow OPOs to receive payment for organ donor costs under the Medicare and Medicaid programs using a definition that is consistent with the definition used by the Scientific Registry of Transplant Recipients (SRTR).

All 58 OPOs are required to meet two out of three outcome measures detailed in the CfCs for OPOs regulations at 42 CFR 486.318(b). The second outcome measure relies on the aforementioned definition, and therefore all OPOs would be affected by the proposed change. This revision would eliminate the potential for confusion in the OPO community due to different definitions of the same term. However, it would not affect data collection or reporting by OPTNs and SRTRs, nor their statistical evaluation of OPO performance, and therefore it would not result in any quantifiable impact.

G. Potential Revisions to the Laboratory Date of Service Policy

In section XIX of this proposed rule, we solicit comments on potential revisions to the laboratory date of service policy exception at 42 CFR 414.510(b)(5) for molecular pathology tests and tests designated by CMS as an ADLT under paragraph (1) of the definition of advanced diagnostic laboratory test in § 414.502. Because these tests are excluded from our packaging policy under the OPPS, and are paid at the applicable rate for the laboratory test under the CLFS, regardless of whether the hospital or the performing laboratory bills Medicare for the test, any aspect of this discussion will not result in net costs or savings to the Medicare program. Accordingly, the discussion in section XIX. of this proposed rule is not reflected in Table 41 in the regulatory impact analysis under section XXVI.C.1. of this proposed rule.

H. Effect of Proposed Changes to Requirements for Grandfathered Children's Hospitals-Within-Hospitals (HwHs)

In section XXII. of this proposed rule, we discuss our proposal to revise the regulations to allow grandfathered children's HwHs to increased beds while maintaining their grandfathered status. This proposed policy change would allow providers to address changing community needs for services without any increased incentive for inappropriate patient shifting to maximize Medicare payments given the low Medicare utilization in children's hospitals. Based on the best available information, there are currently very few grandfathered children's HwHs (3 or less). For these reasons, we estimate any impact on Medicare expenditures as a result of this proposal would be negligible. On average there are approximately 50 Medicare discharges per year from children's hospitals at an average cost of approximately $33,000 per discharge. There are two possible sources for an increase, if any, in Medicare discharges at grandfathered children's hospitals as a result of our proposal: Either the discharges would have been treated at another children's hospital or the cases would have been treated at an IPPS hospital. In either case given the few number of Medicare discharges at children's hospitals, the impact of this proposal on Medicare spending is negligible.

I. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret a rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review a rule, we assume that the number of commenters on the CY 2019 OPPS/ASC proposed rule (2,990) will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this

proposed rule. It is possible that not all commenters will review this proposed rule in detail, and it is also possible that some reviewers will choose not to comment on this proposed rule. Nonetheless, we believe that the number of commenters on the CY 2019 OPPS/ASC proposed rule will 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 the final rule with comment period, 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 $109.36 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 8 hours for the staff to review half of this proposed rule. For each facility that reviews this proposed rule, the estimated cost is $874.88 (8 hours × $109.36). Therefore, we estimate that the total cost of reviewing this proposed rule is $2,615,891.20 ($874.88 × 2,990 reviewers).

J. 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, we refer readers to the Small Business Administration's ''Table of 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 612 small rural hospitals. We note that the estimated payment impact for any category of small entity will depend on both the services that they provide as well as the payment policies and/or payment systems that may apply to them. Therefore, the most applicable estimated impact may be based on the specialty, provider type, or payment system.

We do not believe proposals related to requirements for hospitals to make public their standard charges would have a significant economic impact on small rural hospitals operations or their market positions. As indicated in section XX.VI.D. in this proposed rule, the total annual burden for making public standard charges is minimal on the operations of hospitals, including small rural hospitals. Moreover, small rural hospitals often are situated in a less competitive health care market and studies have indicated that the pricing transparency impact tends to be minimal when the provide competition is weak, which is a representative characteristic of rural healthcare markets.[251] Therefore, we believe this proposed rule imposes minimal operational and/or economic impacts on small rural hospitals.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

K. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $154 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

L. 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 regulatory action for the purposes of Executive Order 13771. We estimate that this proposed rule would generate $7.85 million in annualized cost at a 7-percent discount rate, discounted relative to 2016, over a perpetual time horizon.

M. 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 2020. Table 41 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 2.0 percent increase in payments for all services paid under the OPPS in CY 2020, 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 finalized off-campus provider-based department clinic 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 2020.

The proposed updates to the ASC payment system for CY 2020 would affect each of the approximately 5,600 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC would depend on its mix of patients, the proportion of the ASC's patients who are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the ASC payment system, and the extent to which the ASC provides a different set of procedures in the coming year. Table 42 demonstrates the estimated distributional impact among ASC surgical specialties of the proposed MFP-adjusted hospital market basket update factor of 2.7 percent for CY 2020.

[251] Tu, Ha. Impact of HealthCare Price Transparency on Price Variation: The New Hampshire Experience. Center for Studying Health System Change Issue Brief, November, 2009. and Christiansen, Hans et al. The Effects of Price Transparency Regulation on Prices in the Healthcare Industry, The Baker Institute, 2013.

XXVII. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has federalism implications. We have examined the OPPS and ASC provisions included in this 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 41 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would increase by 1.9 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 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 486

Definitions, Medicare, Organ procurement.

45 CFR Part 180

Definitions, Hospitals, Reporting and recordkeeping requirements.

For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 495(a), 1302, 1302b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 2. Section 405.926 is amended by revising paragraph (t) to read as follows:

§ 405.926 Actions that are not initial determinations.

* * * * *

(t) A contractor's prior authorization determination with regard to—

(1) Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS)); and

(2) Hospital outpatient department (OPD) services.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 3. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 4. Section 410.27 is amended by revising paragraph (a)(1)(iv) to read as follows:

§ 410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.

* * * * *

(a) * * *

(1) * * *

(iv) Under the general supervision (or other level of supervision as specified by CMS for the particular service) of a physician or a nonphysician practitioner as specified in paragraph (g) of this section, subject to the following requirements:

(A) For services furnished in the hospital or CAH, or in an outpatient department of the hospital or CAH, both on and off-campus, as defined in § 413.65 of this subchapter, general supervision as defined in § 410.32(b)(3)(i).

(B) Certain therapeutic services and supplies may be assigned either direct supervision or personal supervision. For purposes of this section, direct supervision means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. And personal supervision means the definition specified at § 410.32(b)(3)(iii);

(C) Nonphysician practitioners may provide the required supervision of services that they may personally furnish in accordance with State law and all additional requirements, including those specified in §§ 410.71, 410.73, 410.74, 410.75, 410.76, and 410.77;

(D) For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or a doctor of osteopathy, as specified in §§ 410.47 and 410.49, respectively; and

* * * * *

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 5. The authority citation for part 412 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 6. Section 412.22 is amended by revising paragraphs (f)(1) and (2) to read as follows:

§ 412.22 Excluded hospitals and hospital units: General rules.

* * * * *

(f) * * *

(1) Continues to operate under the same terms and conditions, including the number of beds, unless the hospital is a children's hospital as defined at § 412.23(d), and square footage considered to be part of the hospital for purposes of Medicare participation and payment in effect on September 30, 1995; or

(2) In the case of a hospital that changes the terms and conditions under which it operates after September 30, 1995, but before October 1, 2003, continues to operate under the same terms and conditions, including the number of beds, unless the hospital is

a children's hospital as defined at § 412.23(d), and square footage considered to be part of the hospital for purposes of Medicare participation and payment in effect on September 30, 2003.

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

■ 7. The authority citation for part 416 continues to read as follows:

Authority: 42 U.S.C. 273, 1302, 1320b-8, and 1395hh.

■ 8. Section 416.171 is amended by adding paragraph (b)(4) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

* * * * *

(b) * * *

(4) Notwithstanding paragraph (b)(2) of this section, low volume device-intensive procedures where the otherwise applicable payment rate calculated based on the standard methodology for device intensive procedures described in this paragraph (b) would exceed the payment rate for the equivalent service set under the payment system established under part 419 of this subchapter, for which the payment rate will be set at an amount equal to the amount under that payment system.

* * * * *

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 9. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

■ 10. Section 419.32 is amended by adding paragraph (b)(1)(iv)(B)(*11*) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(*11*) For calendar year 2020, a multifactor productivity adjustment (as determined by CMS) and 0.75 percentage point.

* * * * *

■ 11. Section 419.66 is amended by revising paragraph (c)(2) to read as follows:

§ 419.66 Transitional pass-through payments: Medical devices.

* * * * *

(c) * * *

(2) CMS determines either of the following:

(i) The device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or

(ii) For applications received on or after January 1, 2020, as an alternative pathway to paragraph (c)(2)(i) of this section, the device has received FDA marketing authorization and is part of the FDA's Breakthrough Devices Program.

* * * * *

■ 12. Subpart I, consisting of §§ 419.80 through 419.89, is added to read as follows:

SUBPART I—PRIOR AUTHORIZATION FOR OUTPATIENT DEPARTMENT SERVICES

Sec.

§ 419.80 Basis and scope of this subpart.

(a) *Basis.* The provisions in this subpart are issued under the authority of section 1833(t)(2)(F) of the Act, which authorizes the Secretary to develop a method for controlling unnecessary increases in the volume of covered hospital outpatient department services.

(b) *Scope.* This subpart specifies the process and requirements for prior authorization for certain hospital outpatient department services as a condition of Medicare payment.

§ 419.81 Definitions.

As used in this subpart, unless otherwise specified, the following definitions apply:

List of hospital outpatient department services requiring prior authorization means the list of hospital outpatient department services described in § 419.83(a) that CMS adopts in accordance with § 419.83(b) that require prior authorization as a condition of Medicare payment.

Prior authorization means the process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the service is provided to the beneficiary and before the claim is submitted for processing.

Provisional affirmation means a preliminary finding that a future claim meets the Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act.

§ 419.82 Prior authorization for certain covered hospital outpatient department services.

(a) *Prior authorization as condition of payment.* As a condition of Medicare payment for the services in the categories of services on the list of hospital outpatient department services requiring prior authorization as specified in § 419.83(a), a provider must submit to CMS or its contractors a prior authorization request in accordance with the requirements of paragraph (c) of this section.

(b) *Denial of claim.* (1) CMS or its contractors will deny a claim for a service that requires prior authorization if the provider has not received a provisional affirmation of coverage on the claim from CMS or its contractor unless the provider is exempt under § 419.83(c).

(2) CMS or its contractor may deny a claim that has received a provisional affirmation based on either of the following:

(i) Technical requirements that can only be evaluated after the claim has been submitted for formal processing; or

(ii) Information not available at the time of a prior authorization request.

(3) CMS or its contractor may deny claims for services related to services on the list of hospital outpatient department services for which the provider has received a denial.

(c) *Submission of prior authorization request.* A provider must submit to CMS or its contractor a prior authorization request for any service on the list of outpatient department services requiring prior authorization.

(1) *Prior authorization request requirements.* A prior authorization request must—

(i) Include all documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act.

(ii) Be submitted before the service is provided to the beneficiary and before the claim is submitted.

(2) *Request for expedited review.* A provider may submit a request for expedited review of a prior

authorization request. The request for expedited review must comply with the requirements in paragraphs (c)(1)(i) and (ii) of this section and include documentation showing that the processing of the prior authorization request must be expedited due to the beneficiary's life, health, or ability to regain maximum function being in serious jeopardy.

(d) *Reviews*—(1) *Review of prior authorization request.* Upon receipt of a prior authorization request, CMS or its contractor will review the request for compliance with applicable Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act.

(i) CMS or its contractor will issue a provisional affirmation to the provider if it is determined that applicable Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act are met.

(ii) CMS or its contractor will issue a non-affirmation to the provider if it is determined that applicable Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act are not met.

(iii) The provisional affirmation or non-affirmation will be issued within 10 business days of receipt of the prior authorization request.

(2) *Review of expedited review request.* Upon receipt of a request for expedited review, CMS or its contractor will complete an expedited review of the prior authorization request if it is determined that a delay could seriously jeopardize the beneficiary's life, health, or ability to regain maximum function, and issue a provisional affirmation or non-affirmation decision in accordance with paragraph (d)(1) of this section within 2 business days of the expedited review request.

(e) *Resubmission.* (1) A provider may resubmit a prior authorization request, upon receipt of a non-affirmation, consistent with the requirements in paragraph (c)(1) of this section.

(2) A provider may resubmit a request for expedited review consistent with the requirements in paragraph (c)(1) of this section.

§ 419.83 List of hospital outpatient department services requiring prior authorization.

(a) *Service categories for the list of hospital outpatient department services requiring prior authorization.* (1) The following service categories comprise the list of hospital outpatient department services requiring prior authorization:

(i) Blepharoplasty.

(ii) Botulinum toxin injections.

(iii) Panniculectomy.

(iv) Rhinoplasty.

(v) Vein ablation.

(2) Technical updates to the list of services, such as changes to the name of the service or CPT code, will be published on the CMS website.

(b) *Adoption of the list of services.* CMS will adopt the list of hospital outpatient department service categories requiring prior authorization and any updates or geographic restrictions through formal notice-and-comment rulemaking.

(c) *Exemptions.* CMS may elect to exempt a provider from the prior authorization process in § 419.82 upon a provider's demonstration of compliance with Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act through such prior authorization process. An exemption will remain in effect until CMS elects to withdraw the exemption.

(d) *Suspension of prior authorization process or services.* CMS may suspend the outpatient department services prior authorization process requirements generally or for a particular service(s) at any time by issuing notification on the CMS website.

§§ 419.84–419.89 [Reserved]

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 13. The authority citation for part 486 is revised to read as follows:

Authority: 42 U.S.C. 273, 1302, 1320b–8, and 1395hh.

■ 14. Section 486.302 is amended by revising the definition of ''Expected donation rate'' to read as follows:

§ 486.302 Definitions.

* * * * *

Expected donation rate means the expected donation rate per 100 eligible deaths that is the rate expected for an OPO based on the national experience for OPOs serving similar eligible donor populations and donation service areas. This rate is adjusted for the distributions of age, sex, race, and cause of death among eligible deaths.

* * * * *

■ 15. Section 486.318 is amended by revising paragraphs (a)(2), (b)(2), and (c)(1) to read as follows:

§ 486.318 Condition: Outcome measures.

(a) * * *

(2) The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for recertification, as calculated by the SRTR. For the 2022 recertification cycle, the observed donation rate is not significantly lower than the expected donation rate for 12 of the 24 months between January 1, 2020 and December 31, 2021, as calculated by the SRTR.

* * * * *

(b) * * *

(2) The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for recertification, as calculated by the SRTR. For the 2022 recertification cycle, the observed donation rate is not significantly lower than the expected donation rate for 12 of the 24 months between January 1, 2020 and December 31, 2021, as calculated by the SRTR.

* * * * *

(c) * * *

(1) Except as specified in paragraph (b)(2) of this section, an OPO's performance on the outcome measures is based on 36 months of data, beginning with January 1 of the first full year of the recertification cycle and ending 36 months later on December 31, 7 months prior to the end of the recertification cycle.

* * * * *

For reasons stated in the preamble of this document, under the authority 5 U.S.C. 301 and 42 U.S.C. 300gg–18, the Department of Health and Human Services proposes to amend title 45, subtitle A of the Code of Federal Regulations as set forth below:

■ 16. Subchapter E, consisting of parts 180 through 199, is added to read as follows:

Title 45—Public Welfare

Subtitle A—Department of Health and Human Services

SUBCHAPTER E—PRICE TRANSPARENCY

181–199 [RESERVED]

PART 180—HOSPITAL PRICE TRANSPARENCY

Sec.

Subpart A—General Provisions

Subpart B—Public Disclosure Requirements

Authority: 42 U.S.C. 300gg–18.

Subpart A—General Provisions

§ 180.10 Basis and scope.

This part implements section 2718(e) of the Public Health Service (PHS) Act, which requires each hospital operating within the United States, for each year, to establish, update, and make public a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the Social Security Act. This part also implements section 2718(b)(3) of the PHS Act, to the extent that section authorizes CMS to promulgate regulations for enforcing section 2718(e).

§ 180.20 Definitions.

The following definitions apply to this part, unless specified otherwise:

Ancillary service means an item or service a hospital customarily provides as part of or in conjunction with a shoppable primary service.

Chargemaster (Charge Description Master or CDM) means the list of all individual items and services maintained by a hospital for which the hospital has established a charge.

Gross charge means the charge for an individual item or service that is reflected on a hospital's chargemaster, absent any discounts.

Hospital means an institution in any State in which State or applicable local law provides for the licensing of hospitals, that is licensed as a hospital pursuant to such law or is approved, by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing. For purposes of this definition, a State includes each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

Items and services means all items and services, including individual items and services and service packages, that could be provided by a hospital to a patient in connection with an inpatient admission or an outpatient department visit for which the hospital has established a standard charge. Examples include, but are not limited to, supplies, procedures, room and board, use of the facility and other items (generally described as facility fees), services of employed physicians and non-physician practitioners (generally reflected as professional charges), and any other items or services for which a hospital has established a standard charge.

Machine-readable format means a digital representation of data or information in a file that can be imported or read into a computer system for further processing. Examples of machine-readable formats include, but are not limited to, .XML, JSON and .CSV formats.

Payer-specific negotiated charge means the charge that a hospital has negotiated with a third party payer for an item or service.

Service package means an aggregation of individual items and services into a single service with a single charge.

Shoppable service means a service package that can be scheduled by a health care consumer in advance.

Standard charge means the regular rate established by the hospital for an item or and service provided to a specific group of paying patients

Third party payer means an entity that is, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service.

§ 180.30 Applicability.

(a) *General applicability.* Except as provided in paragraph (b) of this section, the requirements of this part apply to hospitals as defined at § 180.20.

(b) *Exception.* Federally owned or operated hospitals are deemed by CMS to be in compliance with the requirements of this part including but not limited to:

(1) Federally owned hospital facilities, including hospitals operated by the U.S. Department of Veterans Affairs and Military Treatment Facilities operated by the U.S. Department of Defense.

(2) Hospitals operated by an Indian Health Program as defined in section 4(12) of the Indian Health Care Improvement Act.

(c) *Online availability.* Unless otherwise stated, hospital charge information must be made public electronically via the internet.

Subpart B—Public Disclosure Requirements

§ 180.40 General requirements.

A hospital must make public the following:

(a) A machine-readable file containing a list of all standard charges for all items and services as provided in § 180.50.

(b) A consumer-friendly list of payer-specific negotiated charges for a limited set of shoppable services as provided in § 180.60.

§ 180.50 Requirements for making public hospital standard charges for all items and services.

(a) *General rules.* (1) A hospital must establish, update, and make public a list of all standard charges for all items and services online in the form and manner specified in this section.

(2) Each hospital location operating under a single hospital license (or approval) that has a different set of standard charges than the other location(s) operating under the same hospital license (or approval) must separately meet the requirements of this section.

(b) *Required data elements.* A hospital must include all of the following corresponding data elements in its list of standard charges, as applicable:

(1) Description of each item or service provided by the hospital.

(2) Gross charge that applies to each individual item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.

(3) Payer-specific negotiated charge that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting. Each list of payer-specific charges must be clearly associated with the name of the third party payer.

(4) Any code used by the hospital for purposes of accounting or billing for the item or service, including, but not limited to, the Current Procedural Terminology (CPT) code, the Healthcare Common Procedure Coding System (HCPCS) code, the Diagnosis Related Group (DRG), the National Drug Code (NDC), or other common payer identifier.

(5) Revenue codes, as applicable.

(c) *Format.* The information described in paragraph (b) of this section must be published in a single digital file that is in a machine-readable format.

(d) *Location and accessibility.* (1) A hospital may select a publicly available website for purposes of making public the standard charge information required under this section.

(2) The standard charge information must be displayed in a prominent manner and clearly identified with the hospital location with which the standard charge information is associated.

(3) The hospital must ensure that the standard charge data is easily accessible, without barriers, including but not

limited to ensuring the data is accessible:

(i) Free of charge,

(ii) Without having to establish a user account or password; and

(iii) Without having to submit personal identifying information (PII).

(4) The digital file and standard charge information contained in it must be digitally searchable.

(e) *Frequency of updates.* The hospital must update the standard charge information described in paragraph (b) of this section at least once annually. The hospital must clearly indicate the date that the standard charge data was most recently updated, either within the file itself or otherwise clearly associated with the file.

§ 180.60 Requirements for making public payer-specific negotiated charges for selected shoppable services.

(a) *General rules.* (1) A hospitals must make public its payer-specific negotiated charges for as many of the 70 CMS-selected shoppable services that are provided by the hospital, and as many additional hospital-selected shoppable services as is necessary for a combined total of at least 300 shoppable services.

(2) [Reserved]

(b) *Required data elements.* A hospital must include, as applicable, all of the following corresponding data elements when displaying its payer-specific negotiated charges for the shoppable services selected under paragraph (a) of this section:

(1) A plain-language description of each shoppable service.

(2) The payer-specific negotiated charge that applies to each shoppable service. For shoppable services not provided by the hospital, the charge must be indicated as ''N/A''. Each payer-specific charge must be clearly associated with the name of the third party payer.

(3) A list of all associated ancillary items and services that the hospital provides with the shoppable service, including the payer-specific negotiated charge for each ancillary item or service.

(4) The location at which the shoppable service is provided, including whether the payer-specific negotiated charge for the shoppable service applies at that location to the provision of that shoppable service in the inpatient setting or the outpatient department setting or both.

(5) Any primary code used by the hospital for purposes of accounting or billing for the shoppable service, including, as applicable, the Current Procedural Terminology (CPT) code, the Healthcare Common Procedure Coding System (HCPCS) code, the Diagnosis Related Group (DRG), or other common service billing code.

(c) *Format.* (1) A hospital has discretion to choose a format for making public the information described in paragraph (b) of this section online.

(2) The hospital must make the information described in paragraph (b) of this section in written format upon request within 72 hours of the request.

(d) *Location and accessibility of online data.* (1) A hospital has discretion to select an appropriate publicly available internet location for purposes of making public the standard charge information required under this section.

(2) The standard charge information must be displayed in a prominent manner that identifies the hospital location with which the standard charge information is associated.

(3) The standard charge data must be easily accessible, without barriers, including but not limited to ensuring the data is:

(i) Free of charge.

(ii) Accessible without having to register or establish a user account or password.

(iii) Accessible without having to submit personal identifying information (PII).

(iv) Searchable by service description, billing code, and payer.

(e) *Frequency.* The hospital must update the standard charge information described in paragraph (b) of this section at least once annually. The hospital must clearly indicate the date that the information was most recently updated.

Subpart C—Monitoring and Penalties for Noncompliance

§ 180.70 Monitoring and enforcement.

(a) *Monitoring.* (1) CMS evaluates whether a hospital has complied with the requirements under §§ 180.40, 180.50, and 180.60.

(2) CMS may use methods to monitor and assess hospital compliance with the requirements under this part, including, but not limited to, the following, as appropriate:

(i) CMS' evaluation of complaints made by individuals or entities to CMS.

(ii) CMS review of individuals' or entities' analysis of noncompliance.

(iii) CMS audit of hospitals' websites.

(b) *Actions to address hospital noncompliance.* If CMS concludes that the hospital is noncompliant with one or more of the requirements of § 180.40, § 180.50, or § 180.60, CMS may take any of the following actions, which generally, but not necessarily, will occur in the following order:

(1) Provide a written warning notice to the hospital of the specific violation(s).

(2) Request a corrective action plan from the hospital if its noncompliance constitutes a material violation of one or more requirements, according to § 180.80.

(3) Impose a civil monetary penalty on the hospital and publicize the penalty on a CMS website according to § 180.90 if the hospital fails to respond to CMS' request to submit a corrective action plan or comply with the requirements of a corrective action plan.

§ 180.80 Corrective action plans.

(a) *Material violations requiring a corrective action plan.* CMS determines if a hospital's noncompliance with the requirements of this part constitutes material violation(s) requiring a corrective action plan. A material violation may include, but is not limited to, the following:

(1) A hospital's failure to make public its standard charges required by § 180.40.

(2) A hospital's failure to make public its standard charges in the form and manner required under §§ 180.50 and 180.60.

(b) *Notice of violation.* CMS may request that a hospital submit a corrective action plan, specified in a notice of violation issued by CMS to a hospital.

(c) *Compliance with corrective action plan requests and corrective actions.* (1) A hospital required to submit a corrective action plan must do so, in the form and manner, and by the deadline, specified in the notice of violation issued by CMS to the hospital and must comply with the requirements of the corrective action plan.

(2) A hospital's corrective action plan must specify elements including, but not limited to:

(i) The deficiency or deficiencies that caused noncompliance to occur.

(ii) The corrective actions or processes the hospital will take to come into compliance with the requirements of this part.

(iii) The timeframe by which the hospital will complete the corrective action.

(3) A corrective action plan is subject to CMS review and approval.

(4) After CMS' review and approval of a hospital's corrective action plan, CMS may monitor and evaluate the hospital's compliance with the corrective actions.

(d) *Noncompliance with corrective action plan requests and requirements.* (1) A hospital's failure to respond to CMS' request to submit a corrective action plan includes failure to submit a

corrective action plan in the form, manner, or by the deadline, specified in a notice of violation issued by CMS to the hospital.

(2) A hospital's failure to comply with the requirements of a corrective action plan includes failure to correct violation(s) within the specified timeframes.

§ 180.90 Civil monetary penalties.

(a) *Basis for imposing civil monetary penalties.* CMS may impose a civil monetary penalty on a hospital identified as noncompliant according to § 180.70, and that fails to respond to CMS' request to submit a corrective action plan or comply with the requirements of a corrective action plan as described in § 180.80(d).

(b) *Notice of imposition of a civil monetary penalty.* (1) If CMS imposes a penalty in accordance with this part, CMS provides a written notice of imposition of a civil monetary penalty to the hospital via certified mail or another form of traceable carrier.

(2) This notice to the hospital may include, but is not limited to, the following:

(i) The basis for the hospital's noncompliance, including, but not limited to, the following:

(A) CMS' determination as to which requirement(s) the hospital has violated.

(B) The hospital's failure to respond to CMS' request to submit a corrective action plan or comply with the requirements of a corrective action plan, as described in § 180.80(d).

(ii) CMS' determination as to the effective date for the violation(s). This date is the latest date of the following:

(A) The first day the hospital is required to meet the requirements of this part.

(B) If a hospital previously met the requirements of this part but did not update the information annually as required, the date 12 months after the date of the last annual update specified in information posted by the hospital.

(C) A date determined by CMS, such as one resulting from monitoring activities specified in § 180.70, or development of a corrective action plan as specified in § 180.80.

(iii) The amount of the penalty as of the date of the notice.

(iv) A statement that a civil monetary penalty may continue to be imposed for continuing violation(s).

(v) Payment instructions.

(vi) Intent to publicize the hospital's noncompliance and CMS' determination to impose a civil monetary penalty on the hospital for noncompliance with the requirements of this part by posting the notice of imposition of a civil monetary penalty on a CMS website.

(vii) A statement of the hospital's right to a hearing according to subpart D of this part.

(viii) A statement that the hospital's failure to request a hearing within 30 calendar days of the issuance of the notice permits the imposition of the penalty, and any subsequent penalties pursuant to continuing violations, without right of appeal in accordance with § 180.110.

(3) If the civil monetary penalty is upheld, in part, by a final and binding decision according to subpart D of this part, CMS will issue a modified notice of imposition of a civil monetary penalty.

(c) *Amount of the civil monetary penalty.* (1) CMS may impose a civil monetary penalty upon a hospital for a violation of each requirement of this part.

(2) The maximum daily dollar amount for a civil monetary penalty to which a hospital may be subject is $300. Even if the hospital is in violation of multiple discrete requirements of this part, the maximum total sum that a single hospital may be assessed per day is $300.

(3) The amount of the civil monetary penalty will be adjusted annually using the multiplier determined by OMB for annually adjusting civil monetary penalty amounts under part 102 of this title.

(d) *Timing of payment of civil monetary penalty.* (1) A hospital must pay the civil monetary penalty in full within 60 calendar days after the date of the notice of imposition of a civil monetary penalty from CMS under paragraph (b) of this section.

(2) In the event a hospital requests a hearing, pursuant to subpart D of this part, the hospital must pay the amount in full within 60 calendar days after the date of a final and binding decision, according to subpart D of this part, to uphold, in whole or in part, the civil monetary penalty.

(3) If the 60th calendar day described paragraphs (d)(1) and (2) of this section is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(e) *Posting of notice.* (1) CMS will post the notice of imposition of a civil monetary penalty described in paragraphs (b) and (f) of this section on a CMS website.

(2) In the event that a hospital elects to request a hearing, pursuant to subpart D of this part:

(i) CMS will indicate in its posting, under paragraph (e)(1) of this section, that the civil monetary penalty is under review.

(ii) If the civil monetary penalty is upheld, in whole, by a final and binding decision according to subpart D of this part, CMS will maintain the posting of the notice of imposition of a civil monetary penalty on a CMS website.

(iii) If the civil monetary penalty is upheld, in part, by a final and binding decision according to subpart D of this part, CMS will issue a modified notice of imposition of a civil monetary penalty according to paragraph (b)(3) of this section, and will make this modified notice public on a CMS website.

(iv) If the civil monetary penalty is overturned in full by a final and binding decision according to subpart D of this part, CMS will remove the notice of imposition of a civil monetary penalty from a CMS website.

(f) *Continuing violations.* CMS may issue subsequent notice(s) of imposition of a civil monetary penalty, according to paragraph (b) of this section, that result from the same instance(s) of noncompliance.

Subpart D—Appeals of Civil Monetary Penalties

§ 180.100 Appeal of penalty.

(a) A hospital upon which CMS has imposed a penalty under this part may appeal that penalty in accordance with subpart D of part 150 of this title, except as specified in paragraph (b) of this section.

(b) For purposes of applying subpart D of part 150 of this title to appeals of civil monetary penalties under this part:

(1) Civil money penalty means a civil monetary penalty according to § 180.90.

(2) Respondent means a hospital that received a notice of imposition of a civil monetary penalty according to § 180.90(b).

(3) References to a notice of assessment or proposed assessment, or notice of proposed determination of civil monetary penalties, are considered to be references to the notice of imposition of a civil monetary penalty specified in § 180.90(b).

(4) Under § 150.417(b) of this title, in deciding whether the amount of a civil money penalty is reasonable, the ALJ may only consider evidence of record relating to the following:

(i) The hospital's posting(s) of its standard charges, if available.

(ii) Material the hospital timely previously submitted to CMS (including with respect to corrective actions and corrective action plans).

(iii) Material CMS used to monitor and assess the hospital's compliance according to § 180.70(a)(2).

(5) The ALJ's consideration of evidence of acts other than those at

issue in the instant case under § 150.445(g) of this title does not apply.

§ 180.110 Failure to request a hearing.

(a) If a hospital does not request a hearing within 30 calendar days of the issuance of the notice of imposition of a civil monetary penalty described in § 180.90(b), CMS may impose the civil monetary penalty indicated in such notice and may impose additional penalties pursuant to continuing violations according to § 180.90(f) without right of appeal in accordance with this part.

(1) If the 30th calendar day described paragraph (a) of this section is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(2) [Reserved]

(b) The hospital has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with § 150.405 of this title, unless the hospital can show good cause, as determined at § 150.405(b) of this title, for failing to timely exercise its right to a hearing.

181–199 [RESERVED]

Dated: June 21, 2019.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: June 24, 2019.

Alex M Azar II,

Secretary, Department of Health and Human Services.

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Part III

Securities and Exchange Commission

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Notice of Filing of a Proposed Rule Change To Amend and Restate the MSRB's August 2, 2012 Interpretive Notice Concerning the Application of Rule G–17 to Underwriters of Municipal Securities; Notice

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86572; File No. SR–MSRB–2019–10]

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Notice of Filing of a Proposed Rule Change To Amend and Restate the MSRB's August 2, 2012 Interpretive Notice Concerning the Application of Rule G–17 to Underwriters of Municipal Securities

August 5, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 1, 2019 the Municipal Securities Rulemaking Board (''MSRB'') 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 MSRB. 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 MSRB filed with the Commission a proposed rule change (the ''proposed rule change'') to amend and restate the MSRB's August 2, 2012 interpretive notice concerning the application of MSRB Rule G–17 to underwriters of municipal securities (the ''2012 Interpretive Notice'').[3] The proposed rule change seeks to update the 2012 Interpretive Notice in light of its implementation in the market since its first adoption and current market practices.

Following the approval of the proposed rule change, the MSRB will publish a regulatory notice within 90 days of the publication of approval in the **Federal Register** (the 2012 Interpretive Notice, so amended by the proposed rule change, is referred to herein as the ''Revised Interpretive Notice''), and such notice shall specify the compliance date for the amendments described in the proposed rule change, which in any case shall be not less than 90 days, nor more than one year, following the date of the notice establishing such compliance date. Until such compliance date, the current version of the 2012 Interpretive Notice would remain in effect with respect to underwriting relationships commenced prior to the compliance date, at which time underwriters would then be subject to the Revised Interpretive Notice for all of their underwriting relationships beginning on or after that date. The 2012 Interpretive Notice would be superseded by the Revised Interpretive Notice as of such compliance date. Similarly, and as further described herein, the MSRB's implementation guidance dated July 18, 2012 concerning the 2012 Interpretive Notice (the ''Implementation Guidance'') [4] and the regulatory guidance dated March 25, 2013 answering certain frequently asked questions regarding the 2012 Interpretive Notice (the ''FAQs'') [5] would be withdrawn as of such compliance date.

The text of the proposed rule change is available on the MSRB's website at *www.msrb.org/Rules-and-Interpretations/SEC-Filings/2019-Filings.aspx,* at the MSRB's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the MSRB 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 MSRB 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

I. Background

Rule G–17 requires that, in the conduct of municipal securities activities, brokers, dealers and municipal securities dealers (collectively, ''dealers'') deal fairly with all persons, including municipal entity issuers, and not engage in any deceptive, dishonest or unfair practice. The 2012 Interpretive Notice describes certain fair dealing obligations dealers owe to issuers in the course of their underwriting relationships, and promotes fair dealing in the municipal securities market by, among other things, prescribing the delivery of written disclosures to issuers regarding the nature of their underwriting relationships, compensation and other conflicts, and the risks associated with certain recommended municipal security transactions in negotiated offerings. Beyond these matters, the 2012 Interpretive Notice also describes an underwriter's obligation to: Have a reasonable basis for the representations it makes, and other material information it provides, to an issuer in order to ensure that such representations are accurate and not misleading; purchase securities from the issuer at a fair and reasonable price, taking into consideration all relevant factors, including the best judgment of the underwriter as to the fair market value of the issue at the time of pricing; honor the issuer's rules for retail order periods by, among other things, not accepting or placing orders that do not satisfy the issuer's definition of ''retail;'' and avoid certain lavish gifts and entertainment.[6]

II. Proposed Rule Change

In response to informal feedback from market participants regarding their experience with the 2012 Interpretive Notice and, particularly, the effectiveness of the disclosures and related requirements, the MSRB initiated a retrospective review of the 2012 Interpretive Notice and published a request for comment on June 5, 2018 (the ''Concept Proposal'').[7] The Concept Proposal requested feedback on whether amendments to the 2012 Interpretive Notice should be considered to help ensure that it continues to achieve its intended purpose and reflects the current state of the municipal securities market. The MSRB received five comment letters in response to the Concept Proposal, all of which supported the retrospective review and suggested modifications to the 2012 Interpretive Notice.[8] The feedback

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The 2012 Interpretive Notice was approved by the SEC on May 4, 2012 and became effective on August 2, 2012. *See* Release No. 34–66927 (May 4, 2012); 77 FR 27509 (May 10, 2012) (File No. SR–MSRB–2011–09); and MSRB Notice 2012–25 (May 7, 2012). The 2012 Interpretive Notice is available here.

[4] *See* MSRB Notice 2012–38 (July 18, 2012).

[5] *See* MSRB Notice 2013–08 (Mar. 25, 2013).

[6] As further described therein, the 2012 Interpretive Notice provides that, except where otherwise noted, the obligations described are only applicable to negotiated offerings and do not apply to selling group members.

[7] MSRB Notice 2018–10 (June 5, 2018) (*i.e.,* the Concept Proposal).

[8] *See* Letters from: Mike Nicholas, Chief Executive Officer, Bond Dealers of America (BDA), dated August 6, 2018 (''BDA Letter I''); Emily S. Brock, Director, Federal Liaison Center, Government Finance Officers Association (GFOA), dated August 6, 2018 (''GFOA Letter I''); Susan Gaffney, Executive Director, National Association of Municipal Advisors (NAMA), dated August 6, 2018 (''NAMA Letter I''); Leslie M. Norwood, Managing Director and Associate General Counsel, Securities Industry and Financial Markets Association

received formed the foundation for a subsequent request for comment published on November 16, 2018 (the ''Request for Comment'').[9] The MSRB received five comment letters in response to the Request for Comment.[10] Following review of the comments, the MSRB conducted additional outreach with various market participants. The feedback received and follow-up conversations formed the basis for the proposed rule change.

In general, the comment letters observed that the disclosures under the 2012 Interpretive Notice had become too voluminous in length and boilerplate in nature. Commenters generally stated that the length and nature of the disclosures both created a significant burden for dealers and also made it difficult for issuers to assess which conflicts, risks, and other matters were most significant. As more fully discussed below in the MSRB's summary of comments, commenters also addressed the following major topics—the redundancy of certain disclosures received by an issuer, particularly if an issuer frequently goes to market and/or a syndicate is formed in a particular offering; the benefits of separately identifying certain categories of disclosures; the standard applicable to determine whether an underwriter has made a recommendation to an issuer of a particular municipal securities financing; what potential material conflicts of interest must be disclosed by an underwriter; whether an underwriter must disclose the conflicts of other parties involved with the transaction; underwriter communications regarding the issuer's engagement of a municipal advisor; what an underwriter may rely upon to substantiate an issuer's receipt of a disclosure; and various other clarifications and revisions to the 2012 Interpretive Notice that would promote market efficiency and reduce the regulatory burden on underwriters, while not diminishing the protections afforded to municipal entity issuers.

The amendments in the proposed rule change are intended to update and streamline certain obligations specified in the 2012 Interpretive Notice and, thereby, benefit issuers and underwriters alike by reducing the burdens associated with those obligations, including the obligation of underwriters to make, and the burden on issuers to acknowledge and review, written disclosures that itemize risks and conflicts that are unlikely to materialize during the course of a transaction, not unique to a given transaction or a particular underwriter where a syndicate is formed, and/or otherwise duplicative.

A. Consolidating the 2012 Interpretive Notice, the Implementation Guidance, and the FAQs Into the Revised Interpretive Notice and Related Revisions

The proposed rule change would integrate the substantive concepts from the Implementation Guidance [11] and the FAQs [12] into the Revised Interpretive Notice and, thereby, would consolidate the Implementation Guidance, FAQs, and the Revised Interpretive Notice into a single publication. Except as described herein, the proposed rule change would incorporate the substantive content of the Implementation Guidance and FAQs without material revision. Along with the 2012 Interpretive Notice, assuming approval of the proposed rule change, the Implementation Guidance and FAQs would be withdrawn as of the compliance date of the Revised Interpretive Notice. The proposed technical revisions are necessary to conform or supplement the statements from the Implementation Guidance and FAQs into the Revised Interpretive Notice.[13] Unless otherwise expressly stated herein, the MSRB's conforming edits are only intended to promote consistency of language and otherwise are not intended to substantively alter the understanding and implementation of these existing fair dealing concepts.

i. Incorporate Statements Regarding the Applicability of the Revised Interpretive Notice to the Continuous Offering of Municipal Fund Securities

As presently stated in the Implementation Guidance, no type of underwriting is wholly excluded from the application of the 2012 Interpretive Notice. The Implementation Guidance makes clear that the 2012 Interpretive Notice applies not only to primary offerings of new issues of municipal bonds and notes by an underwriter, but also to a dealer serving as primary distributor (but not to dealers serving solely as selling dealers) in a continuous offering of municipal fund securities, such as interests in 529 savings plans.[14] The proposed rule change would incorporate this language into the Revised Interpretive Notice as stated in the Implementation Guidance with one addition. More specifically, the proposed rule change would add a reference to Achieving a Better Life Experience (ABLE) programs [15] as another example of a continuous offering of municipal fund securities. In relevant part, the Revised Interpretive Notice would read, ''[t]his notice applies not only to a primary offering of a new issue of municipal securities by an underwriter, but also to a dealer serving as primary distributor (but not to dealers serving solely as selling dealers) in a continuous offering of municipal fund securities, such as interests in 529 savings plans and Achieving a Better Life Experience (ABLE) programs.''

(SIFMA), dated August 6, 2018 (''SIFMA Letter I''); and J. Ben Watkins III, Director, State of Florida, Division of Bond Finance of the State Board of Administration (''Florida Division of Bond Finance''), dated August 8, 2018 (''Florida Division of Bond Finance Letter'').

[9] *See* MSRB Notice 2018–29 (November 16, 2018) (*i.e.,* the Request for Comment).

[10] *See* Letters from: Mike Nicholas, Chief Executive Officer, BDA, dated January 15, 2019 (''BDA Letter II''); Emily S. Brock, Director, Federal Liaison Center, GFOA, dated January 15, 2019 (''GFOA Letter II''); Susan Gaffney, Executive Director, NAMA, dated January 15, 2019 (''NAMA Letter II''); Leslie M. Norwood, Managing Director and Associate General Counsel, SIFMA, dated January 15, 2019 (''SIFMA Letter II''); and City of San Diego (unsigned and undated) (''City of San Diego Letter'').

[11] Published on July 18, 2012, the Implementation Guidance was intended to assist dealers in revising their written supervisory procedures in accordance with their fair practice obligations under the 2012 Interpretive Notice.

[12] Published on March 25, 2013, the FAQs answered certain frequently asked questions regarding operational matters pertaining to the 2012 Interpretive Notice.

[13] The MSRB notes that the Implementation Guidance and FAQs were issued in distinct formats—*i.e.,* in a list of bulleted statements and frequently asked questions, respectively—from the format of the 2012 Interpretive Notice and, consequently, in many instances cannot be simply copied-and-pasted into the proposed format of the Revised Interpretive Notice without conforming revisions. Similarly, the proposed rule change incorporates newly defined terms and other modified substantive concepts (*e.g.,* assigning the fair dealing obligation to provide the standard disclosures and transaction-specific disclosures to syndicate managers, as further described herein), which require tailoring edits to appropriately integrate the existing concepts of the Implementation Guidance and FAQs into the Revised Interpretive Notice. Thus, the MSRB is proposing to make conforming technical revisions of a non-substantive, drafting nature when integrating the existing language of the Implementation Guidance and FAQs into the Revised Interpretive Notice (referred to hereinafter as, ''conforming edits''). The MSRB has identified in the discussion below when it has proposed such conforming edits and also provided the proposed language of the Revised Interpretive Notice in relevant part for ease of comparison.

[14] As a general matter, a 529 savings plan is a tax-advantaged qualified tuition program established by a state, or an agency, or instrumentality of a state, designed to encourage families to save for a child's future education expenses.

[15] As a general matter, an ABLE program is a tax-advantaged savings account established by a state, or an agency, or instrumentality of a state, designed to allow eligible individuals and their families to save on a tax-deferred basis for qualified disability expenses.

ii. Incorporate Statements Regarding the Applicability of the Revised Interpretive Notice to a Primary Offering That Is Placed With Investors by a Placement Agent

As presently stated in the Implementation Guidance, no type of underwriting is wholly excluded from the application of the 2012 Interpretive Notice, including certain private placement activities. In relevant part, the Implementation Guidance states:

> In a private placement where a dealer acting as placement agent takes on a true agency role with the issuer and does not take a principal position (including not taking a 'riskless principal' position) in the securities being placed, the disclosure relating to an 'arm's length' relationship would be inapplicable and may be omitted due to the agent-principal relationship between the dealer and issuer that normally gives rise to state law obligations—whether termed as a fiduciary or other obligation of trust. . . . As described [in the Implementation Guidance], in a private placement where a dealer acts as a true placement agent, the disclosure relating to fiduciary duty would be inapplicable and may be omitted due to the existence of similar state law obligations. . . . In many private placements, as well as in certain other types of new issue offerings, no official statement may be produced, so that to the extent that such an offering occurs without the production of an official statement, the dealer would not be required to disclose its role with regard to the review of an official statement.

In a footnote to this language, the Implementation Guidance further states:

> In certain other contexts, depending on the specific facts and circumstances, a dealer acting as an underwriter or primary distributor may take on, either through an agency arrangement or other purposeful understanding, a fiduciary relationship with the issuer. In such cases, it would also be appropriate for the underwriter to omit disclosures inapplicable as a result of such relationship. Dealers exercising an option to omit such disclosure should understand that they are effectively acknowledging the existence of a fiduciary responsibility on behalf of the issuer.

The proposed rule change would incorporate these concepts from the Implementation Guidance into the Revised Interpretive Notice with conforming edits and the omission of certain language. It also would incorporate a supplemental concept regarding how a dealer's activities as a placement agent may interact with the Commission's registration and record-keeping requirements for municipal advisors.[16]

In terms of the conforming edits, the proposed rule change would not word-for-word integrate the existing text that, ''. . . in a private placement where a dealer acts as a true placement agent, the disclosure relating to a fiduciary duty would be inapplicable and may be omitted due to the existence of similar state law obligations.'' In light of the other amendments proposed herein, the proposed rule change would revise and supplement the existing text with the following conforming edits that, ''it would also be appropriate for an underwriter to omit *those* disclosures inapplicable as a result of such relationship *and the existence of any analogous legal obligations under other law, such as certain fiduciary duties existing pursuant to applicable state law*'' (emphasis added). The MSRB believes that the guidance provided by this revised and supplemented language is substantively equivalent to the concept articulated by the omitted statement.

Additionally, the proposed rule change would omit the final sentence from the footnote of the Implementation Guidance stating that, ''[d]ealers exercising an option to omit such disclosure should understand that they are effectively acknowledging the existence of a fiduciary responsibility on behalf of the issuer.'' The MSRB believes that this statement is substantively redundant with the statements that precede it and, ultimately, may create more confusion than it would resolve, as its inclusion in the Revised Interpretive Notice might be interpreted to bind underwriters into a binary scenario of either: (1) Including the relevant disclosure(s) and, thereby, communicating the lack of a fiduciary duty to an issuer client, or (2) omitting the relevant disclosure(s) and, thereby, ''effectively acknowledging'' the existence of a fiduciary duty to an issuer client. At bottom, an underwriter has a fair dealing obligation under Rule G–17 to not engage in any deceptive, dishonest, or unfair practice when interacting with a municipal entity client in the course of an underwriting relationship, which requires the underwriter to accurately, honestly, and fairly describe its services and the scope of its relationship with the municipal entity. This overarching fair dealing obligation requires an underwriter to include, omit, and/or supplement the relevant fiduciary disclosures as necessary to meet its fair dealing obligations in light of the particular facts and circumstances of a given transaction. Consequently, the exclusion of this statement from the proposed rule change is not intended to diminish this overarching fair dealing obligation, but, rather, eliminate a potentially confusing and redundant statement.

The Revised Interpretive Notice in relevant part would provide:

> In a private placement where a dealer acting as placement agent takes on a true agency role with the issuer and does not take a principal position (including not taking a 'riskless principal' position) in the securities being placed, the disclosure relating to an 'arm's length' relationship would be inapplicable and may be omitted due to the agent-principal relationship between the dealer and issuer that commonly gives rise to other duties as a matter of common law or another statutory or regulatory regime—whether termed as a fiduciary or other obligation of trust. . . . In certain other contexts, depending on the specific facts and circumstances, a dealer acting as an underwriter or primary distributor may take on, either through an agency arrangement or other purposeful understanding, such a fiduciary relationship with the issuer. In such cases, it would also be appropriate for an underwriter to omit those disclosures inapplicable as a result of such relationship and the existence of any analogous legal obligations under other law, such as certain fiduciary duties existing pursuant to applicable state law.

In addition, the proposed rule change would update the 2012 Interpretive Notice by incorporating supplemental language into the Revised Interpretive Notice intended to harmonize it with the Commission's adoption of its permanent rules regarding the registration and record-keeping requirements applicable to municipal advisors, and related exclusions and exceptions, which went into effect after the effective date of the 2012 Interpretive Notice.[17] The Revised Interpretive Notice would also incorporate language regarding the application of the exclusion from the definition of ''municipal advisor'' applicable to dealers acting as underwriters pursuant to Exchange Act Rule 15Ba1–1(d)(2)(i)[18] and the

[16] *See* Registration of Municipal Advisors, Release No. 34–70462 (September 20, 2013), 78 FR 67467 (hereinafter, the ''MA Rule Adopting Release'') (November 12, 2013) (available at *http://www.sec.gov/rules/final/2013/34-70462.pdf*); *see also* note 18 *infra* and related text.

[17] *See* Final MA Adopting Release (citation and link at note 16 *supra*).

[18] *See* Final MA Rule Adopting Release, 78 FR at 67515–67516 (stating: ''The Commission does not believe that the underwriter exclusion should be limited to a particular type of underwriting or a particular type of offering. Therefore, if a registered broker-dealer, acting as a placement agent, performs municipal advisory activities that otherwise would be considered within the scope of the underwriting of a particular issuance of municipal securities as discussed [therein], the broker-dealer would not have to register as a municipal advisor.''); *see also* the Final MA Rule Adopting Release, 78 FR at 67513–67514 (discussing activities within and outside the scope of serving as an underwriter of

application of this underwriter exclusion to a dealer's placement agent activities. In relevant part, the Revised Interpretive Notice would state:

A dealer acting as a placement agent in the primary offering of a new issuance of municipal securities should also consider how the scope of its activities may interact with the registration and record-keeping requirements for municipal advisors adopted by the Securities and Exchange Commission (the 'Commission') under Section 15B of the Exchange Act (15 U.S.C. 78o–4), including the application of the exclusion from the definition of 'municipal advisor' applicable to a dealer acting as an underwriter pursuant to Exchange Act Rule 15Ba1–1(d)(2)(i).

The MSRB believes that the guidance provided by this harmonizing language is in keeping with the existing references included in the 2012 Interpretive Notice and its guidance regarding the existence of other relevant or similar legal obligations that could have a bearing on an underwriter's fair dealing obligations under Rule G–17.

iii. Incorporate Statements Regarding Negotiated Offerings and Defining Negotiated and Competitive Offerings for Purposes of the Revised Interpretive Notice

By its terms, and as presently stated in the Implementation Guidance, the 2012 Interpretive Notice applies primarily to negotiated offerings of municipal securities, with many of its provisions not applicable to competitive offerings. The Implementation Guidance clarifies what constitutes a negotiated offering for purposes of the 2012 Interpretive Notice, stating that:

The MSRB has always viewed competitive offerings narrowly to mean new issues sold by the issuer to the underwriter on the basis of the lowest price bid by potential underwriters—that is, the fact that an issuer publishes a request for proposals and potential underwriters compete to be selected based on their professional qualifications, experience, financing ideas, and other subjective factors would not be viewed as representing a competitive offering for purposes of the Notice. In light of this meaning of the term 'competitive underwriting,' it should be clear that, although most of the examples relating to misrepresentations and fairness of financial aspects of an offering consist of situations that would only arise in a negotiated offering, Rule G–17 should not be viewed as allowing an underwriter in a competitive underwriting to make misrepresentations to the issuer or to act unfairly in regard to the financial aspects of the new issue.

The proposed rule change would incorporate this language into the Revised Interpretive Notice as stated in the Implementation Guidance. In relevant part, the Revised Interpretive Notice would read:

The MSRB has always viewed competitive offerings narrowly to mean new issues sold by the issuer to the underwriter on the basis of the lowest price bid by potential underwriters—that is, the fact that an issuer publishes a request for proposals and potential underwriters compete to be selected based on their professional qualifications, experience, financing ideas, and other subjective factors would not be viewed as representing a competitive offering for purposes of this notice. In light of this meaning of the term 'competitive underwriting,' it should be clear that, although most of the examples relating to misrepresentations and fairness of financial aspects of an offering consist of situations that would only arise in a negotiated offering, Rule G–17 should not be viewed as allowing an underwriter in a competitive underwriting to make misrepresentations to the issuer or to act unfairly in regard to the financial aspects of the new issue.

iv. Incorporate Statements Regarding the Applicability of the Revised Interpretive Notice to Persons Other Than Issuers of Municipal Securities and Update the Definition of Municipal Entities

The 2012 Interpretive Notice outlines the duties that a dealer owes to an issuer of municipal securities when the dealer underwrites a new issuance. As explained in the Implementation Guidance, the 2012 Interpretive Notice ''does not set out the underwriter's fair dealing obligations to other parties involved with a municipal securities financing, including a conduit borrower.'' As discussed further below,[19] the MSRB sought feedback in the Concept Release and Request for Proposal regarding whether the 2012 Interpretive Notice should be amended to incorporate specifics regarding how an underwriter must fulfill its obligations to a conduit borrower. Ultimately, the MSRB decided not to incorporate such an amendment in the proposed rule change for the reasons discussed further herein, including that the issues presented by the relationship between underwriters and conduit borrowers are sufficiently distinct to merit their own full consideration in separate guidance. Accordingly, the proposed rule change would incorporate the language from the Implementation Guidance into the Revised Interpretive Notice with conforming edits, stating ''[t]his notice does not set out the underwriter's fair-practice duties to other parties to a municipal securities financing (*e.g.,* conduit borrowers).''

The proposed rule change would also update the definition of ''municipal entity'' as used in the 2012 Interpretive Notice. In relevant part, the Revised Interpretive Notice would read, ''. . . the term 'municipal entity' is used as defined by Section 15B(e)(8) of the Securities Exchange Act of 1934 (the 'Exchange Act'), 17 CFR 240.15Ba1–1(g), and other rules and regulations thereunder.'' This revision would harmonize the Revised Interpretive Notice with the Final MA Rules and MSRB Rule G–42.[20] The MSRB believes this revision to be non-substantive.

v. Incorporate Statements Regarding Underwriters' Discouragement of the Engagement of a Municipal Advisor

The Implementation Guidance further clarifies the scope of the prohibition included in the 2012 Interpretive Notice, affirming that an underwriter must not recommend that the issuer not retain a municipal advisor. The prior guidance states that ''an underwriter may not discourage an issuer from using a municipal advisor or otherwise imply that the hiring of a municipal advisor would be redundant because the underwriter can provide the same services that a municipal advisor would.'' The proposed rule change would incorporate this language into the Revised Interpretive Notice as stated in the Implementation Guidance with conforming edits.[21] In relevant part, the Revised Interpretive Notice would provide:

Underwriters also must not recommend issuers not retain a municipal advisor. Accordingly, underwriters may not discourage issuers from using a municipal advisor or otherwise imply that the hiring of a municipal advisor would be redundant

a particular issuance of municipal securities for purposes of the underwriter exclusion).

[19] Relatedly, the comments received by the MSRB regarding the incorporation of this language are discussed further below in the MSRB's summary of comments. *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Disclosures to Conduit Borrowers* and related notes 137 *et. seq. infra; see also Summary of Comments Received in Response to the Request for Comment—Disclosures to Conduit Borrowers* and related note 228.

[20] *See* Rule G–42(f)(vi) (''Municipal entity' shall, for purposes of [Rule G–42], have the same meaning as in Section 15B(e)(8) of the Act, 17 CFR 240.15Ba1–1(g) and other rules and regulations thereunder.'').

[21] Relatedly, the comments received by the MSRB regarding the incorporation of this language are discussed further below in the MSRB's summary of comments. *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Underwriter Discouragement of Use of Municipal Advisor; Addition of a New Standard Disclosure Regarding the Engagement of Municipal Advisors* and related notes 134 *et. seq. infra,* and *Summary of Comments Received in Response to the Request for Comment—Inclusion of Existing Language Regarding the Discouragement of an Issuer's Engagement of a Municipal Advisor and Incorporation of a New Standard Disclosure Regarding the Issuer's Choice to Engage a Municipal Advisor* and related notes 201 *et. seq. infra.*

because the sole underwriter or underwriting syndicate can provide the services that a municipal advisor would.

The MSRB believes this revision to be a non-substantive incorporation of existing guidance. The comments the MSRB received in response to this change are discussed herein in the MSRB's summary of comments.[22]

vi. Incorporate Statements Regarding Third-Party Payments

The Implementation Guidance clarifies the obligation of underwriters to disclose certain third-party payments, as well as other payments, values or credits received by an underwriter. More specifically, the 2012 Implementation Guidance states, ''[t]he third-party payments to which the disclosure requirement under the [2012 Interpretive Notice] would apply are those that give rise to actual or potential conflicts of interest and typically would not apply to third-party arrangements for products and services of the type that are routinely entered into in the normal course of business, so long as any specific routine arrangement does not give rise to an actual or potential conflict of interest.'' The Implementation Guidance further states that, ''[e]ven though . . . the [2012 Interpretive Notice] specifically requires disclosure of the existence of any incentives for the underwriter to recommend a complex municipal securities financing or any other conflicts of interest associated with such recommendation, the specific requirement with respect to complex financings does not obviate the requirement to disclose the existence of payments, values, or credits received by the underwriter or of other material conflicts of interest in connection with any negotiated underwriting, whether it be complex or routine.''

The proposed rule change would incorporate this language into the Revised Interpretive Notice as stated in the Implementation Guidance with the following exception and conforming edits. The proposed rule change omits the statements from the 2012 Implementation Guidance that the disclosure, ''. . . typically would not apply to third-party arrangements for products and services of the type that are routinely entered into in the normal course of business, so long as any specific routine arrangement does not give rise to an actual or potential conflict of interest.'' The MSRB views this language to be redundant with the prior language regarding the applicability of the disclosure to only those third-party payments that give rise to actual material conflicts of interest or potential material conflicts of interest. Consequently, the MSRB views the omission of this text as non-substantive. Thus, with this omission and the conforming edits, the Revised Interpretive Notice would read in relevant part:

> The third-party payments to which the disclosure standard would apply are those that give rise to actual material conflicts of interest or potential material conflicts of interest only. . . . The specific standard with respect to complex financings does not obviate a dealer's fair dealing obligation to disclose the existence of payments, values, or credits received by the underwriter or of other material conflicts of interest in connection with any negotiated underwriting, whether it be complex or routine.

vii. Incorporate Statements Regarding the Need for Each Underwriter in a Syndicate To Deliver Dealer-Specific Conflicts of Interest When Applicable

The FAQs clarify what disclosures may be effected by a syndicate manager on behalf of co-managing underwriters in the syndicate. As stated in the FAQs:

> In general, disclosures of dealer-specific conflicts of interest cannot be satisfied by disclosures made by the syndicate manager because such disclosures are, by their nature, not uniform, and must be prepared by each dealer. However, nothing in the [2012 Interpretive Notice] or [Implementation Guidance] would preclude a syndicate manager from delivering each of the dealer-specific conflicts to the issuer as part of a single package of disclosures. . . . The [2012 Interpretive Notice] does not require an underwriter to notify an issuer if it has determined that it does not have an actual or potential conflict of interest subject to disclosure. However, underwriters are reminded that the obligation to disclose actual or potential conflicts of interest includes conflicts arising after the time of engagement with the issuer, as [further noted in the FAQs].

Despite certain other amendments discussed herein that would require the syndicate manager to deliver the standard disclosures and transaction-specific disclosures where a syndicate is formed, these statements regarding the dealer-specific disclosures in the FAQs would remain true and accurate under the Revised Interpretive Notice. Accordingly, the proposed rule change would incorporate this language into the Revised Interpretive Notice as stated in the FAQs with conforming edits, including the technical clarification that such disclosures apply to ''actual material conflicts of interest'' and ''potential material conflicts of interest'' in order to make the statements consistent with related amendments in the proposed rule change.[23] In relevant part, the Revised Interpretive Notice would read:

> In general, dealer-specific disclosures for one dealer cannot be satisfied by disclosures made by another dealer (*e.g.,* the syndicate manager) because such disclosures are, by their nature, not uniform, and must be prepared by each dealer. However, a syndicate manager may deliver each of the dealer-specific disclosures to the issuer as part of a single package of disclosures, as long as it is clear to which dealer each disclosure is attributed. An underwriter in the syndicate is not required to notify an issuer if it has determined that it does not have any dealer-specific disclosures to make. However, the obligation to provide dealer-specific disclosures includes material conflicts of interest arising after the time of engagement with the issuer, as noted [therein].

viii. Incorporate Statements Regarding the Timing for the Delivery of Certain Disclosures

The Implementation Guidance and FAQs clarify the timing for the delivery of the disclosures under the 2012 Interpretive Notice. More specifically, the Implementation Guidance states that, ''[n]ot all transactions proceed along the same timeline or pathway and on rare occasions precise compliance with some of the timeframes set out in the [2012 Interpretive Notice] may not be feasible.'' It further states:

> The timeframes set out in the [2012 Interpretive Notice] should be viewed in light of the overarching goals of Rule G–17 and the purposes that required disclosures are intended to serve as described in the [2012 Interpretive Notice]. . . . That is, the issuer (i) has clarity throughout all substantive stages of a financing regarding the roles of its professionals, (ii) is aware of conflicts of interest promptly after they arise and well before it effectively becomes fully committed (either formally or due to having already expended substantial time and effort) to completing the transaction with the underwriter, and (iii) has the information required to be disclosed with sufficient time to take such information into consideration before making certain key decisions on the financing.

[22] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Underwriter Discouragement of Use of Municipal Advisor* and under *Summary of Comments Received in Response to the Request for Comment—Inclusion of Existing Language Regarding the Discouragement of an Issuer's Engagement of a Municipal Advisor and Incorporation of a New Standard Disclosure Regarding the Issuer's Choice to Engage a Municipal Advisor* and related notes 201 *et. seq. infra.*

[23] The MSRB notes that the proposed rule change would preserve existing language from the 2012 Interpretive Notice that the syndicate manager may deliver the dealer-specific disclosures of the other syndicate members in a single package, but the MSRB views this simply as a permissive function of delivery rather than an obligation to craft adequate disclosures on the part of other parties.

On this particular point, the Implementation Guidance concludes by stating that, ''. . . the timeframes set out in the [2012 Interpretive Notice] are not intended to establish hair-trigger tripwires resulting in technical rule violations so long as underwriters act in substantial compliance with such timeframes and have met the key objectives for providing such disclosures under the [2012 Interpretive Notice].''

The FAQs provide that certain disclosures be made at different points in a transaction. More specifically, the FAQs specify that:

- The underwriter's disclosure regarding the arm's length nature of the relationship must be disclosed ''at the earliest stage of the relationship, generally at or before a response to a request for proposals or promotional materials are delivered to an issuer;''
- the other role disclosures and disclosures regarding the underwriter's compensation must be disclosed ''[a]t or before the time the underwriter has been engaged to perform the underwriting services;''
- those dealer-specific conflicts of interest known at the time of the engagement must be disclosed ''[a]t or before the time the dealer has been engaged to serve as underwriter'' in the case of a sole underwriter or syndicate manager where a syndicate has been formed;
- a co-managing underwriter joining a syndicate must disclose any dealer-specific conflicts of interest known at that time concurrent with the formation of the syndicate or upon the co-managing underwriter joining an already-formed syndicate;
- those dealer-specific conflicts of interest discovered or arising after being engaged as an underwriter must be disclosed ''as soon as practicable after [being] discovered and with sufficient time for the issuer to evaluate the conflict and its implications;''
- any conflicts arising in connection with a recommendation of a complex municipal securities financing must be disclosed ''[b]efore the execution of a commitment by the issuer (which may include a bond purchase agreement) relating to such recommendation, and with sufficient time to allow the issuer to evaluate the conflict and its implication;''
- the disclosures regarding the material aspects of a routine financing must be disclosed ''[b]efore the execution of a commitment by the issuer (which may include a bond purchase agreement) relating to the financing, and with sufficient time to allow the issuer to evaluate the features of the financing;'' and
- the disclosures regarding the material financial risks and characteristics of a complex financing must be disclosed ''[b]efore the execution of a commitment by the issuer (which may include a bond purchase agreement) relating to the financing, and with sufficient time to allow the issuer to evaluate the features of the financing.''

The proposed rule change would incorporate these timeline concepts from the Implementation Guidance and FAQs into the Revised Interpretive Notice with certain conforming edits (*e.g.,* by utilizing the Revised Interpretive Notice's defined terms of ''standard disclosure'', ''dealer-specific disclosures,'' and ''transaction-specific disclosures'').

The proposed rule change would also incorporate clarifying language regarding the intent of these timelines. More specifically, the intent that the timelines are defined to ensure that underwriters act promptly to deliver disclosures in light of all the relevant facts and circumstances, but are not ''intended to establish strict, hair-trigger tripwires resulting in mere technical rule violations.'' [24] In relevant part, the Revised Interpretive Notice would read:

> The MSRB acknowledges that not all transactions proceed along the same timeline or pathway. The timeframes expressed herein should be viewed in light of the overarching goals of Rule G–17 and the purposes that the disclosures are intended to serve as further described in this notice. The various timeframes set out in this notice are not intended to establish strict, hair-trigger tripwires resulting in mere technical rule violations, so long as an underwriter acts in substantial compliance with such timeframes and meets the key objectives for providing disclosure under the notice. Nevertheless, an underwriter's fair dealing obligation to an issuer of municipal securities in particular facts and circumstances may demand prompt adherence to the timelines set out in this notice. Stated differently, if an underwriter does not timely deliver a disclosure and, as a result, the issuer: (i) Does not have clarity throughout all substantive stages of a financing regarding the roles of its professionals, (ii) is not aware of conflicts of interest promptly after they arise and well before the issuer effectively becomes fully committed—either formally (*e.g.,* through execution of a contract) or informally (*e.g.,* due to having already expended substantial time and effort)—to completing the transaction with the underwriter, and/or (iii) does not have the information required to be disclosed with sufficient time to take such information into consideration and, thereby, to make an informed decision about the key decisions on the financing, then the underwriter generally will have violated its fair-dealing obligations under Rule G–17, absent other mitigating facts and circumstances.

[24] Relatedly, the comments received by the MSRB regarding the incorporation of this language are discussed further below in the MSRB's summary of comments. *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Consolidating the 2012 Interpretive Notice, the Implementation Guidance, and the FAQs into a Single Interpretive Notice—Modification of Implementation Guidance's Language Regarding the ''No Hair-Trigger''* and related note 95 and *Summary of Comments Received in Response to the Request for Comment—Consolidating the 2012 Interpretive Notice, the Implementation Guidance, and the FAQs into a Single Interpretive Notice—Reincorporation of the ''No Hair-Trigger'' Language from the Implementation Guidance* and related notes 157 *et. seq. infra.*

ix. Incorporate Statements Regarding Whether Underwriters May Rely on Certain Representations of Issuer Officials

The FAQs clarify the circumstances under which an underwriter may rely on the representations of issuer officials, stating:

> Absent red flags, an underwriter may reasonably rely on a written representation from an issuer official in, among other things, the issuer's request for proposals that he or she has the ability to bind the issuer by contract with the underwriter. Moreover, the underwriter may reasonably rely on a written statement from such person that he or she is not a party to a disclosed conflict.

The proposed rule change would incorporate this language from the FAQs into the Revised Interpretive Notice with clarifying language regarding the relevance of facts discovered during the course of an underwriter's due diligence, including diligence related to the transaction generally or pursuant to an underwriter's own determination of whether it has any actual material conflicts of interest or potential material conflicts of interest. Specifically, the Revised Interpretive Notice supplements the existing statement from the FAQs with the following text:

> The reasonableness of an underwriter's reliance on such a written statement will depend on all the relevant facts and circumstances, including the facts revealed in connection with the underwriter's due diligence in regards to the transaction generally or in determining whether the underwriter itself has any actual material conflicts of interest or potential material conflicts of interest that must be disclosed.

This statement is intended to clarify that if an underwriter becomes aware of a fact through the normal course of its diligence that would lead it to doubt a representation of an issuer official, such information may rise to the level of a red flag that would not allow the underwriter to reasonably rely on the written representation.

x. Incorporate Statements Regarding an Underwriter Having a Reasonable Basis for Its Representations and Other Material Information Provided to Issuers

The 2012 Interpretive Notice states that underwriters must ''have a reasonable basis for representations and other material information provided to issuers'' and clarifies that the obligation ''extends to the reasonableness of assumptions underlying the material information being provided.'' The Implementation Guidance further contextualizes this reasonable basis standard, stating:

> The less certain an underwriter is of the validity of underlying assumptions, the more cautious it should be in using such assumptions and the more important it will be that the underwriter disclose to the issuer the degree and nature of any uncertainties arising from the potential for such assumptions not being valid. . . . If an underwriter is uncomfortable having an issuer rely on any statements made or information provided to such issuer, it should refrain from making the statement or providing the information, or should provide any appropriate disclosures or other information that would allow the issuer to adequately assess the reliability of the statement or information. . . . As a general matter, a response to a request for proposal should not be treated as merely a sales pitch without regulatory consequence, but instead should be treated with full seriousness that issuers have the expectation that representations made in such responses are true and accurate. . . . Underwriters should be careful to distinguish statements made to issuers that represent opinion rather than factual information and to ensure that the issuer is aware of this distinction.

The proposed rule change would incorporate this language from the Implementation Guidance into the Revised Interpretive Notice with conforming edits and the following exception.[25] The proposed rule change omits the statements from the 2012 Implementation Guidance that:

> The less certain an underwriter is of the validity of underlying assumptions, the more cautious it should be in using such assumptions and the more important it will be that the underwriter disclose to the issuer the degree and nature of any uncertainties arising from the potential for such assumptions not being valid.

The MSRB views this statement to be potentially confusing and likely redundant with the preceding statement regarding the need for an underwriter to have a reasonable basis for its assumptions underlying any material information being provided to an issuer. Accordingly, the MSRB views the omission of this text as non-substantive. In relevant part, the Revised Interpretive Notice would read as follows:

> The need for underwriters to have a reasonable basis for representations and other material information provided to issuers extends to the reasonableness of assumptions underlying the material information being provided. If an underwriter would not rely on any statements made or information provided for its own purposes, it should refrain from making the statement or providing the information to the issuer, or should provide any appropriate disclosures or other information that would allow the issuer to adequately assess the reliability of the statement or information before relying upon it. Further, underwriters should be careful to distinguish statements made to issuers that represent opinion rather than factual information and to ensure that the issuer is aware of this distinction.

xi. Incorporate Statements Regarding Whether a Particular Recommended Financing Structure or Product Is Complex

The 2012 Implementation Guidance describes a complex municipal securities financing as ''a new issue financing that is structured in a unique, atypical, or otherwise complex manner that issuer personnel responsible for the issuance of municipal securities would not be well positioned to fully understand or to assess the implications of a financing in its totality.'' The Implementation Guidance clarifies that, ''[u]nderwriters must make reasonable judgments regarding whether a particular recommended financing structure or product is complex, understanding that the simple fact that a structure or product has become relatively common in the market does not automatically result in it being viewed as not complex.'' The 2012 Interpretive Notice then provides a non-exclusive, illustrative list of examples of new issue structures that constitute a complex municipal securities financing, inclusive of variable rate demand obligations (VRDOs); financings involving derivatives (such as swaps); and financings in which the interest rate is benchmarked to an index that is commonly used in the municipal marketplace (*e.g.,* LIBOR or SIFMA), which may be complex to an issuer that does not understand the components of that index or its possible interaction with other indexes.

The proposed rule change would incorporate this language from the Implementation Guidance into the Revised Interpretive Notice with conforming edits and an update to the illustrative, non-exclusive list of interest rate benchmarks to include the Secured Overnight Financing Rate (SOFR).[26] The MSRB believes this edit is a necessary update to ensure that the Revised Interpretive Notice would reflect current market practices. In relevant part, the Revised Interpretive Notice would read as follows, ''[e]xamples of complex municipal securities financings include, but are not limited to, variable rate demand obligations (VRDOs), financings involving derivatives (such as swaps), and financings in which interest rates are benchmarked to an index (such as LIBOR, SIFMA, or SOFR).'' The Revised Interpretive Notice would also incorporate the following footnote to this language:

> Respectively, the London Inter-bank Offered Rate (*i.e.,* 'LIBOR'), the SIFMA Municipal Swap Index (*i.e.,* 'SIFMA'), and Secured Overnight Financing Rate ('SOFR'). The MSRB notes that its references to LIBOR, SIFMA, and SOFR are illustrative only and non-exclusive. Any financings involving a benchmark interest rate index may be complex, particularly if an issuer is unlikely to fully understand the components of that index, its material risks, or its possible interaction with other indexes.

xii. Incorporate Statements Regarding the Specificity of Disclosures

The 2012 Interpretive Notice provides that an underwriter of a negotiated issue that recommends a complex municipal securities transaction or product to an issuer has an obligation to disclose all financial material risks known to the underwriter and reasonably foreseeable at the time of the disclosure, financial characteristics, incentives, and conflicts of interest regarding the transaction or product. The Implementation Guidance clarified the scope of this obligation, stating:

> The disclosures concerning a complex municipal securities financing must address the specific elements of the financing, rather than being general in nature. . . . An

[25] Relatedly, the comments received by the MSRB regarding the incorporation of this language are discussed further below in the MSRB's summary of comments. *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Consolidating the 2012 Interpretive Notice, the Implementation Guidance, and the FAQs into a Single Interpretive Notice—General Comments Encouraging the Consolidation of the Implementation Guidance, and the FAQs* and related notes 91 *et. seq. infra,* and *Summary of Comments Received in Response to the Request for Comment—Consolidating the 2012 Interpretive Notice, the Implementation Guidance, and the FAQs into a Single Interpretive Notice—Inclusion of Language Regarding a Reasonable Basis for Underwriter Representations* related note 155 *infra.*

[26] SOFR is published by the Federal Reserve Bank of New York and is based on a broad measure of the cost of borrowing cash overnight collateralized by U.S. Treasury securities in the repurchase agreement market. SOFR was chosen by the Alternative Reference Rates Committee (''ARRC'') as the rate that represents best practice for use in certain new USD derivatives and other financial contracts, representing the ARRC's preferred alternative to USD LIBOR. *See http://www.msrb.org/EducationCenter/Municipal-Market/About/Market/Market-Indicators.aspx.*

underwriter cannot satisfy this requirement by providing an issuer a single document setting out general descriptions of the various complex municipal securities financing structures or products it may recommend from time to time to its various issuer clients that would effectively require issuer personnel to discover which disclosures apply to a particular recommendation and to the particular circumstances of that issuer. . . . An underwriter can create, in advance, individualized descriptions, with appropriate levels of detail, of the material financial characteristics and risks for each of the various complex municipal securities financing structures or products (including any typical variations) it may recommend from time to time to its various issuer clients, with such standardized descriptions serving as the base for more particularized disclosure for the specific complex financing the underwriter is recommending to a particular issuer. The underwriter could incorporate, to the extent applicable, any refinements to the base description needed to fully describe the material financial features and risks unique to that financing.

The Implementation Guidance further states that ''[p]age after page of complex legal jargon in small print would not satisfy this requirement'' and that ''[u]nderwriters should be able to leverage such materials for purposes of assisting issuers to more efficiently prepare disclosures to the public included in official statements in a manner that promotes more consistent marketplace disclosure of a particular financing type from issue to issue, and also should be able to leverage the materials for internal training and risk management purposes.'' The Implementation Guidance also clarifies that ''[n]ot all negotiated offerings involve a recommendation by the underwriter, such as where an underwriter merely executes a transaction already structured by the issuer or its financial advisor.'' The proposed rule change would incorporate this language from the Implementation Guidance into the Revised Interpretive Notice with conforming edits and the following exception.

In terms of the exception, the proposed rule change omits the statement regarding how such materials might assist issuers. Accordingly, in relevant part, the Revised Interpretive Notice would simply read, ''[u]nderwriters should be able to leverage such materials for internal training and risk management purposes.'' The MSRB views this statement as unnecessary and so its deletion is non-substantive for purposes of the Revised Interpretive Notice.

xiii. Incorporate Statements Regarding Profit Sharing Arrangements

The 2012 Interpretive Notice states that, ''[a]rrangements between the underwriter and an investor purchasing new issue securities from the underwriter according to which profits realized from the resale by such investor of the securities are directly or indirectly split or otherwise shared with the underwriter also would, depending on the facts and circumstances (including in particular if such resale occurs reasonably close in time to the original sale by the underwriter to the investor), constitute a violation of the underwriter's fair dealing obligation under Rule G–17.'' The Implementation Guidance further clarifies that:

> Underwriters should be mindful that, depending on the facts and circumstances, such an arrangement may be inferred from a purposeful but not otherwise justified pattern of transactions or other course of action without the existence of a formal written agreement. . . . An underwriter should carefully consider whether any such arrangement, regardless of whether it constitutes a violation of MSRB Rule G–25(c) precluding a dealer from directly or indirectly sharing in the profits or losses of a transaction in municipal securities with or for a customer, may evidence a potential failure of the underwriter's duty with regard to new issue pricing [as further described in the Implementation Guidance].

The proposed rule change would incorporate this concept into the Revised Interpretive Notice as stated in the Implementation Guidance, which reads, in relevant part, ''[u]nderwriters should be mindful that, depending on the facts and circumstances, such an arrangement may be inferred from a purposeful but not otherwise justified pattern of transactions or other course of action, even without the existence of a formal written agreement.''

B. Amending the Nature, Timing, and Manner of Disclosures

The proposed rule change would define certain categories of underwriter disclosures and assign the responsibility for the delivery of certain disclosures to the syndicate manager in circumstances where a syndicate is formed, as further described below.

i. Define Certain Categories of Underwriter Disclosures

The proposed rule change would define the following terms in order to delineate a dealer's various fair dealing obligations under the Revised Interpretive Notice: ''standard disclosures'' as collectively referring to the disclosures concerning the role of an underwriter [27] and an underwriter's compensation; [28] ''dealer-specific disclosures'' as collectively referring to the disclosures concerning an underwriter's actual material conflicts of interest and potential material conflicts of interest; and ''transaction-specific disclosures'' as collectively referring to the disclosures concerning the material aspects of financing structures that the underwriter recommends.

ii. Assign the Syndicate Manager the Exclusive Responsibility for the Standard Disclosures and Transaction-Specific Disclosures

The 2012 Interpretive Notice states that a syndicate manager is permitted, but not required, to make the standard disclosures and the transaction-specific disclosures on behalf of the other underwriters in the syndicate. The amendments in the proposed rule change would obligate only the

[27] Under the 2012 Interpretive Notice, these disclosures currently state: (i) Municipal Securities Rulemaking Board Rule G–17 requires an underwriter to deal fairly at all times with both municipal issuers and investors; (ii) the underwriter's primary role is to purchase securities with a view to distribution in an arm's-length commercial transaction with the issuer and it has financial and other interests that differ from those of the issuer; (iii) unlike municipal advisors, underwriters do not have a fiduciary duty to the issuer under the federal securities laws and are, therefore, not required by federal law to act in the best interests of the issuer without regard to their own financial or other interests; (iv) the underwriter has a duty to purchase securities from the issuer at a fair and reasonable price, but must balance that duty with its duty to sell municipal securities to investors at prices that are fair and reasonable; and (v) the underwriter will review the official statement for the issuer's securities in accordance with, and as part of, its responsibilities to investors under the federal securities laws, as applied to the facts and circumstances of the transaction. The proposed rule change incorporates one additional disclosure into the Revised Interpretive Notice, that the issuer may choose to engage the services of a municipal advisor with a fiduciary obligation to represent the issuer's interests in the transaction. *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Underwriter Discouragement of Use of Municipal Advisor; Addition of a New Standard Disclosure Regarding the Engagement of Municipal Advisors* and related notes 134 *et. seq. infra.,* and *Summary of Comments Received in Response to the Request for Comment—Inclusion of Existing Language Regarding the Discouragement of an Issuer's Engagement of a Municipal Advisor and Incorporation of a New Standard Disclosure Regarding the Issuer's Choice to Engage a Municipal Advisor* and related notes 201 *et. seq. infra.*

[28] Under the 2012 Interpretive Notice, an underwriter must disclose to an issuer whether its underwriting compensation will be contingent on the closing of a transaction. It must also disclose that compensation that is contingent on the closing of a transaction or the size of a transaction presents a conflict of interest, because it may cause the underwriter to recommend a transaction that it is unnecessary or to recommend that the size of the transaction be larger than is necessary.

syndicate manager [29] of a syndicate—or sole underwriter, as the case may be—to make the standard disclosures and transaction-specific disclosures and eliminates any obligation of other co-managing underwriters in the syndicate to make the standard disclosures and transaction-specific disclosures. By eliminating the obligation of such other syndicate members to deliver the standard disclosures and transaction-specific disclosures upon the formation of the syndicate, the syndicate manager would no longer be delivering the disclosures ''on behalf of'' any other syndicate members, and such other syndicate members would be under no obligation to ensure the delivery of such disclosures on their behalf.[30] As further described in the MSRB's summary of comments,[31] the MSRB believes that this proposed change will result in issuers receiving fewer duplicative boilerplate disclosures, because a syndicate member will not be obligated to deliver its own disclosures.

In addition, the proposed rule change provides that any disclosures delivered by a syndicate manager prior to or concurrent with the formation of a syndicate would not need to be identified as delivered in the capacity of the syndicate manager or otherwise redelivered ''on behalf'' of the syndicate. It would suffice for purposes of the proposed rule change that an underwriter—later syndicate manager—has delivered the standard disclosures and/or transaction-specific disclosures to the issuer regardless of whether a syndicate may form or has already been formed in the course of the transaction.[32]

Each member of the syndicate would remain responsible for ensuring the delivery of any dealer-specific disclosures if, but only if, such syndicate member had actual material conflicts of interest or potential material conflicts of interest that must be disclosed. The MSRB continues to believe that the obligation for each underwriter to deliver dealer-specific disclosures is warranted because such disclosures are, by their nature, not uniform, and must be tailored to each underwriter's unique circumstances.[33] As currently stated in the 2012 Interpretive Notice, if an underwriter does not have any actual material conflicts of interest or potential material conflicts of interest, the proposed rule change would not require the underwriter to deliver an affirmative written statement to the issuer regarding the absence of such dealer-specific conflicts, but the underwriter is permitted to do so.

iii. Require the Separate Identification of the Standard Disclosures

The 2012 Interpretive Notice currently permits the delivery of omnibus disclosure documents, in which the standard disclosures need not be separately identified from the transaction-specific disclosures and dealer-specific disclosures. The proposed rule change would require the separate identification and formatting of the standard disclosures (*i.e.,* disclosures concerning the role of the underwriter and the underwriter's compensation) from the transaction-specific disclosure and the dealer-specific disclosures. For example, when providing the various disclosures in the same document, an underwriter would be required to clearly identify the standard disclosures and separate them from the other disclosures (*e.g.,* by placing the standard disclosures in an appendix or attachment).

iv. Clarify the Meaning of ''Recommendation'' for Purposes of Disclosures Related to Complex Municipal Securities Financings

The 2012 Interpretive Notice provides that an underwriter in a negotiated offering that recommends a complex municipal securities financing to an issuer must disclose the material financial characteristics of the complex municipal securities financing, as well as the material financial risks of the financing that are known to the underwriter and reasonably foreseeable at the time of the disclosure (a ''complex municipal securities financing disclosure''). Accordingly, as stated in the Implementation Guidance, the requirement to provide a complex municipal securities financing disclosure is triggered if—the new issue is sold in a negotiated offering; the new issue is a complex municipal securities financing; and such financing was recommended by the underwriter. These aspects of the 2012 Interpretive Notice would remain applicable under the Revised Interpretive Notice.

However, the 2012 Interpretive Notice does not define the term ''recommendation'' for purposes of this requirement. As further described in the MSRB's summary of comments,[34] the MSRB believes it is important to provide this clarification to facilitate dealer compliance with the proposed rule change. The proposed rule change would clarify that a communication by an underwriter is a ''recommendation'' that triggers the obligation to deliver a complex municipal securities financing disclosure if—given its content, context, and manner of presentation—the communication reasonably would be viewed as a call to action to engage in a complex municipal securities financing or reasonably would influence an issuer to engage in a particular complex municipal securities financing.[35] For the reasons described in

[29] For purposes of the proposed rule change, the term ''syndicate manager'' refers to the lead manager, senior manager, or bookrunning manager of the syndicate. In circumstances where an underwriting syndicate is formed, the proposed rule change would clarify that the syndicate manager is obligated to make the standard disclosures and transaction-specific disclosures. In the event that there are joint-bookrunning senior managers, the proposed rule change would state that only one of the joint-bookrunning senior managers would be obligated under the Revised Interpretive Notice to make the standard disclosures and transaction-specific disclosures. Unless otherwise agreed to, such as pursuant to an agreement among underwriters, the joint-bookrunning senior manager responsible for maintaining the order book of the syndicate would be solely responsible for providing the standard disclosures and transaction-specific disclosures under the Revised Interpretive Notice. Notwithstanding the obligation of a syndicate manager to deliver the standard disclosures and transaction-specific disclosures under the Revised Interpretive Notice, nothing in the Revised Interpretive Notice would prohibit an underwriter from making a disclosure in order to, for example, comply with another regulatory or statutory obligation.

[30] In light of, and consistent with, these obligations placed on the syndicate manager, only the syndicate manager must maintain and preserve records of the applicable disclosures it delivers in accordance with MSRB rules.

[31] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Amending the Nature, Timing, and Manner of Disclosures—Syndicate Manager Responsibility for the Standard Disclosures and Transaction-Specific Disclosures* and notes 102 *et. seq. infra,* and *Summary of Comments Received in Response to the Request for Comment—Amending the Nature, Timing, and Manner of Disclosures—Syndicate Manager Responsibility for the Standard Disclosures and Transaction—Specific Disclosures* and notes 169 *et. seq. infra.*

[32] For the avoidance of any doubt, the proposed change would apply to all applicable timeframes for the development of a syndicate, including situations when an underwriter—later syndicate manager—has previously delivered the disclosures prior to the formation of the syndicate and also when a syndicate manager delivers the disclosures concurrent with or after the formation of the syndicate.

[33] As currently stated in the 2012 Interpretive Notice and Implementation Guidance, nothing in the Revised Interpretive Notice would preclude—or require—a syndicate manager from delivering each of the dealer-specific conflicts to the issuer as part of a single package of disclosures, if the syndicate manager and other co-managing underwriters of the syndicate so agreed.

[34] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Clarification of the Meaning of* ''*Recommendation*'' and related notes 131 *et. seq. infra.,* and *Summary of Comments Received in Response to the Request for Comment—Guidance Regarding Meaning of* ''*Recommendation*'' and related notes 219 *et. seq. infra.*

[35] In proposing this change the MSRB draws upon, by analogy, the analysis applicable to dealers making recommendations to customers under

the MSRB's summary of comments below,[36] the MSRB considered, and ultimately determined not to, adopt the standard that has been developed for purposes of municipal advisor recommendations under Rule G–42, on the duties of non-solicitor municipal advisors.[37]

v. Establish a ''Reasonably Likely'' Standard for Disclosure of Potential Material Conflicts of Interest

The 2012 Interpretive Notice currently requires the underwriter to disclose to the issuer any actual material conflicts of interest and any potential material conflicts of interest. As described in the Implementation Guidance, the requirement to provide such disclosure is triggered if: The new issue is sold in a negotiated underwriting; the matter to be disclosed represents a conflict of interest, either in reality or potentially; and any such actual or potential conflict of interest is material. These aspects of the 2012 Interpretive Notice would remain applicable under the Revised Interpretive Notice. However, the proposed rule change provides that an underwriter's potential material conflict of interest must be disclosed as part of the dealer-specific disclosures if, but only if, the potential material conflict of interest is ''reasonably likely'' to mature into an actual material conflict of interest during the course of that specific transaction. This revision would narrow the dealer-specific disclosures currently required under the 2012 Interpretive Notice from all potential material conflicts to those potential material conflicts that meet this more focused standard.

As further described below in the MSRB's summary of comments, the MSRB believes this amendment will benefit issuers and underwriters alike by reducing the volume of disclosure that must to be provided to those conflicts that are most concrete and probable.[38] Underwriters will benefit from this change by no longer having to draft and deliver longer disclosures that identify and describe remote or hypothetical conflicts that are unlikely to materialize during the course of a given transaction. The MSRB believes that issuers will also benefit from this change because they will no longer have to review and analyze such longer-form disclosures, which will allow them to focus their time and other resources to the consideration of those material conflicts that are present, or reasonably likely to be present, during the course of the transaction, and, thereby, not expend time and resources discerning likely dealer conflicts from unlikely conflicts, or otherwise evaluating potential material conflicts that are not reasonably likely to materialize during the course of the transaction.

Additionally, the proposed rule change will not diminish an underwriter's fair dealing obligation to update, or otherwise supplement, its dealer-specific disclosures in circumstances when a previously undisclosed potential conflict of interest later ripens into an actual material conflict of interest. Thus, the MSRB believes that the proposed rule change does not compromise municipal entity protection, because municipal entity issuers would continue to receive timely information about all material conflicts of interest that ripen during the course of a transaction. More specifically, at or before the time an underwriter is engaged, issuers would continue to receive a dealer-specific disclosure describing any actual material conflicts of interest that are present at that time and any potential material conflicts of interest that, based on the reasonable judgement of the dealer at that time, are likely to mature into an actual material conflict of interest—assuming there are any such actual material conflicts of interest or potential material conflicts of interest.[39] Thereafter, an underwriter's fair dealing obligation would continue to require it to deliver an updated or supplemental dealer-specific disclosure for any actual material conflict of interest or potential material conflict of interest that has not been previously disclosed to the issuer and arising after the triggering of the initial dealer-specific disclosure.[40]

vi. Clarify That Underwriters Are Not Obligated To Provide Written Disclosure of Conflicts of Other Parties

As outlined above, the 2012 Interpretive Notice requires underwriters to provide issuers with certain standard disclosures, dealer-specific disclosures, and transaction-specific disclosures, when and if applicable. By their respective definitions, the standard disclosures cover generic conflicts of interest that could apply to any underwriter in any underwriting; the dealer-specific disclosures are the actual material conflicts of interest and potential material conflicts of interest generally unique to a specific underwriter; and

MSRB Rule G–19, on the suitability of recommendations and transactions. While Rule G–19 does not apply to the recommendations made by underwriters to issuers in connection with new issues of municipal securities for the reasons discussed below, the Revised Interpretive Notice draws, by analogy, on the analysis of when a dealer has made recommendation under Rule G–19. As discussed in existing MSRB guidance, this analysis under Rule G–19 is informed by the related suitability standard promulgated by the Financial Industry Regulatory Authority (FINRA). More specifically, when proposed amendments to Rule G–19 were approved in March 2014, the MSRB noted that ''[g]iven the extensive interpretive guidance surrounding FINRA Rule 2111 [on suitability] and the impracticality and inefficiency of republishing each iteration of that guidance, substantively similar provisions of Rule G–19 will be interpreted in a manner consistent with FINRA's interpretations of Rule 2111.'' *See* Release No. 34–71665; 77 FR 14321 (March 7, 2014) (File No. SR–MSRB–2013–07) (Mar. 7, 2014) and MSRB Regulatory Notice 2014–07 (March 2014). FINRA's suitability guidance has long provided that the determination of whether a ''recommendation'' has been made is an objective rather subjective inquiry. *See* FINRA Notice to Members 01–23 (March 2001). In guidance relating to FINRA Rules 2090 and 2011, FINRA reiterated this prior guidance, stating that an important factor in this inquiry ''is whether—given its content, context and manner of presentation—a particular communication from a firm or associated person to a customer reasonably would be viewed as a suggestion that the customer take action or refrain from taking action regarding a security or investment strategy.'' *See* FINRA Regulatory Notice 11–02 (Know Your Customer and Suitability) (January 2011). Rule G–19 in this situation does not directly apply to a recommendation made by an underwriter to an issuer in transactions involving the sale by the issuer of a new issue of its securities, because, by its terms, Rule G–19 governs recommendations to ''customers,'' and MSRB Rule D–9 provides that an issuer is not a ''customer'' within the meaning of that rule in the case of a sale by it of a new issue of its securities. *See* MSRB Rule D–9 (available here) and related interpretive guidance (available here).

[36] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Clarification of the Meaning of* ''*Recommendation*'' and related notes 131 *et. seq. infra.,* and *Summary of Comments Received in Response to the Request for Comment—Guidance Regarding Meaning of* ''*Recommendation*'' and related notes 219 *et. seq. infra.*

[37] *See* FAQs Regarding MSRB Rule G–42 and Making Recommendations (June 2018) (hereinafter, the ''G–42 FAQs'').

[38] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Amending the Nature, Timing, and Manner of Disclosures—Disclosure of Potential Material Conflicts of Interest* and related notes 98 *et. seq. infra,* and *see also Summary of Comments Received in Response to the Request for Comment—Amending the Nature, Timing, and Manner of Disclosures—Disclosure of Potential Material Conflicts of Interest* and related notes 161 *et. seq. infra.*

[39] In the absence of any such actual material conflict of interest or potential material conflict of interest, an underwriter would not have a fair dealing obligation under the Revised Interpretive Notice to disclose the absence of such a conflict, but may choose to provide an affirmative written statement regarding the absence of such conflicts at its discretion (*e.g.,* for the benefit of establishing a written record of such absence).

[40] For example, the 2012 Interpretive Notice states: ''. . . a conflict may not be present until an underwriter has recommended a particular financing. In that case, the disclosure must be provided in sufficient time before the execution of a contract with the underwriter to allow the official to evaluate the recommendation, as described below under 'Required Disclosures to Issuers.' '' This concept would remain applicable under the Revised Interpretive Notice.

the transaction-specific disclosures relate to the specific financing structure recommended by an underwriter. None of the requirements in the 2012 Interpretive Notice prescribe that the underwriter must provide the issuer with written disclosures on the part of any other transaction participants, including issuer personnel, but does not expressly state this fact. In response to the concern of a commenter more fully described in the MSRB's summary of comments below,[41] the MSRB believes that this express clarification is warranted to avoid potential misinterpretation of the disclosure requirements of the proposed rule change. Accordingly, the proposed rule change would expressly state that underwriters are not required to make any written disclosures on the part of issuer personnel or any other parties to the transaction as part of the standard disclosures, dealer-specific disclosures, or the transaction-specific disclosures.

vii. Clarify That Disclosures Must Be ''Clear and Concise''

The 2012 Interpretive Notice currently requires disclosures to be ''designed to make clear to such official the subject matter of such disclosures and their implications for the issuer.'' The proposed rule change would clarify that an underwriter's disclosures must be delivered in a ''clear and concise'' manner, which the MSRB believes is consistent with, and substantially equivalent to, the standard currently articulated in the 2012 Interpretive Notice. Nevertheless, in response to the concern of commenters more fully described in the MSRB's summary of comments below, the MSRB believes that this clarification is warranted to provide further guidance to all stakeholders regarding the accessibility and readability of an underwriter's disclosures.

viii. Update the Definition of Municipal Entity

The 2012 Interpretive Notice currently provides a definition of ''municipal entity'' that references Section 15B(e)(8) under the Exchange Act.[42] Notably, the 2012 Interpretive Notice does not reference the definition of municipal entity under Exchange Act Rule 15Ba1–1, because the 2012 Interpretive Notice was issued prior to the effectiveness of the Commission's permanent registration regime for ''municipal advisors'' pursuant to the amendments to Section 15B of the Exchange Act effectuated by Section 975 of the Dodd-Frank Wall Street Reform and Consumer Protection Act[43] (collectively, the ''Final MA Rules''), including Exchange Act Rule 15Ba1–1.[44] Exchange Act Rule 15Ba1–1 defines a ''municipal entity'' to mean: ''any State, political subdivision of a State, or municipal corporate instrumentality of a State or of a political subdivision of a State, including—(1) Any agency, authority, or instrumentality of the State, political subdivision, or municipal corporate instrumentality; (2) Any plan, program, or pool of assets sponsored or established by the State, political subdivision, or municipal corporate instrumentality or any agency, authority, or instrumentality thereof; and (3) Any other issuer of municipal securities.'' [45] Relatedly, Rule G–42 includes this same reference to the definition of municipal entity as used in the Final MA Rules.

In light of the Commission's definition contained in the Final MA Rules and the MSRB's definition of ''municipal entity'' as used under Rule G–42, the proposed rule change would incorporate a specific reference to this rule definition, in addition to the general statutory definition, to avoid any confusion about the scope of the Revised Interpretive Notice and to promote harmonization with the Final MA Rules and Rule G–42. In relevant part, the Revised Interpretive Notice would read, ''. . . the term 'municipal entity' is used as defined by Section 15B(e)(8) of the Securities Exchange Act of 1934 (the 'Exchange Act'), 17 CFR 240.15Ba1–1(g), and other rules and regulations thereunder.''

C. Require an Additional Standard Disclosure Regarding the Engagement of Municipal Advisors

The 2012 Interpretive Notice currently requires an underwriter to make five discrete statements regarding the underwriter's role as part of the standard disclosures, including a disclosure that, ''unlike a municipal advisor, the underwriter does not have a fiduciary duty to the issuer under the federal securities laws and is, therefore, not required by federal law to act in the best interest of the issuer without regard to its own or other interests.'' [46] The proposed rule change would incorporate a new standard disclosure that ''the issuer may choose to engage the services of a municipal advisor with a fiduciary obligation to represent the issuer's interests in the transaction.'' As a standard disclosure, this additional disclosure would be subject to the same principles for its timing as the other similar standard disclosures (*i.e.,* at or before the time the underwriter has been engaged to perform the underwriting services) and separate delivery as the other standard disclosures (*i.e.,* separately identified when provided with the transaction-specific disclosures and/or dealer-specific disclosures). In response to the concern of commenters more fully described in the MSRB's summary of comments below,[47] the MSRB believes that this additional disclosure will further clarify the distinctions between an underwriter—who is subject to a duty of fair dealing when providing advice regarding the issuance of municipal securities to municipal entities—and a municipal advisor—who is subject to a federal statutory fiduciary duty when providing advice regarding the issuance of municipal securities to municipal entities—and, thereby, promotes the protection of municipal entity issuers in accordance with the MSRB's statutory mandate at a relatively minimal burden to underwriters.

[41] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Amending the Nature, Timing, and Manner of Disclosures—Clarification that Underwriters Are Not Obligated to Provide Written Disclosure of Conflicts of Other Parties* and related note 114, and *Summary of Comments Received in Response to the Request for Comment—Amending the Nature, Timing, and Manner of Disclosures—Clarification that Underwriters Are Not Obligated to Provide Written Disclosure of Conflicts of Other Parties* and related notes 194 *et. seq. infra.*

[42] The 2012 Interpretive Notice states: ''The term 'municipal entity' is defined by Section 15B(e)(8) of the Securities Exchange Act of 1934 (the 'Exchange Act') to mean: 'any State, political subdivision of a State, or municipal corporate instrumentality of a State, including—(A) any agency, authority, or instrumentality of the State, political subdivision, or municipal corporate instrumentality; (B) any plan, program, or pool of assets sponsored or established by the State, political subdivision, or municipal corporate instrumentality or any agency, authority, or instrumentality thereof; and (C) any other issuer of municipal securities.' ''

[43] Public Law 111–203 § 975, 124 Stat. 1376 (2010).

[44] *See* Registration of Municipal Advisors, Release No. 34–70462 (September 20, 2013), 78 FR 67467 (hereinafter, the ''MA Rule Adopting Release'') (November 12, 2013) (available at *http://www.sec.gov/rules/final/2013/34-70462.pdf*).

[45] *See* Exchange Act Rule 15Ba1–1(g).

[46] *See* note 27 *supra* for the other four disclosures currently required under the 2012 Interpretive Notice.

[47] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Underwriter Discouragement of Use of Municipal Advisor; Addition of a New Standard Disclosure Regarding the Engagement of Municipal Advisors* and related notes 134 *et. seq. infra,* and *Summary of Comments Received in Response to the Request for Comment—Inclusion of Existing Language Regarding the Discouragement of an Issuer's Engagement of a Municipal Advisor and Incorporation of a New Standard Disclosure Regarding the Issuer's Choice to Engage a Municipal Advisor* and related notes 201 *et. seq. infra.*

D. Permit Email Read Receipt To Serve as Issuer Acknowledgement

The 2012 Interpretive Notice currently requires underwriters to attempt to receive written acknowledgement of receipt by the official of the issuer other than by evidence of automatic email receipt. The proposed rule change would permit an email read receipt to serve as the issuer's acknowledgement under the Revised Interpretive Notice.[48] The proposed rule change would define the term ''email read receipt'' to mean ''an automatic response generated by a recipient issuer official confirming that an email has been opened.'' The proposed rule change would also clarify that, ''[w]hile an email read receipt may generally be an acceptable form of an issuer's written acknowledgement under this notice, an underwriter, may not rely on such an email read receipt as an issuer's written acknowledgement where such reliance is unreasonable under all of the facts and circumstances, such as where the underwriter is on notice that the issuer official to whom the email is addressed has not in fact received or opened the email.''

In response to the concern of commenters more fully described in the MSRB's summary of comments below,[49] the MSRB believes that this amendment will ease the burden of the acknowledgement requirement on underwriters and issuers alike, as both issuer and underwriter commentators indicated that an underwriter's fair dealing obligation to obtain a written acknowledgement, as currently defined under the 2012 Interpretive Notice, creates burdens without offsetting benefits.[50] The MSRB believes that underwriters would benefit from this change by being able to more efficiently obtain issuer acknowledgement of the disclosures electronically through the automated process of an email system, while issuers that desire to provide such acknowledgement to an underwriter can similarly take advantage of the efficiency of the email system to electronically reply to an underwriter's electronic request. At the same time, under the Revised Interpretive Notice, issuers would still have the choice not to provide acknowledgement to an underwriter in this manner by opting not to send an email read receipt in response to the underwriter's email communication.

Moreover, the MSRB believes that this proposed change will not compromise issuer protection, because, like any other form of acknowledgement under the Revised Interpretive Notice, the proposed rule change would require the email read receipt to come from an issuer official that is not party to a conflict, based on the underwriter's knowledge, and either has been specifically identified by the issuer to receive such disclosure communications or, in the absence of such specific identification, is an issuer official who the underwriter reasonably believes has the authority to bind the issuer by contract with the underwriter. Similarly, the proposed rule change would provide that an underwriter may not rely on an email read receipt as the issuer's written acknowledgement when such reliance is unreasonable under all of the facts and circumstances. Accordingly, the proposed change will not compromise issuer protection because an underwriter still must meet the overarching fair dealing obligation of Rule G–17 when relying on an email read receipt, and, thus, an underwriter cannot reasonably rely on email read receipts as written acknowledgement when the particular facts and circumstances indicate that doing so would be deceptive, dishonest, or unfair, as in the case where an underwriter is on notice that the issuer official to whom the email is addressed has not in fact received or opened the email.

2. Statutory Basis

The MSRB believes that the proposed rule change is consistent with Section 15B(b)(2) of the Act,[51] which provides that:

> The Board shall propose and adopt rules to effect the purposes of this title with respect to transactions in municipal securities effected by brokers, dealers, and municipal securities dealers and advice provided to or on behalf of municipal entities or obligated persons by brokers, dealers, municipal securities dealers, and municipal advisors with respect to municipal financial products, the issuance of municipal securities, and solicitations of municipal entities or obligated persons undertaken by brokers, dealers, municipal securities dealers, and municipal advisors.

Section 15B(b)(2)(C) of the Act[52] provides that the MSRB's rules shall:

> . . . be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in municipal securities and municipal financial products, to remove impediments to and perfect the mechanism of a free and open market in municipal securities and municipal financial products, and, in general, to protect investors, municipal entities, obligated persons, and the public interest.

The proposed rule change is consistent with Section 15B(b)(2)(C) of the Exchange Act[53] because it will protect issuers of municipal securities from fraudulent and manipulative acts and practices, remove impediments to and perfect the mechanism of a free and open market, and promote just and equitable principles of trade, and promote the protection of municipal entities, for the reasons set forth below.

A. Defining the Various Categories of Underwriter Disclosures and Consolidating the 2012 Interpretive Notice, the Implementation Guidance, and the FAQs Into the Revised Interpretive Notice

The proposed rule change would promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market through its amendment of the 2012 Interpretive Notice to define the various categories of underwriter disclosures and through the incorporation of the content of the Implementation Guidance and FAQs. These amendments promote equitable principles of trade and the removal of impediments to and perfection of the mechanism of a free and open market by allowing underwriters to reference and review a single consolidated document with uniform terms under Rule G–17, which facilitates the efficient determination of any applicable fair dealing obligations and, thereby, allows for more efficient and less burdensome compliance. At the same time, this amendment does not compromise issuer protection, because these amendments to the 2012 Interpretive Notice are primarily of a technical nature that do not alter the substance of the information delivered to issuers of municipal securities.

[48] While an email read receipt would serve as acknowledgement of disclosures delivered for purposes of an underwriter's fair dealing obligations under the Revised Interpretive Notice, the MSRB does not intend to create any implication or inference that an email read receipt may serve as an acknowledgment for any other regulatory purposes.

[49] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Email Read Receipt as Issuer Acknowledgement* and related notes 125 *et. seq. infra.,* and *Summary of Comments Received in Response to the Request for Comment—Email Read Receipt as Issuer Acknowledgement* and related notes 213 *et. seq. infra.*

[50] *See, e.g.,* SIFMA Letter I, at p. 17 (''SIFMA and its members strongly believe that the issuer's acknowledgement of receipt of disclosures do not provide any benefit, create significant burdens and should be eliminated'').

[51] 15.U.S.C. 78*o*–4(b)(2).

[52] 15 U.S.C. 78*o*-4(b)(2)(C).

[53] 15.U.S.C. 78*o*–4(b)(2).

B. Amending the Nature, Timing, and Manner of Disclosures

i. Assign the Syndicate Manager the Exclusive Responsibility for the Standard Disclosures and Transaction-Specific Disclosures

The proposed rule change would promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market by amending the 2012 Interpretive Notice to obligate only the syndicate manager—or the sole underwriter, as the case may be—to deliver the standard disclosures and transaction-specific disclosures, and eliminating the concept that the disclosures must be provided ''on behalf of'' any other members of the syndicate. This would remove impediments to and perfect the mechanism of a free and open market by eliminating certain redundant and generic disclosures currently delivered by underwriters to issuers that provide little, if any, novel informational benefits to issuers, but do create non-trivial compliance and record-keeping burdens on underwriters. The amendment will also promote the goal of protecting municipal entity issuers because issuers will be able to more efficiently evaluate the information contained in the disclosures they do receive, rather than having to differentiate generic and duplicative disclosures from disclosures that are more particularized to the facts and circumstances of the transaction.

ii. Require the Separate Identification of the Standard Disclosures

The proposed rule change would prevent fraudulent and manipulative acts and practices and promote the protection of municipal entity issuers by amending the 2012 Interpretive Notice to require the separate identification and formatting of the standard disclosures by underwriters. This would prevent fraudulent and manipulative acts and practices and promote the protection of municipal entity issuers because issuers will be able to more efficiently differentiate an underwriter's dealer-specific disclosures and transaction-specific disclosures from an underwriter's standard disclosures, and, thereby, more efficiently evaluate those disclosures that are unique to a given underwriting firm and transaction type from those that are more generic and common to all underwriting relationships.

iii. Clarify the Meaning of ''Recommendation'' for Purposes of Disclosures Related to Complex Municipal Securities Financings

The proposed rule change would promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market by amending the 2012 Interpretive Notice to define the analysis applicable to when an underwriter has made a recommendation triggering the obligation to deliver complex municipal securities financing disclosures. The 2012 Interpretive Notice does not currently define what constitutes a ''recommendation'' for these purposes. The absence of a definition creates a burden for underwriters to appropriately interpret and operationalize the 2012 Interpretive Notice. Clarifying the applicable definition would eliminate any legal ambiguity under the Revised Interpretive Notice regarding the applicable standard for determining when a recommendation of a complex municipal securities financing has been made. For similar reasons, the proposed change will promote just and equitable principles of trade by clarifying the circumstances when underwriters must provide these particularized transaction-specific disclosures to issuers, which will reduce the compliance burden for all dealers who act as underwriters.

iv. Establish a ''Reasonably Likely'' Standard for Disclosure of Potential Material Conflicts of Interest

The proposed rule change would remove impediments to and perfect the mechanism of a free and open market by amending the 2012 Interpretive Notice to more narrowly define which potential material conflicts of interest must be disclosed by underwriters. The disclosures regarding remote and unlikely conflicts provide little, if any, actionable informational benefits to issuers, but do create non-trivial compliance and record-keeping burdens on underwriters. The proposed rule change would prevent fraudulent and manipulative acts and practices and also promote the protection of municipal entity issuers by facilitating issuers' ability to more efficiently evaluate and consider those potential material conflicts of interest that are most concrete and probable, rather than having to differentiate likely material conflicts of interest from a longer inventory of conflicts that includes remote material conflicts of interest that are hypothetical and unlikely to materialize during the course of the transaction.

As further described below in the MSRB's summary of comments, the MSRB believes this amendment will benefit market participants by reducing the volume of disclosure that must be provided to those conflicts that are most concrete and probable.[54] Moreover, the MSRB believes that the proposed rule change does not compromise municipal entity protection, and may in fact bolster issuer protection, by providing more focused and actionable information to issuers. The MSRB believes that issuers will benefit from this change because they will no longer have to review and analyze longer-form disclosures discussing potential material conflicts of interest that are not reasonably likely to materialize during the course of the transaction. Streamlining the disclosures in this way will allow issuers to focus their time and other resources to the consideration of those material conflicts that are currently present and/or reasonably likely to be present during the course of the transaction.

Additionally, the proposed rule change will not diminish an underwriter's fair dealing obligation to update, or otherwise supplement, its dealer-specific disclosures in circumstances when a previously undisclosed potential conflict of interest later ripens into an actual material conflict of interest.[55] An underwriter must provide disclosure to the issuer regarding the actual presence of a material conflict that arises during the course of the transaction in accordance with the following timelines:

- If an actual material conflict of interest is present at the time the underwriter is engaged, then the underwriter must disclose the conflict at or before the time the underwriter is so engaged.
- If a conflict of interest does not rise to the level of an actual material conflict of interest at the time of the underwriter's initial engagement, but is reasonably likely to mature into an actual material conflict of interest during the course of the transaction

[54] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Amending the Nature, Timing, and Manner of Disclosures* and related notes 96 *et. seq. infra,* and *Summary of Comments Received in Response to the Request for Comment—Amending the Nature, Timing, and Manner of Disclosures* and related notes 159 *et. seq. infra.*

[55] The FAQs presently state that dealer-specific conflicts of interest ''discovered or arising after engagement'' must be disclosed ''[a]s soon as practicable after discovered and with sufficient time for the issuer to evaluate the conflict and its implication.''

between the issuer and the underwriter, then the underwriter must disclose the conflict as a potential material conflict of interest at or before the time the underwriter is so engaged.

• If the material conflict of interest is not present at the time of the underwriter's initial engagement, and the underwriter reasonably determines at that time that a conflict of interest is not likely to mature into an actual material conflict of interest during the course of the transaction, then the underwriter would not have a fair dealing obligation under this notice to disclose the conflict upon its engagement. But, for example, if that same undisclosed conflict later ripened into an actual material conflict of interest during the course of the transaction, then the underwriter would continue to have a fair dealing obligation under the Revised Interpretive Notice to disclose the conflict as soon as practicable after it arises or upon its discovery by the dealer.

In this regard, the Revised Interpretive Notice would not diminish the amount of information provided to an issuer about the presence of any actual material conflicts of interest as compared to the 2012 Interpretive Notice. It may only change the timing by which certain of those conflicts of interest are first disclosed to an issuer.[56]

To the degree that the Revised Interpretive Notice does result in a change in timing, the MSRB believes that the proposed rule change provides more actionable information to issuers regarding such conflicts, even if at a potentially later date, and, thereby, any detriment to issuers in regard to timing under the Revised Interpretive Notice generally would be positively offset in terms of issuers' increased informational certainty. While issuers may have less time to act in such scenarios, issuers would have the benefit of knowing that the conflicts being disclosed are more concrete and non-hypothetical.

Thus, the MSRB believes that the proposed rule change does not compromise municipal entity protection, and may in fact bolster issuer protection, by providing more actionable information to issuers, because issuers would continue to receive timely information about all material conflicts of interest that are present during the course of the transaction, and, more importantly, the revised standard eliminates some of the uncertainty regarding how an issuer should evaluate an underwriter's conflicts disclosure. Specifically, if the underwriter provides a material conflict disclosure to an issuer, then, under the Revised Interpretive Notice, the issuer is certain that the material conflict is actually present and/or reasonably likely to be present during the course of the transaction, rather than a mere hypothetical potential conflict. Thereby, issuers will benefit by not expending time and resources in distinguishing likely dealer conflicts from unlikely conflicts, or otherwise evaluating potential material conflicts of interest that are not reasonably likely to materialize during the course of the transaction.

v. Clarify That Underwriters Are Not Obligated To Provide Written Disclosures Regarding the Conflicts of Other Parties to the Transaction

The proposed rule change would remove impediments to and perfect the mechanism of a free and open market by amending the 2012 Interpretive Notice to clarify that underwriters are not obligated to provide written disclosures regarding the conflicts of issuer personnel or other parties to the transaction as part of the standard disclosures, dealer-specific disclosures, or the transaction-specific disclosures. The 2012 Interpretive Notice does not expressly state this fact, although the MSRB understands that the 2012 Interpretive Notice by its terms was not intended to create such a burden of written disclosure. Accordingly, the amendments providing this technical clarification in the Revised Interpretive Notice would reduce ambiguity regarding the nature of disclosures to be made under the 2012 Interpretive Notice and, thereby, reduce the burden on dealers that may be operating with such ambiguity.

vi. Clarify That Disclosures Must Be Clear and Concise

The proposed rule change would remove impediments to and perfect the mechanism of a free and open market by amending the 2012 Interpretive Notice to clarify that disclosures must be made in a clear and concise manner. These amendments promote equitable principles of trade and the removal of impediments to and perfection of the mechanism of a free and open market by granting underwriters clarity regarding the standard by which the disclosures will be evaluated. The 2012 Interpretive Notice does not currently express this standard by its terms, although the MSRB understands that this standard is consistent with the 2012 Interpretive Notice. Accordingly, providing this technical clarification in the Revised Interpretive Notice would reduce ambiguity regarding the application of the 2012 Interpretive Notice and, thereby, reduce the burden on dealers that may be operating with such ambiguity.

C. Require an Additional Standard Disclosure Regarding the Engagement of Municipal Advisors

The proposed rule change would prevent fraudulent and manipulative acts and practices and promote the protection of municipal entity issuers by amending the 2012 Interpretive Notice to require underwriters to incorporate a new standard disclosure that ''the issuer may choose to engage the services of a municipal advisor with a fiduciary obligation to represent the issuer's interests in the transaction.'' This proposed change would augment current disclosures by further emphasizing to an issuer the arm's-length, commercial nature of the underwriting relationship and expressly informing the issuer that it may obtain the advice of a municipal advisor, who serves as a fiduciary to the issuer, rather than relying solely upon the advice of an underwriter, who may have commercial interests that differ from the issuer's best interests.

D. Permit Email Read Receipt To Serve as Issuer Acknowledgement

Finally, the proposed rule change would remove impediments to and perfect the mechanism of a free and open market, and facilitate transactions in municipal securities, by amending the 2012 Interpretive Notice under Rule G–17 to permit an email read receipt to serve as the issuer's acknowledgement

[56] As an illustration of this point, in the factual scenario discussed in the last bullet above, an underwriter may have identified the conflict as a potential material conflict of interest under the terms of the 2012 Interpretive Notice's broader disclosure standard, which requires an underwriter to disclose any potential material conflict of interest, not just those that are reasonably likely. Consequently, under the terms of the 2012 Interpretive Notice, the underwriter may have incorporated the conflict into its initial dealer-specific disclosure as a potential conflict and so delivered notice of the conflict to the issuer at or before the time of the underwriting engagement.

Under the proposed rule change, the same conflict would still be disclosed to the issuer, but the timing of its initial disclosure to the issuer could be delayed until no later than the conflict ripening into an actual material conflict of interest. In such a scenario, an issuer would receive notice of such a conflict at a potentially later date into the transaction under the Revised Interpretive Notice than under the 2012 Interpretive Notice, and, correspondingly, the amount of time an issuer would have to analyze and react to such a conflict would be abridged as a result. However, by knowing such conflicts are concrete and non-hypothetical, an issuer may not need as much time to act to analyze and resolve any such conflict. Moreover, the MSRB believes that differing timing outcomes exemplified by this scenario described in the last bullet above, in actuality, would occur relatively infrequently.

of receipt of the applicable disclosures. For purposes of the Revised Interpretive Notice, the term ''email read receipt'' would mean an automatic response generated by a recipient issuer official confirming that an email has been opened. This amendment would remove impediments to and perfect the mechanism of a free and open market by improving the efficiency of the disclosure process by allowing underwriters to seek, and issuers to provide, acknowledgement electronically through the built-in, automatic process of an email system. In those instances where a municipal entity is familiar with an underwriter's disclosures, because, for example, it frequently utilizes the underwriter in the sale of its municipal securities, the issuer can choose to affirm an email read receipt to provide electronic acknowledgement of receipt of the underwriter's disclosures, rather than taking the additional time to recognize such receipt by, for example, returning a signature execution of a hard copy acknowledgement.[57] This potential for increased efficiency and added flexibility removes impediments to and perfects the mechanism of a free and open market, and facilitates transactions in municipal securities, by flexibly permitting underwriters and issuers to utilize additional electronic methods to seek and provide, respectively, acknowledgements in a less-burdensome manner.[58]

Moreover, an email read receipt enables an issuer to respond to an underwriter's request for an acknowledgement that more efficiently ensures the issuer is only providing an acknowledgement of receipt, rather than agreeing to legal terms beyond receipt confirmation. The MSRB understands that issuers can be hesitant to provide a signature acknowledgement to a hard-copy receipt of disclosures out of an abundance of caution that providing such a signature may be an execution of legal terms beyond the acknowledgement of receipt, and, relatedly, issuers oftentimes seek legal counsel before providing a signature acknowledgement in such circumstances to ensure that the execution of an underwriter disclosure does not legally bind them to any terms. Allowing for an email read receipt to constitute acknowledgement may help alleviate issuer concerns in such circumstances and, thereby, save issuers from spending the time and resources to more fully evaluate whether a hard copy execution of an underwriter disclosure may legally commit an issuer to more than just a mere acknowledgement of having received a disclosure. Accordingly, the proposed rule change would eliminate the need for underwriters to repeatedly request a hard-copy, signature execution of an acknowledgement from an issuer in such circumstances where the issuer has determined not to provide such a hard-copy execution, but will provide an email read receipt, and also would eliminate the need for issuers to respond to such repeated underwriter requests for hard-copy acknowledgements.[59] This potential reduction in issuer and underwriter burdens removes impediments to and perfects the mechanism of a free and open market, and facilitates transactions in municipal securities, by enabling the more efficient execution of municipal securities transactions.

At the same time, the MSRB believes that this proposed amendment would not compromise municipal entity issuer protection, because underwriters would be required under the Revised Interpretive Notice to attempt to receive written acknowledgement by an official identified as the issuer's primary contact for the receipt of such disclosures. Thus, under the Revised Interpretive Notice, if an underwriter wanted to rely on an email read receipt as written acknowledgement, then the underwriter would have a fair dealing obligation to receive the email read receipt from a specific official identified as the issuer's primary contact for the receipt of such disclosures. In the absence of such an issuer's designation of a primary contact, the underwriter would have a fair dealing obligation to receive an email read receipt from an issuer official that the underwriter reasonably believes has authority to bind the issuer by contract with the underwriter. Moreover, the Revised Interpretive Notice would not permit an underwriter to rely on an email read receipt as an issuer's acknowledgement where such reliance is unreasonable under all of the facts and circumstances, such as where the underwriter is on notice that the issuer official to whom the email is addressed has not in fact received or opened the email.

The electronic delivery of the disclosures to such an official in either scenario (*i.e.,* in a scenario in which an issuer has identified a specific primary contact, or in the alternative scenario in which no such identification has been made by an issuer, and, so, the underwriter must make a reasonable determination about an issuer official with the requisite authority) ensures that the issuer's decision of whether to provide acknowledgement by means of an email read receipt is made by an official with the authority and ability to make such decisions on the issuer's behalf. Stated differently, not any email read receipt will suffice under the Revised Interpretive Notice, as the proposed rule change would permit an email read receipt only from certain issuer officials to satisfy an underwriter's fair dealing obligation.

In proposing this change to the acknowledgement requirement, the MSRB notes that Rule G–42, which was adopted subsequent to the 2012 Interpretive Notice, does not require an acknowledgement from an issuer or obligated person client of the client's receipt of the applicable conflict and disciplinary event disclosures under Rule G–42(b), nor in the case of disclosures required to be made by a municipal advisor who has given inadvertent advice under Supplementary Material. 07 to Rule G–42, so long as the municipal advisor has a reasonable belief that the documentation was in fact received by the client.[60] In view of the MSRB's experience with disclosures under Rule G–42, where no client acknowledgement is expressly required, the MSRB believes that it is appropriate,[61] and consistent with the protection of issuers, to adopt a revised acknowledgement standard as part of the Revised Interpretive Guidance.

Additionally, the MSRB believes that this proposed amendment would not compromise municipal entity issuer protection because recipients of such an automatic email read receipt request would still have the option to not

[57] The MSRB understands that personnel of certain frequent issuers may desire more flexible methods to provide acknowledgment of receipt. *See, e.g.,* NAMA Letter I, at p. 2 (''Issuers currently acknowledge receiving disclosures from underwriters. This practice should continue, and should allow for issuers to execute acknowledgment as they see fit.'').

[58] *Id.*

[59] The FAQs provide that, ''[i]f an authorized issuer official agrees to proceed with the underwriting after receipt of the disclosures but will not provide a written acknowledgment, an underwriter must document specifically why it was unable to obtain such written acknowledgment.'' The MSRB understands that some underwriters will repeatedly ask for an issuer's acknowledgement, despite having been told no such acknowledgement will be provided, in order to comply with this guidance.

[60] *See* Exchange Act Release No. 34–76753 (December 23, 2015), 80 FR 81614, at 81617 note 18 (December 30, 2015) (''While no acknowledgement from the client of its receipt of the documentation would be required, the MSRB notes that a municipal advisor must, as part of the duty of care it owes its client, reasonably believe that the documentation was received by its client.'').

[61] *Id.*

provide this form of acknowledgement. Thus, if an issuer official did not desire to provide such an email read receipt, for whatever reason, then the underwriter would continue to have the obligation to seek acknowledgement by other means in order to document why it was unable to obtain such acknowledgement, as currently required under the 2012 Interpretive Notice.

B. Self-Regulatory Organization's Statement on Burden on Competition

Section 15B(b)(2)(C) of the Exchange Act requires that MSRB rules not be designed to impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act.[62] The MSRB has considered the economic impact of the proposed rule change, including a comparison to reasonable alternative regulatory approaches.[63] The MSRB does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act.

The MSRB's proposed amendments to the 2012 Interpretive Notice are intended to update and streamline certain obligations specified in the 2012 Interpretive Notice and, thereby, benefit issuers and underwriters alike by reducing the burdens associated with those obligations, including the obligation of underwriters to make, and the burden on issuers to acknowledge and review, written disclosures that are duplicative, itemize risks and conflicts that are unlikely to materialize during the course of a transaction, and/or are not unique to a particular transaction or underwriting engagement. The MSRB believes that the overall impact of the proposed rule change will improve market practices, better protect issuers, and reduce the burdens on market participants.

Based on the feedback of some market participants, the 2012 Interpretative Notice has created unintended consequences in the market. For example, certain market participants, including issuers and underwriters, have indicated their belief that the disclosure obligations specified in the 2012 Interpretive Notice have led to the delivery of voluminous disclosures with mostly boilerplate information. Similarly, market participants have indicated that the disclosure obligations specified in the 2012 Interpretive Notice place a significant burden on underwriters to draft and deliver disclosures that are dense and otherwise difficult or inefficient for issuers to utilize in making informed decisions about the issuance of municipal securities, and also inadvertently bury disclosures of important conflicts and risks. Commenters also stated that the duplicative nature of some disclosures unnecessarily increases the overall volume of disclosures and, equally important, increases the likelihood that an issuer will receive similar information in a non-uniform or redundant manner, which makes it more difficult for an issuer to evaluate the information included in the disclosures it receives.[64]

The MSRB believes the proposed rule change is necessary to update and streamline the burdens placed on market participants and to increase the efficiency of certain market practices, such as enhancing the ability of issuers to efficiently and properly evaluate the risks associated with a given transaction, and, thereby, improving the protection of issuers. The MSRB further believes that the proposed rule change will provide clarity to underwriters regarding the scope of their regulatory obligations to municipal entity issuers by expressly affirming and defining certain significant concepts in the Revised Interpretive Notice.

Identifying and Evaluating Reasonable Alternative Regulatory Approaches

The MSRB has assessed alternative approaches to amend the 2012 Interpretative Notice and has determined that the respective amendments in the proposed rule change are superior to these alternatives.

To clarify the nature, timing, and manner of disclosures of conflicts of interest, the MSRB considered strictly limiting the dealer-specific disclosures required under the Revised Interpretive Notice to only an underwriter's actual material conflicts of interest (rather than an underwriter's actual material conflicts of interest and potential material conflicts of interest, as prescribed in the proposed rule change).[65] Eliminating the requirement for an underwriter to make disclosures regarding its potential material conflicts of interest would reduce the overall regulatory burden on dealers, but also delay the timing of disclosures regarding material conflicts of interest that are known at the outset of the engagement as being likely to materialize during the course of the transaction until such time as the conflicts in fact arise and, thereby, compromise certain protections currently afforded to issuers under the 2012 Interpretive Notice.[66] Accordingly, the MSRB determined that such an alternative was inferior and did not incorporate this alternative regulatory approach into the Revised Interpretive Notice.

The MSRB also considered amending the 2012 Interpretative Notice to permit issuers to opt out of receiving certain disclosures required under the 2012 Interpretive Notice. The 2012 Interpretive Notice does not provide such an opt-out process and, as a result, underwriters are generally required to deliver the applicable disclosures to an issuer regardless of an issuer's preference in this regard. The MSRB declined to incorporate this alternative regulatory approach into the Revised Interpretive Notice, because it was concerned that it may increase the likelihood that an issuer who has opted-out of certain disclosures may not receive all the information necessary to evaluate a given underwriting relationship and/or transaction structure.[67] Based on certain comments it received, the MSRB is persuaded that the risks associated with such an opt-out concept outweigh the potential benefits.[68]

The MSRB also considered amending the 2012 Interpretative Notice to incorporate the meaning of ''recommendation'' under Rule G–42, on duties of non-solicitor municipal advisors, which describes a two-prong analysis for determining whether advice is a recommendation for purposes of that rule (a ''G–42 Recommendation''). The relevant guidance under Rule G–42 provides the following two-prong analysis for such a G–42 Recommendation:

First, the [municipal advisor's] advice must exhibit a call to action to proceed with a

[62] 15 U.S.C. 78*o*–4(b)(2)(C).

[63] *Id.*

[64] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Amending the Nature, Timing, and Manner of Disclosures* and related notes 96 *et. seq. infra; see also Summary of Comments Received in Response to the Request for Comment—Amending the Nature, Timing, and Manner of Disclosures* and related notes 159 *et. seq. infra.*

[65] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Amending the Nature, Timing, and Manner of Disclosures—Disclosure of Potential Material Conflicts of Interest* and related notes 98 *et. seq. infra,* and *Summary of Comments Received in Response to the Request for Comment—Amending the Nature, Timing, and Manner of Disclosures—Disclosure of Potential Material Conflicts of Interest* and related notes 161 *et. seq. infra.*

[66] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Issuer Opt-Out* and *Summary of Comments Received in Response to the Request for Comment—Issuer Opt-Out.*

[67] *Id.*

[68] *Id.*

municipal financial product or an issuance of municipal securities and second, the [municipal advisor's] advice must be specific as to what municipal financial product or issuance of municipal securities the municipal advisor is advising the [municipal entity client or obligated person client] to proceed with.[69]

However, as discussed in more detail below, the MSRB declined to incorporate this G–42 Recommendation standard into the Revised Interpretive Notice, because of the likelihood that issuers may receive less disclosures on the risks associated with complex municipal securities financings under this standard.[70]

The MSRB considered amending the 2012 Interpretative Notice to eliminate all requirements regarding an issuer's acknowledgement of receipt of the disclosures. However, the MSRB believes that such an alternative approach would eliminate an important issuer protection and increase overall risks in the market without significant offsetting benefits.[71] Instead, to reduce the burden on underwriters and issuers alike, the proposed rule change incorporates into the Revised Interpretive Notice the concept that an underwriter may substantiate its delivery of a required disclosure by an email read receipt.[72]

The MSRB also considered amending the 2012 Interpretive Notice to only obligate the syndicate manager, rather than each underwriter in the syndicate, to make the dealer-specific disclosures. The 2012 Interpretive Notice currently requires each underwriter to deliver such disclosures. The MSRB declined to incorporate this alternative regulatory approach into the Revised Interpretive Notice, because the elimination of this requirement would mean that issuers would no longer receive the benefit of this disclosure from each underwriter in the syndicate and the omission of this unique and tailored information would eliminate an issuer protection without a significant offsetting benefit to the market.

Lastly, the MSRB considered amending the 2012 Interpretive Notice to create different disclosure tiers based on the particular characteristics of an issuer, such as the issuer's size, knowledge, issuance frequency, or experience of issuer personnel. At this time, the MSRB believes that there are significant drawbacks to such an approach that outweigh possible benefits, including the ongoing costs and difficulties of ensuring that a given issuer remained in an appropriate disclosure tier and whether such tiers could be adequately drawn in a definitive fashion that would reduce regulatory burdens without harming overall issuer protection. Accordingly, the MSRB declined to incorporate this alternative regulatory approach into the Revised Interpretive Notice.

Assessing the Benefits and Costs of the Proposed Rule Change

The MSRB's regulation of the municipal securities market is designed to protect investors, municipal entities, obligated persons, and the public interest by promoting a fair and efficient municipal securities market. The proposed rule change is intended, in part, to reduce burdens on underwriters without decreasing benefits to municipal entity issuers or otherwise diminishing municipal entity issuer protections. The MSRB's analysis below shows that the proposed amendments accomplish this objective. For the purpose of this analysis, the baseline is the current 2012 Interpretative Notice.

A. Consolidating the 2012 Interpretive Notice, the Implementation Guidance, and the FAQs Into the Revised Interpretive Notice

Since this is primarily a technical change from the 2012 Interpretative Notice, the MSRB does not believe there are any significant costs relevant to market participants. However, the MSRB believes that incorporating the Implementation Guidance and FAQs into the Revised Interpretive Notice will promote more efficient dealer compliance in that dealers will only have to reference a single regulatory notice in the future, rather than three separate notices.

B. Amending Nature, Timing, and Manner of Disclosures

i. Define Certain Categories of Underwriter Disclosures

The MSRB believes the added definitions of standard disclosures, transaction-specific disclosures, and dealer-specific disclosures in the proposed rule change would clarify the categories of disclosures and assist underwriters with their compliance with certain new standards in the Revised Interpretive Notice. The MSRB does not believe there is any associated cost to underwriters as a result of these changes, as the changes are more in the nature of a technical amendment.

ii. Assign the Syndicate Manager the Exclusive Responsibility for the Standard Disclosures and Transaction-Specific Disclosures

At present, the 2012 Interpretative Notice allows, but does not require, a syndicate manager to make the standard disclosures and transaction-specific disclosures on behalf of the other syndicate members. The MSRB understands that in accordance with current market practices, the syndicate manager rarely, if ever, provides disclosures for the other syndicate members, and, so, issuers typically receive separate disclosures from other underwriters in the syndicate.

The Revised Interpretive Notice would require the syndicate manager (or the sole underwriter as the case may be) to provide the standard disclosures and transaction-specific disclosures, and eliminate the obligation for the other syndicate members to make these disclosures.[73] The MSRB believes this amendment will alleviate certain burdens associated with the duplication of disclosures where there is a syndicate. The MSRB further believes that this amendment will reduce the likelihood of issuers receiving duplicative standard disclosures and transaction-specific disclosures in potentially inconsistent manners. Ultimately, the MSRB believes such a requirement would simplify issuers' review of standard disclosures and transaction-specific disclosures and allow them to more closely analyze any dealer-specific disclosures that may be received. The MSRB also believes that this amendment will make the process

[69] G–42 FAQs, at p. 2 (note 37 supra).

[70] *See* related discussion under *Proposed Rule Change—Amending the Nature, Timing, and Manner of Disclosures—Clarification of the Meaning of ''Recommendation''; see also Summary of Comments Received in Response to the Concept Proposal—Amending the Nature, Timing, and Manner of Disclosures—Clarification of the Meaning of ''Recommendation''* and *Summary of Comments Received in Response to the Request for Comment—Amending the Nature, Timing, and Manner of Disclosures—Clarification of the Meaning of ''Recommendation''*.

[71] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Email Read Receipt as Issuer Acknowledgement* and related notes 125 *et. seq. infra,* and *Summary of Comments Received in Response to the Request for Comment—Email Read Receipt as Issuer Acknowledgement* and related notes 213 *et. seq. infra.*

[72] *Id.*

[73] *See* related discussion under *Proposed Rule Change—Amending the Nature, Timing, and Manner of Disclosures—Assign the Syndicate Manager the Exclusive Responsibility for the Standard Disclosures and Transaction-Specific Disclosures; see also Summary of Comments Received in Response to the Concept Proposal—Amending the Nature, Timing, and Manner of Disclosures—Syndicate Manager Responsibility for Standard Disclosures and Transaction-Specific Disclosures* and related notes 102 *et. seq. infra,* and *Summary of Comments Received in Response to the Request for Comment—Amending the Nature, Timing, and Manner of Disclosures—Syndicate Manager Responsibility for Standard Disclosures and Transaction-Specific Disclosures* and related notes 169 *et. seq. infra.*

procedurally easier for dealers participating in an underwriting syndicate, because they only have a fair dealing obligation under the Revised Interpretive Notice to deliver their dealer-specific disclosures, if any existed, and would have no obligation to deliver the standard disclosures or transaction-specific disclosures.

iii. Require the Separate Identification of the Standard Disclosures

The proposed rule change would create a new requirement for underwriters that, when providing the various disclosures in the same document, an underwriter would have to clearly identify the standard disclosures. The MSRB believes this amendment will help prevent the disclosures regarding underwriter conflicts and transaction risks from being disclosed within other more boilerplate information.[74] The MSRB believes that the benefits of this amended requirement will be to provide clarity to issuers; diminish certain information asymmetries between underwriters and issuers;[75] reduce the burden of disclosure for syndicate members; and make it easier for issuers to assess the conflicts of interest and risks associated with a given transaction. The costs to dealers for clearly identifying and separating the standard disclosures from the dealer-specific and transaction-specific disclosures should be minimal, and the MSRB believes that the benefits would outweigh the costs.[76]

iv. Clarify the Meaning of ''Recommendation'' for Purposes of Disclosures Related to Complex Municipal Securities Financings

The 2012 Interpretative Notice requires an underwriter to make transaction-specific disclosures to the issuer based on the transaction or financing structure it recommends and the level of knowledge and experience of the issuer with that type of transaction or financing structure. In relevant part, the 2012 Interpretive Notice states:

> The level of disclosure required may vary according to the issuer's knowledge or experience with the proposed financing structure or similar structures, capability of evaluating the risks of the recommended financing, and financial ability to bear the risks of the recommended financing, in each case based on the reasonable belief of the underwriter. In all events, the underwriter must disclose any incentives for the underwriter to recommend the complex municipal securities financing and other associated conflicts of interest.

The proposed rule change would clarify what constitutes a recommendation by adopting a definition for ''recommendation'' from analogous dealer guidance from Rule G–19.[77] As discussed further below, the MSRB believes many underwriters are already familiar with the practical application of this language,[78] and, as a result, the MSRB believes there would be no major implicit or explicit costs associated with the clarification of recommendation, as the MSRB believes the volume of the disclosures generally would remain the same. However, underwriters should experience the benefit of more efficient regulatory compliance by having an expressly defined standard.

v. Establish a ''Reasonably Likely'' Standard for Disclosure of Potential Material Conflicts of Interest

The 2012 Interpretative Notice requires each underwriter to disclose any potential material conflict of interest. The proposed rule change would amend the 2012 Interpretive Notice to require an underwriter to disclose any potential material conflict of interest that is reasonably likely to mature into an actual material conflict of interest during the course of that specific transaction.[79] Potential material conflicts of interest that are not reasonably likely (or do not have such a significant probability) to mature into an actual material conflict of interest during the transaction between the issuer and the underwriter are not required to be disclosed to the issuer at the outset of the engagement. The MSRB believes that a given potential material conflict of interest may have various chances of ripening into an actual material conflict of interest and, at a general level, can reflect a low likelihood, moderate likelihood, or high likelihood of occurring at any given point in time. The proposed rule change should reduce the length and complexity of a dealer's initial dealer-specific disclosures, as the MSRB understands that underwriters presently are inclined to disclose a potential material conflict of interest to an issuer as part of its dealer-specific disclosures even when such conflict is not reasonably likely to mature into an actual material conflict of interest during the course of the transaction because there is some remote likelihood.

The MSRB acknowledges that one potential cost to issuers of this proposed change would be the lost opportunity to evaluate potential material conflicts of interest that, according to the reasonable judgement of the dealer, are not likely to mature into an actual material conflict of interest. Consequently, there is a chance that the proposed change would hinder the issuer's ability to conduct a full risk assessment,

[74] *See* related discussion under *Proposed Rule Change—Amending the Nature, Timing, and Manner of Disclosures—Require the Separate Identification of the Standard Disclosures; see also Summary of Comments Received in Response to the Concept Proposal—Amending the Nature, Timing, and Manner of Disclosures—Require the Separate Identification of the Standard Disclosures* and *Summary of Comments Received in Response to the Request for Comment—Amending the Nature, Timing, and Manner of Disclosures—Require the Separate Identification of the Standard Disclosures.*

[75] In economics, information asymmetry refers to transactions where one party has more or better information than the other.

[76] *See* related discussion under *Proposed Rule Change—Amending the Nature, Timing, and Manner of Disclosures—Require the Separate Identification of the Standard Disclosures; see also Summary of Comments Received in Response to the Concept Proposal—Amending the Nature, Timing, and Manner of Disclosures—Require the Separate Identification of the Standard Disclosures* and *Summary of Comments Received in Response to the Request for Comment—Amending the Nature, Timing, and Manner of Disclosures—Require the Separate Identification of the Standard Disclosures.*

[77] *See* related discussion under *Proposed Rule Change—Amending the Nature, Timing, and Manner of Disclosures—Clarify the Meaning of Recommendation for Purposes of Disclosures Related to Complex Municipal Securities Financings; see also Summary of Comments Received in Response to the Concept Proposal—Clarification of the Meaning of* ''*Recommendation*'' and related notes 131 *et. seq. infra,* and *Summary of Comments Received in Response to the Request for Comment—Guidance Regarding Meaning of* ''*Recommendation*'' and related notes 219 *et. seq. infra.* As further discussed herein, the proposed rule change would clarify that a communication by an underwriter is a ''recommendation'' that triggers the obligation to deliver a complex municipal securities financing disclosure if—given its content, context, and manner of presentation—the communication reasonably would be viewed as a call to action to engage in a complex municipal securities financing or reasonably would influence an issuer to engage in a particular complex municipal securities financing.

[78] *Id.* In the absence of an express standard in the 2012 Interpretive Notice, it is likely that at least some underwriters are already applying a form of this standard in determining whether a ''recommendation'' has been made.

[79] *See* related discussion under *Proposed Rule Change—Amending the Nature, Timing, and Manner of Disclosures—Establish a Reasonably Likely Standard for Disclosure of Potential Material Conflicts of Interest; see also Summary of Comments Received in Response to the Concept Proposal—Amending the Nature, Timing, and Manner of Disclosures—Disclosure of Potential Material Conflicts of Interest* and related notes 98 *et. seq. infra,* and *Summary of Comments Received in Response to the Request for Comment—Amending the Nature, Timing, and Manner of Disclosures—Disclosure of Potential Material Conflicts of Interest* and related notes 161 *et. seq. infra.*

particularly around the decision of whether to engage a particular underwriter for a given transaction.[80]

Nevertheless, the MSRB believes the benefits of the proposed change outweigh its potential costs, as this change will both reduce the burden placed on underwriters and also reduce the volume of disclosures received by issuers, while continuing to ensure that issuers are notified in writing of relevant conflicts of interest, and, thereby, promoting the protection of issuers by facilitating the ability of issuers to more efficiently evaluate and consider those potential material conflicts of interest that are most concrete and probable. Issuers would not have to review potential material conflicts of interest that are not reasonably likely to ripen during the course of the transaction. When there are too many disclosures, it is possible that an issuer's ability to make a comprehensive and efficient assessment of the disclosures is diminished. With the proposed rule change, issuers should be able to discern which conflicts of interest present actual material risks or material risks that are reasonably likely to actually develop during the course of the transaction, therefore reducing asymmetric information between the underwriters and issuers. Relatedly, excluding potential material conflicts of interest that are unlikely to occur would create initial/upfront costs to underwriters since underwriters would have to amend their policies and procedures to specify what constitutes a ''reasonably likely'' potential material conflict of interest, though the MSRB believes that such costs would be minor and are justified by offsetting benefits.

vi. Clarify That Underwriters Are Not Obligated To Provide Written Disclosure of Conflicts of Other Parties

None of the requirements in the 2012 Interpretative Notice require the underwriter to provide the issuer with disclosures on the part of any other transaction participants, including issuer personnel. However, the MSRB received comments requesting clarification on this point,[81] and the proposed rule change would provide a clarification that underwriters are not required to make any disclosures on the part of issuer personnel or any other parties to the transaction. This clarification should reduce the burden on firms that were mistakenly under the impression that underwriters are required to disclose the conflicts of other transaction participants, as well as provide clarity to regulatory authorities examining and enforcing MSRB rules. Assuming underwriters are already compliant with the 2012 Interpretative Notice, there are no implicit or explicit economic benefits or costs associated with the clarification in the proposed rule change. To the degree that regulators may be inappropriately interpreting and applying the 2012 Interpretative Notice in connection with examination and enforcement proceedings, regulators and underwriters will benefit from the clarification in that it should reduce the amount of time spent on such activity.[82]

vii. Clarify That Disclosures Must Be ''Clear and Concise''

Assuming underwriters are already compliant with the requirements under the 2012 Interpretative Notice, the MSRB believes there are no implicit or explicit economic benefits or costs associated with not amending the statement from the 2012 Interpretive Notice that ''disclosures must be made in a manner designed to make clear to such officials the subject matter of such disclosures and their implications to the issuer'' [83] and amending the 2012 Interpretive Notice to further clarify that, consistent with the existing language, disclosures must be drafted in a ''clear and concise manner.'' [84]

C. Require an Additional Standard Disclosure Regarding the Engagement of Municipal Advisors

The 2012 Interpretative Notice prohibits an underwriter from recommending that an issuer not retain a municipal advisor. By supplementing this language with the requirement that underwriters affirmatively state in their standard disclosures that ''the issuer may choose to engage the services of a municipal advisor with a fiduciary obligation to represent the issuer's interests in the transaction,'' the proposed rule change would further promote an issuer's understanding of the distinct roles of an underwriter and a municipal advisor.[85] Moreover, the MSRB believes that coupling this amendment with the incorporation of the existing language from the Implementation Guidance will promote issuer protection in the market by further ensuring that issuers are able to more freely evaluate their potential engagements with municipal advisors without undue bias.[86]

The possible benefits of this proposed change are demonstrated by a study from 2006, showing that an issuer's use of a financial advisor in the municipal bond issuance process reduces underwriter gross spreads, provides statistically significant borrowing costs savings, and lower reoffering yields.[87]

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[80] For example, if a potential material conflict of interest is first omitted from the dealer-specific disclosures—because the dealer correctly deems the risk to be possible, but not reasonably likely—and the conflict of interest, in actuality, has a higher likelihood and, ultimately, ripens into an actual material conflict of interest during the course of the transaction, then the dealer would still be required to timely disclose the conflict of interest when it ripens into an actual material conflict. However, the failure to disclose this possible conflict of interest at the first delivery of the dealer-specific disclosures, as currently required under the 2012 Interpretative Notice, may result in an inadequate due diligence performed by the issuer on the underwriter due to the information asymmetry between the issuer and the underwriter. *See Id.*

[81] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Amending the Nature, Timing, and Manner of Disclosures—Clarification that Underwriters Are Not Obligated to Provide Written Disclosure of Conflicts of Other Parties* and related note 114 and *Summary of Comments Received in Response to the Request for Comment—Amending the Nature, Timing, and Manner of Disclosures—Clarification that Underwriters Are Not Obligated to Provide Written Disclosure of Conflicts of Other Parties* and related notes 194 *et. seq. infra.*

[82] SIFMA expressed concern that ''regulators conflate conflicts of interest.'' *See* SIFMA Letter I, at p. 7 note 15 (''We also note that, in some cases, it appears that regulators conflate conflicts of interest that might exist on the part of other parties to a financing, including in particular conflicts on the part of issuer personnel, with conflicts on the part of the underwriter, and therefore regulators appear to expect that the conflicts disclosure under the [2012 Interpretive Notice] should include these conflicts of other parties. SIFMA and its members request that the MSRB clarify that the [2012 Interpretive Notice] does not require the underwriter to disclose conflicts on the part of parties other than the underwriter.'').

[83] *See* related discussion under *Proposed Rule Change—Amending the Nature, Timing, and Manner of Disclosures—Clarify that Disclosures Must Be Clear and Concise; see also Summary of Comments Received in Response to the Concept Proposal—Amending the Nature, Timing, and Manner of Disclosures—Clarity of Disclosures* and related notes 117 *et. seq. infra,* and *Summary of Comments Received in Response to the Request for Comment – Amending the Nature, Timing, and Manner of Disclosures—Clarity of Disclosures* and related notes 196 *et. seq. infra.*

[84] As indicated by one commenter, this standard should minimize any re-drafting of existing disclosure templates. *See* SIFMA Letter II, at p. 6 (stating a clear and concise standard ''is in line with the MSRB's disclosure principles as well as the goals of the retrospective review'').

[85] *See* related discussion under *Proposed Rule Change—Require an Additional Standard Disclosure Regarding the Engagement of Municipal Advisors; see also Summary of Comments Received in Response to the Concept Proposal—Underwriter Discouragement of Use of Municipal Advisor; Addition of a New Standard Disclosure Regarding the Engagement of Municipal Advisors* and related notes 134 *et. seq. infra,* and *Summary of Comments Received in Response to the Request for Comment—Inclusion of Existing Language Regarding the Discouragement of an Issuer's Engagement of a Municipal Advisor and Incorporation of a New Standard Disclosure Regarding the Issuer's Choice to Engage a Municipal Advisor* and related notes 201 *et. seq. infra.*

[86] *Id.*

[87] Vijayakumar Jayaraman and Kenneth N. Daniels, ''The Role and Impact of Financial

The results of the study are consistent with the interpretation that the monitoring and information asymmetry reduction roles of financial advisors potentially reduce the perceived risk for issuers. Another study from 2010 found lower interest costs with municipal issues using financial advisors, and the interest cost savings were significantly large especially for more opaque and complex issues.[88] Given that an underwriter does not have the same fiduciary responsibility of a municipal advisor, the MSRB believes that clarifying the distinct roles of underwriters and municipal advisors should continue to improve market practices and further ensure that an issuer's decision to engage a municipal advisor is made without undue interference, which may obscure the issuer's overall evaluation of the costs and benefits of municipal advisory services.

As to the potential costs of compliance, underwriters would have to affirmatively state in their standard disclosures that an issuer may choose to engage the services of a municipal advisor with a fiduciary obligation to represent the issuer's interests in the transaction. Therefore, underwriters would incur additional cost associated with revising their policies and procedures (a one-time upfront cost) and delivering the statement in their standard disclosures during a transaction. Beyond this update to their standard disclosures and any related updates to their policies and procedures, the MSRB does not believe there will be any further ongoing implementation costs to underwriters.

D. Permit Email Read Receipt To Serve as Issuer Acknowledgement

Currently, the 2012 Interpretative Notice requires underwriters to attempt to receive written acknowledgement of receipt of the disclosures by an official of the issuer. The proposed rule change would allow for an email read receipt to serve as an acknowledgement.[89] The MSRB believes that the acknowledgement requirement continues to have value to ensure that issuers receive the disclosures. Allowing for an email read receipt to constitute written acknowledgement should reduce burdens on underwriters (including syndicate managers, when there is a syndicate) and on issuers, in that underwriters and issuers will no longer be required to follow up with written acknowledgements when such receipt is utilized. Nevertheless, underwriters should expect minor initial upfront costs (which are optional) associated with the implementation of the use of email read receipts, and related compliance, supervisory, training, and record-keeping procedures. However, the MSRB believes that the benefits associated with the reduced burden of spending time to obtain written acknowledgement would accrue over time and should exceed the initial costs.

Effect on Competition, Efficiency and Capital Formation

The MSRB believes that the proposed amendments to the 2012 Interpretative Notice as reflected in the Revised Interpretive Notice should improve the municipal securities market's operational efficiency by promoting consistency in underwriters' disclosures to issuers and promoting greater transparency. At present, the MSRB is unable to quantitatively evaluate the magnitude of the efficiency gains or the cost of compliance with the new requirements, but believes the benefits outweigh the costs. Additionally, the MSRB believes that the proposed rule change should also reduce confusion and risk to both underwriters and issuers; reduce information asymmetry between underwriters and issuers; and allow issuers to make more informed financing decisions. Therefore, the proposed amendments to the 2012 Interpretative Notice would improve capital formation. Finally, since the proposed rule change would be applicable to all underwriters, it would not have a negative impact on market competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The MSRB published the Concept Proposal on June 5, 2018 and published the Request for Comment on November 16, 2018. The Concept Proposal sought public comment on various aspects of the 2012 Interpretive Notice, including the benefits and burdens of the 2012 Interpretive Notice at a general level, and how the 2012 Interpretive Notice might be amended to ensure that it continues to achieve its intended purpose in light of current practices in the municipal securities market.

The Request for Comment incorporated the comments received on the Concept Proposal by providing specific amendments to the text of the 2012 Interpretive Notice. Additionally, through a series of questions, the MSRB sought more specific feedback from market participants in the Request for Comment regarding how the 2012 Interpretive Notice might be improved to remove unnecessary burdens on market participants, while at the same time ensuring that it continues to achieve its intended purpose.

The following discussion summarizes the comments received in response to the Concept Proposal and the Request for Comment and sets forth the MSRB's responses thereto. The discussion does not provide specific responses for every comment, as, for example, when the MSRB only received a high-level general comment on a topic area. Comments to the Concept Proposal are discussed first and comments to the Request for Comment are discussed in the immediately following section. The summary includes cross-references from the discussion of the Concept Proposal to the discussion of the Request for Comment, and vice versa, in order to identify the discussion of comments received on the same or similar topics for ease of review. For topics that were incorporated into the Concept Proposal, but subsequently not incorporated into the Request for Comment, the discussion below incorporates a footnote statement indicating that no further discussion of the topic is included in the summary of comments to the Request for Comment, along with a brief summary discussion of any significant comments received to the Request for Comment.

I. Summary of Comments Received in Response to the Concept Proposal

The MSRB received five comment letters in response to the Concept Proposal.[90] Each of the commenters generally indicated their support of the retrospective review of the 2012 Interpretive Notice as outlined in the Concept Proposal and each had specific suggestions on how the 2012 Interpretive Notice could be improved, as discussed further below.

Advisors in the Market for Municipal Bonds,'' Journal of Financial Services Research, 2006. After investigating how using a financial advisor affects the interest costs of issuers, Vijayakumar and Daniels, find that a financial advisor significantly reduces municipal bond interest rates, reoffering yields, and underwriters' gross spreads.

[88] Allen, Arthur and Donna Dudney, ''Does the Quality of Financial Advice Affect Prices?'' The Financial Review 45, 2010.

[89] *See* related discussion under *Proposed Rule Change—Permit Email Read Receipt to Serve as Issuer Acknowledgement; see also* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Email Read Receipt as Issuer Acknowledgement* and related notes 125 *et. seq. infra,* and *Summary of Comments Received in Response to the Request for Comment—Email Read Receipt as Issuer Acknowledgement* and related notes 213 *et. seq. infra.*

[90] *See* note 8 *supra.*

A. Consolidating the 2012 Interpretive Notice, the Implementation Guidance, and the FAQs Into a Single Interpretive Notice

i. General Comments Encouraging the Consolidation of the Implementation Guidance and the FAQs

SIFMA's response to the Concept Proposal stated that, if the MSRB were to amend the 2012 Interpretive Notice, ''. . . it would be critical to incorporate or otherwise preserve the guidance included in the Implementation Guidance and FAQs, with any modifications appropriate in light of the changes to the [2012 Interpretive Notice].'' [91] SIFMA further elaborated on this request, indicating that the Implementation Guidance provides a ''deeper understanding'' of the 2012 Interpretive Notice and that the FAQs provide important guidance in ''response to questions raised by underwriters based on their experience with initial implementation'' of the 2012 Interpretive Notice.[92] No other commenters on the Concept Proposal addressed this issue.[93] In response to SIFMA's comments, the MSRB proposed to incorporate the substance of the Implementation Guidance and FAQs into the Request for Comment, along with certain conforming edits and supplemental modifications to address other proposed amendments.[94]

ii. Modification of Implementation Guidance's Language Regarding the ''No Hair-Trigger''

As stated above, the Implementation Guidance provides the following regarding the timing and delivery of disclosures under the 2012 Interpretive Notice:

> The timeframes set out in the Notice should be viewed in light of the overarching goals of Rule G–17 and the purposes that required disclosures are intended to serve as described in the [2012 Interpretive Notice]. That is, the issuer (i) has clarity throughout all substantive stages of a financing regarding the roles of its professionals, (ii) is aware of conflicts of interest promptly after they arise and well before it effectively becomes fully committed (either formally or due to having already expended substantial time and effort) to completing the transaction with the underwriter, and (iii) has the information required to be disclosed with sufficient time to take such information into consideration before making certain key decisions on the financing. Thus, the timeframes set out in the [2012 Interpretive Notice] are not intended to establish hair-trigger tripwires resulting in technical rule violations so long as underwriters act in substantial compliance with such timeframes and have met the key objectives for providing such disclosures under the [2012 Interpretive Notice].

SIFMA's comment letter on the Concept Proposal urged the MSRB to reconfirm this language, stating SIFMA's belief that the language is a critical acknowledgement of the market reality that transactions rarely proceed on uniform timelines. Like the incorporation of the other language from the Implementation Guidance and FAQs described above, the MSRB agrees that this language provides an important supplementary gloss to the language of the 2012 Interpretive Notice. However, the MSRB believed at the time that it drafted the Request for Comment that it was worthwhile to propose certain modifications to this language in order to solicit additional input regarding the practical effects of the language in the market and, in particular, its practical impact on dealer compliance. Accordingly, the MSRB incorporated modified language in the Request for Comment by omitting its final sentence (*i.e.,* deleting the statement that, ''. . . the timeframes set out in the [2012 Interpretive Notice] are not intended to establish hair-trigger tripwires resulting in technical rule violations so long as underwriters act in substantial compliance with such timeframes and have met the key objectives for providing such disclosures under the [2012 Interpretive Notice].''). In effect, the Request for Comment proposed withdrawing this particular language of the Implementation Guidance.[95]

B. Amending the Nature, Timing, and Manner of Disclosures

Each of the five commenters on the Concept Proposal offered improvements to the nature, timing, and manner of disclosures required under the 2012 Interpretive Notice. At a more general level, several commenters shared the view that the municipal securities market would benefit from reducing the volume and ''boilerplate'' nature of the disclosures required under the 2012 Interpretive Notice, as there was a shared belief among these commenters that the level of disclosure required by the 2012 Interpretive Notice, in many respects, overly burdened underwriters and issuers alike without any offsetting benefits.[96]

i. Disclosures Concerning the Contingent Nature of Underwriting Compensation

The 2012 Interpretive Notice requires underwriters to disclose the contingent nature of their underwriting compensation. The Concept Proposal requested feedback on this topic. SIFMA commented that disclosures concerning the contingent nature of underwriting compensation should be eliminated, because contingent underwriting compensation effectively is a universal practice. In response, the MSRB incorporated a proposed amendment into the Request for Comment that would require the disclosure concerning the contingent nature of underwriting compensation to be incorporated into an underwriter's standard disclosures, in acknowledgement of the fact that contingent compensation is a nearly-universal practice, yet continues to present an inherent conflict of interest. The Request for Comment clarified, however, that if a dealer were to underwrite an issuer's offering with an alternative compensation structure, the dealer would need to both indicate in its transaction-specific disclosures that the information included in its standard disclosure on underwriter compensation does not apply and also explain the alternative compensation structure as part of its transaction-specific disclosures, to the extent that such alternative compensation structure also presents a conflict of interest.[97]

[91] SIFMA Letter I, at p. 4.

[92] *Id.,* at pp. 3–4.

[93] It should be noted that the MSRB did not seek specific comment on this topic in the Concept Proposal.

[94] As further discussed herein, the MSRB ultimately chose to incorporate these amendments into the proposed rule change. This general concept of incorporating the substantive language of the Implementation Guidance and FAQs into the Revised Interpretive Notice is not discussed again under the Summary of Comments Received in Response to the Request for Comment, but the MSRB does provide a summary of comments received in response to the incorporation of particular concepts and language from the Implementation Guidance and FAQs (*e.g.,* comments regarding whether the no-hair trigger language should be incorporated into the Revised Interpretive Notice).

[95] The proposed rule change reincorporates this language with certain revisions, as further discussed herein. *See* related discussion under *Summary of Comments Received in Response to the Request for Comment—Consolidating the 2012 Interpretive Notice, the Implementation Guidance, and the FAQs into a Single Interpretive Notice—Reincorporation of the ''No Hair-Trigger'' Language from the Implementation Guidance* and related notes 157 *et. seq. infra.*

[96] In this regard, GFOA commented that the disclosures currently required ''are often boilerplate and cumbersome.'' GFOA Letter I, at p. 1. NAMA similarly commented that ''disclosures are buried within lengthy documents that contain hypothetical potential conflicts and risks.'' NAMA Letter I, at p. 1. Similarly, SIFMA encouraged the MSRB to ''be cognizant of the substantial compliance burden on underwriters and complaints expressed by some issuers regarding excessive documentation resulting from the [2012 Interpretive Notice]'' and ''more precisely define the content of and the process for providing the disclosures required by the [2012 Interpretive Notice].'' SIFMA Letter I, at p. 5.

[97] Ultimately, the proposed rule change did not incorporate this amendment to the 2012 Interpretive Notice, as further discussed herein. *See* related discussion under *Summary of Comments*

ii. Disclosure of Potential Material Conflicts of Interest

The 2012 Interpretive Notice requires an underwriter to disclose certain actual material conflicts of interest and potential material conflicts of interest (*i.e.,* the dealer-specific disclosures), including certain conflicts regarding payments received from third parties, profit-sharing arrangements with investors, credit default swap activities, and/or incentives related to the recommendation of a complex municipal securities financing. Several commenters to the Concept Proposal suggested that the dealer-specific disclosures, as currently required, cause underwriters to deliver overly voluminous disclosures, which do not differentiate the most concrete and probable material conflicts from those that are merely possible.

From the dealer perspective, SIFMA stated its belief that ''issuers in many cases are receiving excessive amounts of disclosures of potential and often remote conflicts that are of little or no practical relevance to issuers or the particular issuances and would benefit from more focused disclosure on conflicts that actually matter to them.'' [98] BDA concurred, stating its belief that ''one of the factors that contributes to the length and complexity of Rule G–17 Disclosures is that underwriters disclose all potential conflicts of interests instead of known, actual conflicts of interests.'' [99] Similarly, GFOA stated that ''the documents are full of non-material potential disclosures where key material disclosures are not highlighted nor flagged, and in many cases buried in the information provided.'' [100]

Based on these comments, the MSRB proposed an amendment to the 2012 Interpretive Notice in the Request for Comment clarifying that a dealer would have a fair obligation to disclose a potential material conflict of interest if, but only if, it is ''reasonably foreseeable'' that such a conflict would mature into an actual material conflict of interest during the course of a specific transaction between the issuer and the underwriter. The MSRB believed that the revision would preserve the requirement that issuers continue to receive disclosures regarding potential material conflicts of interest, while narrowing the amount of potential material conflicts to eliminate the need for those disclosures that are highly remote and generally unlikely to ripen into actual material conflicts of interest.[101]

iii. Syndicate Manager Responsibility for the Standard Disclosures and Transaction-Specific Disclosures

Under the 2012 Interpretive Notice, a syndicate manager may make the standard disclosures and transaction-specific disclosures on behalf of other syndicate members. The Concept Proposal requested feedback on how often this option has been utilized and whether such option was effective. The MSRB received four specific comments in response. BDA commented that large, frequent issuers receive so many disclosures because co-managers of a syndicate do not exercise their ability to collectively make the required disclosures in this manner and, further, recommended that the MSRB amend the 2012 Interpretive Notice to provide that ''co-managers have no requirement to deliver any Rule G–17 disclosures except for the circumstance where the co-manager has a discrete conflict of interest that materially impacts its engagement with the issuer.'' [102] The Florida Division of Bond Finance also recognized the issue of duplication when there is a syndicate,[103] and NAMA stated its belief that syndicate members should not be allowed to provide boilerplate disclosures when they are provided by the syndicate manager.[104] Finally, SIFMA noted that dealers do not consistently utilize the option of having a syndicate manager make the standard and transaction-specific disclosures on behalf of other co-managing underwriters in the syndicate, and suggested that this may be the result because it is procedurally easier for a co-managing underwriter to provide these disclosures when delivering their dealer-specific disclosures, or because it may be more difficult or risky from a compliance perspective to rely on the syndicate manager.[105]

Given the stated positions of these commenters that disclosures provided by co-managing underwriters in a syndicate often are duplicative and, therefore, voluminous, the MSRB incorporated a proposed amendment into the Request for Comment requiring, rather than permitting, the standard disclosures and transaction-specific disclosures to be made by a syndicate manager on behalf of the syndicate. The MSRB believed that such a revision would promote market efficiency by reducing the amount of duplicative disclosures that underwriters in a syndicate must deliver and, consequently, the number of duplicative disclosures that an issuer must acknowledge and review.[106]

iv. Alternative to the Transaction-by-Transaction Delivery of the Disclosures Proposed in the Request for Comment

The 2012 Interpretive Notice currently requires underwriters to provide issuers all of the disclosures on a transaction-by-transaction basis. In response to the Concept Proposal, SIFMA suggested an alternative manner of providing the required disclosures to address the issues of volume and duplication, and to reduce the burdens on both dealers and issuers. Specifically, SIFMA proposed that, when an underwriter engages in one or more negotiated underwritings with a particular issuer, the underwriter would be able to fulfill its disclosure requirements with respect to an offering by reference to, or by reconfirming to the issuer, its disclosures provided in the previous 12 months (*e.g.,* disclosures provided in connection with a prior offering during such period or provided on an annual basis in anticipation of serving as underwriter

Received in Response to the Request for Comment—Amending the Nature, Timing, and Manner of Disclosures—Disclosures Concerning the Contingent Nature of Underwriting Compensation and related notes 159 *et. seq. infra.*

[98] SIFMA Letter I, at p. 7.

[99] BDA Letter I, at p. 2.

[100] GFOA Letter I, at p. 1.

[101] Ultimately, the proposed rule change incorporates a version of this concept, but refined to a ''reasonably likely'' standard, rather than a ''reasonably foreseeable'' standard, as further discussed herein. *See* related discussion under *Summary of Comments Received in Response to the Request for Comment—Amending the Nature, Timing, and Manner of Disclosures—Disclosure of Potential Material Conflicts of Interest* and notes 161 *et. seq. infra.*

[102] BDA Letter I, at pp. 2–3.

[103] Florida Division of Bond Finance Letter (stating ''such disclosures are duplicative when multiple underwriters are involved in the same transaction'').

[104] NAMA Letter I, at p. 2.

[105] SIFMA Letter I, at p. 14 (''One reason this may be the case is that each syndicate member is obligated to provide its own disclosure of actual or potential conflicts of interest, and it is often procedurally easier to combine role disclosures and conflicts disclosures into a single document. Another reason may be that a particular underwriter has determined not to rely on another firm's actions to meet the underwriter's own regulatory obligations, or only permits such reliance upon confirmation that the syndicate manager has provided the required disclosure and has found that providing its own disclosure may be administratively easier than obtaining confirmation of the syndicate manager's disclosure.'').

[106] Ultimately, the proposed rule change incorporates a version of this concept, but with certain refinements, as further discussed herein. *See* related discussion under *Summary of Comments Received in Response to the Request for Comment—Amending the Nature, Timing, and Manner of Disclosures—Syndicate Manager Responsibility for the Standard Disclosures and Transaction-Specific Disclosures* and notes 169 *et. seq. infra.*

on offerings during the next 12 months).[107] Under this construct, SIFMA explained that the underwriter would be required to provide any new disclosures or changes to previously disclosed information when they arise. SIFMA recommended that this manner of providing disclosures would be a permissible alternative and that an underwriter could continue to provide its disclosures on a transaction-by-transaction basis. Relatedly, and as previously mentioned, GFOA indicated in its response to the Concept Proposal that providing non-material or boilerplate disclosures annually might improve the disclosure process.[108] NAMA's response to the Concept Proposal stated its belief that it would be difficult to make disclosures on an annual basis without the need for supplementary material throughout the year and, therefore, commented that the easiest manner of disclosure delivery is to leave the relevant portions of the 2012 Interpretive Notice unchanged.

The MSRB was persuaded by SIFMA's suggestion to allow for an alternative to a transaction-by-transaction approach to disclosure, but also thought that NAMA's concern about the need to allow for updates and other supplementary material merited incorporation into any such alternative approach. Accordingly, the MSRB incorporated proposed amendments to the 2012 Interpretive Notice in the Request for Comment that would have permitted standard disclosures to be furnished to an issuer one time and then subsequently referenced and reconfirmed in future offerings, unless the issuer requests that the standard disclosures be made on a transaction-by-transaction basis.[109]

v. Separate Identification of the Standard Disclosures

The Concept Proposal asked for general feedback on alternative approaches for the delivery of the disclosures required under the 2012 Interpretive Notice. Among other comments discussed herein, GFOA suggested that the MSRB emphasize the current obligation within the 2012 Interpretive Notice requiring underwriters to identify generic or boilerplate disclosures.[110] Similarly, NAMA stated that the MSRB should ''ensure that underwriters provide material transaction risks and conflicts disclosures in a manner that is easily identifiable by the issuer (including various members of the issuing entity's internal finance team and governing body),'' [111] and the Florida Division of Bond Finance stated that ''the disclosures provided to issuers are boilerplate, and may inadvertently bury disclosures of specific conflicts and risks within pages of nonmaterial information and legalese.'' [112] Accordingly, the MSRB incorporated a requirement in the Request for Comment that would have required clear identification of each category of disclosures and separated them by placing the standard disclosures in an appendix or attachment. The MSRB suggested that such a change would allow issuers to discern and focus on the disclosures most important to them.[113]

vi. Clarification That Underwriters Are Not Obligated To Provide Written Disclosure of Conflicts of Other Parties

As previously stated, the 2012 Interpretive Notice requires underwriters to provide issuers with the standard, dealer-specific, and transaction-specific disclosures. In its response to the Concept Proposal, SIFMA commented that, in some cases, it appears that other regulators conflate conflicts of interest that might exist on the part of other parties to a financing, including, in particular, conflicts of issuer personnel,[114] and, therefore, those other regulators appear to expect that the conflicts disclosure under the 2012 Interpretive Notice should include these conflicts of interest of other parties. SIFMA requested clarification on this point.[115] In response, the MSRB incorporated a proposed amendment in the Request for Comment that explicitly stated that ''underwriters are not required to make any disclosures on the part of issuer personnel or any other parties to the transaction.'' [116]

vii. Clarity of Disclosures

The 2012 Interpretive Notice requires that disclosures be made in a manner designed to make clear to an issuer official the subject matter of such disclosures and their implications for the issuer. In their comments to the Concept Proposal, GFOA encouraged the MSRB to require the disclosures be provided in a ''plain English'' manner,[117] and NAMA indicated that the disclosures should be presented in a straight-forward manner.[118] Believing that the standard for the manner of disclosures currently in the 2012 Interpretive Notice are consistent and substantially similar to GFOA's proposed ''plain English'' standard, the MSRB proposed amendments to the 2012 Interpretive Notice in the Request for Comment that explicitly clarified that the disclosures be drafted in plain English.[119]

viii. Disclosures Regarding Third-Party Marketing Arrangements

SIFMA's comment letter on the Concept Proposal encouraged the MSRB to eliminate the dealer-specific disclosures regarding third-party marketing arrangements, stating that ''we do not believe that the conflicts disclosure requirement under the 2012

[107] SIFMA Letter I, at p. 10–11.

[108] GFOA Letter I, at p. 2.

[109] The Request for Comment further clarified that, if the original standard disclosure needed to be amended, the syndicate manager would be permitted to deliver such amended standard disclosures. Similarly, in cases where such syndicate members may, themselves, subsequently be syndicate managers or sole underwriters, the Request for Comment would have allowed them to reference and reconfirm prior disclosures made on their behalf. Ultimately, the proposed rule change does not incorporate a version of this concept for the reasons discussed herein. *See* related discussion under *Summary of Comments Received in Response to the Request for Comment—Amending the Nature, Timing, and Manner of Disclosures—Alternative to the Transaction-by-Transaction Delivery of the Disclosures* as Proposed in the Request for Comment and related notes 183 *et. seq. infra.*

[110] GFOA Letter I, at p. 2.

[111] NAMA Letter I, at p. 2.

[112] Florida Division of Bond Finance Letter.

[113] Ultimately, the proposed rule change incorporates a version of this concept, as further discussed herein. *See* related discussion under *Summary of Comments Received in Response to the Request for Comment—Amending the Nature, Timing, and Manner of Disclosures—Separate Identification of the Standard Disclosures* and related notes 189 *et. seq. infra.*

[114] *See* SIFMA Letter I, at p. 7 note 15 (''We also note that, in some cases, it appears that regulators conflate conflicts of interest that might exist on the part of other parties to a financing, including in particular conflicts on the part of issuer personnel, with conflicts on the part of the underwriter, and therefore regulators appear to expect that the conflicts disclosure under the [2012 Interpretive Notice] should include these conflicts of other parties. SIFMA and its members request that the MSRB clarify that the [2012 Interpretive Notice] does not require the underwriter to disclose conflicts on the part of parties other than the underwriter.'').

[115] *Id.*

[116] Ultimately, the proposed rule change incorporates a version of this concept, but with certain refinements, as further discussed herein. *See* related discussion under *Summary of Comments Received in Response to the Request for Comment—Amending the Nature, Timing, and Manner of Disclosures—Clarification that Underwriters Are Not Obligated to Provide Written Disclosure of Conflicts of Other Parties* and related notes 194 *et. seq. infra.*

[117] GFOA Letter I, at p. 2.

[118] NAMA Letter I, at p. 2 (stating, ''. . . information should be presented in a straight forward manner, with other general disclosures presented separately from the statements and discussions of material transaction risks and conflicts disclosures (including [the] statement that the underwriter does not have a fiduciary duty to the issuer)'').

[119] *See* related discussion under *Summary of Comments Received in Response to the Request for Comment—Amending the Nature, Timing, and Manner of Disclosures—Clarity of Disclosures* and related notes 196 *et seq. infra.*

Guidance is the appropriate mechanism for ensuring that issuers understand the participation of such third-parties.'' [120] SIFMA argued that these disclosure requirements should be eliminated because ''the use of retail distribution agreements is not an activity involving suspicious payments to a third party and does not increase costs to issuers; rather, it simply passes on a discounted rate to a motivated dealer, which is commonly available to dealers after the bonds have become free to trade in any event, notwithstanding any agreement.'' [121]

The MSRB chose not to incorporate this amendment into the Request for Comment and did not incorporate any such amendment into the proposed rule change. While the MSRB agrees with SIFMA's point that third-party marketing agreements are not inherently ''suspicious'' activity, the MSRB believes that such agreements could create material conflicts of interest and that there may be circumstances in which an issuer would not or could not have certain dealers participate in the underwriting in such capacity. For example, an issuer may be subject to jurisdictional requirements that could dictate the participation or non-participation of certain dealers, or an issuer may have a preference to not involve certain dealers in their offering due to reputational concerns. The MSRB believes that it remains important for underwriters to disclose this information to issuers and, accordingly, did not propose any such changes in the Request for Comment and is not proposing any such change to this aspect of the 2012 Interpretive Notice in the proposed rule change.[122]

ix. Disclosures Regarding Credit Default Swaps

The 2012 Interpretive Notice specifically references an underwriter's engagement in certain credit default swap activities as a potential material conflict of interest that would require disclosure to the issuer. Similar to its request that the MSRB eliminate the disclosure requirements regarding third-party marketing arrangements, SIFMA also requested that the MSRB eliminate this specific reference to credit default swaps. SIFMA noted that dealer use of, and participation in, credit default swaps has significantly decreased since the financial crisis and the adoption of the Dodd-Frank Wall Street Reform and Consumer Protection Act, and, as a result, in SIFMA's view, the reference is no longer as relevant.[123] The MSRB believes that, even if credit default swaps are less prevalent in the municipal securities market, the possibility for underwriters to issue or purchase credit default swaps for which the reference is the issuer remains. The MSRB believes that it remains important for underwriters to disclose this information to issuers and, accordingly, did not propose any such changes in the Request for Comment and is not proposing any such change to this aspect of the 2012 Interpretive Notice in the proposed rule change.[124]

C. Email Read Receipt as Issuer Acknowledgement

The 2012 Interpretive Notice requires underwriters to attempt to receive written acknowledgement of receipt of the disclosures by an official of the issuer (other than by automatic email receipt). If the official of the issuer agrees to proceed with the underwriting engagement after receipt of the disclosures but will not provide written acknowledgement of receipt, the underwriter may proceed with the engagement after documenting with specificity why it was unable to obtain such written acknowledgement during the course of the engagement.

In its response to the Concept Proposal, SIFMA commented that this requirement creates a significant burden for underwriters with no corresponding benefit to issuers.[125] SIFMA encouraged the MSRB to eliminate the acknowledgement requirement.[126] To address this issue, SIFMA recommended that receipt of an email return receipt should be conclusive proof of delivery if other transaction documentation has also been provided to the same email address.[127] GFOA did not comment on this issue of changing the form or type of acknowledgement, but did indicate that frequent issuers are burdened by the acknowledgement requirement in that they must ''tackle and acknowledge the paperwork'' many times.[128] NAMA stated its belief that the acknowledgement requirement should remain in place, but provide greater flexibility to allow ''issuers to execute acknowledgements as they see fit.'' [129]

Based on such comments, the MSRB proposed in the Request for Comment to retain the acknowledgement requirement, but allow for email delivery of the disclosures to the official of the issuer identified as the primary contact for the issuer and provide that an automatic email receipt confirming electronic delivery of the applicable disclosures may be a means to satisfy the acknowledgement requirement.[130]

D. Clarification of the Meaning of ''Recommendation''

Under the 2012 Interpretive Notice, whether an underwriter must make the transaction-specific disclosures, as well as the type of transaction-specific disclosures it must deliver, depends on whether the underwriter recommends certain financing structures to the issuer. In its response to the Concept Proposal, SIFMA requested clarification as to whether the MSRB's guidance on the meaning of ''recommendation'' under Rule G–42, on duties of non-solicitor municipal advisors, describing a two-prong analysis for determining whether advice is a recommendation for purposes of that rule (*i.e.,* a G–42 Recommendation) applies when determining whether an underwriter has recommended a complex municipal securities financing.[131] More specifically, the relevant guidance under Rule G–42 provides the following

[120] SIFMA Letter I, at p. 8.

[121] *Id.*

[122] This concept is not discussed again under the *Summary of Comments Received in Response to the Request for Comment.* The MSRB did not receive any further significant comments on this concept subsequent to the Request for Comment other than SIFMA's reiteration that these disclosures should be eliminated. SIFMA Letter II, at pp. 4–5, note 12.

[123] SIFMA Letter I, pp. 8–9.

[124] Given that the MSRB did not incorporate this particular concept into the proposed rule change, this concept is not discussed again under the *Summary of Comments Received in Response to the Request for Comment.* The MSRB did not receive any further significant comments on this concept subsequent to the Request for Comment other than SIFMA's reiteration that these disclosures should be eliminated. SIFMA Letter II, at pp. 4–5, note 12.

[125] SIFMA Letter I, at p. 13 (stating, ''. . . we believe the requirement for the underwriter to attempt to receive an issuer acknowledgment and the efforts to document cases where the issuer does not provide such acknowledgment create a significant degree of non-productive work on the part of underwriter personnel and provide no value to the issuer, but often produce unwanted follow-up inquiries from the underwriter'').

[126] *Id.*

[127] *Id.*

[128] GFOA Letter I, at p. 2. Relatedly, GFOA's comments to the Concept Proposal also stated that certain ''boilerplate disclosures'' could be provided on an annual basis for frequent issuers, indicating that a more flexible approach to the acknowledgement of at least boilerplate disclosures could alleviate burdens on such issuers. *Id.*

[129] NAMA Letter I, at p. 2.

[130] The proposed rule change incorporates a version of this concept, but with certain refinements that would distinguish email read receipts—which would be permitted to serve as acknowledgement under the Revised Interpretive Notice—from email delivery receipts—which would not be permitted to serve as acknowledgement under the Revised Interpretive Notice, but may be used to evidence the timing of such disclosures—all as further discussed herein. *See* related discussion under *Summary of Comments Received in Response to the Request for Comment—Email Read Receipt as Issuer Acknowledgement* and related notes 213 *et seq. infra.*

[131] SIFMA Letter I, at p. 9.

two-prong analysis for a G–42 Recommendation:

> First, the [municipal advisor's] advice must exhibit a call to action to proceed with a municipal financial product or an issuance of municipal securities and second, the [municipal advisor's] advice must be specific as to what municipal financial product or issuance of municipal securities the municipal advisor is advising the [municipal entity client or obligated person client] to proceed with.[132]

Persuaded by SIFMA's request for clarification on this point, the MSRB proposed an amendment to the 2012 Interpretive Notice in the Request for Comment clarifying that ''[f]or purposes of determining when an underwriter recommends a financing structure, the MSRB's guidance on the meaning of 'recommendation' under Rule G–42, on duties of non-solicitor municipal advisors is applicable'' and seeking further input on this issue.[133]

E. Underwriter Discouragement of Use of Municipal Advisor; Addition of a New Standard Disclosure Regarding the Engagement of Municipal Advisors

The 2012 Interpretive Notice currently states that ''[t]he underwriter must not recommend that the issuer not retain a municipal advisor.'' In their responses to the Concept Proposal, both GFOA and NAMA commented that this language should be strengthened by requiring the underwriter to affirmatively state that the issuer may hire a municipal advisor and by stating that the underwriter take no action to discourage or deter the use of a municipal advisor. More specifically, GFOA's comment asked the MSRB to amend the 2012 Interpretive Notice to require underwriters to ''affirmatively state'' both that ''issuers may choose to hire a municipal advisor to represent their interests in a transaction'' and also that underwriters are ''to take no actions to discourage issuers from engaging a municipal advisor.'' [134] Similarly, NAMA asked that the MSRB amend the 2012 Interpretive Notice to include a statement that: ''[t]he underwriter may not make direct or indirect statements to the issuer that the issuer not hire a municipal advisor or otherwise make statements to deter the use of a municipal advisor or blur the distinction between the underwriting and municipal advisor functions and/or duties.'' [135]

The MSRB attempted to address NAMA's and GFOA's comments to the Concept Proposal by incorporating existing language from the Implementation Guidance, as described above, which states that ''an underwriter may not discourage an issuer from using a municipal advisor or otherwise imply that the hiring of a municipal advisor would be redundant because the underwriter can provide the same services that a municipal advisor would.'' The MSRB believed that, as a practical matter, this would address the concerns of NAMA and GFOA.[136]

F. Disclosures to Conduit Borrowers

As discussed above, the 2012 Interpretive Notice specifies underwriters' fair-dealing obligations to issuers, but does not apply specific requirements to underwriters dealing with conduit borrowers. At the same time, the Implementation Guidance expressly acknowledges that underwriters must deal fairly with all persons, including conduit borrowers, and that a dealer's fair-dealing obligations to a conduit borrower depends on the specifics of the dealer's relationship with the borrower and other facts and circumstances specific to the engagement.

The Concept Proposal requested feedback on whether the MSRB should extend the requirements enumerated in the 2012 Interpretive Notice to underwriters' fair dealing obligations with conduit borrowers. Providing this feedback, GFOA stated in its comment letter on the Concept Proposal its belief that the MSRB should make clear that the information in the disclosures would best be utilized if it was sent to the party making decisions about the issuance and liable for the debt, which it indicated is the conduit borrower in most cases.[137] SIFMA indicated in its response to the Concept Proposal that it is common, but not universal, for underwriters to provide a conduit borrower with a copy of the disclosures provided to the conduit issuer.[138] SIFMA, otherwise, did not comment on whether that common practice should be required under Rule G–17.

Although it may be common practice by some underwriters, the MSRB, at this time, does not believe the 2012 Guidance should be amended to extend the obligations contained therein to underwriters' dealings with conduit borrowers. The MSRB understands that the level of engagement between underwriters and conduit borrowers is not consistent across the market, such that, in some circumstances, the underwriter(s) works directly with the conduit borrower to build the deal team and structure a financing prior to enlisting a conduit issuer to facilitate the transaction, while, in others, the underwriter(s) are engaged by the conduit issuer and subsequently connected to a conduit borrower seeking financing. The MSRB declined to address these issues in the Request for Comment—and continues to decline to incorporate such obligations into the proposed rule change—because the issues presented by the relationship between underwriters and conduit borrowers are unique enough to merit their own full consideration apart from this retrospective review.[139] Accordingly, the MSRB may consider this issue of the fair dealing obligations underwriters owe to conduit borrowers at a later date.

G. Tiered Disclosure Requirements Based on Issuer Characteristics

The 2012 Interpretive Notice applies to underwriters in their dealings with all issuers in the same manner. The Concept Proposal posed the question whether there should be different disclosure obligations for different classes of issuers. In response, the Florida Division of Bond Finance stated that a ''one size fits all'' approach is not effective and that issuers could benefit from underwriters tailoring such disclosures based on issuer size and sophistication.[140] Similarly, SIFMA noted in its response to the Concept Proposal that the size of the issuer may have some bearing on issuer sophistication, but that it is most appropriate to focus on the knowledge, expertise, and experience of the issuer

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[132] G–42 FAQs, at p. 2 (note 39 supra).

[133] Ultimately, the proposed rule change does define the term ''recommendation,'' but not in relation to the interpretive guidance issued under Rule G–42 as first proposed in the Concept Proposal, as further described herein. *See Summary of Comments Received in Response to the Request for Comment—Guidance Regarding Meaning of* ''*Recommendation*'' and related notes 219 *et seq. infra.*

[134] GFOA Letter I, at p. 3.

[135] NAMA Letter I, at p. 3.

[136] Ultimately, the proposed rule change does incorporate these concepts, but also incorporates a new standard disclosure regarding an issuer's choice to engage a municipal advisor, as further discussed herein. *See* related discussion under *Summary of Comments Received in Response to the Request for Comment—Inclusion of Existing Language Regarding the Discouragement of an Issuer's Engagement of a Municipal Advisor and Incorporation of a New Standard Disclosure Regarding the Issuer's Choice to Engage a Municipal Advisor* and related notes 201 *et seq. infra.*

[137] GFOA Letter I, at p. 2.

[138] SIFMA Letter I, at p. 16.

[139] This concept is not discussed again under the *Summary of Comments Received in Response to the Request for Comment.* The MSRB did receive one comment from SIFMA on this concept in response to the Request for Comment, which stated SIFMA's belief that the Revised Interpretive Notice should not require disclosures to conduit borrowers. SIFMA Letter II, at pp. 5–6.

[140] Florida Division of Bond Finance Letter.

personnel, as well as the issuer's engagement of the advice of an independent registered municipal advisor (''IRMA'').[141] Relatedly, BDA commented that the disclosure obligations of the 2012 Interpretive Notice should not apply if an issuer has an IRMA with respect to the same aspects of an issuance of municipal securities.[142]

BDA's response to the Concept Proposal further stated that its belief that there should not be different obligations for different types of issuers for two reasons. First, because even the personnel of large issuers that frequently issue municipal securities ''change regularly'' and so continue to need the disclosures; and, second, because the uniform requirement allows for a ''consistent, standard process for dealers.'' [143] In their responses to the Concept Proposal, NAMA indicated that it does not support the varying of underwriters' responsibilities for different issuers,[144] and GFOA stated its belief that the wide variety of issuers would make it nearly impossible to develop ways to modify the 2012 Guidance for some issuers but not others.[145]

The MSRB does not believe there is an obvious, appropriate methodology for classifying issuers in a manner that would advance the policies underlying the 2012 Interpretive Notice or that would materially relieve burdens for underwriters or issuers, and requiring different disclosure standards for different issuers may have unintended consequences that compromise issuer protections. In light of these considerations, the MSRB did not propose any classification of, and varied disclosure requirements for, issuers in the Request for Comment, nor is it proposing to do so in the proposed rule change.[146]

On the more specific topic of SIFMA's and BDA's comments regarding the IRMA exemption, the MSRB believes that the issuer's retention of an IRMA and the underwriter's corresponding invocation of the IRMA exemption should not relieve the underwriter from the obligations to provide disclosures. The MSRB believes that many of the disclosures are so fundamental that they should not be optional and that issuers should always have the benefit of receiving them. For example, even if an IRMA assists an issuer in understanding the role and responsibilities of the underwriter, the MSRB believes that an underwriter should still be required to make the representations regarding its role in the transaction. For transaction-specific disclosures, the MSRB does not believe that an issuer's retention of an IRMA should obviate the need to provide transaction-specific disclosure—particularly, disclosures regarding complex municipal securities financings—because the transaction-specific disclosures would continue to serve the crucial purpose of highlighting important risks for an issuer to discuss with its municipal advisor. However, in response to SIFMA's and BDA's comments, the Request for Comment incorporated the concepts that the level of transaction-specific disclosures can vary over time and, among other factors, an underwriter may consider the issuer's retention of an IRMA when assessing the issuer's level of knowledge and experience with a given type of transaction.[147]

H. Issuer Opt-Out

Under the 2012 Interpretive Notice, all issuers receive the disclosures required to be provided by underwriters and they may not opt out. In response to a specific inquiry in the Concept Proposal, GFOA opposed the concept of an issuer opt-out, while SIFMA argued that issuers should have the choice to not receive the standard disclosures in a written election based on their knowledge, expertise, experience, and financial ability, upon which underwriters should be permitted to conclusively rely. The MSRB believes that it is important for issuers to receive or have access to the disclosures for all of their negotiated transactions and that it has addressed many of commenters concerns regarding the need for an issuer opt-out through other proposed amendments to the 2012 Interpretive Notice. Accordingly, the MSRB did not incorporate such an opt-out concept into the Request for Comment, nor is it proposing to do so in the proposed rule change.[148]

I. Evaluating Issuer Sophistication and the Delivery of the Transaction-Specific Disclosures

The 2012 Interpretive Notice provides that, absent unusual circumstances or features, the typical fixed rate offering may be presumed to be well understood by issuer personnel, which may obviate the need for an underwriter to provide a disclosure on the material aspects of a fixed rate financing when the underwriter recommends such a structure in connection with a negotiated offering. Conversely, the 2012 Interpretive Notice allows for a variance in the level of disclosure required for complex municipal securities financings based on the reasonable belief of the underwriter regarding: The issuer's knowledge or experience with the proposed financing structure or similar structures; the issuer's capability of evaluating the risks of the recommended financing; and the issuer's financial ability to bear the risks of the recommended financing.

SIFMA's comment letter on the Concept Proposal stated its belief that all transaction-specific disclosures, for negotiated offerings of fixed rate and complex municipal securities financings, should be triggered by the same standard, which would create the possibility that an underwriter need not provide disclosures about the material aspects of a complex municipal securities financing if it reasonably believes that the issuer has sufficient knowledge or experience with the proposed financing structure. The MSRB acknowledges that the rationale espoused by SIFMA is conceptually consistent with the 2012 Interpretive Notice and that it is possible for certain issuers to develop a level of knowledge and experience with certain complex municipal securities financings that would diminish the need for the disclosures related to the structure of such financings. However, the MSRB believes that the inherent nature of such unique and atypical financings requires a higher standard for the protection of issuers. Specifically, the MSRB believes that the risk of an underwriter inaccurately determining that such transaction-specific disclosures are not necessary is too great. The possible harms of an issuer's inability to understand the structure of a complex municipal securities financing and

[141] SIFMA Letter I, at p. 12 (In terms of factoring in the engagement of an IRMA, SIFMA stated that, ''. . . if the issuer is relying on the advice of a municipal advisor that meets the independent registered municipal advisor exemption . . . and the underwriter invokes the IRMA exemption to the SEC's registration rule for municipal advisors,'' the underwriter should be able to factor this into its analysis regarding the appropriate level of disclosure.).

[142] BDA Letter I, at p. 2.

[143] BDA letter I, at p. 1.

[144] NAMA Letter I, at pp. 1–2.

[145] GFOA Letter I, at p. 2.

[146] This concept is not discussed again under the *Summary of Comments Received in Response to the Request for Comment.* The MSRB did receive a comment on this concept in response to the Request for Comment. SIFMA reiterated that tiered disclosure requirements may be beneficial issuers and underwriters. SIFMA Letter II, at p. 9.

[147] *See* related discussion under *Summary of Comments Received in Response to the Request for Comment—Tiered Disclosure Requirements Based on Issuer Characteristics* and related note 229 *infra.*

[148] *See* related discussion under *Summary of Comments Received in Response to the Request for Comment—Issuer Opt-Out* and related note 231 *infra.*

corresponding risks are very difficult to remedy after the transaction. Accordingly, the MSRB did not incorporate such a concept into the Request for Comment, nor is it proposing to do so in the proposed rule change.[149]

J. EMMA as a Tool for Disclosures

The 2012 Interpretive Notice requires underwriters to deliver in writing the required disclosures. In response to a question in the Concept Proposal on whether EMMA could or should be used as a tool to improve the utility of disclosures and the process for providing them to issuers, there was agreement among the commenters that responded to this question that EMMA was not an appropriate vehicle for the disclosures. Specifically, GFOA indicated in its response to the Concept Proposal that the use of EMMA could cause underwriters to provide even more boilerplate disclosures and that underwriters may be concerned about investor use of the information.[150] In their responses to the Concept Proposal, SIFMA stated that using EMMA would not be appropriate in light of the information disclosed,[151] and NAMA stated that it would undermine the purpose of the 2012 Interpretive Notice by requiring issuers to have to seek out the disclosures instead of receiving them directly.[152] Accordingly, the MSRB did not incorporate such a concept into the Request for Comment, nor is it proposing to do so in the proposed rule change.[153]

II. Summary of Comments Received in Response to the Request for Comment

The MSRB received five comment letters in response to the Request for Comment.[154] Each of the commenters generally indicated their support of the retrospective review of the 2012 Interpretive Notice as outlined in the Request for Comment and each had specific suggestions on how the proposed amendments to the 2012 Interpretive Notice incorporated into the Request for Comment could be improved, as discussed further below.

A. Consolidating the 2012 Interpretive Notice, the Implementation Guidance, and the FAQs Into a Single Interpretive Notice

In response to the Request for Comment, the MSRB received comments from GFOA, NAMA, BDA and SIFMA on the MSRB's proposal of amending the 2012 Interpretive Notice to consolidate the Implementation Guidance and the FAQs into a single publication. Commenters were generally supportive of the inclusion of the Implementation and the FAQs, but had specific suggestions in supplementing, revising, and/or deleting the proposed amendments, which are discussed below.

i. Inclusion of Language Regarding Underwriters' Fair Dealing Obligations to Other Parties in a Municipal Securities Financing

As previously discussed, the Request for Comment incorporated existing language from the Implementation Guidance that:

> The fair practice duties outlined in this notice are those duties that a dealer owes to a municipal entity when the dealer underwrites its new issue of municipal securities. This notice does not set out the underwriter's fair-practice duties to other parties to a municipal securities financing (*e.g.,* conduit borrowers). The MSRB notes, however, that Rule G–17 does require that an underwriter deal fairly with all persons.

BDA's response to the Request for Comment stated its belief that this this inclusion is ''unnecessary'' and will make compliance with the proposed rule change ''burdensome.'' [155] The MSRB believes that the proposed change merely reiterates Rule G–17's general principle of fair dealing in relation to a dealer's municipal securities activities and so is a useful and necessary reminder to dealers of their obligations to other parties participating in a given municipal securities transaction. Moreover, given that this language is taken from the existing Implementation Guidance, the MSRB believes that it should not create a new compliance burden for underwriters, as it should be incorporated into existing policies, procedures, and training. Accordingly, the MSRB incorporated this language into the proposed rule change with a slight modification to clarify that a dealer's fair dealing obligation under Rule G–17 extends only as far as its municipal securities activities. In relevant part, the Revised Interpretive Notice would read:

> The fair practice duties outlined in this notice are those duties that a dealer owes to a municipal entity when the dealer underwrites a new issue of municipal securities. This notice does not set out the underwriter's fair-practice duties to other parties to a municipal securities financing (*e.g.,* conduit borrowers). The MSRB notes, however, that Rule G–17 does require that an underwriter deal fairly with all persons in the course of the dealer's municipal securities activities.

ii. Inclusion of Language Regarding a Reasonable Basis for Underwriter Representations

The Request for Comment incorporated existing language from the Implementation Guidance stating:

> The need for underwriters to have a reasonable basis for representations and other material information provided to issuers extends to the reasonableness of assumptions underlying the material information being provided. The less certain an underwriter is of the validity of underlying assumptions, the more cautious it should be in using such assumptions and the more important it will be that the underwriter disclose to the issuer the degree and nature of any uncertainties arising from the potential for such assumptions not being valid. If an underwriter would not rely on any statements made or information provided for its own purposes, it should refrain from making the statement or providing the information to the issuer, or should provide any appropriate disclosures or other information that would allow the issuer to adequately assess the reliability of the statement or information before relying upon it. Further, underwriters should be careful to distinguish statements made to issuers that represent opinion rather than factual information and to ensure that the issuer is aware of this distinction.

BDA objected to the inclusion of this language in its response to the Request for Comment as redundant, in that the language is ''already covered in the existing language'' of the 2012 Interpretive Notice.[156] The MSRB understands BDA's comment to suggest that, because the 2012 Interpretive Notice already addresses the requirement for an underwriter to have a reasonable basis for its representations, the Implementation Guidance language is a superfluous addition. The MSRB believes that this language from the Implementation Guidance generally provides an important illustrative gloss on Rule G–17's general principle of fair dealing in relation to a dealer's specific obligations regarding certain representations and the assumptions upon which such representations are based. Moreover,

[149] *See* related discussion under *Summary of Comments Received in Response to the Request for Comment—Tiered Disclosure Requirements Based on Issuer Characteristics* and related note 229 *infra.*

[150] GFOA Letter I, at p. 3.

[151] SIFMA Letter I, at pp. 8, 19–20.

[152] NAMA Letter I, at p. 2.

[153] This concept is not discussed again under the *Summary of Comments Received in Response to the Request for Comment.* The MSRB did receive a specific comment on this concept from NAMA, which was supportive of not using EMMA as a means to satisfy the G–17 requirement. NAMA Letter II, at p. 2.

[154] *See* note 10 *supra.*

[155] BDA Letter II, at p. 1.

[156] BDA Letter II, at p. 2.

given that this language is taken from the existing Implementation Guidance, the MSRB believes that it should not create a new compliance burden for underwriters, as it should be incorporated into existing policies, procedures, and training.

Accordingly, the MSRB incorporated this language into the proposed rule change as generally proposed in the Request for Comment with one minor exception. The MSRB omitted the statement that, ''[t]he less certain an underwriter is of the validity of underlying assumptions, the more cautious it should be in using such assumptions and the more important it will be that the underwriter disclose to the issuer the degree and nature of any uncertainties arising from the potential for such assumptions not being valid.'' The MSRB agrees with BDA that this language is redundant and potentially confusing. In relevant part, the Revised Interpretive Notice would read as follows:

> The need for underwriters to have a reasonable basis for representations and other material information provided to issuers extends to the reasonableness of assumptions underlying the material information being provided. If an underwriter would not rely on any statements made or information provided for its own purposes, it should refrain from making the statement or providing the information to the issuer, or should provide any appropriate disclosures or other information that would allow the issuer to adequately assess the reliability of the statement or information before relying upon it. Further, underwriters should be careful to distinguish statements made to issuers that represent opinion rather than factual information and to ensure that the issuer is aware of this distinction.

iii. Reincorporation of the ''No Hair-Trigger'' Language From the Implementation Guidance

As described above, the Request for Comment did not incorporate the existing language from the Implementation Guidance providing that, ''. . . the timeframes set out in the [2012 Interpretive Notice] are not intended to establish hair-trigger tripwires resulting in technical rule violations so long as underwriters act in substantial compliance with such timeframes and have met the key objectives for providing such disclosures under the [2012 Interpretive Notice].'' SIFMA ''strongly objected'' to the omission of this language, stating that the ''language has been an important reassurance to our members who have acted in substantial compliance with prescribed timeframes despite transactions that have proceeded along unforeseen timelines and pathways.'' [157] SIFMA argued that this statement in the Implementation Guidance has benefited dealers and regulators alike, by preserving valuable time and resources, and, more importantly, that it should be retained ''as-is'' unless the MSRB ''can point to prevalent abuses.'' [158] The other commenters to the Request for Comment did not address the omission of this language. The MSRB is persuaded by SIFMA's concerns and believes there is a benefit to preserving aspects of the existing language from the Implementation Guidance, as it should be incorporated into existing policies, procedures, and training.

Accordingly, the proposed rule change would incorporate this concept from the Implementation Guidance into the Revised Interpretive Notice with certain clarifying and conforming edits to the language in order to promote consistency with the other amendments and to emphasize the facts and circumstances nature of the scope of an underwriter's fair dealing obligation under the Revised Interpretive Notice. In relevant part, the Revised Interpretive Notice would read as follows:

> The MSRB acknowledges that not all transactions proceed along the same timeline or pathway. The timeframes expressed herein should be viewed in light of the overarching goals of Rule G–17 and the purposes that the disclosures are intended to serve as further described in this notice. The various timeframes set out in this notice are not intended to establish strict, hair-trigger tripwires resulting in mere technical rule violations, so long as an underwriter acts in substantial compliance with such timeframes and meets the key objectives for providing disclosure under the notice. Nevertheless, an underwriter's fair dealing obligation to an issuer of municipal securities in particular facts and circumstances may demand prompt adherence to the timelines set out in this notice. Stated differently, if an underwriter does not timely deliver a disclosure and, as a result, the issuer: (i) Does not have clarity throughout all substantive stages of a financing regarding the roles of its professionals, (ii) is not aware of conflicts of interest promptly after they arise and well before the issuer effectively becomes fully committed—either formally (*e.g.,* through execution of a contract) or informally (*e.g.,* due to having already expended substantial time and effort)—to completing the transaction with the underwriter, and/or (iii) does not have the information required to be disclosed with sufficient time to take such information into consideration and, thereby, to make an informed decision about the key decisions on the financing, then the underwriter generally will have violated its fair-dealing obligations under Rule G–17, absent other mitigating facts and circumstances.

[157] SIFMA Letter II, at p. 5.

[158] *Id.*

B. Amending the Nature, Timing, and Manner of Disclosures

Each of the five commenters on the Request for Comment offered improvements to the nature, timing, and manner of disclosures required under the 2012 Interpretive Notice. At a more general level, commenters continued to share the view that the municipal securities market would benefit from reducing the volume and ''boilerplate'' nature of the disclosures required under the 2012 Interpretive Notice as generally proposed in the Request for Comment.

i. Disclosures Concerning the Contingent Nature of Underwriting Compensation

As described above, the Request for Comment proposed an amendment to the 2012 Interpretive Notice that would require underwriters to deliver disclosures concerning the contingent nature of their underwriting compensation in their standard disclosures.[159] To the degree that an underwriter's compensation on a particular transaction deviates from the structure described in the standard disclosures, under the language of the Request for Comment, the dealer would need to indicate in its transaction-specific disclosures that the information included in the standard disclosure on underwriter compensation does not apply and explain the alternative compensation structure as part of the transaction-specific disclosures, to the extent that such alternative compensation structure also presents a conflict of interest.

In its response to the Request for Comment, SIFMA indicated its belief that the proposed changes in the Request for Comment are contrary to the goals of the retrospective review, because ''it would invariably result in more standardized and generic disclosures that may district from more specific ones.'' [160] SIFMA stated its preference to retain the current method of providing the disclosures. The MSRB did not receive any other comments on this proposed change and is persuaded by SIFMA's concerns. The MSRB believes that retaining the existing requirements regarding the disclosures of underwriter's compensation would be consistent with the goals of the retrospective review and not harm current municipal entity issuer protections. Accordingly, the proposed

[159] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Amending the Nature, Timing, and Manner of Disclosures—Disclosures Concerning the Contingent Nature of Underwriting Compensation* and related notes 97 *et. seq. supra.*

[160] *Id.,* at p. 8.

rule change does not adopt the Request for Comment's approach to the disclosure of underwriter compensation and proposes to retain the existing requirements and structure under the 2012 Interpretive Notice.

ii. Disclosure of Potential Material Conflicts of Interest

As previously described, the Request for Comment proposed certain revisions to the 2012 Interpretive Notice clarifying that a potential material conflict of interest must be disclosed if, but only if, it is ''reasonably foreseeable'' that it will mature into an actual material conflict of interest during the course of that specific transaction between the issuer and the underwriter.[161] The MSRB received several comments to the Request for Comment on this proposed change. GFOA and the City of San Diego supported the revision, while SIFMA continued to advocate for the elimination of this category of disclosure altogether. More specifically, GFOA stated that this ''reasonably foreseeable'' standard should be used, because continuing to require the disclosure of all potential material conflicts of interest ''could diminish the meaningful inclusions that issuers need to know.'' [162] The City of San Diego indicated that the reasonably foreseeable standard provided a reasonable ''limit'' to what constitutes a potential material conflict of interest and indicated that the MSRB should not set a standard with ''a greater likelihood.'' [163]

On the other hand, SIFMA reiterated its concern that the disclosure requirement, ''. . . be limited to actual, and not merely potential, material conflicts of interest, or in the very least, a highly likely standard.'' [164] SIFMA stated that continuing to require the disclosure of potential material conflicts of interest would be ''unnecessary, distracting, and does not advance the goal of the retrospective review'' and suggested that the proposed reasonably foreseeable standard ''would be exceedingly difficult to implement and monitor from a compliance standpoint.'' [165] SIFMA's response to the Request for Comment further explained that, because any potential material conflict of interest that ripens into an actual conflict prior to the execution of the bond purchase agreement must be disclosed under the 2012 Interpretive Notice, the advance disclosure of such potential material conflicts of interest are unnecessary and distracting. Moreover, SIFMA stated that the consequence of misjudging whether and when a potential conflict of interest becomes material is too great, and, consequently, the reasonably foreseeable standard proposed in the Request for Comment would not reduce the volume of disclosures provided to issuers, as underwriters ''would be inclined,'' out of an abundance of caution or otherwise, to deliver the same level of disclosure as they currently deliver under the 2012 Interpretive Notice.[166] SIFMA encouraged the MSRB to either eliminate the category of potential material conflicts altogether or, in the alternative, adopt a ''highly likely'' standard for those potential material conflicts of interest that must be disclosed.[167]

As indicated in the Request for Comment, the MSRB believes that the disclosure of material conflicts of interest remains significant to an issuer's evaluation of the dealer providing underwriting services, which justifies the obligation for underwriters to continue to provide these disclosures.[168] To the degree that an underwriter has knowledge that a material conflict of interest does not currently exist, but is reasonably likely to ripen into an actual material conflict of interest during the course of the underwriting transaction, the MSRB believes that the municipal securities market is best served by the underwriter providing advanced notification to the issuer of the likelihood of such material conflict of interest, rather than waiting to disclose the conflict until it has ripened into an actual conflict.

At the same time, the MSRB understands from issuers and dealers that the disclosures required under the 2012 Interpretive Notice can result in a long list of generic boilerplate disclosures with little actionable information, and which may distract an issuer's attention from conflicts of interest that are more concrete and specific to the transaction's participants, facts and circumstances. In this regard, the MSRB is persuaded by SIFMA's concerns that the Request for Comment's proposed ''reasonably foreseeable'' standard could be difficult to implement from a compliance perspective and so may not serve the goal of reducing boilerplate disclosure regarding potential material conflicts of interest and facilitating the more focused disclosure of the most likely and immediate conflicts.

Accordingly, the proposed rule change incorporates a ''reasonably likely'' standard to define what potential material conflicts of interest must be disclosed in advance of ripening into an actual material conflict of interest during the course of a transaction. The MSRB believes that a reasonably likely standard appropriately balances competing policy interests, including by ensuring that issuers continue to benefit from the disclosure of potential material conflicts of interest, while at the same time attempting to reduce the volume of disclosures received by issuers and focusing the content of the disclosures to those conflicts that are more concrete and probable.

iii. Syndicate Manager Responsibility for the Standard Disclosures and Transaction-Specific Disclosures

As described above, the Request for Comment proposed an amendment to the 2012 Interpretive Notice that would require, rather than permit, the standard disclosures and transaction-specific disclosures to be made by a syndicate manager ''on behalf of'' the other syndicate members.[169] The MSRB

[161] *See* related discussion under *Summary of Comments Received in Response to the Concept Release—Amending the Nature, Timing, and Manner of Disclosures—Disclosure of Potential Material Conflicts of Interest* and related notes 98 *et. seq. infra.*

[162] GFOA Letter II, at p. 2.

[163] City of San Diego Letter.

[164] SIFMA Letter II, at p. 4.

[165] *Id.,* pp. 4–5.

[166] *Id.*

[167] *Id.*

[168] For example, the MSRB notes the requirements to disclose conflicts of interest—including potential material conflicts of interest—under the 2012 Interpretive Notice may serve as an important tool for the issuer and underwriter to discuss and address other disclosure obligations that may arise in the course of a primary offering of municipal securities. *See, e.g.,* Exchange Act Release No. 34–33741, ''Statement of the Commission Regarding Disclosure Obligations of Municipal Securities Issuers and Others'' (Mar. 9, 1994) (the ''SEC's 1994 Interpretive Release''), 59 FR 12748, at p. 12751 (March 17, 1994) (stating that ''. . . revelations about practices in the municipal securities offering process have highlighted the potential materiality of information concerning financial and business relationships, arrangements or practices, including political contributions, that could influence municipal securities offerings. . . . For example, such information could indicate the existence of actual or potential conflicts of interest, breach of duty, or less than arm's length transactions. Similarly, these matters may reflect upon the qualifications, level of diligence, and disinterestedness of financial advisors, underwriters, experts and other participants in an offering. Failure to disclose material information concerning such relationships, arrangements or practices may render misleading statements made in connection with the process, including statements in the official statement about the use of proceeds, underwriter's compensation and other expenses of the offering.'').

[169] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Amending the Nature, Timing, and Manner of Disclosures—Syndicate Manager*

received specific comments from the City of San Diego, SIFMA, and BDA on this proposed change. As discussed below, the City of Sand Diego questioned the proposed change and encouraged the MSRB to retain a version of the existing requirements under the 2012 Interpretive Notice,[170] while BDA and SIFMA supported the proposed change, but encouraged the MSRB to adopt clarifying amendments to the concept. The following provides a separate discussion regarding the MSRB's rationale for: Assigning to the syndicate manager's the sole obligation to deliver the standard disclosures and transaction-specific disclosures where a syndicate is formed; continuing to require co-managing underwriters in the syndicate to disclose in writing any applicable dealer-specific conflicts of interest; and the elimination of the Request for Comment's ''on behalf of'' concept related to the syndicate manager's obligation to deliver the standard disclosures and transaction-specific disclosures.

1. Amending the 2012 Interpretive Notice To Require the Syndicate Manager To Make the Standard Disclosures and Transaction-Specific Disclosures

The City of San Diego objected to the inclusion of the proposed change and encouraged the MSRB to adopt a standard that would ensure each syndicate member is ''responsible for delivering the standard and transaction specific disclosures'' and ''required to obtain acknowledgement of receipt from the issuer.'' [171] The City of San Diego reasoned that the burden placed on issuers of receiving multiple disclosures is manageable, even for frequent issuers.

As outlined above, the MSRB remains persuaded by the comments to the Concept Proposal from BDA, NAMA, and the Florida Division of Bond Finance that requiring, rather than merely allowing, the syndicate manager to deliver the standard disclosures and transaction-specific disclosures is an efficient way to reduce the duplication of disclosures received by issuers where a syndicate is formed. The MSRB understands that in many instances syndicate members may be reluctant to rely on the syndicate manager's delivery of the disclosures, as currently permitted by the 2012 Interpretive Guidance, because confirming delivery of its disclosures provides greater regulatory certainty that it has met its fair dealing obligations to the issuer. Additionally, the MSRB continues to be persuaded by GFOA's comment on the Concept Proposal that ''issuers who may be frequently in the market have to tackle and acknowledge the paperwork many times.'' [172] Accordingly, the proposed rule change incorporates the concept of only obligating the syndicate manager to provide the standard disclosures and transaction-specific disclosures where a syndicate is formed.

2. Declining To Amend the 2012 Interpretive Notice To Require Only the Syndicate Manager To Provide the Dealer-Specific Disclosures

In contrast to the City of San Diego's view on this topic, BDA's comment on the Request for Comment encouraged the MSRB to go even further in reducing an underwriter's disclosure obligations by only requiring the syndicate manager to have an obligation to deliver the dealer-specific disclosures, and eliminating the obligation that co-managers must deliver their individual dealer-specific disclosures. BDA cautioned the MSRB that continuing to require dealers who serve as co-managers to provide the dealer-specific conflicts of interest result in ''roughly the same number of disclosures to issuers as currently is the case.'' [173] BDA reasoned that, ''[a]s a practical matter, conflicts of interest tend to be specific to dealers in that each dealer has specific arrangements that create the conflict,'' yet the disclosures of only the syndicate manager's dealer-specific conflicts of interest are sufficient, because ''the role of co-manager does not entail the kind of active discussions with an issuer to merit disclosure by all co-managers of their specific conflicts.'' [174]

The MSRB understands BDA's concern that continuing to require co-managing underwriters to deliver their dealer-specific disclosures may not advance the goal of seeking to reduce the volume of disclosures to issuers.[175] The MSRB, however, continues to be persuaded by comments to the Concept Proposal and the Request for Comment that non-boilerplate disclosures regarding specific material conflicts of interest must be received by an issuer from each underwriter in the syndicate. While the general uniformity of the standard disclosures and the transaction-specific disclosures lend themselves to a single delivery in most circumstances, the MSRB believes that the relative uniqueness of the dealer-specific disclosures require a delivery obligation on the part of each co-managing underwriter. A co-managing underwriter's failure to deliver such disclosures could result in an issuer being unable to fully evaluate such co-managing underwriter's engagement in the syndicate and to make any appropriate disclosures to investors about the municipal securities offering. Accordingly, the MSRB declines to incorporate BDA's suggestion into the proposed rule change that only the syndicate manager is obligated to deliver the dealer-specific disclosures. Relatedly, the proposed rule change would not amend the guidance that, while each co-managing underwriter in the syndicate must disclose any applicable dealer-specific conflicts of interest, a co-managing underwriter has no obligation to affirmatively disclose in writing the absence of such conflicts.[176]

3. Clarifying That an Underwriter That Becomes a Syndicate Manager is Not Required To Make the Standard Disclosures and Transaction-Specific Disclosures on Behalf of Co-Managing Underwriters

SIFMA's response to the Request for Comment ''welcome[d] this proposal to reduce oftentimes duplicative disclosures to issuers,'' but also requested certain refinements to it.[177] Specifically, SIFMA was concerned that the proposed change would require the syndicate manager to ''affirmatively state'' that the standard disclosures are provided ''on behalf of the other syndicate members.'' [178] SIFMA suggested that this would be problematic in instances when an underwriter may need to provide the disclosures in order to meet the deadlines proposed in the 2012 Interpretive Notice, but co-managing

Responsibility for the Standard Disclosures and Transaction-Specific Disclosures and notes 102 *et. seq. supra.*

[170] City of San Diego Letter, at p 1.

[171] *Id.*

[172] GFOA Letter I, at p. 1.

[173] BDA Letter II, at p. 3.

[174] *Id.*

[175] The MSRB also notes that pursuant to the existing requirements under the 2012 Interpretive Notice and the FAQs, a co-managing underwriter would not have an obligation to deliver an affirmative statement in writing to the issuer indicating that no such dealer-specific conflicts exist, although a co-managing underwriter is not prohibited from doing so. The MSRB believes that one benefit of not requiring a co-managing underwriter to deliver such a disclosure is that issuers should be able to focus on the dealer-specific disclosures it does receive.

[176] For the avoidance of doubt, the proposed rule change would preserve the ability of an underwriter to deliver an affirmative statement providing that the underwriter does not have an actual material conflict of interest or potential material conflicts of interest subject to disclosure. Moreover, the proposed rule change incorporates the reminder in the Implementation Guidance that underwriters are obligated to disclose such conflicts of interest arising after the time of engagement with the issuer.

[177] SIFMA Letter II, at pp. 8–9.

[178] *Id.*

underwriters have not yet been appointed and/or the underwriter is uncertain whether such a syndicate will be formed. SIFMA encouraged the MSRB to reconsider this ''on behalf of'' language to ensure that an underwriter is not required to suggest the appointment of co-managing underwriters in such instances or, presumably, to otherwise provide disclosures on behalf of a non-existent or still-forming syndicate.

Similarly, BDA encouraged the MSRB to clarify the timing of a syndicate manager's delivery of disclosures, requesting specifics regarding the scenario in which an ''underwriter may deliver the standard disclosures and transaction-specific disclosures well before a syndicate is formed.'' [179] BDA stated that the amendments should ''clarify that standard disclosures and transaction-specific disclosures delivered by a syndicate manager can be delivered before a syndicate is formed and that the syndicate manager is not required to deliver new disclosures after a syndicate is formed or new syndicate members are added.'' [180]

The MSRB is persuaded by the scenarios that SIFMA and BDA describe and believes that requiring a syndicate manager to make the standard disclosures and the transaction-specific disclosures ''on behalf of'' the other members of the syndicate may unnecessarily be understood as requiring underwriters to deliver disclosures on behalf of non-existent syndicate members or otherwise defeat the purpose of the retrospective review by requiring an underwriter to re-deliver disclosures that had been provided, but delivered without such ''on behalf of'' language, in order to fulfill the dealer's fair dealing obligations to the issuer.[181] Accordingly, the proposed rule change would strike the '' on behalf of'' language as generally proposed in the Request for Comment and would expressly clarify that, in those instances in which an underwriter has provided the standard disclosures and/or transaction-specific disclosures prior to the formation of the syndicate, it would suffice that the disclosures have been delivered and no affirmative statement that such disclosures are made ''on behalf of'' any future co-managing underwriter would be necessary.[182]

iv. Alternative to the Transaction-by-Transaction Delivery of the Disclosures as Proposed in the Request for Comment

As further described above, the MSRB incorporated proposed amendments to the 2012 Interpretive Notice in the Request for Comment that permitted underwriters to provide standard disclosures to an issuer one time and then subsequently refer to and reconfirm those disclosures.[183] The MSRB received specific comments from GFOA, NAMA, the City of San Diego, and SIFMA regarding this proposal and each comment was generally critical of the MSRB's proposed approach. GFOA's comment on the Request for Comment stated that the MSRB's proposal is ''problematic'' and encouraged the MSRB to adopt an approach ''mandat[ing] that disclosures are provided to issuers for each transaction, to ensure that the issuers are aware of the fair dealing requirement for each issuance of securities.'' [184] Similarly, NAMA opposed any amendments that would eliminate the requirement for underwriters to provide disclosures for each transaction or otherwise allowed underwriters to reference back to previously provided disclosures. The City of San Diego agreed, stating that ''[i]t is most straight forward to require disclosures on a transaction by transaction basis.'' [185] SIFMA appreciated the MSRB's attempt to respond to its request to provide an alternative manner of disclosure, but expressed concern that the MSRB's proposal ''complicates matters even further.'' [186] SIFMA concluded that the MSRB's alternative proposal would be ''operationally burdensome'' and ''do little to reduce the volume and nature of the paperwork.'' [187] SIFMA reiterated its original suggestion for an annual disclosure process ''with bring-downs as necessary during the succeeding year.'' [188]

Given the lack of support from commenters regarding the MSRB's proposal, the MSRB did not incorporate the concept into the proposed rule change and declines to incorporate a different concept into the proposed rule change regarding an alternative to the transaction-by-transaction delivery of the disclosures, such as SIFMA's suggestion of annual disclosure process with bring-downs. The MSRB is persuaded by the comments from GFOA, NAMA, and City of San Diego that a transaction-by-transaction approach to disclosure better ensures that issuers and their personnel are apprised of an underwriter's fair dealing obligations for each offering.

v. Separate Identification of the Standard Disclosures

The MSRB incorporated a requirement in the Request for Comment that underwriters clearly identify each category of disclosure and generally separate them by placing the standard disclosures in an appendix or attachment.[189] The MSRB suggested that such a change would allow issuers to discern and focus on the disclosures most important to them. The MSRB received several specific comments on this proposed change. GFOA's response to the Request for Comment supported the separation of disclosures, stating: ''[w]hen determining clarity and communication of disclosures, standard disclosures should be discussed separately from specific transaction and underwriter disclosures.'' [190] NAMA similarly supported the separation of the standard disclosures from the transaction-specific disclosures as a way to highlight key items to its issuer clients.[191] SIFMA suggested that the ''separation of actual and non-standard disclosures is a reasonable proposal.'' [192] Accordingly, the proposed rule change incorporates the separation of the standard disclosures

[179] BDA Letter II, at p. 3.

[180] *Id.*

[181] Here, the MSRB contemplates scenarios in which an underwriting syndicate unexpectedly forms subsequent to the delivery of the standard disclosures and/or transaction-specific disclosures and desires to clarify that underwriters are not obliged to re-deliver such disclosures ''on behalf of'' the syndicate in order to meet their fair dealing obligations. The proposed rule change is intended to clarify that a syndicate manager is not required to re-deliver any disclosures previously provided to an issuer upon the subsequent or concurrent formation of a syndicate. Notwithstanding this obligation, and for the avoidance of doubt, to the extent that the content of those disclosures may need to be supplemented or amended to account for a change in circumstances, an underwriter is still permitted to deliver such a supplement or amendment. As stated in the FAQs, ''unless directed otherwise by an issuer, an underwriter may update selected portions of disclosures previously provided so long as such updates clearly identify the additions or deletions and are capable of being read independently of the prior disclosures.''

[182] The proposed rule change is intended to similarly permit a syndicate manager to provide the standard disclosures and/or transaction-specific disclosures concurrent with or after the formation of the syndicate without the reference to the ''on behalf of'' language.

[183] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Amending the Nature, Timing, and Manner of Disclosures—Alternative to the Transaction-by-Transaction Delivery of the Disclosures* and related notes 107 *et. seq. supra.*

[184] GFOA Letter II, at pp. 1–2.

[185] City of San Diego Letter, at p. 1.

[186] SIFMA Letter II, at p. 7.

[187] *Id.,* at p. 8.

[188] *Id.*

[189] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Amending the Nature, Timing, and Manner of Disclosures—Separate Identification of the Standard Disclosures* and related notes 110 *et. seq. infra.*

[190] GFOA Letter II, at p. 1.

[191] NAMA Letter II, at p. 2.

[192] SIFMA Letter II, at pp. 3–4.

from the transaction-specific disclosures and dealer-specific disclosures.[193]

vi. Clarification That Underwriters Are Not Obligated To Provide Written Disclosure of Conflicts of Other Parties

The Request for Comment incorporated a proposed amendment to the 2012 Interpretive Notice in order to expressly emphasize that underwriters are not required to make any disclosures on the part of issuer personnel or any other parties to the transaction.[194] The MSRB received one specific comment on this topic. More specifically, SIFMA's response to the Request for Comment ''welcome[d]'' the MSRB's proposed clarification.[195] The MSRB believes that this clarification is warranted to avoid any misinterpretation of the disclosure requirements of the proposed rule change. Accordingly, the proposed rule change would incorporate this language as generally proposed in the Request for Comment with supplemental language specifically clarifying that the an underwriter has no obligation to make any written disclosures described therein on the part of issuer personnel or any other parties to the transaction, as the standard disclosures, transaction-specific disclosures, and dealer-specific disclosures are limited to underwriter conflicts.

vii. Clarity of Disclosures

The MSRB proposed amendments to the 2012 Interpretive Notice in the Request for Comment that explicitly clarified that the disclosures be drafted in ''plain English.'' [196] The MSRB received several comments on this topic in response to the Request for Comment. The City of San Diego, GFOA and NAMA each supported the requirement that the disclosures be drafted in plain English, while SIFMA objected to the incorporation of this particular standard.

Of those in support of the standard, notably, the City of San Diego encouraged the MSRB to require underwriters to state whether their descriptions of certain complex municipal securities financing structures can be explained in plain English and, if not, to explicitly state that fact within the disclosure to alert an issuer that it may need to ask more questions.[197] In contrast, SIFMA objected to the inclusion of a plain English standard, stating its belief that the standard would be ''susceptible to different interpretations'' and the formal adoption of such a standard would defeat the purposes of the retrospective review by causing underwriters to ''completely redo all manner of their G–17 disclosures.'' [198] As an alternative, SIFMA suggested that the MSRB adopt a ''clear and concise'' standard.[199]

As discussed above, the MSRB's intent of incorporating the ''plain English'' standard into the Request for Comment was merely to formalize a substantially equivalent standard to the one presently required under the 2012 Interpretive Notice. The MSRB did not intend to create a substantively different standard that would require underwriters to redraft their existing disclosure language. Consequently, the MSRB is persuaded by SIFMA's concerns that the adoption of a ''plain English'' standard may defeat the purposes of the retrospective review, because it would require underwriters to redraft existing disclosures to meet, in SIFMA's view, a new and elusive standard. For similar reasons, the MSRB is declining to incorporate the City of San Diego's suggestion, at this time, that would require underwriters to explicitly state if a disclosure could not be provided in plain English. Rather, the MSRB is persuaded by SIFMA's alternative proposal that the MSRB adopt a ''clear and concise'' standard. The MSRB believes that this addition is warranted to provide further clarification on the accessibility and readability of the disclosures required under the proposed rule change. Moreover, the MSRB believes that such a ''clear and concise'' standard is appropriate, because it has been adopted in other contexts related to the issuance of municipal securities, and, as a result, should be relatively familiar to issuers and underwriters alike.[200] Accordingly, the MSRB proposed rule change incorporates a clear and concise standard and omits any specific reference to plain English.

C. Inclusion of Existing Language Regarding the Discouragement of an Issuer's Engagement of a Municipal Advisor and Incorporation of a New Standard Disclosure Regarding the Issuer's Choice To Engage a Municipal Advisor

As discussed above, the Request for Comment incorporated existing language from the Implementation Guidance stating that ''underwriters may not discourage issuers from using a municipal advisor or otherwise imply that the hiring of a municipal advisor would be redundant because the sole underwriter or underwriting syndicate can provide the services that a municipal advisor would.'' [201] BDA and SIFMA objected to the inclusion of this language, while GFOA and NAMA encouraged the MSRB to adopt even stronger requirements in this regard.

BDA objected to the inclusion of the language from the Implementation Guidance as redundant. Specifically, BDA stated that this language from the Implementation Guidance is ''entirely covered'' by the 2012 Interpretive Notice's statement that underwriters not ''recommend issuers not retain a municipal advisor.'' [202] SIFMA also thought that the proposed language was not necessary, and further stated that it would have unintended consequences by limiting ''otherwise permissible advice, such as describing what services can and cannot be provided, between underwriters and their [issuer] clients

[193] As discussed above, the MSRB reiterates, but is not amending at this time, the existing language from the 2012 Interpretive Notice that disclosures must be ''designed to make clear'' to issuer officials ''the subject matter of such disclosures and their implications for the issuer.'' Thus, an underwriter's fair dealing obligation requires it to identify and separate transaction-specific disclosures from dealer-specific disclosures to the extent possible without putting form over substance, as in the case of failing to fully discuss a conflict in a disclosure because it may not fit squarely into one category of disclosure versus another.

[194] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Amending the Nature, Timing, and Manner of Disclosures—Clarification that Underwriters Are Not Obligated to Provide Written Disclosure of Conflicts of Other Parties* and related note 114.

[195] SIFMA further asked the MSRB to provide examples of how the 2012 Interpretive Notice does not apply to other parties. Specifically, SIFMA requested ''examples of conflicts of other parties that would not need to be disclosed.'' SIFMA Letter II, at p. 4. The MSRB is open to SIFMA's request for examples, but believes that it is premature to provide such examples prior to the approval of the amended language in the proposed rule change. Given the facts and circumstances nature of such examples, the MSRB believes that it can better respond to SIFMA's request, assuming approval of the proposed change, through an FAQ or other compliance resource at a later date, if there is a continuing need for such examples.

[196] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Amending the Nature, Timing, and Manner of Disclosures—Clarity of Disclosures* and related notes 117 *et. seq. infra.*

[197] City of San Diego Letter, at p. 2.

[198] SIFMA Letter II, at p. 6.

[199] *Id.*

[200] For example, the SEC has stated that, ''[l]ike other disclosure documents, official statements need to be clear and concise to avoid misleading investors through confusion and obfuscation.'' *See* the SEC's 1994 Interpretive Release, at p. 12753.

[201] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Underwriter Discouragement of Use of Municipal Advisor; Addition of a New Standard Disclosure Regarding the Engagement of Municipal Advisors* and related notes 134 *et. seq. supra.*

[202] BDA Letter II, at p. 2 (''The BDA believes that the additional sentence is entirely covered by the existing sentence that precedes the new sentence. Any underwriter who discourages an issuer from retaining a municipal advisor for any reasons would be making already a prohibited recommendation to do so.'').

for fear of implying that a [municipal advisor] may be redundant.'' [203] SIFMA further stated its belief that the language may create a ''bias'' against underwriter-only transactions that ''could confuse issuers and discourage an issuer's flexibility to control the cost and scope of its financings in cases where it chooses not to use a [municipal advisor].'' [204] SIFMA requested the MSRB eliminate the proposed language; clarify that neither municipal advisors, nor underwriters may misrepresent the services and duties that the other is permitted to provide; and prohibit municipal advisors from misrepresenting that there is a regulatory requirement for an issuer to hire a municipal advisor.[205]

Conversely, in their responses to the Request for Comment, GFOA and NAMA each indicated that the proposed language was helpful, but encouraged the MSRB to go beyond just incorporating the language of the Implementation Guidance by adopting new, stronger prohibitions regarding underwriters deterring the engagement of municipal advisors. GFOA restated its request that the MSRB include a requirement that ''underwriters affirmatively state that issuers may choose to hire a municipal advisor to represent their interests in a transaction.'' [206] NAMA stated that its members are ''aware of instances where both underwriters and bond counsel directly deter the use of a municipal advisor or bond counsel dictates who the municipal advisor should be.'' [207]

The MSRB is persuaded by the comments from GFOA and NAMA about deal participants improperly dissuading issuers from considering the engagement of a municipal advisor and unfairly influencing issuers to engage one particular municipal advisor over another. However, the MSRB also believes there is merit to BDA and SIFMA's concerns, particularly regarding how further prohibitions may unintendedly chill otherwise valid underwriter advice and, thus, deprive issuers of the full benefit of an underwriters' expertise and experience in the market.

Given that the language prohibiting underwriters from discouraging the engagement of a municipal advisor or implying a redundancy of services provided by a municipal advisor is taken from the existing Implementation Guidance, the MSRB believes that underwriters should already be familiar with the practical application of this language. The MSRB further believes that the language should already have been incorporated into existing policies, procedures and training and, as a result, should not significantly increase the regulatory burden on underwriters. Equally important, the MSRB does not believe that the statements are redundant, as BDA contends, because they add an important gloss on the general fair dealing obligation of underwriters. As the additional language makes clear, a recommendation not to engage a municipal advisor can come in many express or implied forms, including, but not limited to, express communications discouraging the use of a municipal advisor or by strong implication of the redundancy of a given municipal advisor's services.

The MSRB believes there is potential merit to SIFMA's concerns that the proposed language may chill certain underwriter communications with issuers regarding municipal advisors and/or create a bias against underwriter only transactions that could lead to increased issuer borrowing costs. Nevertheless, the MSRB finds GFOA's comments to the Concept Proposal and Request for Proposal to be most persuasive on this topic, particularly in light of the MSRB's statutory mandate to protect municipal entities.[208] In this way, municipal entity issuers, as represented by GFOA, desire the prohibitions on such underwriter communications to be strengthened, rather than relaxed. Moreover, while GFOA's comments did not directly address SIFMA's concerns regarding the possible negative effects that this proposed change may have on issuer decision-making, the MSRB generally understands GFOA's view to be that, at this time, the risks that an issuer misunderstands the distinctions between a municipal advisor's role and an underwriter's role, and/or that an issuer is unduly persuaded by an underwriter against the engagement of a municipal advisor, generally outweighs the risks that an underwriter will be compelled, out of an abundance of caution or otherwise, to abstain from certain conversations with an issuer during the course of a negotiated offering, or that an issuer may uninformedly decline an underwriter-only transaction to the detriment of its borrowing costs by engaging a municipal advisor.

In terms of SIFMA's other comments, the MSRB agrees that ''neither [municipal advisors] nor underwriters may misrepresent the services and duties that the other is permitted to provide,'' and that municipal advisors cannot make a misrepresentation regarding ''a regulatory requirement for an issuer to hire a [municipal advisor].'' [209] However, the MSRB does not believe that the proposed rule change is the appropriate vehicle to address potential misrepresentations by municipal advisors, as the proposed rule change is limitedly focused on underwriters' fair dealing obligations to issuers, not the duties of loyalty and care that municipal advisors owe to their municipal entity clients.[210] Accordingly, the MSRB declines to incorporate SIFMA's suggestions on these particular matters into the proposed rule change.[211]

For these reasons, the MSRB is incorporating into the Revised Interpretive Notice language from the Implementation Guidance that ''underwriters may not discourage issuers from using a municipal advisor or otherwise imply that the hiring of a municipal advisor would be redundant because the sole underwriter or underwriting syndicate can provide the services that a municipal advisor would,'' as generally proposed in the Request for Comment. Beyond this, the proposed rule change would incorporate GFOA's and NAMA's requests to further bolster the disclosures regarding an issuer's choice to engage a municipal advisor by incorporating a new disclosure into an underwriter's standard disclosures. Specifically, the

[203] SIFMA Letter II, at p. 6.

[204] *Id.*

[205] *Id.*

[206] GFOA Letter II, at p. 2.

[207] NAMA Letter II, at p. 3.

[208] In terms of municipal entity protection, the MSRB is further persuaded by academic evidence finding that issuers obtain real economic benefits from using municipal advisors. *See* note 87 *supra* and related discussion in the *Self-Regulatory Organization's Statement on Burden on Competition.*

[209] SIFMA Comment Letter II, at p. 7.

[210] *See* Rule G–42. More specific to SIFMA's concern that a municipal advisor may misrepresent a regulatory requirement for an issuer to hire a municipal advisor, the MSRB notes that an issuer may be subject to state or local jurisdictional statutes, regulations, or other policies that may dictate such a requirement (*i.e.,* if and when a municipal entity may or must engage a municipal advisor). To the degree that there is an actual jurisdictional requirement for a municipal entity to engage a municipal advisor, consistent with its duties of care and loyalty, a municipal advisor may accurately communicate such jurisdictional requirements to a municipal entity issuer.

[211] As a threshold matter, however, the MSRB notes that Rule G–42, on the duties of non-solicitor municipal advisors, requires a municipal advisor to conduct its municipal advisory activities with a municipal entity client in accord with a duty of care and a duty of loyalty. Absent potential exculpating facts and circumstances, knowingly misrepresenting the services of an underwriter or the regulatory requirements applicable to a municipal entity client would be a violation of a municipal advisor's duty of care and/or duty of loyalty.

proposed rule change would require an underwriter to inform an issuer that ''the issuer may choose to engage the services of a municipal advisor to represent its interests in the transaction'' in a similar format and at the same time as the underwriter delivers certain other disclosures currently required under the 2012 Interpretive Notice.[212]

D. Email Read Receipt as Issuer Acknowledgement

The Request for Comment proposed a change to the acknowledgement requirement of the 2012 Interpretive Notice that would allow for an automatic email return receipt to satisfy the acknowledgement requirement, as more fully described above.[213] The MSRB received several supportive comments specific to this proposed change. NAMA and SIFMA each expressed their support of the proposed change. Specifically, NAMA stated that it was ''. . . pleased that the [Request for Comment] . . . would continue to mandate a form of acknowledgement from issuers that the disclosures are received, even through an email return receipt.'' [214] SIFMA similarly expressed its support for the incorporation into the Request for Comment of the concept that an automatic email return receipt could ''evidence receipt of the underwriter disclosures.'' [215] The City of San Diego was similarly supportive, stating that ''a read receipt should be permitted so long as the underwriter has delivered the disclosure to the issuer designated primary contact.'' [216] Notably, GFOA did not directly address this particular issue in its response to the Request for Comment, but did reiterate its preference that ''[t]ransaction specific and material underwriter conflicts of interest should be provided for each issuance of securities.'' [217]

Based on these comments, the MSRB believes the acknowledgement requirement continues to have value to ensure that issuers receive the disclosures. However, the MSRB does not believe underwriters should have to repeatedly seek a particularized form of acknowledgement, which an issuer may not provide. Accordingly, the proposed rule change would incorporate this change as generally proposed in the Request for Comment with additional emphasis and clarifications on three important aspects of the proposed change to the acknowledgement requirement.

First, the proposed rule change would provide greater clarity regarding what type of automatic email receipt can meet an underwriter's fair dealing obligation to obtain written acknowledgement of an issuer's receipt of the applicable disclosures. Specifically, the proposed rule change would make clear that an automatic email *read* receipt must be obtained, rather than a mere automatic email *delivery* receipt, in order to meet the proposed rule change's acknowledgement obligations. The proposed rule change would define the term ''email read receipt'' to mean an automatic response generated by a recipient issuer official confirming that an email has been opened. An email delivery receipt that simply shows that a disclosure was successfully delivered fails to demonstrate whether the recipient actually received the disclosure in a working email inbox folder or if, for example, the disclosure was in fact delivered to a spam or junk file folder. An email delivery receipt that does not confirm that a recipient has in fact opened the email communication would not satisfy an underwriter's fair dealing obligation to obtain acknowledgement regarding the receipt of disclosures under the Revised Interpretive Notice.[218]

Second, the proposed rule change would clarify that while an email read receipt may generally be an acceptable form of an issuer's written acknowledgement under the Revised Interpretive Notice, an underwriter, would not be able to rely on an email read receipt as an issuer's written acknowledgement where such reliance is unreasonable under all of the facts and circumstances, such as where the underwriter is on notice that the issuer official to whom the email is addressed has not in fact received or opened the email. If an underwriter is on notice that, for example, an issuer official has not in fact received and/or opened an email with the applicable disclosures, despite having received an affirmative email read receipt confirmation, then the underwriter would not have met its fair dealing obligation under the Revised Interpretive Notice to obtain written acknowledgement from the issuer. This language in the proposed rule change is intended to ensure that disclosures are in fact delivered to an issuer, and, thereby, issuer protection is not compromised.

Finally, the proposed rule change would emphasize that an underwriter's fair dealing obligation to obtain an issuer's written acknowledgement can be satisfied by an email read receipt, but only if such email read receipt is from an appropriate issuer official. The Revised Interpretive Notice would state the underwriter has a fair dealing obligation to obtain such an email read receipt from the official of the issuer identified as the primary contact for receipt of such disclosures. In the absence of such identification, the underwriter would have a fair dealing obligation to receive an email read receipt from an issuer official that the underwriter reasonably believes has authority to bind the issuer by contract with the underwriter. Only email read receipts from such officials would meet an underwriter's fair dealing obligation under the Revised Interpretive Notice. Thus, the Revised Interpretive Notice would require underwriters to pay particular attention to the recipient providing an email read receipt. The additional emphasis in the proposed rule change is intended to ensure that disclosures are in fact delivered to the appropriate issuer personnel, and, thereby, issuer protection is not compromised by the return of an email read receipt from inappropriate issuer personnel.

E. Guidance Regarding Meaning of ''Recommendation''

The Request for Comment proposed an amendment to the 2012 Interpretive Notice and requested comment on whether the use of the recommendation analysis applicable to a G–42 Recommendation should be applicable to the determination of whether an underwriter is recommending a complex municipal securities financing.[219] As currently provided in MSRB guidance, a G–42 Recommendation depends on the following ''two-prong'' analysis:

First, the [municipal advisor's] advice must exhibit a call to action to proceed with a municipal financial product or an issuance of municipal securities and second, the [municipal advisor's] advice must be specific as to what municipal financial product or

[212] Like the existing, similar disclosures regarding the underwriter's role, the proposed rule change would require the underwriter to deliver this new disclosure at or before the time the underwriter has been engaged to perform underwriting services.

[213] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Email Read Receipt as Issuer Acknowledgement* and related notes 125 *et. seq. supra.*

[214] NAMA Letter II, at p. 2.

[215] SIFMA Letter II, at p. 2.

[216] City of San Diego Letter, at p. 2.

[217] GFOA Letter II, at p. 2.

[218] Although, the proposed rule change would make clear that such an email delivery receipt can still be used to evidence the timing regarding an underwriter's attempt to timely deliver a disclosure.

[219] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Clarification of the Meaning of ''Recommendation''* and related notes 131 *et seq. supra.*

issuance of municipal securities the municipal advisor is advising the [municipal entity client or obligated person client] to proceed with.[220]

The MSRB received several comments on this topic. SIFMA's response to the Request for Comment stated its appreciation for the proposed change,[221] while GFOA's and NAMA's responses cautioned the MSRB on the adoption of such a standard. More specifically, GFOA questioned whether this standard is ''the most appropriate'' and stated its belief that the proposed standard in the Request for Comment ''could prevent some issuers from receiving the right information they need to determine what financing structures are best for their government.'' [222] NAMA's response to the Request for Comment stated that the G–42 Recommendation analysis ''is not the right standard'' for this context.[223] NAMA cautioned that, ''[a]pplying the G–42 [R]ecommendation[] standard to underwriter G–17 disclosures creates a false regulatory parity that is not appropriate given the MSRB's mission to protect issuers and the very different roles and duties that municipal advisors and underwriters have to issuers.''

The MSRB understands GFOA's and NAMA's comments to be grounded in a concern that municipal advisors have a baseline fiduciary duty to protect the interests of municipal entity issuers, whereby any municipal advisor communication constituting advice to or on behalf of a municipal entity issuer must be in the best interests of the municipal entity client without regard to the financial or other interests of the municipal advisor. In contrast, underwriters have a more limited fair dealing obligation. Building upon this distinction, the MSRB's two-pronged analysis under Rule G–42 is primarily intended to clarify when a municipal advisor has additional suitability and record-keeping obligations when making a particular type of recommendation (*i.e.,* a G–42 Recommendation) [224] to a municipal client and is not the analysis for more generally determining when a communication constitutes ''advice'' because it ''involves a recommendation.'' [225] In consequence, GFOA's and NAMA's comments indicate their shared concern that, compared to the current disclosure obligations under the 2012 Interpretive Notice, issuers may receive less disclosure under the G–42 Recommendation standard and, thereby, have less information available to evaluate complex transactions.[226]

The MSRB is persuaded by GFOA's and NAMA's concerns that issuers may receive less disclosure under the G–42 Recommendation standard than issuers currently receive under the 2012 Interpretive Notice and, therefore, the MSRB has not incorporated the G–42 Recommendation standard in the proposed rule change. At the same time, the MSRB is still persuaded by SIFMA's comment on the Concept Proposal that the MSRB should clarify the standard that determines whether an underwriter has made a ''recommendation'' of a municipal securities financing to an issuer in a negotiated offering.

Accordingly, the proposed rule change expressly clarifies that the analysis to determine if an underwriter has made a ''recommendation'' triggering the complex municipal securities financing disclosures is whether—given its content, context, and manner of presentation—a particular communication from an underwriter to an issuer reasonably would be viewed as a call to action or reasonably would influence an issuer to engage in a complex municipal securities financing. This analysis to determine whether a recommendation has been made is not dissimilar to the analysis for municipal advisors,[227] and borrows an objective rather than subjective inquiry analysis applicable to dealers in the context of MSRB Rule G–19, on suitability of recommendations and transactions, and, in this way, the MSRB believes it should be familiar to dealers.

F. Disclosures to Conduit Borrowers

As discussed above, the MSRB declined to incorporate an amendment into the Request for Comment that would explicitly extend the requirements of the 2012 Interpretive Notice to the fair dealing obligations underwriters owe to conduit borrowers. The MSRB received a single specific comment from SIFMA on this topic, which supported the MSRB's approach in the Request for Comment. The proposed rule change does not include any changes in this regard.[228]

G. Tiered Disclosure Requirements Based on Issuer Characteristics

As discussed above, the MSRB declined to incorporate an amendment into the Request for Comment that would classify issuers into differing disclosure requirements based on various issuer characteristics, nor otherwise tailor the disclosure requirements applicable to specific categories of issuers.[229] However, in response to requests from SIFMA and BDA regarding assessing the level of knowledge and experience of the issuer in order to determine the appropriate level of disclosure regarding a recommended financing structure, the Request for Comment incorporated the concept that, among other factors, an underwriter may consider the issuer's retention of an IRMA when assessing the issuer's level of knowledge. The Request for Comment provided:

Among other factors, a sole underwriter or syndicate manager (when there is an

[220] *See* G–42 FAQs (note 37 *supra*).

[221] SIFMA Letter II, at p. 2 (stating, ''[w]e appreciate that the MSRB has proposed adopting some of the suggestions we made in our comment letter to the MSRB's [Concept Proposal], including . . . clarifying the applicability of MSRB Rule G–42's two-prong analysis to a recommendation for complex municipal financings . . .'').

[222] GFOA Letter II, at p. 2.

[223] NAMA Letter II, at p. 2.

[224] *See* the G–42 FAQs, at p. 2 (providing that, ''. . . in order for a communication by a municipal advisor to be a G–42 Recommendation, it must, as a threshold matter, be advice and that advice must meet both prongs of a two-prong analysis. First, the advice must exhibit a call to action to proceed with a municipal financial product or an issuance of municipal securities and second, the advice must be specific as to what municipal financial product or issuance of municipal securities the municipal advisor is advising the MA Client to proceed with.'').

[225] The definition of the advice standard pursuant to Exchange Act Rule 15Ba1–1(d)(1)(ii), as adopted, ''does not exclude information that involves a recommendation.'' Registration of Municipal Advisors, Release No. 34–70462 (Sept. 20, 2013), 78 FR 67467, at 67480 (Nov. 12, 2013). Additionally, the Commission stated that, ''. . . for purposes of the municipal advisor definition, the Commission believes that the determination of whether a recommendation has been made is an objective rather than a subjective inquiry. An important factor in this inquiry is whether, considering its content, context and manner of presentation, the information communicated to the municipal entity or obligated person reasonably would be viewed as a suggestion that the municipal entity or obligated person take action or refrain from taking action regarding municipal financial products or the issuance of municipal securities.'' *Id.*

[226] As one illustration of the possible distinctions in outcomes, if an underwriter presents a range of possible financing structures, but does not advise the issuer to proceed with any one specific structure, it may be ambiguous whether the underwriter met the second prong of the G–42 Recommendation analysis (*i.e.,* whether the underwriter was *specific* enough as to what particular financing structure the issuer should proceed with). Under the Revised Interpretive Notice, if such a presentation reasonably would be viewed as a suggestion that the issuer take action regarding a financing structure or reasonably would influence the issuer to engage in a financing structure, then the underwriter would be deemed to have a made a recommendation regarding that financing structure and, thereby, triggered the applicable disclosure requirements.

[227] *See* note 35 *supra* and related discussion.

[228] *See* discussion *supra* under *Self-Regulatory Organization's Statement on Burden on Competition—Identifying and Evaluating Reasonable Alternative Regulatory Approaches.*

[229] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Tiered Disclosure Requirements Based on Issuer Characteristics* and related note 140 *supra.*

underwriting syndicate) may consider the issuer's retention of an IRMA, who can help the issuer evaluate underwriter recommendations and identify potential conflicts of interest, when assessing the issuer's level of knowledge and experience with the recommended financing structure, which may support a determination by the sole underwriter or syndicate manager that a more limited disclosure would satisfy the obligation for that transaction.

To further illustrate this point regarding the various factors involved in determining the appropriate level of disclosure, the Request for Comment also integrated existing language from the Implementation Guidance suggesting that the level of transaction-specific disclosures can vary over time, particularly if an issuer's personnel become more or less experienced with a given structure. In this regard, the Request for Comment provided:

> The level of transaction-specific disclosure to be provided to a particular issuer also can vary over time. To the extent that an issuer gains experience with a complex financing structure or product over the course of multiple new issues utilizing that structure or product, the level of transaction-specific disclosure required to be provided to the issuer with respect to such complex financing structure or product would likely be reduced over time. If an issuer that previously employed a seasoned professional in connection with its complex financings who has been replaced by personnel with little experience, knowledge or training serving in the relevant responsible position or in undertaking such complex financings, the level of transaction-specific disclosure required to be provided to the issuer with respect to such complex financing structure or product would likely increase.

BDA objected to the inclusion of this language regarding the replacement of issuer personnel leading to increased disclosure, stating that, ''[i]n the abstract, there is no way to determine whether the level should increase or not because it will depend on many factors.'' [230] The MSRB agrees with BDA's objection that the level of disclosure required in any given situation depends on numerous factors specific to that set of facts and circumstances and so the example provided from the Implementation Guidance may lead to confusion. For similar reasons, the MSRB also believes that the Request for Comment's language regarding an issuer's IRMA may similarly lead to confusion.

Accordingly, the proposed rule change does not incorporate this language from the Implementation Guidance regarding the replacement of issuer personnel and, for similar reasons, does not incorporate the language from the Request for Comment regarding an issuer's engagement of an IRMA, as the concepts may lead to more, rather than less, confusion regarding the underwriter's obligation to reasonably determine the level of transaction-specific disclosures required. However, the proposed rule change does incorporate existing language from the Implementation Guidance regarding the variability of such disclosures, providing:

> The level of disclosure required may vary according to the issuer's knowledge or experience with the proposed financing structure or similar structures, capability of evaluating the risks of the recommended financing, and financial ability to bear the risks of the recommended financing, in each case based on the reasonable belief of the underwriter. In this way, the level of disclosure to be provided to a particular issuer also can vary over time.

H. Issuer Opt-Out

As discussed above, the MSRB did not incorporate an issuer opt-out concept into the Request for Comment that would give issuer's the option of declining to receive certain disclosures from underwriters.[231] GFOA's and NAMA's response to the Request for Comment supported the omission of this concept. Accordingly, the proposed rule change does not incorporate such an opt-out concept.

The MSRB considered the above-noted comments in formulating the proposed rule change herein.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period of up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MSRB- 2019–10 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–MSRB–2019–10. 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 MSRB. 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–MSRB–2019–10 and should be submitted on or before August 30, 2019.

For the Commission, pursuant to delegated authority.[232]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–17047 Filed 8–8–19; 8:45 am]

BILLING CODE 8011–01–P

[230] BDA Letter II, at p. 2.

[231] *See* related discussion under *Summary of Comments Received in Response to the Concept Proposal—Issuer Opt-Out* and related note 148 *supra.*

[232] 17 CFR 200.30–3(a)(12).

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Part IV

Nuclear Regulatory Commission

10 CFR Parts 50 and 52
Mitigation of Beyond-Design-Basis Events; Rule

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50 and 52

[Docket Nos. PRM–50–96, PRM–50–97, PRM–50–98, PRM–50–100, PRM–50–101, and PRM–50–102; NRC–2011–0069, NRC–2011–0189, and NRC–2014–0240]

RIN 3150–AJ49

Mitigation of Beyond-Design-Basis Events

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations that establish regulatory requirements for nuclear power reactor applicants and licensees to mitigate beyond-design-basis events. The NRC is making generically applicable the requirements in NRC orders for mitigation of beyond-design-basis events and for reliable spent fuel pool instrumentation (SFPI). This rule also addresses a number of petitions for rulemaking (PRMs) submitted to the NRC following the March 2011 Fukushima Dai-ichi event. This rulemaking is applicable to power reactor licensees and power reactor license applicants.

DATES: This final rule is effective on September 9, 2019.

ADDRESSES: Please refer to Docket ID NRC–2014–0240 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

• *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2014–0240. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Timothy Reed, Office of Nuclear Reactor Regulation, telephone: 301–415–1462, email: *Timothy.Reed@nrc.gov*; or Eric Bowman, Office of Nuclear Reactor Regulation, telephone: 301–415–2963, email: *Eric.Bowman@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION

Executive Summary

A. Need for the Regulatory Action

The NRC is amending its regulations to establish regulatory requirements for nuclear power reactor applicants and licensees to mitigate beyond-design-basis events. This rule makes NRC Order EA–12–049, ''Order Modifying Licenses With Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events'' (Mitigation Strategies Order), and Order EA–12–051, ''Order Modifying Licenses with Regard to Reliable Spent Fuel Pool Instrumentation'' (SFPI Order), generically applicable; establishes regulatory requirements for documentation of changes; and addresses a number of PRMs submitted to the NRC following the March 2011 Fukushima Dai-ichi event. This rule is applicable to power reactor licensees and power reactor license applicants. The NRC conducted this rulemaking to amend the regulations to reflect requirements imposed on current licensees by order and to reflect the lessons learned from the Fukushima Dai-ichi event.

B. Major Provisions

Major provisions of this rule include the following amendments or additions to parts 50 and 52 of title 10 of the *Code of Federal Regulations* (10 CFR):

• Revise the 10 CFR part 50 ''Contents of applications; technical information'' and 10 CFR part 52 ''Contents of applications; additional technical information'' requirements to reflect the additional information that would be required for applications.

• Add § 50.155, which contains beyond-design-basis mitigation requirements that make the Mitigation Strategies and SFPI Orders generically applicable.

C. Costs and Benefits

The NRC prepared a regulatory analysis to determine the expected costs and benefits of this Mitigation of Beyond-Design-Basis Events (MBDBE) final rule (MBDBE rule). The analysis examines the costs and benefits of the rule requirements relative to the baseline case (*i.e.,* no action alternative, which equates to implementation of the Mitigation Strategies and SFPI Orders without this final rule being issued). The final rule encompasses provisions that are either completed or being implemented at this time under the Mitigation Strategies Order and the SFPI Order. Because the NRC uses a no action baseline to estimate incremental costs, the total cost of the rule is estimated to be approximately $110,000 per site. The net present value of these costs per site is approximately $110,000 using a 7 percent discount rate. This incremental cost is primarily attributed to licensees' efforts to review the rule against the previous implementation of the Mitigation Strategies and SFPI Orders and make any additional changes to plant programs and procedures. The final rule is expected to result in a total one-time cost of approximately $7.2 million. The net present value of these costs is approximately $7.2 million using a 7 percent discount rate even though the MBDBE requirements have largely been implemented prior to the effective date of the rule under the requirements in the Mitigation Strategies Order and the SFPI Order.

Based on the NRC's assessment of the costs and benefits of the rule, the NRC has concluded that the MBDBE rule is justified. For more information, please see the regulatory analysis.

As required by § 50.109, ''Backfitting,'' (the Backfit Rule) and § 52.98, ''Finality of combined licenses; information requests,'' a backfitting and issue finality assessment was prepared. This document presents the reasons why the MBDBE rule provisions, with one exception, do not constitute backfits and are consistent with issue finality. The one instance of inconsistency with the issue finality provisions of § 52.98 is due to a correction to a drafting error in the former § 50.54(hh)(3), renumbered in this rulemaking as § 50.54(hh)(2), which was intended to remove the requirements of § 50.54(hh) upon the submittal of the certifications of permanent cessation of operation and permanent removal of fuel from the reactor vessel. This rulemaking corrects the citation of the requirements for these certifications from § 52.110(a)(1) to § 52.110(a) in order to include both the certification of permanent cessation of

operations and the certification of permanent removal of fuel from the reactor vessel. Further details are provided in Section X, ''Backing and Issue Finality,'' of this document.

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I. Background

A. Fukushima Dai-ichi

On March 11, 2011, the Great East Japan Earthquake, rated a magnitude 9.0, occurred off the coast of Honshu Island, resulting in the automatic shutdown of 11 nuclear power plants (NPPs) at four sites along the northeast coast of Japan, including three of six reactors at the Fukushima Dai-ichi NPP (the three remaining plants were shutdown for maintenance). The earthquake caused a large tsunami that is estimated to have exceeded 14 meters in height at the Fukushima Dai-ichi NPP. The earthquake and tsunami produced widespread devastation across northeastern Japan, significantly impacting the infrastructure and industry in the northeastern coastal areas of Japan. The earthquake and tsunami disabled the majority of the external and internal electrical power systems at the Fukushima Dai-ichi NPP, creating a significant challenge for operators in responding to the event. In addition, the combination of severe events challenged the implementation of emergency plans and procedures.

B. Near-Term Task Force

The NRC Chairman's tasking memorandum, COMGBJ–11–0002, ''NRC Actions Following the Events in Japan,'' established a senior-level task force, referred to as the ''Near-Term Task Force'' (NTTF), to review the NRC's regulations and processes to determine if the agency should make improvements to the NRC's regulatory system in light of the events in Japan. On July 12, 2011, the NRC staff provided the report of the NTTF (NTTF Report) to the Commission as an enclosure to SECY–11–0093, ''Near-Term Report and Recommendations for Agency Actions Following the Events in Japan.'' The NTTF concluded that continued U.S. plant operation and NRC licensing activities present no imminent risk to public health and safety. While the NTTF also concluded that the current regulatory system has served the NRC and the public well, it found that enhancements to safety and emergency preparedness are warranted and made 12 general recommendations for Commission consideration. In examining the Fukushima Dai-ichi event for insights for reactors in the United States, the NTTF addressed protecting against accidents resulting from natural phenomena, mitigating the consequences of such accidents, and ensuring emergency preparedness. The NTTF found that the Commission's longstanding defense-in-depth philosophy, supported and modified as necessary by state-of-the-art probabilistic risk assessment techniques, should continue to serve as the primary organizing principle of its regulatory framework. The NTTF concluded that the application of the defense-in-depth philosophy could be strengthened by including explicit requirements for beyond-design-basis events.

C. Implementation of the Near-Term Task Force Recommendations

In response to the NTTF Report, the Commission directed the NRC staff on August 19, 2011, in Staff Requirements Memorandum (SRM)—SECY–11–0093, to engage with stakeholders to review and assess the NTTF recommendations in a comprehensive and holistic manner and to provide the Commission with fully-informed options and recommendations. The NRC staff provided the Commission with recommendations for near-term action in SECY–11–0124, ''Recommended Actions To Be Taken without Delay from the Near-Term Task Force Report,'' dated September 9, 2011. The suggested near-term actions addressed several NTTF recommendations associated with this rulemaking, including NTTF recommendations 4, 8, and 9.3. In SRM–SECY–11–0124, dated October 18, 2011, the Commission directed the NRC staff to, among other things: Initiate a rulemaking to address NTTF recommendation 4, station blackout (SBO) regulatory actions, as an advance notice of proposed rulemaking (ANPR); designate the SBO rulemaking associated with NTTF recommendation 4 as a high priority rulemaking; craft recommendations that continue to realize the strengths of a performance-based system as a guiding principle; and consider approaches that are flexible and able to accommodate a diverse range of circumstances and conditions. As discussed more fully in later portions of this document, the regulatory actions associated with NTTF recommendation 4 evolved substantially from this early Commission direction and included issuance of Order EA–12–049, ''Order Modifying Licenses With Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events'' (Mitigation Strategies Order), that, as implemented, ultimately addressed all of NTTF recommendation 4 as well as other recommendations.

In SECY–11–0137, ''Prioritization of Recommended Actions To Be Taken in Response to Fukushima Lessons Learned,'' dated October 3, 2011, the NRC staff, based on its assessment of the NTTF recommendations, proposed to the Commission a three-tiered prioritization for implementing regulatory actions stemming from the NTTF recommendations. The Tier 1 recommendations were those actions having the greatest safety benefit that could be implemented without unnecessary delay. The Tier 2 recommendations were those actions that needed further technical assessment or critical skill sets to implement, and the Tier 3 recommendations were longer-term actions that depended on the completion of a shorter-term action or needed additional study to support a regulatory action. On December 15, 2011, the Commission approved the staff's recommended prioritization in SRM–SECY–11–0137.

The NTTF recommendations that provide the initial regulatory impetus for this rulemaking include the following:

- NTTF recommendation 4: Strengthen SBO mitigation capability at all operating and new reactors for design-basis and beyond-design-basis external events;
- NTTF recommendation 7: Enhance spent fuel pool (SFP) makeup capability and instrumentation for the SFP;
- NTTF recommendation 8: Strengthen and integrate onsite emergency response capabilities such as emergency operating procedures (EOPs), severe accident management guidelines

(SAMGs), and extensive damage mitigation guidelines (EDMGs);

- NTTF recommendation 9: Require that facility emergency plans address staffing, dose assessment capability, communications, training and exercises, and equipment and facilities for prolonged SBO, multi-unit events, or both;
- NTTF recommendation 10: Pursue additional emergency protection topics related to multi-unit events and prolonged SBO, including command and control structure and the qualifications of decision makers; and
- NTTF recommendation 11: Pursue emergency management topics related to decision making, radiation monitoring, and public education, including the ability to deliver equipment to the site with degraded offsite infrastructure.

In response to input received from stakeholders, the NRC accelerated the schedule originally proposed in SECY–11–0137. On February 17, 2012, the NRC staff recommended in SECY–12–0025, ''Proposed Orders and Requests for Information in Response to Lessons Learned From Japan's March 11, 2011, Great Tōhoku Earthquake and Tsunami,'' that the Commission issue orders for items that warranted generic safety improvements and requests for information where further consideration of the need for safety improvements would be necessary on a site-specific basis.

To address Tier 1 NTTF recommendation 4, on March 12, 2012, the NRC issued the Mitigation Strategies Order, requiring all U.S. nuclear power plant licensees to have additional capability to mitigate beyond-design-basis external events through the implementation of strategies and guidelines that enable them to cope without their permanently installed alternating current (ac) electrical power sources for an indefinite period of time. These strategies would provide additional capability to maintain or restore reactor core and spent fuel cooling, as well as protect the reactor containment. This order also addressed: Portions of NTTF recommendation 9 to require that facility emergency plans address prolonged SBOs and multi-unit events; portions of NTTF recommendation 10 to pursue additional emergency protection topics related to multi-unit events and prolonged SBO; and portions of NTTF recommendation 11 to pursue emergency procedure topics related to decision making, radiation monitoring, and public education.

To address Tier 1 NTTF recommendation 7, on March 12, 2012, the NRC issued Order EA–12–051, ''Order Modifying Licenses with Regard to Reliable Spent Fuel Pool Instrumentation'' (SFPI Order), requiring all U.S. nuclear power plant licensees to have a reliable indication of the water level in associated SFPs.

To address Tier 1 NTTF recommendation 8, the NRC issued an ANPR (77 FR 23161) on April 18, 2012, to engage stakeholders in rulemaking activities associated with the methodology for the integration of onsite emergency response processes, procedures, training and exercises.

The requests for information were issued under § 50.54(f) on March 12, 2012, to address elements of NTTF recommendation 2, concerning external hazard walkdowns and reevaluations, and NTTF recommendation 9, concerning staffing and communications.

D. Consolidation of Regulatory Efforts

While developing the rulemakings discussed in the previous section, the NRC staff recognized that efficiencies could be gained by consolidating the rulemaking efforts due to the inter-relationships among the proposed changes. The NRC staff recommended to the Commission that rulemaking activities to address NTTF recommendations 4, 7, 8, 10.2, and 11.1, as well as portions of NTTF recommendation 9, be consolidated. (See COMSECY–13–0002, ''Consolidation of Japan Lessons Learned Near-Term Task Force Recommendations 4 and 7 Regulatory Activities,'' dated January 25, 2013; COMSECY–13–0010, ''Schedule and Plans for Tier 2 Order on Emergency Preparedness for Japan Lessons Learned,'' dated March 27, 2013; and SECY–14–0046, ''Fifth 6-Month Status Update on Response to Lessons Learned From Japan's March 11, 2011, Great Tōhoku Earthquake and Subsequent Tsunami,'' dated April 17, 2014.) Section I.C, ''Implementation of the Near-Term Task Force Recommendations,'' of this document contains a more complete discussion of the scope of NTTF recommendations addressed by the MBDBE rule. The Commission approved these consolidations in the associated SRMs. Consequently, the MBDBE rule combines two NRC activities for which documents have been published in the **Federal Register**—Onsite Emergency Response Capabilities (RIN 3150–AJ11; NRC–2012–0031) and Station Blackout Mitigation Strategies (RIN 3150–AJ08; NRC–2011–0299). The MBDBE rule identification number and regulations.gov docket number are RIN 3150–AJ49 and NRC–2014–0240, respectively. These consolidations were intended to meet the following objectives:

1. Align the regulatory framework with ongoing industry implementation efforts to produce a more coherent and understandable regulatory framework. Given the complexity of these requirements and their associated implementation, the NRC concluded that this was an important objective for the regulatory framework.

2. Reduce the potential for inconsistencies and complexities between the related rulemaking actions that could occur if the efforts remained as separate rulemakings.

3. Facilitate better understanding of the requirements for both internal and external stakeholders, and thereby lessen the impact on internal and external stakeholders who would otherwise need to review and comment on multiple rulemakings while cross-referencing both proposed rules and sets of guidance documents.

II. Opportunities for Public Involvement

As discussed in Section I.D, ''Consolidation of Regulatory Efforts,'' of this document, the MBDBE rule is a consolidation of several regulatory activities, including two previous rulemaking efforts: The Station Blackout Mitigation Strategies rulemaking and the Onsite Emergency Response Capabilities rulemaking. Both of these rulemaking efforts offered extensive external stakeholder involvement opportunities, including public meetings, ANPRs issued for public comment, and draft regulatory basis documents issued for public comment. The major opportunities for stakeholder involvement were as follows:

1. Station Blackout ANPR (77 FR 16175; March 20, 2012);

2. Onsite Emergency Response Capabilities ANPR (77 FR 23161; April 18, 2012);

3. Station Blackout Mitigation Strategies draft regulatory basis and draft rule concepts (78 FR 21275; April 10, 2013); and

4. Onsite Emergency Response Capabilities draft regulatory basis (78 FR 1154; January 8, 2013).

The final Station Blackout Mitigation Strategies regulatory basis was issued on July 23, 2013 (78 FR 44035), and the final Onsite Emergency Response Capabilities regulatory basis, with preliminary proposed rule language, was issued on October 25, 2013 (78 FR 63901). The NRC described in each final regulatory basis document how it considered stakeholder feedback in

developing the respective final regulatory basis, including consideration of ANPR comments and draft regulatory basis document comments. Section 5 of the Station Blackout Mitigation Strategies regulatory basis document includes a discussion of stakeholder feedback used to develop the final regulatory basis. Appendix B to the Onsite Emergency Response Capabilities regulatory basis includes a discussion of stakeholder feedback used to develop that final regulatory basis.

The public has had multiple opportunities to engage in these regulatory efforts. Most noteworthy were the following:

1. Preliminary proposed rule language for Onsite Emergency Response Capabilities made available to the public on November 15, 2013 (78 FR 68774).

2. Consolidated rulemaking proof of concept language made available to the public on February 21, 2014.

3. Preliminary proposed rule language for MBDBE rulemaking made available to the public on August 15, 2014.

4. Preliminary proposed rule language for MBDBE rulemaking made available to the public on November 13, 2014, and December 8, 2014, to support public discussion with the Advisory Committee on Reactor Safeguards (ACRS).

The NRC issued the MBDBE proposed rule on November 13, 2015 (80 FR 70609), for a 90-day public comment period. The comment period closed on February 11, 2016. During the public comment period, on January 21, 2016, the NRC held a public meeting to provide external stakeholders with a better understanding of the proposed requirements and thereby facilitate more informed feedback. Twenty sets of comments were received in response to the proposed rule. The NRC's consideration of these comments is addressed in Section IV, ''Public Comments and Changes to the Rule,'' of this document. The NRC staff has had numerous interactions with the ACRS, and in all cases these were public meetings, including the following:

1. The ACRS Plant Operations and Fire Protection subcommittee met on February 6, 2013, to discuss the Onsite Emergency Response Capabilities regulatory basis.

2. The ACRS Regulatory Policies and Practices subcommittee met on December 5, 2013, and April 23, 2013, to discuss the Station Blackout Mitigation Strategies regulatory basis.

3. The ACRS full committee met on June 5, 2013, to discuss the Station Blackout Mitigation Strategies regulatory basis.

4. The ACRS Fukushima subcommittee met on June 23, 2014, to discuss consolidation of Station Blackout Mitigation Strategies and Onsite Emergency Response Capabilities rulemakings.

5. The ACRS full committee met on July 10, 2014, to discuss consolidation of Station Blackout Mitigation Strategies and Onsite Emergency Response Capabilities rulemakings.

6. The ACRS Fukushima subcommittee met on November 21, 2014, to discuss preliminary proposed MBDBE rulemaking language.

7. The ACRS full committee met on December 4, 2014, to discuss preliminary proposed MBDBE rulemaking language.

8. The ACRS Fukushima subcommittee met on March 19, 2015, to discuss the proposed MBDBE rulemaking package.

9. The ACRS full committee met on April 9, 2015, to discuss the proposed MBDBE rulemaking package.

10. The ACRS full committee met on June 10, 2015, to receive a status update on the efforts to develop supporting guidance to implement the MBDBE rule.

11. The ACRS Fukushima subcommittee met on April 22, 2016, to receive an update on the public comments provided on the proposed MBDBE rule.

12. The ACRS Fukushima subcommittee met on August 17, 2016, to discuss the path forward on the substantive public comments provided on the MBDBE rule.

13. The ACRS Fukushima subcommittee met on October 19, 2016, to discuss the final MBDBE rule guidance.

14. The ACRS Fukushima subcommittee met on November 16, 2016, to discuss the final MBDBE rule package.

15. The ACRS full committee met on November 30, 2016, to discuss the final MBDBE rule package.

The NRC held a public meeting on November 10, 2016, to discuss implementation issues associated with the MBDBE final rule as required by its cumulative effects of regulation (CER) process.

III. Petitions for Rulemaking

During development of this rule, the NRC gave consideration to the issues raised in six PRMs submitted to the NRC, five from the Natural Resources Defense Council, Inc. (NRDC) (PRM–50–97, PRM–50–98, PRM–50–100, PRM–50–101, and PRM–50–102) and one submitted by Mr. Thomas Popik (PRM–50–96). The NRDC petitions were dated July 26, 2011, and docketed by the NRC on July 28, 2011. The NRC published a notice of receipt in the **Federal Register** on September 20, 2011 (76 FR 58165), for the NRDC petitions, and did not ask for public comment at that time. The petitions filed by the NRDC use the NTTF Report as the sole basis for the PRMs. The NTTF recommendations that the NRDC PRMs rely upon are: 4.1, 7.5, 8.4, 9.1, and 9.2. This rule addresses each of these recommendations, and therefore it resolves the issues raised by the NRDC PRMs. Accordingly, the NRC's issuance of the MBDBE rule completes all planned regulatory activities for the NRDC petitions. The PRM–50–96, filed by Mr. Popik, is still under consideration by the NRC and is not fully addressed at this time, as discussed in greater detail below.

In PRM–50–97 (NRC–2011–0189), the NRDC requested emergency preparedness enhancements for prolonged SBOs in the areas of communications ability, Emergency Response Data System (ERDS) capability, training and exercises, and equipment and facilities (NTTF recommendation 9.2). The NRC considered the issues raised in this PRM as part of the MBDBE rulemaking. The NRC's consideration of the issues raised in PRM–50–97 are reflected in the provisions in § 50.155(d) concerning training. The NRC concludes that consideration of the PRM issues and the underlying NTTF Report recommendations, as discussed in this document, addresses PRM–50–97. This completes the NRC's consideration of PRM–50–97.

In PRM–50–98 (NRC–2011–0189), the NRDC requested emergency preparedness enhancements for multi-unit events in the areas of personnel staffing, dose assessment capability, training and exercises, and equipment and facilities (NTTF recommendation 9.1). The NRC considered the issues raised in this PRM as part of the MBDBE rulemaking. The NRC's consideration of the issues raised in PRM–50–98 are reflected in the provisions in § 50.155(b)(1) concerning development, implementation and maintenance of strategies and guidelines, which subsumes staffing, and § 50.155(d) concerning training, which subsumes drills or exercises. The NRC concludes that consideration of the PRM issues and the underlying NTTF Report recommendations, as discussed in this document, addresses PRM–50–98. This completes the NRC's consideration of PRM–50–98.

In PRM–50–100, the NRDC requested enhancement of SFP makeup capability

and instrumentation for the SFP (NTTF recommendation 7.5). The NRC determined that the issues raised in this PRM should be considered in the NRC's rulemaking process, and the NRC published a document in the **Federal Register** with this determination on July 23, 2013 (78 FR 44034). The NRC's consideration of the issues raised in PRM–50–100 within the MBDBE rulemaking are reflected in the provisions in § 50.155(b)(1) concerning mitigation strategies for maintaining or restoring SFP cooling capabilities and § 50.155(e) concerning SFP monitoring. The NRC concludes that consideration of the PRM issues and the underlying NTTF Report recommendations, as discussed in this document, addresses PRM–50–100. This completes the NRC's consideration of PRM–50–100.

In PRM–50–101, the NRDC requested that § 50.63, ''Loss of all alternating current power,'' be revised to establish a minimum coping time of 8 hours for a loss of all ac power; establish the equipment, procedures, and training necessary to cope with an extended loss of ac power (72 hours) for core and SFP cooling and for reactor coolant system and primary containment integrity as needed; and establish requirements to preplan/prestage offsite resources to support uninterrupted core and SFP cooling and reactor coolant system and containment integrity as needed (NTTF recommendation 4.1). The NRC determined that the issues raised in this PRM should be considered in the NRC's rulemaking process, and the NRC published a document in the **Federal Register** with this determination on March 21, 2012 (77 FR 16483). The NRC's consideration of the issues raised in PRM–50–101 within the MBDBE rulemaking is reflected in the provisions in § 50.155(b)(1) concerning mitigation strategies for maintaining or restoring core cooling, containment, and SFP cooling capabilities; § 50.155(c) concerning equipment; § 50.155(d) concerning training; and § 50.155(f) concerning documentation of changes. The NRC concludes that consideration of the PRM issues and the underlying NTTF Report recommendations, as discussed in this document, addresses PRM–50–101. This completes the NRC's consideration of PRM–50–101.

In PRM–50–102, the NRDC requested more realistic, hands-on training and exercises on SAMGs and EDMGs for licensee staff expected to implement those guideline sets and make decisions during emergencies (NTTF recommendation 8.4). The NRC determined that the issues raised in this PRM should be considered in the NRC's rulemaking process, and the NRC published a document in the **Federal Register** with this determination on April 27, 2012 (77 FR 25104). The NRC's consideration of the issues raised in PRM–50–102 within the MBDBE rulemaking are reflected in the provisions in § 50.155(d) concerning training. The NRC concludes that consideration of the PRM issues and the underlying NTTF Report recommendations, as discussed in this document, addresses PRM–50–102. This completes the NRC's consideration of PRM–50–102.

In PRM–50–96, Mr. Thomas Popik requested that the NRC amend its regulations to require facilities licensed by the NRC to assure long-term cooling and unattended water makeup of SFPs in the event of geomagnetic disturbances caused by solar storms resulting in long-term loss of power. The NRC determined that the issues raised in this PRM should be considered in the NRC's rulemaking process, and the NRC published a document in the **Federal Register** with this determination on December 18, 2012 (77 FR 74788). In that **Federal Register** document, the NRC also closed the docket for PRM–50–96. Specifically, the NRC indicated that it would monitor the progress of the MBDBE rule to determine whether the requirements established therein would address, in whole or in part, the issues raised in the PRM. In this context, the requirements in § 50.155(b)(1) and (c) and the associated regulatory guidance, address, in part, the issues raised by the petitioner because these regulations require licensees to establish offsite assistance to support maintenance of the key functions (including both reactor and SFP cooling) following an extended loss of ac power, which has been postulated as a consequence of geomagnetic disturbances.

The other issues raised in PRM–50–96 related to geomagnetic disturbances remain under NRC consideration. The issue of geomagnetic disturbances, as it impacts transmission system protection, is being addressed at a national level by the White House's Office of Science and Technology Policy (OSTP). The OSTP has been meeting with representatives from several different Federal agencies, including the NRC, over the last several years to develop the National Space Weather Strategy (NSWS) and the National Space Weather Action Plan (NSWAP). On October 13, 2016, President Obama issued Executive Order 13744, ''Coordinating Efforts To Prepare the Nation for Space Weather Events'' (81 FR 71573; October 18, 2016), requiring agencies to begin to implement the NSWAP. The Department of Homeland Security (DHS) is the sector-specific agency with lead responsibility for nuclear reactors, materials, and waste; therefore, the NRC is working with DHS on delineating the NRC authorities associated with the NSWAP.

Following completion of the MBDBE rulemaking, the NRC will address PRM–50–96 giving consideration to the NSWAP, the MBDBE rule, requirements established by the Federal Energy Regulatory Commission to address geomagnetic disturbances (81 FR 67120; September 30, 2016), and the additional comments that were submitted on this rulemaking that further inform the consideration of geomagnetic disturbances.

IV. Public Comments and Changes to the Rule

A. Overview of Public Comments and Removal of Requirements That Would Constitute Backfitting

During the public comment period for the MBDBE proposed rule and draft guidance, the NRC received 20 comment submissions containing 185 individual comments. In developing the final rule and supporting guidance, the NRC considered all the comments provided in response to the MBDBE proposed rule and draft guidance. The detailed consideration of the public comments is contained in a separate document that is referenced in Section XIX, ''Availability of Documents,'' of this document. While the NRC received many comments that enabled it to significantly improve the MBDBE rule and its supporting statement of considerations, this section focuses on the subset of those comments that directly resulted in changes to the MBDBE rule requirements or changes to the MBDBE rule supporting statement of considerations. This section also discusses noteworthy feedback received in response to specific questions in the **Federal Register** notice for the proposed rule and through the CER questions.

In addition, the NRC reexamined the potential requirements that had been included in the proposed MBDBE rule, particularly those that had been previously addressed at the regulatory guidance level regarding the Mitigation Strategies and SFPI Orders, in light of the requirements of §§ 50.109 and 52.98. Under § 50.109(a)(3), when the exceptions of § 50.109(a)(4) (in this case the exception to ensure adequate protection) do not apply, the NRC may require backfitting of a facility when it determines, based upon an analysis as described in § 50.109(c), that there is a substantial increase in the overall protection of the public health and

safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of the increased protection.

For items that were addressed at the regulatory guidance level, the NRC considered first whether inclusion of a requirement on the subject in the final rule would be necessary to ensure that there is adequate protection of public health and safety. In each case, the NRC concluded that the requirements imposed by the Orders were sufficient to provide reasonable assurance of adequate protection of public health and safety and no new information was developed with regard to the ''guidance'' items that would modify this conclusion. The NRC then considered whether there would be a substantial increase in the overall protection of the public health and safety or the common defense and security that would result from including requirements in the final rule for those items rather than continuing the practice of addressing them in the regulatory guidance as had been done for the orders. As discussed in the remainder of this section, the NRC concluded in general that, while there would be some benefit in the form of clarity as to what had been found acceptable for compliance with the orders being made generically applicable in this rulemaking, the recharacterization of those items from regulatory guidance to requirements would not constitute a substantial increase in the overall protection of the public health and safety or the common defense and security.

The NRC also took into consideration whether the items that had been addressed in the regulatory guidance were supporting elements to the overarching requirements for a capability to provide protection of public health and safety or whether the items directly affect public health and safety. For example, staffing and communications would be considered supporting elements for the overarching requirement to develop, implement, and maintain the mitigation strategies for beyond-design-basis external events, which contributes to the protection of public health and safety. Because of this, the NRC concludes that a separate requirement for the staffing and communications elements would not be needed, but could constrain an existing licensee or an applicant for a new licensee from developing innovative mitigation strategies that do not rely on staffing or communications. This follows the Commission's direction in SRM–SECY–11–0124 that

> [i]n order to be effective, approaches should be flexible and able to accommodate a diverse range of circumstances and conditions. In consideration of events beyond the design basis, a regulatory approach founded on performance-based requirements will foster development of the most effective and efficient, site-specific mitigation strategies, similar to how the agency approached the approval of licensee response strategies for the ''loss of large area'' event under its B.5.b program.

A discussion of the specific consideration of these items is provided in the remainder of this section.

B. Removal of Requirements To Address Seismic and Flooding Reevaluated Hazards

The NRC received comments stating that the need for a licensee's strategies and guidelines to be capable of execution in the context of the reevaluated flooding and seismic hazards should be addressed in § 50.155(b) rather than § 50.155(c)(2). The commenters noted that addressing the effects of reevaluated hazards on the mitigation strategies in § 50.155(b) rather than § 50.155(c)(2) provides greater flexibility regarding how a licensee can address the hazard effects through changes to mitigation strategies and guidelines, including changes to equipment protection. Additionally, commenters indicated that the regulation should allow for alternative approaches that would not necessarily address the damage state assumed for § 50.155(b)(1) nor necessarily assume the same success criteria and that should also allow for the use of risk-informed approaches.

The NRC agrees in part with these comments and concludes that including a requirement to address the effects of reevaluated hazards on the mitigation strategies in the rule would not be consistent with §§ 50.109 and 52.98 and could unduly limit the flexibility the commenters suggested should be in the rule.

The mitigation strategies under § 50.155(b)(1) originated in the Mitigation Strategies Order and were justified as necessary to provide adequate protection of public health and safety in light of the uncertainties associated with beyond-design-basis external events and the possibility that extreme natural phenomena could challenge the prevention, mitigation, and emergency preparedness defense-in-depth layers. In COMSECY–14–0037, ''Integration of Mitigating Strategies for Beyond-Design-Basis External Events and The Reevaluation of Flooding Hazards,'' dated November 21, 2014, the NRC staff recognized the interaction between the development and implementation of mitigation strategies for beyond-design-basis external events under the Mitigation Strategies Order and the reevaluation of flooding hazard levels using present-day regulatory guidance and methodologies from flooding evaluations used for early site permits and combined license reviews under NTTF Recommendation 2.1. In its SRM dated March 30, 2015, ''Staff Requirements—Integration of Mitigating Strategies for Beyond-Design-Basis External Events and the Reevaluation of Flooding Hazards,'' the Commission addressed this interaction by, in part, directing the staff to evaluate potential changes to the guidance for the integrated assessment of the effects of the flooding hazards on operating reactors and to introduce more realism for the purpose of identifying potential safety enhancements for operating reactors.

The changes to the regulatory decision-making process directed in the SRM to COMSECY–14–0037 reflected the recognition that the present-day regulatory guidance and methodologies are intended to identify a necessary level of protection from flooding that would meet the principal design criterion (PDC) of an application for an operating license or combined license corresponding to Criterion 2, ''Design bases for protection against natural phenomena,'' of appendix A to 10 CFR part 50, ''General Design Criteria for Nuclear Power Plants.'' That criterion requires applicants to design [s]tructures, systems and components (SSCs) important to safety to withstand the effects of natural phenomena such as earthquakes and floods without loss of capability to perform their safety functions. The criterion also requires that the design bases for these SSCs reflect, among other factors, appropriate consideration of the most severe of the natural phenomena that have been historically reported for the site and surrounding area, with sufficient margin for the limited accuracy, quantity, and period of time in which the historical data have been accumulated. Historically, the margin specified in this criterion has been achieved through the incorporation of conservatisms in the analyses used to determine the flooding design bases for power reactors rather than by the use of a minimum margin above the results of the analyses. The existence of these conservatisms was addressed by the Commission in its direction in the SRM to reduce any unnecessary conservatisms and identify

any areas with insufficient conservatisms. In keeping with that determination, the NRC concludes that adequate protection of public health and safety does not require the operating power reactor licensees to provide protection beyond those levels determined under Criterion 2 of appendix A to 10 CFR part 50 and that any backfitting in this area should be accomplished on an individualized basis under the Backfit Rule. The consideration of whether individual operating licenses for power reactor licensees should be modified, suspended, or revoked is being accomplished under the NRC efforts associated with the request for information issued under § 50.54(f) on March 12, 2012.

Therefore, the NRC disagrees with the recommendation of these comments that the reevaluated hazards levels be included in § 50.155(b) because that treatment would be inconsistent with the Backfit Rule and the issue finality provisions of 10 CFR part 52, but agrees that the reevaluated hazards should not be included in § 50.155(c).

The final rule is revised to remove reference to the reevaluated hazards, allowing licensees to address them within their mitigating strategies in a flexible and appropriate manner. Consideration of the treatment of reevaluated hazards resulting from the March 12, 2012, request for information issued under § 50.54(f) is nearing completion under a separate NRC process.

C. Protection of Equipment

The NRC received comments that indicated a lack of clarity associated with the proposed requirements for ''reasonable protection'' of the equipment in § 50.155(b)(1) from the effects of natural phenomena. The commenters indicated that there appeared to be conflict regarding the application of the reasonable protection requirement to portable ''FLEX equipment'' as defined in NEI 12–06, ''Diverse and Flexible Coping Strategies (FLEX) Implementation Guide,'' versus application to installed SSCs relied on for the response to beyond-design-basis external events. These are typically safety-related SSCs relied on in the initial response to a beyond-design-basis external event as well as design-basis events, that as a result of their credited use for such events, have both beyond-design-basis and safety-related functions. Comments suggested that the proposed approach for ''reasonable protection'' was too limiting because it appeared to restrict licensees to applying ''reasonable protection'' only to equipment itself and not allow licensees the flexibility to implement broader changes in protection and/or changes to strategies.

The NRC agrees that the proposed requirements for reasonable protection need to be clarified and revised to provide greater flexibility. First, the reasonable protection requirements in the MBDBE rule are clarified in part due to removal of the reevaluated hazards from § 50.155. Removal of the reevaluated hazards requirement enabled the NRC to directly align the reasonable protection standard, in terms of the magnitude of natural phenomena that must be considered with the current external event design basis. Additionally, § 50.155(c)(2) was revised to characterize more specifically the effects of natural phenomena from which the equipment must be reasonably protected as ''equivalent in magnitude to the phenomena assumed for developing the design basis of the facility'' rather than ''equivalent to the design basis of the facility,'' as was described in the proposed rule.

Section VI of this document is revised to clarify how the concept of ''reasonable protection'' establishes a degree of assurance that is appropriate for the beyond-design-basis regulatory framework established through the MBDBE rule. This concept contrasts with the application of special treatment requirements, such as environmental qualification and quality assurance requirements, which are applied to safety-related SSCs for their design-basis-related functions to achieve a high level of regulatory assurance appropriate for design-basis requirements.

The NRC also clarifies the confusion that appears to stem from the application of the ''reasonable protection'' standard to safety-related SSCs that have both design-basis and beyond-design-basis functions. Safety-related SSCs that function initially in response to beyond-design-basis external events have two sets of functions: safety-related functions and beyond-design-basis functions. The NRC imposes extensive, special treatment requirements on these SSCs for their safety-related functions for design-basis events. This framework produces an increased level of assurance that the SSCs will perform those safety-related functions during and/or following the design-basis events as applicable. (See ''Risk-Informed Categorization and Treatment of Structures, Systems and Components for Nuclear Power Reactors; Final Rule'' (69 FR 68008; November 22, 2004).)

Through this final rule, the NRC places fewer regulatory requirements associated with the beyond-design-basis functions that dual-function SSCs perform to maintain or restore core cooling, containment, and SFP cooling capabilities, as compared to their safety-related, design-basis functions. The ''reasonable protection'' standard is a means for enabling greater flexibility for addressing external hazards, and in the process, enabling a beyond-design-basis regulatory framework that establishes an appropriate level of assurance. The fundamental applicability of the reasonable protection requirement is to equipment that is relied on for the mitigation strategies for beyond-design-basis events without regard to whether the equipment is ''FLEX equipment'' as defined in NEI 12–06 or ''plant equipment'' as that term is used in NEI 12–06. Accordingly, the set of requirements that are applicable, and by direct extension, the resulting level of regulatory assurance required is directly linked to whether the SSC or equipment is performing a design-basis function or a beyond-design-basis function. The level of assurance is established by the function performed by the SSC, not by the equipment or SSC alone.

D. Loss of All Alternating Current Power

The NRC received comments concerning the loss of all ac power requirement in proposed § 50.155(b)(1). Several commenters indicated that the assumed damage state for developing the mitigation strategies and guidelines for beyond-design-basis external events must include a loss of all power systems including the loss of ac power from batteries through inverters and direct current (dc) power direct from batteries. The commenters stated that unless this damage state is assumed, the lessons learned from the Fukushima Dai-ichi event would not be fully addressed. Another set of commenters stated that the MBDBE proposed rule's requirements for a loss of all ac power must be revised to align with the definition of an extended loss of ac power (ELAP) in the industry guidance document developed for the Mitigation Strategies Order. In that ELAP definition, power directly or indirectly from batteries is assumed available. These commenters also suggested that the word ''all'' should be removed from the MBDBE rule requirements for ''loss of all ac power'' to align the requirement with the definition of ELAP. Based on this feedback, the NRC concluded that the MBDBE proposed rule language and supporting statement of considerations lack clarity and therefore revised the

final rule as discussed in the next paragraph.

The final rule language and Section V.C, ''Final Rule Regulatory Bases,'' of this document are clarified to better convey that the loss of all ac power condition must be addressed. The first clarification is the deletion of the word ''extended'' from § 50.155(b)(1) because the NRC concludes that the use of the word ''extended'' contributed to the confusion regarding the requirement. Section 50.155(b)(1) requires licensees to assume a loss of all ac power in developing strategies and guidelines capable of maintaining or restoring the key safety functions, indefinitely or until the mitigation strategies are no longer needed, including the acquisition of offsite resources to sustain those functions. As such, the regulation clearly requires a capability to address an ''extended'' loss of ac power, and the word ''extended'' is not necessary in § 50.155(b)(1). The deletion of the word ''extended'' is intended to avoid confusion between the requirement for licensees to address a loss of all ac power and the condition of an ELAP as defined in the industry guidance. The regulatory guidance for the MBDBE rule, RG 1.226, addresses the loss of all ac power, including ac power from inverters fed by batteries or dc power directly from batteries as follows:

1. An ELAP and loss of normal access to the ultimate heat sink (or loss of access to the normal heat sink for passive power reactor designs), hereafter referred to as LUHS, is assumed for the purposes of developing the supporting analysis, determining the resultant conditions, and establishing times for key actions that support the development and implementation of mitigation strategies providing additional capability for beyond-design-basis external events. As discussed above, an ELAP is defined in the regulatory guidance as a loss of ac power sources but assumes the availability of power directly or indirectly from batteries.

2. To address conditions more severe than the assumed conditions discussed above (*i.e.,* potentially including loss of power from batteries) and thereby provide a set of regulatory guidance that implements the loss of all ac power requirement of the MBDBE rule, the mitigation strategies contain contingencies. These contingencies involve sending personnel to locally and manually operate non-ac driven core cooling pumps (*e.g.,* a turbine-driven auxiliary feedwater or reactor core isolation cooling pump) to maintain or restore core cooling. These contingencies include the capability to obtain instrument readings using portable multimeters at locations that do not rely on the functioning of intervening installed electrical equipment.[1]

E. Multiple Source Term Dose Assessment

As a result of the NRC's consideration of NTTF recommendations 9.1 and 9.3, the proposed MBDBE rule included a requirement for licensees to determine the magnitude of, and continually assess the impact of, the release of radioactive materials, including from all reactor core and SFP sources. This proposed requirement is referred to as ''multiple source term dose assessment,'' as each source (*e.g.,* core or SFP) has a specific ''source term'' of radionuclides that could be released in an accident.

The NRC received a public comment concerning its § 50.109 backfitting justification for the proposed multiple source term dose assessment requirements. The comment indicated that while the NRC had correctly identified these requirements as backfits, it had failed to justify their proposed imposition as satisfying the criterion under § 50.109(a)(4)(ii) that these proposed requirements are necessary for adequate protection of public health and safety. The commenter stated that the NRC's analysis failed to overcome the presumption that current regulations and orders ensure adequate protection and noted that the statement of considerations supporting issuance of the Backfit Rule in 1988 states that ''that presumption can be overcome only by significant new information or some showing that the regulations do not address some significant safety issue.'' The commenter also noted that beyond the extensive, required actions that licensees are already taking, the industry is voluntarily implementing multiple source term dose assessment capabilities to assist in the mitigation of remote, yet potentially serious beyond-design-basis external events. The commenter stated that the NRC needs to provide a systematic and documented analysis that imposition of the new requirements would result in a cost-justified substantial increase in public health and safety.

The NRC agrees that the backfit justification supporting the proposed multiple source term dose assessment requirements was insufficient. Based on the current emergency preparedness regulations in appendix E to 10 CFR part 50, ''Emergency Planning and Preparedness for Production and Utilization Facilities,'' and the Mitigation Strategies Order requirements, which were implemented broadly to provide an enhanced onsite emergency response capability, the NRC concludes that there is no evidence of a safety issue that rises to the level of undue risk that would warrant imposition of multiple source term dose assessment requirements as necessary for adequate protection of public health and safety.

The NRC additionally concludes that imposition of the multiple source term dose assessment requirement would not provide a substantial increase in the protection of public health and safety under § 50.109(a)(3), taking into account the factors in § 50.109(c). This conclusion is based on the following:

1. The events that would challenge multiple source terms are rare events, and the risk associated with such events is a very small portion of the total plant risk. Furthermore, licensees' implementation of the requirements of the Mitigation Strategies Order provides a substantially enhanced mitigation capability for these events and lowers the probability that such rare events would challenge multiple source terms. These requirements constitute a significant portion of the MBDBE rule.

2. The NRC concludes that the risk of offsite consequences from the beyond-design-basis events addressed by the rule is very small based upon a review of the recent work to understand plant risk. This conclusion is based on both the state-of-the-art reactor consequence analyses (see NUREG–1935, ''State-of-the-Art Reactor Consequence Analyses (SOARCA) Report,'' November 2012), and the work performed for the containment protection and release reduction regulatory effort (see SECY–15–0085, ''Evaluation of the Containment Protection & Release Reduction for Mark I and Mark II Boiling Water Reactors Rulemaking Activities (10 CFR part 50) (RIN–3150–AJ26),'' dated June 18, 2015, specifically the enclosure entitled, ''Containment

[1] There are limitations to what instruments can be repowered by a portable multimeter. While it is possible to repower, and obtain readings from, a resistance temperature detector or a thermocouple, there are many types of sensors that would need a more specialized type of equipment to accomplish the repowering and measurement. The choice of instrument readings to obtain through these contingencies should allow a licensee to diagnose the symptoms and verify system response to confirm the success of actions taken or to select actions that should be taken in response to the symptoms. Engineering evaluations and/or calculational aids needed to facilitate the interpretation of readings from such instrumentation when taken under the beyond-design-basis external event conditions expected should be performed as part of the planning process for the mitigating strategies, and should identify constraints and limitations of such capabilities, including uncertainties in the results.

Protection and Release Reduction (CPRR) Rulemaking: Draft Regulatory Basis''). The staff's evaluation took into account the safety enhancements related to prevention of radioactive releases that were achieved through implementation of the Mitigation Strategies Order and implementation of the requirements of Order EA–13–109, ''Order Modifying Licenses with Regard to Reliable Hardened Containment Vents Capable of Operation under Severe Conditions,'' dated June 6, 2013, in reaching this conclusion.

3. Further, the NRC concludes that the portion of overall plant risk associated with the rare events that might challenge multiple source terms is very small. As a result, the potential safety enhancement associated with the multiple source term dose assessment requirements cannot be considered to be substantial.

Accordingly, the NRC concludes that because there would not be a substantial increase in the overall protection of public health and safety, and, because the risk to public health and safety is very small, backfitting a requirement for multiple source term dose assessment cannot be justified as a matter of adequate protection or as a cost-justified substantial safety improvement.

Finally, operating plants have installed this multiple source term dose assessment capability and have committed to maintain the capability. The NRC anticipates that licensees will maintain this multiple source term assessment capability, even without an explicit requirement. This installed capability for multiple source term dose assessment is a computer capability installed in the existing emergency preparedness infrastructure and serves to meet the existing requirements in appendix E to 10 CFR part 50 to monitor and assess the reactor source term. The NRC concludes that the optimal regulatory approach for operating licensees is to continue to maintain the multiple source term dose assessment as a voluntary initiative following the endorsed guidance that supports this rule.

The final rule was revised to remove the multiple source term dose assessment requirements.

F. Removal of the Proposed Staffing and Communications Requirements

The NRC received public comment that the proposed wording for staffing and communications requirements to be located in a new section VII of appendix E to 10 CFR part 50 could be interpreted by future readers to mean that those proposed requirements must be described in the licensee's emergency plan, notwithstanding the NRC language to the contrary. A commenter noted that the clarity of these proposed provisions could be improved if they were moved into § 50.155. The commenter proposed that these requirements could be incorporated into § 50.155 as a separate sub-paragraph.

The NRC agrees that locating the staffing and communications requirements in a new section VII of appendix E to 10 CFR part 50 would detract from clarity. Additionally, the NRC recognizes that the staffing and communications requirements in the proposed MBDBE rule were not requirements in the Mitigation Strategies Order. Instead, the issue of staffing was addressed in the implementation of the order through the inclusion of regulatory guidance on the subject in section 11.7 of each version of the industry document NEI 12–06 as endorsed by the respective versions of JLD–ISG–2012–01 and taken into consideration by licensees in developing and implementing their strategies and guidelines. The issue of internal communications was addressed in section 3.2.2.8 of NEI 12–06 and taken into consideration by licensees in developing and implementing their strategies and guidelines. The issue of communications between the site and offsite response organizations was a subject covered in the March 12, 2012 request for information issued under § 50.54(f), which resulted in licensees making commitments to upgrade their communications capabilities. These upgraded communications capabilities became part of the licensees' final integrated plans for the strategies and guidelines under the Mitigation Strategies Order.

The NRC concludes that the requirements imposed by the Mitigation Strategies Order were sufficient to provide reasonable assurance of adequate protection and no new information was developed with regard to staffing and communications that would modify this conclusion. The NRC concludes that the imposition of requirements for staffing and communications would not result in a substantial increase in the overall protection of public health and safety or the common defense and security. This follows the Commission's direction in SRM–SECY–11–0124 that

> [i]n order to be effective, approaches should be flexible and able to accommodate a diverse range of circumstances and conditions. In consideration of events beyond the design basis, a regulatory approach founded on performance-based requirements will foster development of the most effective and efficient, site-specific mitigation strategies, similar to how the agency approached the approval of licensee response strategies for the ''loss of large area'' event under its B.5.b program.

As a result, the imposition of requirements for staffing and communications would not meet the provisions of the Backfit Rule.

The final rule was revised to remove the staffing and communications requirements.

G. Cumulative Effects of Regulation Feedback, Removal of Requirements for Drills or Exercises, Removal of Requirements for Command and Control, and Withdrawal of Orders

The NRC was aware that the nuclear industry would be challenged by the proposed 2-year compliance date for the MBDBE rule, and requested feedback focused on whether this provided sufficient time to address the reevaluated hazard information. Additionally, the proposed rule contained the standard CER questions that also sought feedback on whether the implementation of the MBDBE requirements might involve CER.

The NRC received feedback that indicated that the degree to which the proposed reevaluated seismic or flooding hazards could impact the implementation of mitigation strategies varies widely across the operating reactor fleet and the various evaluations necessary to prepare for any necessary modifications are in different stages of completion. The NRC considered using a flexible scheduling provision in the final rule to address this concern but concluded that this would not be necessary in light of the removal of requirements to address the reevaluated hazards from the final rule. From a more general perspective, CER feedback indicated that circumstances of each plant's implementation of the final rule requirements would be unique and there may be instances where licensees would need to request additional time for full implementation of the rule. One commenter stated that there will likely be instances where conflicts will arise in the implementation of the MBDBE rule requirements, and that the NRC should allow licensees the latitude to resolve the conflicts in a manner that best meets the objectives of safety and security, including allowing licensees to prioritize regulatory activities where conflicts in schedule are identified or provide alternative means for compliance in instances where conflicts require an alternative to be established. The commenter also advocated that the NRC support the use of risk-informed decision making consistent with the Commission direction on SECY–15–

0050, ''Cumulative Effects of Regulation Process Enhancements and Risk Prioritization Initiative,'' dated April 1, 2015.

Other CER feedback concerned a potential unintended consequence that may occur if implementation of the MBDBE rule conflicts with the existing order requirements. The commenter said that the NRC should set forth a transparent transition from the Mitigation Strategies and SFPI Orders to § 50.155. All operating power reactor licensees have achieved compliance with the orders using approved guidance (JLD–ISG–2012–01, ''Compliance with Order EA–12–049, Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events,'' and JLD–ISG–2012–03, ''Compliance with Order EA–12–051, Reliable Spent Fuel Pool Instrumentation''). The MBDBE rule and the supporting RGs could be perceived to specify actions that are in addition to, or different from, the actions taken by licensees following the approved guidance to achieve compliance with the NRC orders, including actions that could be less restrictive than the corresponding actions needed for compliance with the orders. Further, the NRC received a comment that there is a lack of clarity regarding the difference between compliance with the orders and issuance of § 50.155 and the associated RGs. To avoid unintended consequences associated with two similar—but potentially not identical—sets of requirements, it was commented that the NRC should withdraw the Mitigation Strategies and SFPI Orders once § 50.155 becomes effective.

Additionally, stakeholders provided CER feedback concerning a potential schedule conflict for new plants regarding the need to perform analyses that were proposed as section VII to appendix E to 10 CFR part 50 and the completion of the inspections, tests, and analyses under the 10 CFR part 52 framework.

Finally, the NRC held a public meeting to discuss CER. During this meeting, a representative of the Boiling-Water Reactor Owners Group pointed out that those licensees that received Order EA–13–109, which was issued more than a year after the Mitigation Strategies and SFPI Orders, would have less time after attaining full compliance with Order EA–13–109 than other licensees to complete training and verify that they have completed all preparations to comply with the MBDBE rule.

The NRC agrees that the group of licensees that received Order EA–13–109 would achieve full compliance with each of the orders issued in response to the Fukushima Dai-ichi event approximately one year after the remaining licensees. In order to alleviate CER for this group of licensees, the final rule is revised to provide an additional year for implementation, giving this group of licensees the same amount of time after full compliance with the orders to attain compliance with the rule.

The NRC also agrees that redundancy would exist between requirements in the Mitigation Strategies and SFPI Orders and those in the MBDBE rule. The final rule contains language that is intended to ensure a smooth transition between the order requirements and the MBDBE rule, including withdrawing the orders, to alleviate this issue.

Finally, the schedule issue associated with new reactors was resolved as a result of the removal of the staffing and communication requirements in favor of their treatment in the regulatory guidance for the rule. As a result of the revision made to the MBDBE rule, the scheduling requirements that were of concern are no longer operative.

Additionally, the NRC received feedback suggesting that licensees that received Order EA–13–109 be allowed an additional year for conducting an initial drill or exercise under the proposed rule. Holders of operating licenses for power reactors (including those that received Order EA–13–109) would have been required to conduct an initial drill or exercise within 4 years of the effective date of the final MBDBE rule under this paragraph. The NRC noted that the conduct of drills or exercises was not included as a requirement in the Mitigation Strategies Order, instead being an element of an acceptable approach to meeting the order's requirement for training. Drills are addressed in the regulatory guidance for the Mitigation Strategies Order contained in section 11.6.5 of NEI 12–06, as endorsed by JLD–ISG–2012–01 and carried forward to the regulatory guidance for the final rule. NEI 12–06, Revisions 0 and 2 contained guidance on the content and periodicity of these drills, specifying the same 8-year period as was proposed for this rule. NEI 12–06, Revision 4, which is endorsed by the final version of Regulatory Guide 1.226, incorporates by reference further guidance on the performance of drills contained in the industry document NEI 13–06, Revision 1, ''Enhancements to Emergency Response Capabilities for Beyond Design Basis Accidents and Events,'' which also specifies the 8-year period that was proposed for drill performance for this rule. In addition, Appendix E of NEI 12–06, Revisions 2 and 4 includes guidance on the validation of time sensitive actions. Validation of the time sensitive actions has been performed by all operating power reactor licensees in order to ascertain that they are capable of executing the time sensitive actions necessary to perform the strategies and guidelines required under the Mitigation Strategies Order and under the final rule in sufficient time to meet the time constraints determined by a plant-specific thermal-hydraulic analysis. These validations included, for example, the use of timed drills in simulators for control room actions or physical walkthroughs for actions in the field to demonstrate that the operating staff could perform the time sensitive actions within the identified time constraints.

The NRC concludes that the requirements imposed by the Mitigation Strategies Order were sufficient to provide reasonable assurance of adequate protection and no new information was developed with regard to drills or exercises that would modify this conclusion. The NRC similarly concludes that imposing a requirement for drills and exercises would not provide a substantial increase in the overall protection of public health and safety. Therefore, the imposition of a requirement for drills or exercises would not meet the provisions of the Backfit Rule. The requirement for drills and exercises has been removed from the final rule. The removal of the requirement for an initial drill or exercise from the final rule addresses the commenter's concerns with scheduling of drills for licensees that received Order EA–13–109.

The NRC also received feedback on CER suggesting that flexible scheduling be extended to licensees that received Order EA–13–109 for reasons other than addressing reevaluated hazards. No changes were made to the final MBDBE rule as a result of this feedback. The NRC concludes that any need for further schedule flexibility can be addressed under § 50.12 on an individual basis if it becomes necessary.

The NRC also received stakeholder feedback supporting the command and control requirements in proposed § 50.155(b)(6). The proposed MBDBE rule would have required licensees to have a supporting organizational structure with defined roles, responsibilities, and authorities for directing and performing the strategies, guidelines, and alternative approaches required by proposed § 50.155(b).

The need for defined command and control structures and responsibilities

for use in beyond-design-basis conditions was recognized in the course of the development of the guidance and strategies for EDMGs. As stated in the industry's guidance document for that set of requirements, NEI 06–12, Revision 2, ''[e]xperience with large scale incidents has shown that command and control execution can be a key factor to mitigation success.'' The guidance and strategies developed for that effort include an EDMG for initial response to provide a bridge between normal operational command and control and the command and control that is provided by the emergency response organization personnel in the event that the normal command and control structure is disabled. The NRC considers that the actions taken in the development of the EDMGs for initial response for the guidance and strategies for § 50.155(b)(2) are adequate to support implementation of the MBDBE rule requirements. Evidence of this was demonstrated in the implementation of the EDMGs and Mitigation Strategies Order without specific command and control requirements.

The NRC concludes that the requirements imposed by the Mitigation Strategies Order were sufficient to provide reasonable assurance of adequate protection and no new information was developed with regard to command and control that would modify this conclusion. The NRC concludes that the imposition of requirements for command and control would not result in a substantial increase in the overall protection of public health and safety or the common defense and security. This follows the Commission's direction in SRM–SECY–11–0124 that

> [i]n order to be effective, approaches should be flexible and able to accommodate a diverse range of circumstances and conditions. In consideration of events beyond the design basis, a regulatory approach founded on performance-based requirements will foster development of the most effective and efficient, site-specific mitigation strategies, similar to how the agency approached the approval of licensee response strategies for the ''loss of large area'' event under its B.5.b program.

As a result, the imposition of requirements for command and control would not meet the provisions of the Backfit Rule.

The final rule has been modified to allow one additional year for implementation for operating power reactor licensees that received NRC Order EA–13–109, to remove the proposed requirement for drills or exercises, to remove the proposed requirement for command and control, and to provide for the withdrawal of the Mitigation Strategies and SFPI Orders and associated license conditions.

H. Change Control Enhancements

The NRC requested and received comments on the proposed MBDBE change control provisions. Commenters suggested that the NRC should consider a ''prior review and approval'' type of regulatory approach, and cited as an example the ''reduction in effectiveness'' criterion that is used in several existing change control requirements. The concern expressed by commenters is associated with the potential for licensees to make changes to the implementation of the MBDBE rule requirements that are outside endorsed guidance. Another commenter echoed this concern, citing examples of licensees not properly implementing the mitigation strategies and citing violations associated with the implementation of the requirements of § 50.59, ''Changes, tests, and experiments.'' The NRC also received a comment recommending a reporting requirement be part of the change control provisions. The NRC received comments concerning the statement of considerations, which confused stakeholders and suggested that prior review and approval may still be required. Finally, the NRC received comments suggesting revisions to the change control requirements that were intended to clarify the requirements.

The NRC finds that its basic approach to change control does not need revision. Specifically, the NRC continues to conclude that it does not need to include reporting requirements or criteria for prior NRC review and approval of changes. The suggestion for use of a ''reduction in effectiveness'' criterion was understood to be an example of a ''prior review and approval'' type criterion, and the NRC considered both of those specific examples and any others that it could identify. First, the NRC concluded that use of a ''reduction in effectiveness'' or equivalent type of change control criterion would not clearly differentiate significant changes (that would warrant NRC prior review) from changes not warranting prior review.

Second, given the deterministic regulatory approach followed for development and implementation of the strategies under the Mitigation Strategies Order, many potential changes could have aspects that tend to reduce the effectiveness while also having aspects that tend to improve the effectiveness of the mitigation strategies. For example, replacing a portable diesel-driven pump with a similar one of a larger size could improve the effectiveness of a mitigation strategy by allowing for greater flow rates of makeup water but reduce its effectiveness because of a higher fuel usage rate and an associated shorter run time without refueling. Judging such changes using a prior review and approval type of approach is challenging at best and would very likely result in an unwarranted diversion of licensee and NRC resources to review and approve changes.

Other beyond-design-basis provisions currently applicable to operating reactors in § 50.62, ''Requirements for reduction of risk from anticipated transients without scram (ATWS) events for light-water-cooled nuclear power plants,'' § 50.63, and § 50.54(hh) do not contain change control requirements. The only comparable set of requirements addressing beyond-design-basis events containing provisions that address the control of changes is § 50.150, ''Aircraft impact assessment,'' which is applicable to new reactors. Reviewing that requirement, and noting that the Aircraft Impact Assessment Rule requires that changes meet certain assessment requirements, the NRC concluded that the provisions in § 50.155(f) for documentation of changes are well aligned with the Aircraft Impact Assessment Rule's control of changes provisions because the NRC is requiring that changes be demonstrated to satisfy the requirements of § 50.155.

Finally, the NRC concludes that its regulatory approach that relies on inspection and enforcement will identify any substantial problems with a licensee's MBDBE change control process well before such problems present a safety problem. Based on consideration of the feedback provided, the NRC did not find a suitable criterion (or criteria) that the NRC judged would result in a substantial improvement over what was proposed for addressing changes in the proposed rule, and accordingly the final rule continues with the same approach: Licensees must demonstrate that the proposed change will result in continued compliance with the requirements of § 50.155, licensees must maintain documentation of those changes, and the NRC will oversee through inspection the changes and take enforcement action as appropriate.

Notwithstanding this conclusion, the NRC clarified Section VI of this document to address changes that apply neither to endorsed guidance nor approved alternatives. This section now includes examples of cases that the NRC concludes would not result in demonstrated compliance.

The NRC agrees that there was confusion created when it described the potential for licensees that may wish to consult with the NRC concerning changes to the implementation of the MBDBE rule requirements. This was not intended to suggest that the NRC was requiring a prior review of changes, and this document is revised accordingly.

Finally, the NRC agrees with suggested revisions to the provisions that result in clarification of the requirements. The NRC clarified the final requirements to refer to them as ''Documentation of Changes,'' simplified the provisions by combining two of the proposed provisions, clarified the provision that addresses the application of other change control processes, and removed the word ''all'' from the rule regarding the need to maintain documentation of changes. As a result, the NRC concludes it is necessary to provide additional description in the statement of considerations to clarify what constitutes a ''change'' with regard to the documentation that the NRC requires licensees to maintain. Changes to the implementation of the MBDBE requirements that do not result in a significant change to the functional performance of the equipment and also do not significantly impact the strategies and guidelines would not constitute a ''change'' for this purpose. The NRC recognizes that licensees would maintain all of this documentation as part of their normal procurement and configuration control processes, but for the regulatory purposes of § 50.155(f), these types of changes would not be significant in terms of implementation of the MBDBE requirements. For example, a replacement of a FLEX pump with a pump having the equivalent functional performance (*i.e.,* no significant impact to functional performance), equivalent weight, size, and mobility (*i.e.,* no significant impact to staging and deploying the pump), and equivalent connections would not constitute a ''change'' for the purposes of § 50.155(f).

I. Spent Fuel Pool Instrumentation Requirements

The NRC received several comments that the MBDBE rule must keep the requirements for SFPI separate and distinct from the requirements for mitigation strategies. The commenters noted that the requirement for SFPI was issued by the SFPI Order, while the requirement for mitigation strategies was issued by the Mitigation Strategies Order. The commenters further noted that while the two orders were in response to lessons learned from the Fukushima Dai-ichi event, they are distinctly different in underlying purpose and character.

The NRC agrees with these comments and revised the final rule to keep SFPI and mitigation strategies requirements separate. The MBDBE rule provisions in § 50.155(b)(1), which were initially imposed through the Mitigation Strategies Order, require strategies and guidelines to maintain or restore core cooling, containment, and SFP cooling capabilities for beyond-design-basis external events, and these requirements are independent of those initially imposed in the SFPI Order and now located in § 50.155(e). The SFPI requirements ensure that information regarding the SFP is provided to decision makers to enable the prioritization of resources. The SFPI requirements were not intended to support mitigation action, but to simply provide information. Accordingly, the NRC moved the SFPI requirement to § 50.155(e) and decoupled the requirement from § 50.155(b)(1) to ensure it remains independent of mitigation strategies requirements.

As part of the industry response to the Mitigation Strategies Order, licensees used the SFPI to support mitigation strategies to maintain or restore SFP cooling. If licensees use the SFPI to comply with § 50.155(b)(1), then the SFPI would be subject to the requirements of § 50.155(b)(1).

J. Drill Frequency

The NRC received comments regarding the proposed 8-year frequency for performance of drills under the proposed rule. One commenter expressed the view that there is a relatively high frequency of extreme events, and given the potentially high consequences associated with such events, the final rule must require an exercise interval no longer than once every 3 years. The commenter noted that an 8-year frequency was too infrequent, resulting in a steady decline in capabilities between tests. Finally, the commenter expressed the view that these drills need to be comprehensive and as realistic as possible.

Another commenter suggested drills be conducted annually or every 2 years. The remaining commenters supported the proposed 8-year frequency.

As discussed in Section IV.G, ''Cumulative Effects of Regulation Feedback, Removal of Requirements for Drills or Exercises, and Withdrawal of Orders,'' of this document, the NRC concludes that the requirements imposed by the Mitigation Strategies Order were sufficient to provide reasonable assurance of adequate protection of public health and safety and no new information was developed with regard to drills or exercises that would modify this conclusion. The NRC then considered whether there would be a substantial increase in the overall protection of the public health and safety or the common defense and security that would result from including requirements in the final rule for drills or exercises rather than continuing the practice of addressing them in the regulatory guidance as had been done for the Mitigation Strategies Order. The NRC concluded that, while there would be some benefit in the form of clarity as to what had been found acceptable for compliance with the orders being made generically applicable in this rulemaking, the recharacterization of drills or exercises from regulatory guidance to requirements would not constitute a substantial increase in the overall protection of the public health and safety or the common defense and security.

Because of this, the NRC concludes that a separate requirement for drills or exercises would not be needed, but could constrain an existing licensee or an applicant for a new licensee from developing innovative training techniques that do not rely on drills or exercises. This follows the Commission's direction in SRM–SECY–11–0124 that

> [i]n order to be effective, approaches should be flexible and able to accommodate a diverse range of circumstances and conditions. In consideration of events beyond the design basis, a regulatory approach founded on performance-based requirements will foster development of the most effective and efficient, site-specific mitigation strategies, similar to how the agency approached the approval of licensee response strategies for the ''loss of large area'' event under its B.5.b program.

In addition, the NRC did not revise the MBDBE drill frequency because it is specified in the regulatory guidance for the final rule in response to these comments. The NRC concluded that the 8-year periodicity strikes the correct balance in terms of providing an appropriate level of regulatory assurance, and, by aligning with the current emergency preparedness exercise requirements, it provides licensees with flexibility should they choose to implement the drills in conjunction with emergency preparedness drills or exercises.

K. Consideration of Explicit Requirements for a Three-Phase Response

The NRC received a comment that the MBDBE rule should maintain the three-phase response structure for mitigation that was described in the Mitigation Strategies Order rather than use the proposed rule's performance-based requirements. The commenter stated that the substitution of ''higher level, performance-based requirements'' reduces confidence that the MBDBE measures will be successful if needed. It is the commenter's view that the nuclear industry and the NRC have consistently disagreed on what constitutes appropriate compensatory measures and associated administrative controls and provided an example to support the comment. The commenter expressed the view that the three-phase structure provides clearer definition of what is expected, better enabling licensees to meet those expectations and NRC inspectors to independently verify that this desired outcome has been achieved.

The NRC did not revise the MBDBE rule as a result of this comment. The Mitigation Strategies Order included a separate attachment 3 for the imposition of requirements on Vogtle Electric Generating Plant, Units 3 and 4 to reflect their use of the AP1000 design. In the Mitigation Strategies Order, attachment 3, the NRC documented that the inherent features of the AP1000 design obviate the need for phase two of the three-phase response required of currently operating power reactors that is addressed in attachment 2 of the Mitigation Strategies Order. The RG 1.226 provides implementation guidance for the three-phase approach as one acceptable method of complying with the MBDBE rule. Future designers may be able to develop and implement strategies and guidelines that do not rely on a three-phase approach, and may propose alternative approaches as updates to the existing guidance or in their applications.

This framework is consistent with the Commission's direction in SRM–SECY–11–0124 to follow performance-based approaches for beyond-design-basis events, while harmonizing the treatment of currently operating and new power reactors. Such approaches allow greater flexibility and enable more effective and efficient implementation of the requirements. The NRC, through its current review, audit, and inspection activities supporting implementation of the Mitigation Strategies Order, is identifying differences of interpretation such as those noted by the commenter and ensuring that they are resolved.

L. Clarifications to Decommissioning Provisions

The NRC received comments concerning the proposed MBDBE provisions in § 50.155(a)(3) regarding the applicability of the MBDBE rule to licensees with reactors in a decommissioning phase. The commenters agreed with the underlying approach to the MBDBE decommissioning provision and suggested revisions to clarify those provisions and eliminate unnecessary language.

The NRC agrees with some of the suggestions, and the final rule reflects those changes. Section 50.155(a)(2) in the final rule explicitly identifies which portions of the MBDBE rule apply to a licensee as it proceeds through the decommissioning process.

M. Clarifications to Equipment Requirements and Removal of Proposed Maintenance Requirement

The NRC requested feedback concerning the proposed maintenance provision in § 50.155(c)(3). The Mitigation Strategies Order did not contain a specific maintenance requirement, but instead contained a performance-based requirement ''to develop, implement and maintain strategies.'' This same language was included in proposed § 50.155(b)(1), so that a failure to perform adequate maintenance would likely lead to a failure to meet this requirement.

The feedback indicated that commenters did not see a need for a separate maintenance provision in § 50.155(c)(3) for the § 50.155(b)(1) equipment. Commenters noted that the proposed maintenance requirement of § 50.155(b), along with the guidance in NEI 12–06, as endorsed by JLD–ISG–2012–01 for the Mitigation Strategies Order (now endorsed in RG 1.226), adequately addresses equipment maintenance. The NRC agrees with this feedback. The intent is to carry forward the maintenance requirements of the Mitigation Strategies Order as it was included within the order's requirement for licensees to develop, implement, and maintain the strategies. The corresponding requirement for development, implementation and maintenance of the strategies is included in § 50.155(b) and the proposed separate maintenance requirement is removed from the final rule.

Regarding maintenance, the NRC also received feedback suggesting that the MBDBE rule be revised to state that the Maintenance Rule, § 50.65, ''Requirements for monitoring the effectiveness of maintenance at nuclear power plants,'' does not apply to FLEX equipment or SFPI whose primary design function is to support strategies developed to solely comply with the MBDBE rule. The NRC agrees that the criteria in § 50.65(b) do not include FLEX equipment in the scope of § 50.65 if the FLEX equipment is used solely for compliance with § 50.155.[2] Accordingly, the suggested revision is not necessary. Furthermore, such an addition could result in complications if a licensee chooses to use FLEX equipment in a future regulatory application (separate from § 50.155) that would result in the equipment meeting the scoping criteria in § 50.65.

In response to one comment, the NRC changed § 50.155(c)(1) in the final rule to more clearly communicate the equipment capacity and capability requirements. The remaining changes to

[2] In the event that a licensee relies upon the mitigation strategies equipment for other purposes such as mitigation of a design-basis event, the application of scoping criteria for reliance on the equipment for those purposes would govern. As a result, equipment that has multiple purposes could have design-basis functions that fall within the scope of the Maintenance Rule for one purpose, and a mitigation strategy function that is not covered by the Maintenance Rule, but instead within scope for the maintenance programs established under § 50.155 through the guidance of Regulatory Guide 1.226 and NEI 12–06. For example, a turbine-driven auxiliary feedwater (TDAFW) pump in a pressurized-water reactor would fall within the scope of the monitoring requirements of § 50.65(a) under the criteria of § 50.65(b) for those functions that meet the criteria, but not for the performance of beyond-design basis functions for the strategies and guidelines required by § 50.155. As a result, the monitoring under § 50.65(a) would be with the goal of providing reasonable assurance that the TDAFW pump is capable of fulfilling its intended safety function (*i.e.,* specific function) within the reference bounds of the design bases as defined in § 50.2 for the functions that result in its inclusion in the scope of § 50.65. The capability of the TDAFW pump to remain functional in the context of a loss of all ac power concurrent with an LUHS, which could expose the pump to environmental and operational constraints outside the reference bounds of the design bases for the events resulting in inclusion in the scope of § 50.65(a) due to a longer period with an absence of normally available cooling, would not be addressed by the § 50.65(a) monitoring program, but instead by the maintenance and testing programs established under § 50.155 through the guidance of RG 1.226 and NEI 12–06.

Similarly, some licensees rely on a portable, ac-power independent pump for the strategies and guidelines developed under § 50.155(b)(1), (2), or (3). These strategies and guidelines may be referred to in the licensee's EOPs, but are not necessary in order to conform to the NRC-approved emergency planning guidelines that form the basis for the EOPs. Therefore, because the portable, ac-power independent pump is not used in the EOPs, it would not be one of the nonsafety-related SSCs included within the scope of § 50.65(a)(1) under § 50.65(b)(2)(i), unless otherwise required by § 50.65(b). Further details on scoping of equipment under § 50.65 are provided in NUMARC 93–01, ''Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants.''

paragraph (c) in § 50.155 are discussed in the ''Reasonable Protection,'' ''Spent Fuel Pool Instrumentation,'' and ''Removal of the Proposed Staffing and Communications Requirements'' sections of this portion of the document.

N. Removal of Integration Requirements

In the proposed MBDBE rule, the NRC had included a potential requirement for an overarching integrated response capability including the mitigation strategies for beyond-design-basis external events and the EDMGs and an organizational structure specific to the integrated response capability. In addition, the proposed MBDBE rule included a potential requirement for integration of the integrated response capability with the existing emergency operating procedures. In reexamining the requirements of the proposed MBDBE rule, the NRC recognized that the implementation of the strategies and guidelines under Order EA–02–026, ''Interim Safeguards and Security Compensatory Measures,'' dated February 25, 2002, which resulted in the EDMGs included in § 50.155(b)(2), and the implementation of the strategies and guidelines under the Mitigation Strategies Order that constitute the remainder of the proposed integrated response capability, had both included a need for integration at the regulatory guidance level. For example, the regulatory guidance in NEI 12–06 for the Mitigation Strategies Order covers the interactions between the procedures developed under the order and their interfaces with various accident mitigation procedures to result in an overall coherent and comprehensive structure in section 11.4, ''Procedure Guidance.'' In addition, this regulatory guidance, which provides one acceptable means of complying with the order, includes a need for validation of the resulting strategies to show they are feasible; this validation included drills and walkthroughs of the resulting procedural documentation to show that it can be executed by the personnel that would need to use the strategies in an actual event. The NRC concludes that the requirements imposed by the Mitigation Strategies and the Interim Safeguards and Security Compensatory Measures Orders were sufficient to provide reasonable assurance of adequate protection and no new information was developed with regard to integration that would modify this conclusion. In addition, the NRC concludes that requirements for integration would not result in a substantial increase in the overall protection of public health and safety. Therefore, imposing requirements for an integrated response capability and integration with the existing emergency operating procedures would not meet the provisions of the Backfit Rule. The final rule has been revised to remove the proposed requirements for an integrated response capability and integration with the existing emergency operating procedures.

O. Training

The proposed MBDBE rule included potential requirements for training that included qualification of personnel and the use of the systems approach to training as defined in § 55.4, ''Definitions.'' The training requirement in the proposed rule carried forward a requirement for training from the Mitigation Strategies Order. The elements of this requirement for qualification and the use of the systems approach to training were addressed in the regulatory guidance for the Mitigation Strategies Order. The NRC concluded that the requirements imposed by the orders were sufficient to provide reasonable assurance of adequate protection of public health and safety and no new information was developed with regard to qualification or the systems approach to training that would modify this conclusion. The NRC also considered whether there would be a substantial increase in the overall protection of the public health and safety or the common defense and security that would result from including requirements in the final rule for qualification or the systems approach to training rather than continuing the practice of addressing them in the regulatory guidance as had been done for the orders. The NRC concluded that, while there would be some benefit in the form of clarity as to what had been found acceptable for compliance with the orders being made generically applicable in this rulemaking, the recharacterization of those items from regulatory guidance to requirements would not constitute a substantial increase in the overall protection of the public health and safety or the common defense and security.

The NRC concludes that a separate requirement for qualification and the systems approach to training is not needed, but could constrain an existing licensee or an applicant for a new licensee from developing innovative mitigation strategies that do not rely on them. This follows the Commission's direction in SRM–SECY–11–0124 that

> [i]n order to be effective, approaches should be flexible and able to accommodate a diverse range of circumstances and conditions. In consideration of events beyond the design basis, a regulatory approach founded on performance-based requirements will foster development of the most effective and efficient, site-specific mitigation strategies, similar to how the agency approached the approval of licensee response strategies for the ''loss of large area'' event under its B.5.b program.

The final rule has been revised to remove requirements for qualification and the use of the systems approach to training.

P. Discussion of Four Topics That Were Addressed Generically

The NRC received a number of comments that fell into four topical areas. The comments were considered and addressed generically. These comments did not result in changes to the MBDBE rule. A discussion of these topics is provided below.

1. Comments That Suggest a Completely Different Approach to Mitigation of Beyond-Design-Basis Events

Several commenters provided feedback that the MBDBE rule should contain requirements that address various specific external events. The suggestions included geomagnetic disturbances (which are addressed separately in Section III, ''Petitions for Rulemaking,'' of this document because they are the subject of a petition for rulemaking currently under consideration by the NRC), cyber events that might disable the electric grid, attacks involving devices that may disable the electric grid, malicious attacks on a nuclear facility, and explosions from gas lines running in the vicinity of a nuclear facility. These comments suggest that the NRC take a different regulatory approach in the MBDBE rule than the NRC took under the Mitigation Strategies Order following the Fukushima Dai-ichi event. The comments tend to explicitly identify external events or conditions that commenters believe should be addressed by the MBDBE rule.

Rather than following the approach suggested by these commenters, the NRC is continuing with the regulatory approach taken with the issuance of the Mitigation Strategies Order. The order requires licensees to postulate a challenging damage state that exceeds the design basis, and to develop and implement the mitigation strategies to address that damage state. These strategies give licensees a capability for the mitigation of beyond-design-basis external events. This regulatory approach provides additional mitigation capability as well. Given the unbounded nature of the beyond-design-basis external events to which these

requirements are directed, the NRC determined that licensees need to address uncertainty by assuming a challenging damage state that such events might create, and then adding to that damage state the consideration of the effects the initiating event may have on the physical protection of equipment and strategies. For a more detailed explanation of this response, refer to the NRC response to General Comment 9 in the Comment Response Document (see Section XIX of this document).

2. Comments That Suggest the NRC Revisit Issues Associated With SFP Safety

These comments included suggestions that the NRC, as part of the MBDBE rule, should reconsider SFP fires, events that can lead to SFP fires, malicious attacks involving SFPs, SFP integrity during and following extreme events, and longer-term SFP aging issues. The Commission has previously considered these issues, and the NRC concluded that it was not within the scope of the MBDBE rule to revisit these SFP safety issues. Moreover, the MBDBE rule is addressing and enhancing SFP safety through the imposition of regulations that (1) require licensees to have strategies that maintain or restore SFP cooling capabilities for beyond-design-basis external events, and (2) provide information, through the use of SFPI, that enables operators to appropriately prioritize the use of resources following a beyond-design-basis external event. Explanations of the NRC's considerations of the commenters' issues are provided in the NRC response to General Comment 8 in the Comment Response Document. (See Section XIX of this document.)

3. Comment Regarding Decommissioning

The NRC received comments from stakeholders that were directed towards the basis for previous NRC exemption decisions regarding power reactor licensees in decommissioning. While the MBDBE rule does include provisions that facilitate the reduction of its requirements at the appropriate points within the decommissioning process, the rulemaking's regulatory scope does not include revisiting the bases for previous decisions on decommissioning exemptions. Instead, the MBDBE rule is enabling systematic removal of the mitigation strategies requirements as a facility proceeds through the process of decommissioning. The NRC enables these requirements to be removed through regulation, rather than requiring removal by the more resource-intensive exemption process, based on the same set of acceptance criteria that were used in granting the exemptions to licensees in decommissioning. Concerns about the NRC's decommissioning regulations should be raised in the ongoing regulatory effort to more broadly address decommissioning issues for all applicable requirements. (See ''Regulatory Improvements for Decommissioning Power Reactors; Advance notice of proposed rulemaking'' (80 FR 72358; November 19, 2015).) If, as a result of that regulatory effort, the NRC changes its position with regard to the bases for decommissioning and, specifically, if those changes affect the decommissioning provisions that are part of the MBDBE rule, then the NRC will make future conforming changes to the MBDBE rule to align it with the revised decommissioning requirements.

4. Comments on Geomagnetic Disturbances

The NRC received comments on the subject of geomagnetic disturbances. While these could be viewed as comments on a specific beyond-design-basis external event, the NRC determined that the issue warrants discussion given the NRC's ongoing consideration of geomagnetic disturbances. Although the MBDBE rule puts in place mitigation strategies that could be initially deployed and used to address the effects of geomagnetic disturbances (should such disturbances lead to adverse impacts on the transmission system and an associated loss-of-offsite power), the rulemaking's regulatory scope does not address the issue of geomagnetic disturbances in its entirety. The impact of geomagnetic disturbances is the subject of PRM–50–96, which the NRC accepted for consideration within its rulemaking process. The NRC published this determination in the **Federal Register** on December 18, 2012 (77 FR 74788). Accordingly, while not fully addressed within the MBDBE rule, the issue of geomagnetic disturbances will be addressed as part of the NRC's consideration of PRM–50–96, as discussed in Section III of this document.

V. Discussion

A. Rulemaking Objectives

The MBDBE rule accomplishes the following objectives: (1) Makes the requirements in the Mitigation Strategies and SFPI Orders generically applicable, giving consideration to lessons learned from implementation of the orders and public comment on the MBDBE proposed rule and (2) addresses issues raised by PRMs that were submitted to the NRC.

1. *Makes the requirements in the Mitigation Strategies and SFPI Orders generically applicable, giving consideration to lessons learned from implementation of the orders and public comment on the MBDBE proposed rule.*

This final rule places the requirements in the Mitigation Strategies Order and SFPI Order into the NRC's regulations so that they apply to all current and future power reactor applicants and provides regulatory clarity and stability to power reactor licensees. In the absence of this rule, these requirements would need to be imposed on new reactor applicants or licensees through additional orders or license conditions (as was done for all combined licenses (COLs) issued to date). As part of this rulemaking, the NRC considered stakeholder feedback and lessons learned from the implementation of the orders, including any challenges or unintended consequences associated with implementation. The NRC reflected this stakeholder input in the final rule as discussed in the previous section of this document as well as in regulatory guidance for this rule.

2. *Addresses a number of PRMs submitted to the NRC.*

This rulemaking addresses, and completes the regulatory actions planned for, the five PRMs filed by the NRDC that raise issues that pertain to the technical aspects of this rulemaking. The petitions rely solely on the NTTF Report and request that the NRC undertake rulemaking in a number of areas that are addressed by this rule. This rule also addresses, in part, PRM–50–96 submitted by Mr. Thomas Popik; however, broader issues raised in that petition regarding geomagnetic disturbances remain under consideration by the NRC.

B. Rulemaking Scope

The MBDBE rule addresses a significant number of regulatory issues that stem from NRC review of the NTTF recommendations that provided the regulatory impetus for this rule:

1. NTTF recommendations 4 and 7 and portions of NTTF recommendation 11.1 regarding onsite emergency resources to support multi-unit events with SBO, including the need to deliver equipment to the site despite degraded offsite infrastructure. The implementation of licensees' responses to these provisions of the MBDBE rule is largely complete, because they were implemented under the Mitigation Strategies Order.

2. NTTF recommendation 8, and the command and control issues in NTTF recommendation 10.2.

3. Numerous requirements regarding onsite emergency response actions implemented by the Mitigation Strategies Order, including supporting guidance to implement the emergency response aspects of this rule. The specific regulatory actions related to emergency response in this rule and the associated NTTF recommendations follow:

a. Staffing and communications guidance that address NTTF recommendation 9.3 and were also discussed in NTTF recommendations 9.1 and 9.2. These regulatory issues were initially addressed in the implementation of the Mitigation Strategies Order through the regulatory guidance supporting the order. The regulatory guidance for the MBDBE rule addresses supporting facilities and equipment, as discussed in the same NTTF recommendations.

b. Training requirements and drill guidance that address NTTF recommendation 9.3 and were also discussed in NTTF recommendations 9.1 and 9.2. These regulatory issues were implemented under the Mitigation Strategies Order.

Accordingly, the MBDBE rule addresses NTTF recommendations 4, 7, 8, 9.1, 9.2, 9.3 (except for maintenance of ERDS capability throughout a beyond-design-basis external event), 10.2, and 11.1.

The MBDBE rule also addresses NTTF recommendation 9.4 to modernize ERDS. This action differs from the other regulatory actions because ERDS is not an essential component of a licensee's capability to mitigate a beyond-design-basis external event. However, ERDS is an important form of communication between the licensee and the NRC. A modernization effort for ERDS was completed voluntarily by industry prior to issuance of this rule. The NRC includes amendments in this rule to remove the technology-specific references to outdated equipment in 10 CFR part 50, appendix E, section VI, ''Emergency Response Data System.''

Severe Accident Management Guideline and Multiple Source Term Dose Assessment

The Commission considered a proposed SAMG backfit analysis, provided as part of SECY–15–0065, ''Proposed Rulemaking: Mitigation of Beyond-Design-Basis Events (RIN 3150–AJ49),'' dated April 30, 2015. The Commission concluded that the imposition of SAMG requirements was not warranted and, consequently, SAMGs were removed as requirements in the MBDBE rule (refer to SRM–SECY–15–0065, dated August 27, 2015). Instead, SAMGs continue to be implemented and maintained through an industry initiative. For more information on the industry implementation of SAMGs, refer to the MBDBE proposed rule.

Multiple source term dose assessment requirements were part of the proposed MBDBE rule and addressed NTTF recommendations 9.3 and 9.1. These proposed requirements are removed in the final MBDBE rule and instead have been implemented by licensees as discussed in Section IV.E, ''Multiple Source Term Dose Assessment,'' of this document.

Procedure and Guideline Integration

Procedure and guideline integration were part of the proposed MBDBE rule and addressed NTTF recommendation 8. These proposed requirements are removed in the final MBDBE rule and instead have been implemented by licensees as discussed in Section IV.N, ''Removal of Integration Requirements,'' of this document.

C. Final Rule Regulatory Bases

Applicability

This final rule applies, in whole or in part, to applicants for and holders of an operating license for a nuclear power reactor under 10 CFR part 50 or COL under 10 CFR part 52.

This rule does not apply to applicants for, or holders of, an operating license for a non-power reactor under 10 CFR part 50, because non-power reactors pose lower radiological risks to the public from accidents than power reactors. These reduced risks result from two primary features of non-power reactors: (1) The core radionuclide inventories are lower than in power reactors as a result of their lower power levels and often shorter operating cycle lengths and (2) non-power reactors have lower decay heat associated with a lower risk of core melt and fission product release in a loss-of-coolant accident than power reactors.

A holder of a general or specific 10 CFR part 72 independent spent fuel storage installation (ISFSI) license for dry cask storage is not subject to this rule for the ISFSI because the decay heat load of the irradiated fuel is sufficiently low prior to movement to dry cask storage that it can be air-cooled. This situation would also meet the criteria for ''sunsetting,'' or phased removal, of requirements (discussed later in this section of this document) if the rule were to apply to holders of such licenses.

The GE Morris facility in Illinois, which is the only SFP licensed under 10 CFR part 72 as an ISFSI, does not need to comply with this rule and is excluded by the rule applicability described in § 50.155(a). The NRC considered including the GE Morris facility within the scope of this rule but found that the age and corresponding low decay heat load of the fuel in the facility made it unnecessary. The GE Morris facility would also meet this rule's sunsetting criteria if the rule were to apply to GE Morris. While this rule leaves in force the EDMG requirements of § 50.155(b)(2), those requirements are not applicable to GE Morris because it is not a 10 CFR part 50 licensee. In the course of the development and implementation of the guidance and strategies required by § 50.155(b)(2), the NRC evaluated whether additional mitigation strategies were warranted at GE Morris and concluded that no mitigation strategies were warranted beyond existing measures, due to the extended decay time since the last criticality of the fuel stored there, the resulting low decay heat levels, and the assessment that a gravity drain of the GE Morris SFP is not possible due to the low permeability of the surrounding rock and the high level of upper strata groundwater.

Decommissioning Reactors

The MBDBE rule contains a regulatory structure for phasing out the mitigation strategies requirements for a licensee as its reactor decommissioning process proceeds. This structure consists of three phases:

1. Once fuel is removed permanently from the reactor, the mitigation strategies associated with the reactor and primary containment are no longer needed. Consequently, the requirements of § 50.155 continue to apply, but only for the SFP.

2. When the decay heat of the spent fuel is reduced to a level that provides ample time to enable ad hoc action to be taken in response to an event to sustain the SFP cooling function indefinitely, then all the requirements of § 50.155 can be removed with the exception of § 50.155(b)(2).

3. Once all fuel is removed from the SFP, all requirements of the MBDBE rule no longer apply.

The following provides a more detailed discussion of this structure and the regulatory decisions made for decommissioning licensees that provide the basis for this structure.

Once a licensee has permanently ceased operation, permanently removed

fuel from the reactor vessel, and submitted the certifications of permanent cessation of operations and permanent removal of fuel from the reactor vessel required in § 50.82(a)(1) or § 52.110(a), that licensee need only comply with the requirements of § 50.155(b) through (d), and (f) associated with maintaining or restoring SFP cooling. As discussed previously, these proposed requirements are based on the Mitigation Strategies Order. The licensees for the Kewaunee Power Station, Crystal River Unit 3 Nuclear Generating Plant, San Onofre Nuclear Generating Station, Units 2 and 3, Fort Calhoun Station, Vermont Yankee Nuclear Power Station, and Oyster Creek Nuclear Generating Station submitted certifications of permanent fuel removal required by § 50.82(a)(1)(ii) after issuance of the Mitigation Strategies Order. The NRC has withdrawn the Mitigation Strategies Order for this group of NPP licensees (Shutdown NPP Group). These withdrawals were based on the NRC's conclusion that the lack of fuel in the licensee's reactor core and the absence of challenges to the containment rendered unnecessary the development of guidance and strategies to maintain or restore core cooling and containment capabilities. Consistent with these withdrawals, the MBDBE rule relieves licensees in decommissioning from the requirement to comply with the § 50.155(b) requirements to have mitigation strategies and guidelines to maintain or restore core cooling and containment capabilities. Moreover, these licensees do not need to comply with any of the other requirements in this final rule that support compliance with the § 50.155(b) requirements to have mitigation strategies and guidelines for maintaining or restoring core cooling and containment capabilities.

This MBDBE rule treats the EDMG requirements in a manner similar to the requirements for mitigation strategies developed under the Mitigation Strategies Order as made generically applicable under § 50.155(b)(1). For a licensee that has submitted the § 50.82(a)(1) or § 52.110(a) certifications, the lack of fuel in its reactor core and the absence of challenges to the containment would render unnecessary EDMGs for core cooling and containment capabilities. This licensee would not need to comply with the requirements in the MBDBE rule associated with core cooling or containment capabilities; rather, the licensee would be required to comply with the requirement to have EDMGs based on the presence of fuel in the SFP.

Once the licensee has submitted the certifications required in § 50.82(a)(1) or § 52.110(a), that licensee does not need to comply with the requirement in § 50.155(e) that the licensee provide reliable means to remotely monitor wide-range SFP levels to support effective prioritization of event mitigation and recovery actions. The requirement in § 50.155(e) makes generically applicable the requirements in the SFPI Order. This order requires a reliable means of remotely monitoring wide-range SFP levels to support effective prioritization of event mitigation and recovery actions in the event of a beyond-design-basis external event with the potential to challenge both the reactor and SFP.

The NRC also withdrew the SFPI Order for the Shutdown NPP Group. These withdrawals were based, in part, on the NRC's conclusions that once a licensee certifies the permanent removal of the fuel from its reactor vessel, the safety of the fuel in the SFP becomes the primary safety function for site personnel. In the event of a challenge to the safety of fuel stored in the SFP, decision makers would not have to prioritize actions and the focus of the licensee staff would be the SFP condition. Therefore, once fuel is permanently removed from the reactor vessel, the basis for the SFPI Order no longer applies. Consistent with the NRC order withdrawals, the NRC no longer requires licensees in decommissioning to have a reliable means to remotely monitor wide-range SFP levels to support effective prioritization of event mitigation and recovery actions in the event of a beyond-design-basis external event with the potential to challenge both the reactor and SFP.

The Mitigation Strategies Order also required power reactor licensees to have certain SFP cooling capabilities. In the withdrawal letters to the licensees for the Shutdown NPP Group, the NRC determined that the passage of time, the fuel's low decay heat, and the long time to boil off the water inventory in the SFP obviated the need for the Shutdown NPP Group licensees to have guidance and strategies necessary for compliance with the Mitigation Strategies Order. The withdrawal of the Mitigation Strategies Order for those licensees eliminated the requirement for them to comply with the order's requirements concerning beyond-design-basis event strategies and guidelines for SFP cooling capabilities. Consistent with the basis for the order withdrawals, licensees in decommissioning are relieved from the requirements concerning beyond-design-basis event strategies and guidelines for SFP cooling capabilities and any related requirements. These licensees have to perform and retain an analysis demonstrating that sufficient time has passed since the fuel within the SFP was last irradiated, such that the fuel's low decay heat and boil-off period provide sufficient time for the licensee to obtain offsite resources to sustain the SFP cooling function indefinitely. Licensees in decommissioning may use the equipment in place for EDMGs should that equipment be available, recognizing that the protection for that equipment is against the hazards posed by events that result in losses of large areas of the plant due to fires or explosions rather than beyond-design-basis external events resulting from natural phenomena. If the EDMG equipment is not available, offsite resources would be used by the licensee for onsite emergency response (*i.e.,* SFP cooling). This relief from the requirements related to the Mitigation Strategies Order does not impact any commitments licensees have made to support their requests for exemptions from offsite emergency planning requirements. The NRC's approval of such exemptions is based on the low radiological consequences of a beyond-design-basis event in which a loss of SFP inventory could result in a zirconium cladding fire and, conservatively, do not consider the ability to use offsite resources to mitigate such an event.

The NRC is maintaining the EDMG requirement for decommissioning plants because an event for which EDMGs would be required is not based on the condition of the fuel but may instead result from an aircraft impact or a beyond-design-basis security event that could introduce additional heat into the SFP independent from the decay heat of the fuel. These types of events and their potential consequences were considered as a part of the final rule dated March 7, 2009, on Power Reactor Security Requirements (74 FR 13926). In the course of that rulemaking, the NRC took into account stakeholder input and determined that it would be inappropriate to apply the EDMG requirements to permanently shutdown and defueled reactors where the fuel was removed from the site or moved to an ISFSI. However, the resulting rule inadvertently removed the EDMG requirements once the certifications of permanent cessation of operations and removal of fuel from the reactor vessel were submitted rather than upon removal of fuel from the SFP. The NRC is correcting this error from the 2009

final rule in this final rule as explained in the ''EDMGs'' portion of this section.

The NRC is excluding from § 50.155 the licensee for Millstone Power Station, Unit 1, Dominion Nuclear Connecticut, Inc. Dominion Nuclear Connecticut, Inc. is also the licensee for Millstone Power Station, Units 2 and 3, but this exclusion applies to Dominion Nuclear Connecticut, Inc. in its capacity as licensee for only Unit 1, which is not operating but has irradiated fuel in its SFP and satisfies the proposed criteria for not having to comply with this final rule except for the EDMG requirements. In the course of the development and implementation of the guidance and strategies required by new § 50.155(b)(2), the NRC evaluated whether additional mitigation strategies were warranted at Millstone Power Station, Unit 1 and concluded that no mitigation strategies were warranted beyond existing measures. This conclusion is based principally on the extended decay time since the last criticality occurred on November 4, 1995 and the fact that this results in low decay heat levels that allow sufficient time for the use of existing strategies. The exclusion for Millstone Power Station, Unit 1 in this rule is based upon that conclusion, with the understanding that additional mitigation capabilities will be present because of the licensee's implementation of the § 50.155(b)(2) strategies at the co-located Millstone Power Station, Units 2 and 3.

Mitigating Strategies for Beyond-Design-Basis External Events

The requirements in § 50.155(b)(1) for mitigating strategies make generically applicable requirements previously imposed on licensees by the Mitigation Strategies Order, as well as by license conditions included in the COLs held by Detroit Edison Company (for Enrico Fermi Nuclear Plant, Unit 3), Duke Energy Carolinas, LLC (for William States Lee III Nuclear Station, Units 1 and 2), Dominion Virginia Power (for North Anna Unit 3) and Florida Power and Light Company (for Turkey Point, Units 6 and 7).[3]

Recognizing that beyond-design-basis external events are unbounded, and that these events can result in a multitude of damage states and associated accident conditions, a significant regulatory challenge is developing bounded requirements that meaningfully address the regulatory issue. From a practical standpoint, development of mitigation strategies requires that there be a reasonable definition (or boundary conditions established) for an onsite damage state that the strategies would then address and thereby provide an additional capability to mitigate beyond-design-basis external event conditions that might occur. The assumed damage state should ideally capture a reasonable range of potential damage states that might occur as a result of beyond-design-basis external events and it should present an immediate challenge to the key safety functions for the facilities, so that the resultant strategies provide greater capabilities and can improve safety. An assumed damage state that accomplishes this objective is the loss of all ac power.

The MBDBE rule and the Mitigation Strategies Order both require the mitigation of a loss of all ac power condition. Both the MBDBE rule and the Mitigation Strategies Order address this requirement in two parts: (1) Through an assumed damage stage that is used to develop the strategies and guidelines for the mitigation of beyond-design-basis external events, and (2) through supporting contingencies within the strategies that address conditions that are more severe than those assumed to develop the strategies and guidelines. The assumed damage state for this rule is the same as that assumed to implement the requirements of attachment 2 to the Mitigation Strategies Order for currently operating power reactors: A loss of all ac power condition concurrent with an LUHS. This assumed damage state is effective at immediately challenging the key safety functions of core cooling, containment, and SFP cooling following a beyond-design-basis external event. Requiring strategies to maintain or restore these key functions under such circumstances results in an additional mitigation capability consistent with the Commission's objective when it issued the Mitigation Strategies Order.

As discussed in Section IV.D, ''Loss of All Alternating Current Power,'' of this document, the public comments provided on the MBDBE proposed rule showed some confusion regarding the requirement for loss of all ac power. The proposed rule contained the language ''extended loss of all ac power.'' The requirements in § 50.155(b)(1) provide for a capability to maintain or restore key functional capabilities indefinitely, or until sufficient site functional capabilities can be maintained without the need for mitigation strategies. As such, the word ''extended'' was unnecessary, and the NRC deleted it to reduce confusion with the ''ELAP'' term used in industry guidance; implementation of the requirements in § 50.155(b)(1) involves the use of contingencies that address damage states more severe than an assumed ELAP. Together, therefore, the assumed ELAP and the contingencies are the means for meeting a loss of all ac power requirement.

This MBDBE rule is not prescriptive in terms of the specific set of initial and boundary conditions assumed for the loss of all ac power and LUHS condition. The damage state for currently operating reactors, defined in more detail in RG 1.226, reflects currently operating power reactor designs and the reliance of those designs on ac power, while the assumed damage state for a future design may be different depending upon the design features. Specifically, the damage state of a loss of all ac power condition concurrent with an LUHS in the Mitigation Strategies Order was implemented first through the assumption of an ELAP, while allowing ac power from the inverters to be assumed available. This assumption is used to establish event sequence and the associated times for when mitigation actions would be assumed to be required. Secondly, to address the MBDBE rule and the Mitigation Strategies Order requirement for a loss of all ac power, including ac power from the batteries (through inverters), contingencies are included in the mitigation strategies to enable actions to be taken under those circumstances (*e.g.,* sending operators to immediately take manual control over a non ac-powered core cooling pump). As such, this provision makes generically applicable the current implementation under the Mitigation Strategies Order with no intent to either relax or impose new requirements and is performance-based to allow some flexibility for future designs. As an example, some reactor designs (*e.g.,* Westinghouse AP1000 and General Electric Economic Simplified Boiling Water Reactor (ESBWR)) use passive safety systems to meet NRC requirements for maintaining key safety functions. The inherent design of those passive safety systems makes certain assumptions, such as LUHS, inappropriate. Accordingly, the assumed condition for the mitigation strategies requirements for passive reactors is the loss of normal access to the normal heat sink, discussed further in this section. Nevertheless, in this rule the NRC is requiring that the strategies and guidelines be capable of

[3] License No. NPF–95, condition 2.D(12)(g); License No. NPF–101, condition 2.D(12)(j) and License No. NPF–102, condition 2.D(12)(j); and License No. NPF–103, condition 2.D(12)(f) and License No. NPF–104, condition 2.D(12)(h) and License No. NPF–105, condition 2.D(12)(h).

implementation during a loss of all ac power.

Regarding the assumed LUHS for COLs or applications referencing the AP1000 or the ESBWR designs, the assumption was modified to be a loss of normal access to the normal heat sink (see, *e.g.,* attachment 3 to the Mitigation Strategies Order and the Enrico Fermi Nuclear Plant, Unit 3 license, License No. NPF–95, condition 2.D(12)(g)). This modified language reflects the passive design features of the AP1000 and the ESBWR that provide core cooling, containment, and spent fuel cooling capabilities for 72 hours without reliance on ac power. These features do not rely on access to any external water sources for the first 72 hours because the containment vessel and the passive containment cooling system serve as the safety-related ultimate heat sink for the AP1000 design and the isolation condenser system serves as the safety-related ultimate heat sink for the ESBWR design.

As discussed previously, the range of beyond-design-basis external events is unbounded. The MBDBE rule is not intended, and should not be understood, to mean that the mitigation strategies can adequately address all postulated beyond-design-basis external events. It is always possible to postulate a more severe event that causes greater damage and for which the mitigation strategies may not be able to maintain or restore the functional capabilities (*e.g.,* meteorite impact). Instead, the MBDBE requirements provide additional mitigation capability in light of uncertainties associated with external events, consistent with the NRC's regulatory objective for issuance of the Mitigation Strategies Order.

The MBDBE rule requires that the mitigating strategies for beyond-design-basis external events in § 50.155(b)(1) be capable of being implemented site-wide. This recognizes that severe external events are likely to impact the entire reactor site and for multi-unit sites, damage all the power reactor units on the site. This requirement means that there needs to be sufficient equipment and supporting staff to enable the maintenance or restoration of core cooling, containment, and SFP cooling functions for all the power reactor units on the site. This is a distinguishing characteristic of this set of mitigation strategies from those in § 50.155(b)(2), for which the damage state is a more limited, albeit large area of a single plant, reflecting the hazards for which that set of strategies was developed.

The NRC gave consideration to whether there should be changes made to § 50.63 (the Station Blackout Rule) to link those requirements with this rule. This consideration stemmed from recommendation 4.1 of the NTTF Report to ''initiate rulemaking to revise 10 CFR 50.63'' and the understanding that this rule could result in an increased SBO coping capability, in addition to the regulatory objectives of the MBDBE rule, which provide additional beyond-design-basis external event mitigation. Because of the substantive differences between the requirements of § 50.63 for licensees to be able to withstand and recover from an SBO and the MBDBE requirements, the NRC determined that such a linkage is not necessary and could lead to regulatory confusion.

The principal regulatory objective of § 50.63 was to establish SBO coping durations for a specific scenario: The loss of offsite power coincident with a failure of all trains of emergency onsite ac power (typically, the failure of multiple emergency diesel generators). In meeting this regulatory objective, the NRC understood that there would be safety benefits accrued through the provision of an alternate ac source diverse from the emergency diesel generators and therefore defined ''alternate ac source'' in § 50.2. The NRC defined the event a licensee must withstand and recover from as a ''station blackout'' rather than a ''loss of all ac power.'' An SBO allows for continued availability of ac power to buses fed by station batteries through inverters or by alternate ac sources. The MBDBE rule requires an additional capability to mitigate beyond-design-basis external events. Because the condition assumed for the mitigation strategies to establish the additional mitigation capability includes a loss of all ac power, which is more conservative than an SBO as defined in § 50.2 (because it covers an indefinite period, not a loss for a certain amount of time, and it also assumes the loss of alternate ac sources), there can be a direct relationship between the two different sets of requirements with regard to the actual implementation at the facility. Specifically, implementation of the mitigation strategies links into the SBO procedures (*e.g.,* the applicable strategies would be implemented to maintain or restore the key safety functions when the EOPs reach a ''response not obtained'' juncture).[4]

Step-by-step procedures are not necessary for many aspects of the mitigation strategies and guidelines. Rather, the strategies and guidelines are intended to be flexible, and enable plant personnel to adapt them to the conditions that result from the beyond-design-basis external event. The provisions typically would result in strategies and guidelines that use both installed and portable equipment, instead of only relying on installed ac power sources (with the exception of protected battery power) to maintain or restore core cooling, containment, and SFP cooling capabilities. By using equipment that is separate from the normal installed ac-powered equipment, the strategies and guidelines have a diverse attribute. By having available multiple sets of portable equipment that can be deployed and used in multiple ways depending on the circumstances of the event, operators are able to implement strategies and guidelines that are flexible and adaptable.

The mitigation strategies requirements are both performance-based and functionally-based. The performance-based requirements recognize that the new requirements provide most benefit to future reactors whose designs could differ significantly from current power reactor designs and as such, use of more prescriptive requirements could be problematic and create unnecessary regulatory impact and need for exemptions. Use of functionally-based requirements results from the need to have requirements that can address a wide range of damage states that might exist following beyond-design-basis external events. Maintaining or restoring three key functions (core cooling, containment, and SFP cooling) supports maintenance of the fission product barriers (*i.e.,* fuel clad, reactor coolant pressure boundary, and containment) and results in an effective means to mitigate these events, while remaining flexible such that the strategies and guidelines can be adapted to the damage state that occurs. Functionally-based requirements also result in strategies that align well with the symptom-based procedures used by power reactors to respond to accidents. Accordingly, the Mitigation Strategies Order contained requirements for a three-phased approach for current operating reactors. The MBDBE rule does not specify a number of phases; instead, it establishes higher-level, performance-based

[4] One of the formats for symptom-based EOPs that are used in the operating power reactors has the operators take an action and verify that the system responds to the action in a manner that confirms that the action was effective. For example, a step in an EOP could be to open a valve in order to allow cooling water flow, and the verification would be obtained by confirming there are indications that flow has commenced, such as a decrease in temperature of the system being cooled. If those indications are not obtained, the procedure would provide instructions on the next step to accomplish in a separate column labeled ''response not obtained.''

requirements consistent with this discussion. Section IV.K, ''Consideration of Explicit Requirements for a Three-Phase Response,'' of this document contains further discussion of this aspect of the MBDBE rule.

The NRC considered incorporating into this rule a requirement that licensees be capable of implementing the strategies and guidelines ''whenever there is irradiated fuel in the reactor vessel or spent fuel pool.'' This provision would have been a means of making generically applicable the requirement from the Mitigation Strategies Order that licensees be capable of implementing the strategies and guidelines ''in all modes.'' The NRC considered the terminology ''whenever there is irradiated fuel in the reactor vessel or spent fuel pool'' to be a better means to address the order requirement because the phrase did not use technical specification type language (*i.e.,* modes), which is in effect when a licensee completely offloads the fuel from the reactor vessel into the SFP during an outage. The NRC did not use the phrases, ''whenever there is irradiated fuel in the reactor vessel or spent fuel pool,'' or, ''in all modes,'' in the MBDBE rule and instead structured the applicability provisions to achieve this same objective by requiring licensees to have mitigation strategies for beyond-design-basis external events for the various configurations that can exist for the reactor and SFPs throughout the operational, refueling, and decommissioning phases.

The mitigation strategies and guidelines implemented under the Mitigation Strategies Order assume a demanding condition that maximizes decay heat that would need to be removed from the reactor core and SFP source terms on site. This implementation results in a more restrictive timeline (*i.e.,* mitigation actions required sooner to maintain or restore cooling to these source terms) and a greater resulting additional capability. These assumed at-power conditions are 100 days at 100 percent power prior to the occurrence of the beyond-design-basis event for the reactor core, consistent with the assumption used for § 50.63. This assumption establishes a conservative decay heat for the reactor source term. The assumed SFP conditions include the design basis heat load for the SFP, which is typically a full core offload following a refueling outage, as the heat load that is used for the sizing of FLEX equipment. For the purposes of determining the response time for the SFP strategies when fuel is in the reactor vessel, the rate of inventory loss of the SFP is calculated based on the worst case conditions for SFP heat load assuming the plant is at power. The NRC considers the development of timelines for the mitigation strategies using these assumptions for the reactor core and SFP to be appropriate.

The NRC recognizes the difficulty of developing engineered strategies for the extraordinarily large number of possible plant and equipment configurations that might exist under shutdown conditions (*i.e.,* at shutdown when equipment may be removed from service, when there is ongoing maintenance and repairs or refueling operations, or modifications are being implemented). Licensees must be cognizant of such configurations, equipment availability, and decay heat states that could present greater challenges under these conditions and design mitigation strategies that can be implemented under such circumstances.

The NRC considered incorporating requirements into the MBDBE rule that would require strategies to be developed that specifically assume that delays in the receipt of offsite resources occur as a result of damage to the transportation infrastructure. While severe events could damage local infrastructure, and could create challenges with regard to the delivery of offsite resources, the NRC concluded that having this level of specificity in the MBDBE rule is not necessary. Instead, this rule contains provisions that are more performance-based, requiring continued maintenance or restoration of the functional capabilities until acquisition of offsite assistance and resources. Potential delays and other challenges presented by extreme events that affect acquisition and use of offsite resources are addressed by licensee programs that implement the provisions of this rule.

The Mitigation Strategies Order included a requirement that licensees develop guidance and strategies to obtain ''sufficient offsite resources to sustain [the functions of core cooling, containment, and SFP cooling] indefinitely.'' The NRC considered using this language in this rule, but concluded that this would be better phrased as ''indefinitely, or until sufficient site functional capabilities can be maintained without the need for the mitigation strategies.'' The NRC concluded that this phrase more clearly communicates the existence of a transition from the use of the mitigation strategies to recovery operations.

EDMGs

In recognition of the similarity of the existing EDMGs formerly in § 50.54(hh)(2) to the strategies required by § 50.155(b)(1), the NRC relocated the EDMGs into the MBDBE rule as § 50.155(b)(2). In addition to moving the text, the NRC made a few editorial changes. The wording used to describe these requirements has evolved from ''guidance and strategies,'' in Order EA–02–026, ''Interim Safeguards and Security Compensatory Measures,'' dated February 25, 2002, to ''strategies,'' in the corresponding license conditions, to ''guidance and strategies,'' in § 50.54(hh)(2), to its current form, ''strategies and guidelines.'' The word ''guidelines'' was chosen rather than ''guidance'' to more accurately reflect the nature of the instructions that a licensee could develop and to avoid confusion with the term ''regulatory guidance.'' The word ''strategies'' is used in this rule to reflect its meaning, ''plans of action.'' The resulting plans of action may include plant procedures, methods, or other guideline documents, as deemed appropriate by the licensee during the development of these strategies. These plans of action also include the arrangements made with offsite responders for support during an actual event. No substantive change to the requirements is intended by this change in the wording.

The final rule clarifies the § 50.155(b)(2) requirements by adding the phrase ''impacted by the event'' in order to differentiate these requirements from those located in § 50.155(b)(1). The requirements in § 50.155(b)(2), which address the loss of large areas of the plant, are limited to the areas of the plant impacted by the event, and as such, are not intended to address a site-wide event. This clarification was necessary as a result of the relocation of these requirements to the MBDBE rule and their juxtaposition with the mitigation strategies for beyond-design-basis external events in § 50.155(b)(1), which are for a site-wide event. The events for which EDMGs would be used can impact key equipment that is shared between power reactor units (*i.e.,* SFPs), and that is why the NRC did not use language that would have limited the application of these requirements to an individual power reactor unit. This clarification is to preserve the scope of this requirement and specifically avoid an unintended imposition of a new requirement.

Applicability of the requirements of § 50.155(b)(2) was formerly governed by § 50.54(hh)(3), which made these requirements inapplicable following the submittal of the certifications required under § 50.82(a) or § 52.110(a)(1). As discussed in the Power Reactor Security Requirements final rule, the NRC concludes that it is inappropriate for the requirements for EDMGs to apply to a

permanently shutdown, defueled reactor, where the fuel was removed from the site or moved to an ISFSI. The NRC is requiring EDMGs for a licensee with permanently shutdown defueled reactors, but with irradiated fuel still in its SFP, because the licensee must be able to implement effective mitigation measures for large fires and explosions that could impact the SFP while it contains irradiated fuel. The MBDBE rule corrects the former § 50.54(hh)(3) to implement the sunsetting of the associated requirement as intended by the Commission in 2009. This change does not constitute backfitting for currently operating reactors (except Watts Bar Nuclear Plant, Unit 2), current COL holders, and currently decommissioning reactors with spent irradiated fuel in their SFP (except Millstone Power Station, Unit 1, as it is not subject to § 50.155) because the EDMGs are also required by the licensee's license conditions. Watts Bar Nuclear Plant, Unit 2, does not have the license condition, but TVA has consented to the imposition of this requirement without the NRC conducting a backfit analysis for this imposition on Watts Bar Nuclear Plant, Unit 2. The NRC request for TVA's consent and TVA's response are referenced in Section XIX, ''Availability of Documents,'' of this document.

In the proposed MBDBE rule, the NRC discussed secondary containment aspects of the mitigation strategies in the decommissioning provisions of § 50.155(a) for licensees that rely on secondary containment as a fission product barrier for their SFPs. The intent of the proposed requirement was to document the requirement without changing the requirements that had been imposed under the Mitigation Strategies Order and § 50.54(hh)(2). In the course of interactions with the ACRS and during the CER meeting, the NRC received feedback that this phrasing of the requirement was confusing. Therefore, the NRC has revised the final MBDBE rule to eliminate the discussion of secondary containment in the decommissioning provisions of § 50.155(a).

Equipment

The MBDBE rule contains requirements for licensee equipment that is relied upon for use in mitigation strategies and guidelines. This final rule makes generically applicable requirement (2) in attachments 2 and 3 of the Mitigation Strategies Order, which reads as follows: ''These strategies must . . . have adequate capacity to address challenges to core cooling, containment, and SFP cooling capabilities at all units on a site subject to this Order.''

The industry guidance of NEI 12–06, as endorsed by NRC interim staff guidance JLD–ISG–2012–01, included specifications for each licensee's provision of a spare capability in order to assure the reliability and availability of the equipment required to provide the capacity and capability requirements of the Mitigation Strategies Order. This ''spare capability'' was also referred to within the guidance as an ''N+1'' capability, where ''N'' is the number of power reactor units on a site. The NRC considered including requirements similar to the spare capability specification of NEI 12–06 in this rule but determined that such an inclusion would be too prescriptive and could result in the need to grant exemptions for alternate approaches that provide an effective and efficient means to provide the required capability. One example of this is in the area of flexible hoses, for which a strict application of the spare capability guidance could necessitate a licensee's provision of spare hose or cable lengths sufficient to replace the longest run of hoses being used by the licensee, when significant operating experience with similar hoses for fire protection does not show a failure rate that would support the need for such a spare capability.

The development of the mitigation strategies in response to the Mitigation Strategies Order relied upon a variety of initial and boundary conditions that were provided in the regulatory guidance of JLD–ISG–2012–01 and NEI 12–06. These initial and boundary conditions followed the philosophy of the basis for imposition of the requirements of the Mitigation Strategies Order, which was to require additional defense-in-depth measures to provide continued reasonable assurance of adequate protection of public health and safety. As a result, the industry response to the Mitigation Strategies Order includes diverse and flexible means of accomplishing safety functions rather than providing an additional further hardened train of safety equipment. These requirements and conditions included the acknowledgement that, due to the fact that initiation of an event requiring use of the strategies would include multiple failures of safety-related SSCs, it is inappropriate to postulate further failures that are not consequential to the initiating event. As a result, the NRC has determined that the conditions to which the instrumentation (as a class of equipment), that would be relied on for the mitigation strategies, would be exposed do not include conditions stemming from fuel damage. Instead, those conditions are limited to the initial and boundary conditions set forth in the guidance and include the conditions assumed to result from a postulated beyond-design-basis external event used in developing the guidelines and strategies under the MBDBE rule. The NRC has determined that it should not be necessary for the instrumentation to be designed specifically for use in the mitigation strategies and guidelines, but instead it would be necessary that the design and associated functional performance be sufficient to meet the demands of those strategies (*i.e.,* a licensee may rely upon existing instrumentation that is capable of operating in the conditions anticipated for the required strategies and guidelines rather than replacing it with new instrumentation specifically designed for those conditions). For example, NEI 12–06, which is endorsed in RG 1.226, includes a discussion in section 3.2.1.12 regarding the basis that should be provided for plant equipment that is relied upon in the mitigation strategies.

The MBDBE requirements cover events that are not included in design-basis events as that term is used in the § 50.2 definition of ''safety-related structures, systems, and components.'' Because of this, reliance on equipment for use in the mitigation strategies does not result in the applicability of the PDC as described in GDC 2 of appendix A to 10 CFR part 50. The MBDBE rule requires reasonable protection for the equipment relied on for the mitigation strategies against the effects of natural phenomena that are equivalent in magnitude to the phenomena assumed for developing the design basis for the facility.

Because the events for which the mitigation strategies are to be used are outside the scope of the design-basis events considered in establishing the basis for the design of the facility, equipment that is relied upon solely for those mitigation strategies does not fall within the scope of § 50.65 (the Maintenance Rule). Nevertheless, the equipment used to implement the mitigation strategies must receive adequate maintenance in order to assure that it is capable of fulfilling its intended function, and thereby ensure that the requirement to develop, implement, and maintain the mitigation strategies continues to be met.

This rulemaking does not revise the regulatory treatment of equipment relied upon for the EDMGs now relocated to § 50.155(b)(2). The regulatory treatment of that equipment remains as it is described in NEI 06–12, the endorsed

guidance document for those strategies and guidelines.

The NRC recognizes that existing nuclear power reactors with operating licenses issued under 10 CFR part 50 and those new nuclear power reactors with COLs issued under 10 CFR part 52 or operating licenses issued under 10 CFR part 50 may establish different approaches in developing strategies to mitigate beyond-design-basis events. For example, new nuclear power plants may use installed plant equipment for both the initial and long-term response to a loss of all ac power with less reliance on offsite resources than existing nuclear power reactors. Under § 50.155(c), the NRC will consider the specific plant approach when evaluating the SSCs relied on as part of the mitigation strategies for beyond-design-basis events.

Training

The mitigation of the effects of beyond-design-basis events using the strategies and guidelines is principally accomplished through manual actions rather than automated plant responses. Additionally, the instructions provided for event mitigation may be largely provided as high level strategies and guidelines rather than step-by-step procedures. The use of strategies and guidelines supports the ability to adapt the mitigation measures to the specific plant damage and operational conditions presented by the event. However, effective use of this flexibility depends upon the knowledge and abilities of personnel to select appropriate strategies or guidelines from a range of options and implement mitigation measures using equipment or methods that may differ from those employed for normal operation or design-basis event response. As a result, the NRC considers personnel training necessary to ensure that individuals are capable of effectively performing the roles and responsibilities established in the strategies and guidelines that are required by this rule.

Spent Fuel Pool Monitoring

The MBDBE rule requires licensees to have a means to remotely monitor wide-range SFP level as a separate requirement within the MBDBE rule, which makes the requirements of the SFPI Order generically applicable. While many licensees make use of this instrumentation to support implementation of the mitigation strategies, the instrumentation requirement was imposed under the SFPI Order to address the potential for the licensee personnel to be distracted from other issues by the status of the SFP and thereby enable the operators to re-prioritize resources, if necessary, following a beyond-design-basis external event. This requirement has a separate purpose from the mitigation strategies requirements: To provide a reliable indication of the water level in the SFP to allow prioritization of response actions between the core and the SFP. Therefore, this requirement was moved to paragraph (e) in the final rule to ensure a continued separation of the requirements. The NRC considered including the detailed requirements from the SFPI Order within the MBDBE rule but determined that the more performance-based approach taken with this rule allows an applicant for a new reactor license or design certification to provide innovative solutions to address the need to effectively prioritize event mitigation and recovery actions between the source term contained in the reactor vessel and that contained within the SFP.

In the course of implementation of the SFPI Order requirements, one lesson learned was that the need for prioritization of event mitigation and recovery actions is inapplicable to SFPs for which the decay heat load is sufficiently low that SFP cooling is not challenged in the same time frame as event progression for the reactor core. This was documented in the regulatory guidance of JLD–ISG–2012–03 and NEI 12–02, ''Industry Guidance for Compliance with NRC Order EA–12–051, 'To Modify License with Regard to Reliable Spent Fuel Pool Instrumentation,' '' Revision 1, which eliminates from the definition of an applicable SFP a pool that does not contain fuel used for the generation of power within the preceding 5 years. This is clarified in the MBDBE rule in § 50.155(e) by including a termination of the requirement once 5 years have elapsed since the fuel within the pool was last used for power generation in a reactor vessel.

Documentation of Changes

Because the MBDBE rule requirements address beyond-design-basis events, currently existing change control processes, including most notably § 50.59, may not address all aspects of a contemplated change to the strategies and guidelines under this rule. Therefore, the MBDBE rule includes a provision intended to supplement the existing change control processes and focus on the beyond-design-basis aspects of proposed changes. The MBDBE rule does not contain criteria typically included in other change control processes that are used as a threshold for determining when a licensee needs to seek NRC review and approval prior to implementing the proposed change. Instead, the MBDBE rule requires that licensees perform evaluations of proposed changes sufficient to reach a conclusion that the MBDBE rule requirements continue to be met and to document and maintain this evaluation to support NRC oversight of these activities. The final rule is revised to more clearly reflect this approach by referring to these requirements in § 50.155(f) as ''Documentation of Changes.''

The NRC requested stakeholder feedback concerning the change control provisions for the MBDBE rule. The feedback provided is discussed in Section IV of this document. The NRC concludes that the final rule will follow the same approach contained in the proposed rule as discussed in Section VI of this document. Notwithstanding this conclusion, the NRC is revising the discussion in this document for this provision to clarify its meaning and intent.

The NRC determined that the changes whose acceptability would be most difficult to judge are those that do not fall within endorsed guidance or are not NRC-approved alternative approaches taken at another licensed facility that can be demonstrated to apply to the licensee's facility. Changes to the implementation of the MBDBE requirements that remain consistent with regulatory guidance are clearly acceptable because such changes ensure continued compliance with the MBDBE requirements. The NRC recognizes that licensees may wish to make changes to the implementation of these requirements that do not follow current regulatory guidance for this rulemaking and that are not an approved alternative that the licensee can demonstrate applies to their facility. To clarify the MBDBE rule requirements for documentation of changes, the NRC added additional information to Section VI of this document that discusses potential changes, which are outside endorsed guidance or approved alternatives, that would clearly not constitute ''demonstrated compliance.''

During public discussions before issuance of the proposed rule, a stakeholder suggested that the NRC should consider a provision to allow a licensee to request NRC review of a proposed change, and that if the NRC did not act upon the request for a suggested time period (*e.g.,* 180 days), then the request would be considered ''acceptable,'' similar to the process for changes to the quality assurance program description under

§ 50.54(a)(4)(iv). The NRC did not include this form of tacit approval process in the MBDBE rule and instead included provisions in the MBDBE rule to place on licensees the responsibility for ensuring that proposed changes result in continued compliance with the rule, subject to NRC oversight, or are otherwise submitted to the NRC under the § 50.12 exemption process.

A licensee may intend to change its facility, procedures, or guideline sets to revise some aspect of beyond-design-basis mitigation governed by the MBDBE rule in a manner that can impact multiple aspects of the facility, including ''design basis'' aspects of the facility subject to other regulations and change control processes. As previously discussed, the NRC anticipates that licensees will ensure that changes to the implementation of the MBDBE requirements are consistent with endorsed guidance, or otherwise demonstrate continued compliance with the MBDBE rule. This same change also could impact safety-related SSCs, either directly (*e.g.,* a proposed change that impacts a physical connection of mitigation strategies equipment to a safety-related component or system) or indirectly (*e.g.,* a proposed change that involves the physical location of mitigation equipment in the vicinity of safety-related equipment that presents a potential for adverse physical/spatial interactions with safety-related components). As a result, § 50.59 and other change control processes, as appropriate, would need to be applied to evaluate the proposed change for acceptability under any other applicable change control process.

Additionally, proposed changes can impact numerous aspects of the facility beyond the safety-related impacts, including implementation of fire protection requirements, security requirements, emergency preparedness requirements, or safety/security interface requirements. A licensee must therefore ensure that all applicable change control provisions are used to judge the acceptability of facility changes. Additionally, recognizing the nature of mitigation strategies and the reliance on human actions, a licensee also needs to ensure that the proposed changes satisfy the safety/security interface requirements of § 73.58. While the obligation of a licensee to comply with all applicable requirements might be viewed as making the provision in § 50.155(f)(2) unnecessary, the NRC recognizes the potential complexity of proposed facility changes and the complexity of existing regulatory requirements that govern change control. Therefore, the NRC concluded that adding the § 50.155(f)(2) provision for documentation of changes was warranted for the purposes of regulatory clarity.

Implementation

Section 50.155(g) provides a 2-year implementation period to provide sufficient time to allow licensees to review their previous compliance with the Mitigation Strategies and SFPI Orders and make any necessary changes to programs, plans, procedures, and guidelines to reflect and reference the newly issued § 50.155 requirements. This implementation period is 3 years for licensees that received Order EA–13–109. These licensees are allowed an additional year of implementation in order to alleviate CER by allowing the same amount of time following achievement of full compliance with that order, which was issued a year after the Mitigation Strategies and SFPI Orders.

In contrast with the portions of the final MBDBE rule that make the Mitigation Strategies and SFPI Orders generically applicable, § 50.155(b)(2) continues the requirements that were previously in § 50.54(hh)(2). Currently operating power reactor licensees have all achieved compliance with these requirements. Therefore, § 50.155(g) requires that licensees subject to the requirements of § 50.155(b)(2) continue to comply with those requirements during the implementation period for the remainder of the final MBDBE rule.

Order Withdrawal and Removal of License Conditions

The NRC is including in the final rule specific terms that withdraw orders and remove license conditions that are substantively redundant with provisions in the final rule. As discussed in this section, a primary objective of this rulemaking is to make the requirements of the Mitigation Strategies and SFPI Orders generically applicable to power reactor licensees and applicants, taking into account lessons learned in the orders' implementation and stakeholder feedback received through the regulatory process. As such, the requirements of § 50.155 fully replace the requirements of those orders. Although the orders provide for their relaxation or rescission on a licensee-specific basis, use of that process would be an inefficient and unnecessary administrative burden on licensees and the NRC—with no impact on public health and safety—because the final rule simultaneously replaces the orders in their entirety for all applicable licensees. Therefore, the NRC finds that good cause is shown to withdraw the Mitigation Strategies and SFPI Orders for all licensees that received those orders once the MBDBE rule goes into effect and licensees are in compliance with it. The withdrawal date for these orders was set to be the latest date for compliance by licensees in receipt of the orders to prevent a regulatory gap.

The NRC is also removing certain license conditions contained within the COLs held by Detroit Edison Company (for Enrico Fermi Nuclear Plant, Unit 3), Duke Energy Carolinas, LLC (for William States Lee III Nuclear Station, Units 1 and 2), Dominion Virginia Power (for North Anna Unit 3) and Florida Power and Light Company (for Turkey Point, Units 6 and 7). These licensees did not receive the Mitigation Strategies and SFPI Orders because the NRC had not issued COLs to these licensees at the time the NRC issued the Orders. When the NRC issued those COLs, it included license conditions that are equivalent to the orders' requirements. Because the license conditions contain the same requirements as the orders, and the provisions of § 50.155 replace the requirements imposed by the orders, the license conditions contain requirements equivalent to § 50.155 and will not be necessary once the MBDBE rule goes into effect. Therefore, the mitigation strategies for beyond-design-basis external events license conditions will be deemed removed from the Enrico Fermi Nuclear Plant, Unit 3, William States Lee III Nuclear Station, Units 1 and 2, North Anna Unit 3, and Turkey Point, Units 6 and 7 COLs on September 9, 2019.

In addition to license conditions corresponding to the Mitigation Strategies Orders, the COLs for Enrico Fermi Nuclear Plant, Unit 3, William States Lee III Nuclear Station, Units 1 and 2, North Anna Unit 3, and Turkey Point, Units 6 and 7 included license conditions for the performance of staffing and communications assessments that correspond to the requests for information on those subjects in the NRC letter issued under § 50.54(f) on March 12, 2012. As discussed in COMSECY–13–0010, ''Schedule and Plans for Tier 2 Order on Emergency Preparedness for Japan Lessons Learned,'' with regard to the interaction between licensee response to the § 50.54(f) letter and compliance with the Mitigation Strategies Order, ''the implementation of NEI 12–06 has a dependency on NEI 12–01, 'Guideline for Assessing Beyond Design Basis Accident Response Staffing and Communications Capabilities,' which was developed to address Tier 1 NTTF 9.3 Recommendation regarding staffing

and communications. NEI 12–06 will utilize the staffing and communication resources identified in NEI 12–01.'' Because the implementation of the final rule uses the same guidance as an acceptable means of compliance, there is no longer a need to collect this information for these licensees because there will be no additional regulatory action taken to modify, suspend, or revoke their licenses and the licensees are obligated to instead comply with the new requirements. Therefore, the license conditions calling for staffing and communications assessments for these licensees will be deemed removed on September 9, 2019.

Because the final rule removes certain license conditions without actually amending the associated licenses, the NRC will issue by letter an administrative license amendment to each applicable licensee that will remove the relevant license condition(s) from that licensee's license and include revised license pages.

For each of these orders being withdrawn and license conditions being removed, the NRC is replacing it with equivalent requirements in the MBDBE rule. Although the NRC did not include these measures in the MBDBE proposed rule, the NRC provided sufficient notice and an opportunity to comment under the Administrative Procedure Act (5 U.S.C. 553(b)) when it issued the MBDBE proposed rule. In the proposed rule, the Commission explained that the NRC would make generically applicable certain requirements in the Mitigation Strategies and SFPI Orders and related license conditions. The Commission's decision to remove these license conditions now that they are unnecessary was reasonably foreseeable, just as it was foreseeable that the Commission would withdraw the orders. Additionally, the Commission was informed by comments from the public that warned of potential unintended consequences from having duplicate requirements in orders, license conditions, and regulations. Thus, this aspect of the final rule, like the rest of the final rule, is a logical outgrowth of the proposed rule. Under the logical outgrowth line of legal decisions (*e.g., Long Island Care at Home, Ltd.* v. *Coke,* 551 U.S. 158 (2007); *National Mining Ass'n* v. *Mine Safety and Health Administration,* 512 F.3d 696 (D.C. Cir. 2008)), the public had adequate notice and opportunity to comment on the withdrawal of orders and removal of license conditions.

Technology-Neutral Emergency Response Data System

The requirements of section VI of appendix E to 10 CFR part 50, for the ERDS are amended to reflect the use of up-to-date technologies and remain technology-neutral so that the equipment supplied by the NRC continues to be replaced as needed, without the need for future rulemaking as equipment becomes obsolete. In 2005, the NRC initiated a comprehensive, multi-year effort to modernize aspects of the ERDS, including the hardware and software that constitute the ERDS infrastructure at NRC headquarters, as well as the technology used to transmit data from licensed power reactor facilities. As described in NRC Regulatory Issue Summary 2009–13, ''Emergency Response Data System Upgrade from Modem to Virtual Private Network Appliance,'' the NRC engaged licensees in a program that replaced the existing modems used to transmit ERDS data with virtual private network devices. The licensees now have less burdensome testing requirements, faster data transmission rates, and increased system security.

VI. Section-by-Section Analysis

§ 50.8 Information Collection Requirements: OMB Approval

This section, which lists all information collections in 10 CFR part 50 that have been approved by the Office of Management and Budget (OMB), is revised by adding a reference to § 50.155, the MBDBE rule. As discussed in Section XIV, ''Paperwork Reduction Act,'' of this document, the OMB has approved the information collection and reporting requirements in the MBDBE rule. No specific requirement or prohibition is imposed on applicants or licensees in this section.

§ 50.34 Contents of Applications; Technical Information

Section 50.34 identifies the technical information that must be provided in applications for construction permits and operating licenses. Paragraphs (a) and (b) of this section identify the information to be submitted as part of the preliminary or final safety analysis report, respectively. Revised paragraph (i) of this section identifies information to be submitted as part of an operating license application but not necessarily included in the final safety analysis report.

The NRC is making an administrative change to § 50.34(a)(13) and (b)(12) to remove the word ''stationary'' from the requirement for power reactor applicants who apply for a construction permit or operating license, respectively. Section 50.34(a)(13) and 50.34(b)(12) were added to the regulations in 2009 to reflect the requirements of § 50.150(b) regarding the inclusion of information within the preliminary or final safety analysis reports for applicants subject to § 50.150. Section 50.34(a)(13) and (b)(12) were inadvertently limited to ''stationary power reactors,'' matching the wording of § 50.34(a)(1), (a)(12), (b)(10), and (b)(11), which pertain to seismic risk hazards for stationary power reactors. The NRC is not changing the meaning of this requirement by removing the word ''stationary'' from these requirements. This change is to ensure consistency in describing the types of applications to which the requirements apply.

Section 50.34(i) requires each application for an operating license to include the applicant's plans for implementing the requirements of § 50.155 including a schedule for achieving full compliance with these requirements. This paragraph also requires the application to include a description of the equipment upon which the strategies and guidelines required by § 50.155(b)(1) rely, including the planned locations of the equipment and how the equipment and SSCs would meet the design requirements of § 50.155(c).

§ 50.54 Conditions of Licenses

This rulemaking redesignates § 50.54(hh)(3) as § 50.54(hh)(2) to reflect the movement of the requirements formerly in § 50.54(hh)(2) to § 50.155(b)(2). Section 50.54(hh)(2) is revised to reflect that § 50.54(hh)(1) applies to the licensee rather than the facility and to correct the section numbers for the required certifications. To avoid an unnecessary backfit in § 50.54(hh)(2), in the final rule the NRC removed the words ''once the NRC has docketed those certifications'' from the proposed § 50.54(hh)(2).

§ 50.155 Mitigation of Beyond-Design-Basis Events

This final rule adds new § 50.155, ''Mitigation of beyond-design-basis events,'' to 10 CFR part 50. The details of each paragraph within § 50.155 are explained in greater detail in the following paragraphs in this section.

Paragraph (a), ''Applicability''

Paragraph (a) describes which entities are subject to the MBDBE rule. Paragraph (a)(1) provides that each holder of an operating license for a

nuclear power reactor under 10 CFR part 50, as well as each holder of a COL under 10 CFR part 52 for which the Commission has made the finding under § 52.103(g) that the acceptance criteria are met, is required to comply with the requirements of this rule until the time when the NRC has docketed the certifications described in § 50.82(a)(1) or § 52.110(a). These certifications inform the NRC that the licensee has permanently ceased to operate the reactor and permanently removed all fuel from the reactor vessel. The permanent removal of fuel from the reactor vessel removes the possibility of core damage and containment failure, making it appropriate to terminate the requirements for strategies and guidelines to maintain or restore core cooling and containment capabilities. At the time the licensee submits these certifications, control of the applicability of the requirements of § 50.155 for licensees transitions to § 50.155(a)(2).

Although neither an applicant for an operating license under 10 CFR part 50 nor a COL holder before the § 52.103(g) finding is required to comply with § 50.155 until issuance of the operating license or the § 52.103(g) finding, respectively, these entities must include in their applications information under § 50.34(i) or § 52.80(d), respectively, including a schedule for achieving full compliance with the requirements of § 50.155.

Paragraph (a)(2) addresses power reactor licensees that permanently stop operating and defuel their reactors and begin decommissioning the reactors. Paragraph (a)(2)(i) provides that when an entity subject to the requirements of § 50.155 submits to the NRC the certifications described in § 50.82(a)(1) or § 52.110(a), then that licensee is required to comply only with the requirements of § 50.155(b) through (d), and (f) associated with maintaining or restoring SFP cooling capabilities for the reactor described in the § 50.82(a)(1) or § 52.110(a) certifications. In other words, the licensee may discontinue compliance with the requirements in § 50.155 associated with maintaining or restoring core cooling or the containment capability for the reactor described in the § 50.82(a)(1) or § 52.110(a) certifications. Compliance with the requirements of § 50.155(b) through (d), and (f) associated with maintaining or restoring SFP cooling capabilities continues as long as spent fuel remains in the SFPs associated with the reactor described in the § 50.82(a)(1) or § 52.110(a) certifications, or until the criterion of § 50.155(a)(2)(ii) can be satisfied. Once those conditions are satisfied, control of the applicability of the requirements of § 50.155 for licensees transitions to paragraphs (a)(2)(iv) or (a)(2)(ii), respectively.

Paragraph (a)(2)(ii) discontinues all the requirements of § 50.155 except those provided in § 50.155(b)(2) once the decay heat of the fuel in the SFP can be removed solely by heating and boiling of water within the SFP and the boil-off period provides sufficient time for the licensee to obtain off-site resources to sustain the SFP cooling function indefinitely. To comply with the requirement of § 50.155(a)(2)(ii), licensees must perform and retain an analysis demonstrating that sufficient time has passed since the fuel within the SFP was last irradiated such that the fuel's low decay heat and boil-off period provide sufficient time in an emergency for the licensee to obtain off-site resources to sustain the SFP cooling function indefinitely.

Paragraph (a)(2)(iii) exempts the licensee for Millstone Power Station, Unit 1, Dominion Nuclear Connecticut, Inc. from the requirements of § 50.155.

Paragraph (a)(2)(iv) allows holders of operating licenses or COLs for which the certifications described in § 50.82(a)(1) or § 52.110(a) have been submitted to cease compliance with all requirements in § 50.155, once a power reactor licensee has permanently stopped operating, defueled its reactor, and removed all irradiated fuel from the SFP(s) associated with the reactor described in the § 50.82(a)(1) or § 52.110(a) certifications.

Paragraph (b), ''Strategies and Guidelines''

Paragraph (b) requires that each applicant or licensee develop, implement, and maintain mitigation strategies for beyond-design-basis external events and EDMGs. The intent of this requirement is that the operating license and COL holders described in § 50.155(a) be able to mitigate the consequences of a wide range of initiating beyond-design-basis events and plant damage states that can challenge public health and safety.

Paragraph (b) specifies that the mitigation strategies for beyond-design-basis external events and EDMGs be ''developed, implemented, and maintained.'' The term ''implement'' is used in § 50.155(b) to mean that the mitigation strategies for beyond-design-basis external events and EDMGs are established and available to respond, if needed (*e.g.,* the licensee has approved the strategies, guidelines, and procedures for use). The term ''maintain'' as used in § 50.155(b) reflects the NRC's intent that licensees ensure that the mitigation strategies for beyond-design-basis external events and EDMGs, once established, be preserved, including the need to maintain equipment relied on for the mitigation strategies such that the equipment is capable of fulfilling its intended function, and consistent with the provisions for documentation of changes in § 50.155(f).

Paragraph (b)(1) requires applicants and licensees to develop, implement and maintain strategies and guidelines to mitigate beyond-design-basis external events from natural phenomena. These strategies and guidelines are developed assuming a loss of all ac power concurrent with either an LUHS or, for passive reactor designs, a loss of normal access to the normal heat sink. These provisions require that the strategies and guidelines be capable of being implemented site-wide and include the following:

i. Maintaining or restoring core cooling, containment, and SFP cooling capabilities; and

ii. Enabling the use and receipt of offsite assistance and resources to support the continued maintenance of the functional capabilities for core cooling, containment, and SFP cooling indefinitely, or until sufficient site functional capabilities can be maintained without the need for the mitigation strategies.

New reactors may establish different approaches from those of operating reactors in developing strategies to mitigate beyond-design-basis events. For example, new reactors may use installed plant equipment for both the initial and long-term response to a loss of all ac power with less reliance on portable equipment and offsite resources than currently operating nuclear power plants. The NRC would consider the specific plant approach when evaluating the SSCs relied on as part of the mitigation strategies for beyond-design-basis events. Additional information on these strategies is provided in RG 1.226, which endorses an updated version of the industry guidance, for use by applicants and licensees, that incorporates lessons learned and feedback stemming from the implementation of the Mitigation Strategies Order, consistent with Commission direction.

Paragraph (b)(1) limits the requirements for mitigation strategies to addressing ''external events from natural phenomena.'' This language is meant to differentiate these requirements from those that previously existed in § 50.54(hh)(2) that are now located in § 50.155(b)(2), and which address beyond-design-basis external

events leading to loss of large areas of the plant due to explosions and fire.

The requirement to enable ''the acquisition and use of offsite assistance and resources to support the functions required by § 50.155(b)(1)(i) of this section indefinitely, or until sufficient site functional capabilities can be maintained without the need for the mitigation strategies'' means that licensees need to plan for obtaining sufficient resources (*e.g.,* fuel for generators and pumps, cooling and makeup water) to continue removing decay heat from the irradiated fuel in the reactor vessel and SFP as well as to remove heat from containment as necessary until an alternate means of removing heat is established. The alternate means of removing heat could be achieved through repairs to existing SSCs, commissioning of new SSCs, or reduction of decay heat levels through the passage of time sufficient to allow heat removal through losses to the ambient environment. More detailed planning for offsite assistance and resources is necessary for the initial period following the event; less detailed planning is necessary as the event progresses and the licensee can mobilize additional support for recovery.

Paragraph (b)(2) contains the requirements for EDMGs that previously existed in § 50.54(hh)(2) and are described in the Power Reactor Security Requirements final rule. The movement of these requirements consolidates the requirements for beyond-design-basis strategies and guidance into a single section to promote efficiency in their consideration and allow for better integration. Although the wording of § 50.155(b)(2) differs from that of previous § 50.54(hh)(2), no substantive change in the requirements is intended.

The introductory text of § 50.155(b)(2) that is contained in § 50.155(b) is worded so that it requires that licensees ''develop, implement, and maintain'' the strategies and guidance required in § 50.155(b)(2) rather than using the wording of previous § 50.54(hh)(2) to require that licensees ''develop and implement'' the described guidance and strategies. The addition of the word ''maintain'' is to correct an inconsistency with the wording of § 50.54(hh)(1), which was issued along with § 50.54(hh)(2) in the Power Reactor Security Requirements final rule. The requirement as it was originally issued in Order EA–02–026 was worded to require licensees to ''develop'' specific guidance, while the corresponding license conditions imposed by the conforming license amendment was worded to require each affected licensee to ''develop and maintain'' strategies. The NRC concludes that the phrase ''develop, implement, and maintain'' provides better clarity of what is necessary for compliance with the requirements without substantively changing the requirements.

Paragraph (c), ''Equipment''

Paragraph (c)(1) requires that equipment relied on for the mitigation strategies and guidelines of § 50.155(b)(1) must have sufficient capacity and capability to perform the functions required by § 50.155(b)(1).

The phrase ''sufficient capacity and capability'' in § 50.155(c)(1) means that the equipment, and the instrumentation relied on to support the decision making necessary to accomplish the associated mitigation strategies of § 50.155(b)(1), has the design specifications necessary to assure that it functions and provides the requisite information on plant status when subjected to the conditions it is expected to be exposed to in the course of the execution of those mitigation strategies. These design specifications include appropriate consideration of environmental conditions that are predicted in the thermal-hydraulic and room heat up analyses used in the development of the mitigation strategies required by § 50.155(b)(1).

Paragraph (c)(2) requires reasonable protection of the equipment in § 50.155(b)(1) from the effects of natural phenomena that are equivalent in magnitude to the phenomena assumed for developing the external design basis of the facility. ''Reasonable protection'' is the means by which the NRC applies the appropriate level of treatment to equipment and SSCs that are required to function for § 50.155, without regard to whether the equipment is ''FLEX equipment,'' as defined in NEI 12–06, or ''plant equipment,'' as that term is used in NEI 12–06. Safety-related SSCs that function initially in response to beyond-design-basis external events have two sets of functions: Safety-related functions and beyond-design-basis functions. The requirements placed on these SSCs to perform their safety-related functions for the design-basis events are extensive and are intended to result in an increased level of assurance that the SSCs will perform those safety-related functions, during and/or following the design-basis events as applicable.

For these dual-function SSCs, the regulatory requirements and resulting level of regulatory assurance for the beyond-design-basis functions addressed by § 50.155(b)(1) for these dual-function SSCs are intended to be less stringent than the requirements associated with their safety-related functions. The ''reasonable protection'' requirement is the means for applying a reduced level of treatment for the beyond-design-basis functions and establishes an appropriate level of assurance. The phrase ''reasonable protection'' was initially proposed in recommendation 4.2 of the NTTF Report in the context of a recommendation for the NRC to issue an order to licensees to provide ''reasonable protection'' of equipment required by the former § 50.54(hh)(2) from the effects of design-basis external events along with providing additional sets of equipment as an interim measure during a subsequent rulemaking on prolonged SBO. The NTTF based this recommendation on the potential usefulness of the EDMGs in circumstances that do not involve the loss of a large area of the plant and explained that reasonable protection from external events as used in the NTTF Report meant that the equipment must ''be stored in existing locations that are reasonably protected from significant floods and involve robust structures with enhanced protection from seismic and wind-related events.''

The NRC carried forward the use of the phrase ''reasonable protection'' in the Mitigation Strategies Order with regard to the protection required for equipment associated with the mitigation strategies. That order did not, however, define ''reasonable protection.'' The NRC guidance in JLD–ISG–2012–01, Revision 0, discussed ''reasonable protection'' as follows:

> Storage locations chosen for the equipment must provide protection from external events as necessary to allow the equipment to perform its function without loss of capability. In addition, the licensee must provide a means to bring the equipment to the connection point under those conditions in time to initiate the strategy prior to expiration of the estimated capability to maintain core and spent fuel pool cooling and containment functions in the initial response phase.

In JLD–ISG–2012–01, Revision 0, the NRC endorsed NEI 12–06, Revision 0, as providing an acceptable method to provide reasonable protection, storage, and deployment of the equipment associated with the Mitigation Strategies Order. NEI 12–06, Revision 0, also omitted a definition for the phrase ''reasonable protection,'' but did provide guidelines for licensees for protecting the equipment from the hazards that would be commonly applicable: (1) Seismic hazards; (2) flooding hazards; (3) severe storms with high winds; (4) snow, ice and extreme cold; and (5) high temperatures. Later revisions to the guidance for the

Mitigation Strategies Order included further discussions on reasonable protection. NEI 12–06, Revision 2, defined reasonable protection as ''[s]toring on-site FLEX equipment in configurations such that no one external event can reasonably fail the site FLEX capability (N) when the required FLEX equipment is available.'' The JLD–ISG–2012–01, Revision 1, endorsed the approach of NEI 12–06, Revision 2, as an acceptable method of providing reasonable protection to the equipment associated with the strategies and guidelines developed under the Mitigation Strategies Order, clarifying that the elements of the approach that should be addressed are the following:

—Identification of the natural phenomena for which reasonable protection is necessary,
—determination of the method of protection to be used,
—establishment of controls on unavailability of the equipment, and
—provision of a method of transporting the portable equipment from its storage location to the site in which it will be used.

The RG 1.226 carries forward this guidance on reasonable protection, endorsing the current version of NEI 12–06 as providing an acceptable method of complying with § 50.155(c)(2).

The guidance of RG 1.226 and NEI 12–06 includes the use of structures designed to, or evaluated as equivalent to, American Society for Civil Engineers Standard 7–10, ''Minimum Design Loads for Buildings and Other Structures,'' for the seismic and high winds hazards, rather than requiring the use of a structure that meets the plant's design basis for the safe shutdown earthquake or high winds hazards including missiles. The NEI 12–06 guidelines also allow storage of the equipment above the flood elevation from the most recent site flood analysis, storage within a structure designed to protect the equipment from the flood, or storage below the flood level if sufficient time would be available and plant procedures would address the need to relocate the equipment above the flood level based on the timing of the limiting flood scenario(s). The NEI 12–06 guidelines further provide that multiple sets of equipment may be stored in diverse locations in order to provide assurance that sufficient equipment could be deployed to assure the success of the strategies following an initiating event. The NRC-endorsed guidelines in NEI 12–06 do not consider concurrent, unrelated beyond-design-basis external events to be within the scope of the initiating events for the mitigation strategies. There is an assumption of a beyond-design-basis external event that establishes the event conditions for reasonable protection, and then it is assumed in NEI 12–06 that the event leads to an ELAP and LUHS. There is not, for example, an assumption of multiple beyond-design-basis external events occurring at the same time. As a result, reasonable protection for the purposes of compliance with § 50.155(c)(2) allows the provision of specific sets of equipment for specific hazards with the required protection for those sets of equipment being against the hazard for which the equipment is intended to be used.

The NRC use of the phrase ''reasonable protection'' in § 50.155(c)(2) is intended to distinguish this approach from the approach of the PDCs, consistent with GDC 2, which requires that SSCs important to safety be designed to withstand the effects of natural phenomena. Section 50.155(c)(2) allows damage to, or loss of, specific pieces of equipment so long as the capability to use sufficient sets of the remaining equipment to accomplish strategies and guidelines is retained. ''Reasonable protection'' also allows for protection of the equipment using structures that could deform as a result of natural phenomena, so long as the equipment could be deployed from the structure to its place of use.

The remaining portion of § 50.155(c)(2) sets the hazard level for which ''reasonable protection'' of the equipment must be provided. The hazard level is the level determined for the design basis for the facility for protection of safety-related SSCs from the effects of natural phenomena under § 50.155(c)(2).

Paragraph (d), ''Training Requirements''

Paragraph (d) requires that each licensee specified in § 50.155(a) provide for the training of licensee personnel that perform activities in accordance with the capabilities required under § 50.155(b).

Paragraph (e), ''Spent Fuel Pool Monitoring''

Paragraph (e) requires each licensee to provide a reliable means to remotely monitor wide-range water level for each SFP at its site until 5 years have elapsed since all of the fuel within that SFP was last used in a reactor vessel for power operation. This requirement enables effective prioritization of event mitigation and recovery actions following beyond-design-basis external events. This provision does not apply to General Electric Mark III upper containment pools. These pools are referred to in the UFSARs for the applicable plants, Clinton Power Station, Grand Gulf Nuclear Station, Perry Nuclear Power Plant, and River Bend Station, by different terms, such as ''upper containment fuel storage pool,'' ''upper containment fuel pool,'' and ''containment upper pool.'' The use of the term ''upper containment pool'' in § 50.155(e) and in this discussion of the paragraph means the pools described in those UFSARs by those terms. The Mark III upper containment pools are only to store fuel during refueling outages, at which time the upper pool and reactor coolant system are merged, mitigating the potential for operator distraction should an extreme event happen at that time. After refueling is completed, and the reactor is critical, no fuel can be stored in the upper pool, and instead fuel must either be in the reactor and used to generate power or it is spent fuel and stored in the SFP.

Paragraph (f), ''Documentation of Changes''

Paragraph (f) establishes requirements that govern changes in the implementation of the requirements of § 50.155. Prior to implementing a change, § 50.155(f)(1) requires the licensee to demonstrate that the provisions of § 50.155 continue to be met and to maintain documentation of changes until the requirements of § 50.155 no longer apply. This documentation requirement applies to all changes that impact the implementation of § 50.155. The NRC recognizes that the licensee will maintain documentation of non-significant changes as part of their normal procurement and configuration management programs.

Regarding the meaning of demonstrated compliance, changes to the implementation of § 50.155 that are consistent with the regulatory guidance supporting the MBDBE rule are acceptable. Additionally, changes to the implementation of the MBDBE requirements that are approved alternative approaches, which are shown to apply to the licensee's facility consistent with the NRC's approval, are also acceptable. Changes that are outside of endorsed guidance or approved alternatives can be demonstrated to comply with § 50.155; however, in this regard the NRC emphasizes that licensees should be mindful of the following context.

1. The NRC initially issued requirements for the mitigation of beyond-design-basis external events in the Mitigation Strategies Order under the adequate protection provision of

§ 50.109(a)(4)(ii). The NRC seeks to ensure through § 50.155(f) that the resulting capabilities are maintained. A failure to maintain the functional capabilities first imposed by the Mitigation Strategies Order and now part of the MBDBE rule would challenge the continued reasonable assurance of adequate protection of public health and safety and not equate to demonstrated compliance with § 50.155.

2. The mitigation strategies are intended to address uncertainties associated with beyond-design-basis external events, and the requirements as implemented provide a capability that can be used and adapted to any event that exceeds the external design basis of the facility. While it was necessary for practical reasons to make assumptions concerning a damage state and conditions that could then be used to provide this additional capability, it is equally important to preserve the attributes of the mitigation strategies that provide flexibility, and enable adaptation to unknown events. Significantly impacting these attributes would reduce the capability for a licensee to successfully apply the strategies to real events. Such a change would not constitute demonstrated compliance with § 50.155. For example, the mitigation strategies use multiple sets of equipment, use strategies and guidelines rather than step-by-step procedures, have contingencies for conditions more severe than the assumed damage state used to develop the capability, employ alternate connection points, and are supported with offsite resources to provide for an indefinite capability. All of these are important elements of the additional mitigation capability for beyond-design-basis external events required by § 50.155. Changes that result in a significant reduction of these attributes would result in the mitigation strategies being less flexible and adaptable and therefore being less likely to be successfully deployable following a beyond-design-basis external event. Such changes would not constitute demonstrated compliance. For example, permanent removal of a set of equipment clearly removes flexibility and lessens the potential for successful mitigation of a beyond-design-basis external event.

Paragraph (f)(2) requires that changes in the implementation of the requirements of § 50.155 subject to other change control requirements be processed via their respective change control processes, unless the changes being evaluated impact only the implementation of § 50.155. Changes to the implementation of § 50.155 can impact multiple aspects of the facility. Paragraph (f)(2) is intended to clearly identify that other change control requirements such as those in §§ 50.59, 50.54(p), 50.54(q), 73.58, and fire protection change controls may apply depending on the extent of the change and the aspects of the facility that are impacted. This requirement is not essential because it is the licensee's obligation to comply with all applicable regulations; however, given the complexity of facility changes, the NRC is maintaining this requirement to provide regulatory clarity in the final rule, consistent with public comment. For example, a change to an SSC having both a beyond-design-basis function for § 50.155 and a design-basis function, would have the aspects of the change involving its beyond-design-basis functions addressed under § 50.155(f), and the aspects of the change involving the design-basis functions addressed under § 50.59 or any other applicable change control requirement. Another example may be a change to deploy in place equipment for § 50.155, that in turn impacts ingress and egress for an area of the facility important for security, and therefore needs to be evaluated under § 73.58.

Paragraph (g), ''Implementation''

Paragraph (g) establishes the compliance schedule for the MBDBE rule. Paragraph (g) establishes a compliance date of 3 years following the effective date of the MBDBE rule for each holder of a 10 CFR part 50 operating license who received NRC Order EA–13–109 and a compliance date of 2 years following the effective date of the MBDBE rule for each holder of a 10 CFR part 50 operating license that did not receive NRC Order EA–13–109 and each holder of a 10 CFR part 52 combined license for which the Commission has made the § 52.103(g) finding as of the effective date of the rule.

Paragraph (h), ''Withdrawal of Orders and Removal of License Conditions''

Under § 50.155(h)(1), the Mitigation Strategies and SFPI Orders will be withdrawn on September 9, 2022.

Under § 50.155(h)(2), the reliable SFP/buffer pool level instrumentation, mitigation strategies for beyond-design-basis external events, and emergency planning license conditions, except for license condition 2.D(12)(g)1, will be deemed removed from the Enrico Fermi Nuclear Plant, Unit 3 license on September 9, 2019.

Under § 50.155(h)(3), the mitigation strategies for beyond-design-basis external events, reliable SFP instrumentation, and emergency planning license conditions will be deemed removed with the exception of license conditions 2.D(12)(j)1, from the William States Lee III Nuclear Station, Units 1 and 2 licenses September 9, 2019.

Under § 50.155(h)(4), the reliable SFP/buffer pool level instrumentation, mitigation strategies for beyond-design-basis external events, and emergency planning license conditions will be deemed removed with the exception of license condition 2.D(12)(f)1 from the North Anna Unit 3 license on September 9, 2019.

Under § 50.155(h)(5), the mitigation strategies for beyond-design-basis external events, reliable SFP instrumentation, and emergency planning license conditions will be deemed removed with the exception of license condition 2.D(12)(h)1 from the Turkey Point, Units 6 and 7 licenses on September 9, 2019.

10 CFR Part 50, Appendix E, Section IV, Training

This final rule modifies the reference in the § 50.54(hh)(2) exercise requirement within 10 CFR part 50, appendix E, section IV.F.2.j, to § 50.155(b)(2) to reflect the movement of the EDMG requirement. The final rule also includes administrative changes to use the numeral ''8'' rather than the word ''eight'' in the phrases ''8-year'' and ''8-calendar-year'' for consistency with other sections.

10 CFR Part 50, Appendix E, Section VI, Emergency Response Data Systems

The NRC is amending its Emergency Response Data Systems regulations to allow the use of technology-neutral equipment. The requirements in appendix E, section VI, paragraph 3.c are amended to replace the phrase ''onsite modem'' with ''equipment'' and remove the word ''unit.''

§ 52.80 Contents of Applications; Additional Technical Information

Section 52.80 identifies the required additional technical information to be included in an application for a combined license. Paragraph (d) is amended to require a combined license applicant to include the applicant's plans for implementing the requirements of § 50.155, including a schedule for achieving full compliance with these requirements. This paragraph requires the application to include a description of the equipment upon which the strategies and guidelines that are required by § 50.155(b)(1) rely, including the planned locations of the equipment and how the equipment and

SSCs meet the design requirements of § 50.155(c).

VII. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the NRC certifies that this rule does not have a significant economic impact on a substantial number of small entities. This rule affects only the licensing and operation of nuclear power plants. The companies that own these plants do not fall within the scope of the definition of ''small entities'' set forth in the Regulatory Flexibility Act or established in § 2.810, ''NRC size standards.''

VIII. Availability of Regulatory Analysis

The NRC has prepared a regulatory analysis on this regulation. The analysis examined the costs and benefits of the alternatives considered by the NRC. The regulatory analysis is available as indicated in Section XIX of this document.

IX. Availability of Guidance

The NRC is issuing regulatory guidance for the implementation of the MBDBE rule. The guidance is available in ADAMS under Accession Nos. ML19058A012 and ML19058A013. You may access information and comment submissions related to the guidance by searching on *http://www.regulations.gov* under Docket ID NRC–2014–0240. The guidance to implement the MBDBE rule consists of two RGs which are discussed below.

The RG 1.226, ''Flexible Mitigation Strategies for Beyond-Design-Basis Events,'' endorses, with clarifications, the methods and procedures in NEI 12–06, ''Diverse and Flexible Coping Strategies (FLEX) Implementation Guide.'' This regulatory guidance provides licensees and applicants with an acceptable method of implementing the MBDBE rule primarily with regard to the provisions in § 50.155(b)(1), (c), and (f) regarding measures for the mitigation of beyond-design-basis external events. Previous versions of this guidance were endorsed to support compliance with the Mitigation Strategies Order. Licensees who used previous endorsed versions of NEI 12–06 are not required to revise their implementation under the Mitigation Strategies Order to address the MBDBE rule requirements. The later revisions of the endorsed guidance contain additional information for addressing reevaluated hazard information, frequently asked questions, and acceptable alternatives, and accordingly provide a larger set of guidance that licensees may use to implement the MBDBE rule, or to consult when deciding on the acceptability of changes to the implementation of the MBDBE rule requirements.

The RG 1.227, ''Wide-Range Spent Fuel Pool Level Instrumentation,'' endorses with exceptions and clarifications NEI 12–02, Revision 1. This guidance provides an acceptable method of implementing the MBDBE rule requirement in § 50.155(e). This RG does not differ in a significant manner from previously endorsed guidance for the SFPI Order, which was JLD–ISG–2012–03.

The NRC is discontinuing further regulatory action on Draft Regulatory Guide (DG) DG–1319, ''Integrated Response Capabilities for Beyond-Design-Basis Events.'' Draft Regulatory Guide DG–1319 was a proposed new regulatory guide (RG 1.228) developed by the staff to provide implementing guidance for provisions that have been removed from the final rule for the reasons discussed in Section IV, ''Public Comments and Changes to the Rule.'' Because the relevant regulatory requirements have been removed from the final rule, further NRC action to develop and adopt DG–1319 as a final guidance document is not needed. Therefore, this notice announces the NRC's decision to discontinue further action on DG–1319 and documents the final NRC action on DG–1319.

X. Backfitting and Issue Finality

Rule

As required by §§ 50.109 and 52.98, the Commission has completed a backfitting and issue finality assessment for this rule. The Commission finds that the change to the types of certifications that COL holders must submit before the requirements of § 50.54(hh)(1) no longer apply is inconsistent with the issue finality provisions of 10 CFR part 52. The change is justified as necessary for adequate protection of public health and safety or common defense and security. Availability of the backfit and issue finality assessment is indicated in Section XIX of this document.

Regulatory Guidance

The NRC is issuing two RGs that provide guidance for the implementation of this rule: RG 1.226 and RG 1.227. These RGs provide guidance on the methods acceptable to the NRC for complying with this final rule. The RGs apply to all current holders of, and applicants for operating licenses under 10 CFR part 50 and COLs under 10 CFR part 52.

Issuance of the RGs does not constitute backfitting under § 50.109 and is not otherwise inconsistent with the issue finality provisions under 10 CFR part 52. As discussed in the ''Implementation'' section of each RG, the NRC has no current intention to impose the RGs on current holders of an operating license or COL.

Applying the RGs to applications for operating licenses or COLs does not constitute backfitting as defined in § 50.109 and is not otherwise inconsistent with issue finality under 10 CFR part 52, because such applicants are not within the scope of entities protected by § 50.109 or the applicable issue finality provisions in 10 CFR part 52.

XI. Cumulative Effects of Regulation

The NRC engaged extensively with external stakeholders throughout this rulemaking and related regulatory activities. Public involvement has included: (1) Issuance of two ANPRs and two draft regulatory basis documents that requested stakeholder feedback; (2) issuance of conceptual and preliminary proposed rule language in support of public meetings; (3) numerous public meetings with the ACRS; (4) issuance of draft final rule language to support meeting with the ACRS, (5) a public meeting held during the final rule stage to gather additional feedback concerning CER, and (6) many more public meetings that supported both the development of the draft regulatory basis documents as well as development of the implementing guidance for the two orders that this rulemaking makes generically applicable (*i.e.,* the Mitigation Strategies and SFPI Orders). Section II, ''Opportunities for Public Involvement,'' of this document provides a more detailed discussion of public involvement.

The NRC requested and received feedback following its CER process. The feedback received is discussed in more detail in conjunction with the consideration of a flexible scheduling provision, in Section IV of this document. Most significantly, this final rule includes an additional year for implementation for licensees that received Order EA–13–109 that is intended to address the CER feedback received.

Regarding the CER process requirements for issuance of guidance, the NRC is issuing two RGs in conjunction with the issuance of the final rule as discussed in Section IX of this document. Additionally, the NRC issued draft guidance with the proposed rule for comment, which enabled more informed external stakeholder feedback to be obtained.

XII. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31883).

XIII. Environmental Assessment and Finding of No Significant Environmental Impact

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, that this rule is not a major Federal action significantly affecting the quality of the human environment, and therefore an environmental impact statement is not required. The basis of this determination reads as follows: The action will not result in any radiological effluent impact as it will not change any design basis structures, systems, or components that function to limit the release of radiological effluents during or after an accident. This final rule does not change the standards and requirements for radiological releases and effluents. None of the revisions or additions in this rule affect current occupational or public radiation exposure. The final rule will not cause any significant non-radiological impacts, as it will not affect any historic sites or any non-radiological plant effluents. The NRC concludes that this rule will not cause any significant radiological or non-radiological impacts on the human environment.

The NRC requested the views of the States on the environmental assessment for this rule. No views were received.

The determination of this environmental assessment is that there will be no significant effect on the quality of the human environment from this action. The environmental assessment is available as indicated in Section XIX of this document.

XIV. Paperwork Reduction Act

This rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The collections of information were approved by the Office of Management and Budget, approval numbers 3150–0011 and 3150–0151.

The burden to the public for the information collections is estimated to average 415 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection.

The information collection is being conducted to make changes to existing programs, plans, procedures, and guidelines implemented as a result of the Mitigating Strategies and SFPI Orders to reflect the new requirements of this rule, which replaces the order requirements. This information will be used by the NRC to support oversight activities associated with these requirements. Responses to this collection of information are mandatory.

You may submit comments on any aspect of the information collections, including suggestions for reducing the burden, by the following methods:

- *Federal rulemaking website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2014–0240.
- *Mail comments to:* Information Services Branch, Office of the Chief Information Officer, Mail Stop: T6–A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 or to: OMB Office of Information and Regulatory Affairs (3150–0011), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503; email: *oira_submission@omb.eop.gov.*

Public Protection Notification

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

XV. Congressional Review Act

This final rule is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

XVI. Criminal Penalties

For the purposes of Section 223 of the Atomic Energy Act of 1954, as amended (AEA), the NRC is issuing this rule that amends 10 CFR parts 50 and 52 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule are subject to criminal enforcement. Criminal penalties as they apply to regulations in 10 CFR parts 50 and 52 are discussed in §§ 50.111 and 52.303.

XVII. Compatibility of Agreement State Regulations

Under the ''Policy Statement on Adequacy and Compatibility of Agreement State Programs,'' approved by the Commission on June 20, 1997, and published in the **Federal Register** (62 FR 46517; September 3, 1997), this rule is classified as compatibility category ''NRC.'' Compatibility is not required for Category ''NRC'' regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the AEA or the provisions of title 10 of the *Code of Federal Regulations,* and although an Agreement State may not adopt program elements reserved to the NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with a particular State's administrative procedure laws, but does not confer regulatory authority on the State.

XVIII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this rule, the NRC is adding requirements for the mitigation of beyond-design-basis events. This action does not constitute the establishment of a standard that contains generally applicable requirements.

XIX. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS accession No./ web link/**Federal Register** citation
Primary Rulemaking Documents	
Regulatory Analysis Addendum—Final Rule to Address Mitigation of Beyond-Design-Basis Events	ML19058A009
Backfitting and Issue Finality Assessment Supporting the Mitigation of Beyond-Design-Basis Events Final Rule	ML19059A150
Environmental Assessment Supporting the Mitigation of Beyond-Design-Basis Events Final Rule	ML19058A008
Supporting Statement for Information Collections Contained in Mitigation of Beyond-Design-Basis Events Final Rule—10 CFR Part 50.	ML19058A010
Supporting Statement for Information Collections Contained in Mitigation of Beyond-Design-Basis Events Final Rule—10 CFR Part 52.	ML19058A011
NRC Response to Public Comments—Final Rule: Mitigation of Beyond-Design-Basis Events	ML19058A007
Regulatory Guides	
RG 1.226, Flexible Mitigation Strategies for Beyond-Design-Basis Events	ML19058A012
RG 1.227, Wide-Range Spent Fuel Pool Level Instrumentation	ML19058A013
Other References	
ACRS Transcript—Fukushima Subcommittee, ''Discuss Preliminary Mitigation of Beyond-Design-Basis Events Rulemaking Language,'' November 21, 2014.	ML14337A671
ACRS Transcript—Full Committee, ''Discuss Consolidation of Station Blackout Mitigation Strategies and Onsite Emergency Response Capabilities Rulemakings,'' July 10, 2014.	ML14223A631
ACRS Transcript—Full Committee, ''Discuss Preliminary Mitigation of Beyond-Design-Basis Events Rulemaking Language,'' December 4, 2014.	ML14345A387
ACRS Transcript—Full Committee, ''Discuss the Station Blackout Mitigation Strategies Regulatory Basis,'' June 5, 2013.	ML13175A344
ACRS Transcript—Joint Fukushima and Probabilistic Risk Assessment Subcommittees, ''Discuss CPRR Technical Analysis,'' August 22, 2014.	ML14265A059
ACRS Transcript—Plant Operations and Fire Protection Subcommittee, ''Discuss the Onsite Emergency Response Capabilities Regulatory Basis,'' February 6, 2013.	ML13063A403
ACRS Transcript—Regulatory Policies and Practices Subcommittee, ''Discuss the Station Blackout Mitigation Strategies Regulatory Basis,'' December 5, 2013, and April 23, 2013.	ML13148A404
ACRS Transcript—Reliability and Probabilistic Risk Assessment Subcommittee, ''Discuss CPRR Technical Analysis,'' November 19, 2014.	ML14337A651
American National Standards Institute/American Nuclear Society 3.2–2012, ''Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants''.	*http://www.ans.org/store/*
American Society for Civil Engineers Standard 7–10, ''Minimum Design Loads for Buildings and Other Structures,'' 2013.	*http://www.ascelibrary.org/*
COMGBJ–11–0002, ''NRC Actions Following the Events in Japan,'' March 21, 2011	ML110800456
COMSECY–13–0002, ''Consolidation of Japan Lessons Learned Near-Term Task Force Recommendations 4 and 7 Regulatory Activities,'' January 25, 2013.	ML13011A037
COMSECY–13–0010, ''Schedule and Plans for Tier 2 Order on Emergency Preparedness for Japan Lessons Learned,'' March 27, 2013.	ML12339A262
COMSECY–14–0037, ''Integration of Mitigating Strategies for Beyond-Design-Basis External Events and The Reevaluation of Flooding Hazards,'' November 21, 2014.	ML14309A256
''Consolidated Rulemaking—Proof of Concept'' (Conceptual Consolidated Preliminary Proposed Rule Language for NTTF Recommendations 4, 7, 8 and 9), February 21, 2014.	ML14052A057
''Crystal River Unit 3—NRC Response to Duke Energy's Final Response to the March 2012 Request for Information Letter,'' January 22, 2014.	ML13325A847
''Crystal River Unit 3 Nuclear Generating Plant—Rescission of Order EA–12–049, 'Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond Design Basis External Events,''' August 27, 2013.	ML13212A366
''Crystal River Unit 3—Final Response to March 12, 2012 Information Request Regarding Recommendations 2.1, 2.3 and 9.3,'' September 25, 2013.	ML13274A341
''Crystal River Unit 3 Nuclear Generating Plant—Rescission of Order EA–12–051, 'Order Modifying Licenses with Regard to Reliable Spent Fuel Pool Instrumentation,''' August 27, 2013.	ML13203A161
''Draft Regulatory Basis for Containment Protection and Release Reduction for Mark I and Mark II Boiling Water Reactors (10 CFR Part 50),'' May 2015.	ML15022A214
Executive Order 13744, ''Coordinating Efforts To Prepare the Nation for Space Weather Events,'' October 13, 2016.	81 FR 71573
Federal Register Notice—Enhancements to Emergency Preparedness Regulations, Final Rule, November 23, 2011.	76 FR 72560
Federal Register Notice—Mitigation of Beyond-Design-Basis Events, Proposed Rule, November 13, 2015	80 FR 70609
Federal Register Notice—Mitigation of Beyond-Design-Basis Events, Proposed Rule; correction, November 30, 2015.	80 FR 74717
Federal Register Notice—Onsite Emergency Response Capabilities, Advance Notice of Proposed Rulemaking, April 18, 2012.	77 FR 23161
Federal Register Notice—Onsite Emergency Response Capabilities, Draft Regulatory Basis, January 8, 2013	78 FR 1154
Federal Register Notice—Onsite Emergency Response Capabilities, Preliminary Proposed Rule Language, November 15, 2013.	78 FR 68774
Federal Register Notice—Onsite Emergency Response Capabilities, Regulatory Basis, October 25, 2013	78 FR 63901
Federal Register Notice—Power Reactor Security Requirements, Final Rule, March 27, 2009	74 FR 13926

Document	ADAMS accession No./ web link/**Federal Register** citation
Federal Register Notice—PRM–50–100, Petition for Rulemaking Submitted by the Natural Resources Defense Council, Inc., July 23, 2013.	78 FR 44034
Federal Register Notice—PRM–50–101, Petition for Rulemaking Submitted by the Natural Resources Defense Council, Inc., March 21, 2012.	77 FR 16483
Federal Register Notice—PRM–50–102, Petition for Rulemaking; Submitted by the Natural Resources Defense Council, Inc., April 27, 2012.	77 FR 25104
Federal Register Notice—PRM–50–96, Long-Term Cooling and Unattended Water Makeup of Spent Fuel Pools, Consideration in the Rulemaking Process, December 18, 2012.	77 FR 74788
Federal Register Notice—PRM–50–97, PRM–50–98, PRM–50–99, PRM–50–100, PRM–50–101, PRM–50–102, Petitions for Rulemaking Submitted by the Natural Resources Defense Council, Inc., Notice of Receipt, September 20, 2011.	76 FR 58165
Federal Register Notice—Regulatory Improvements for Decommissioning Power Reactors, Advance Notice of Proposed Rulemaking, November 19, 2015.	80 FR 72358
Federal Register Notice—Risk-Informed Categorization and Treatment of Structures, Systems and Components for Nuclear Power Reactors; Final Rule, November 22, 2004.	69 FR 68008
Federal Register Notice—Statement of Principles and Policy for the Agreement State Program; Policy Statement on Adequacy and Compatibility of Agreement State Programs, Final Policy Statements, September 3, 1997.	62 FR 46517
Federal Register Notice—Station Blackout, Advance Notice of Proposed Rulemaking, March 20, 2012	77 FR 16175
Federal Register Notice—Station Blackout Mitigation Strategies, Draft Regulatory Basis and Draft Rule Concepts, April 10, 2013.	78 FR 21275
Federal Register Notice—Station Blackout Mitigation Strategies, Regulatory Basis, July 23, 2013	78 FR 44035
''Fort Calhoun Station, Unit 1—Relaxation of the Schedule Requirements for Order EA–12–049, 'Issuance of Order to Modify Licenses with Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events' (CAC No. MF0969),'' November 21, 2016.	ML16277A509
''Fort Calhoun Station, Unit 1—Rescission of Order EA–12–051, 'Order Modifying Licenses with Regard to Reliable Spent Fuel Pool Instrumentation' (CAC No. MF0968),'' December 8, 2016.	ML16320A287
Inspection Manual Chapter (IMC) 0308, ''Reactor Oversight Process Basis Document,'' Attachment 2, ''Technical Basis for Inspection Program,'' October 16, 2006.	ML062890421
Interim Staff Guidance, NSIR/DPR–ISG–01, ''Emergency Planning for Nuclear Power Plants,'' November 2011	ML113010523
JLD–ISG–2012–01, ''Compliance with Order EA–12–049, Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events,'' Revision 0, August 29, 2012.	ML12229A174
JLD–ISG–2012–01, ''Compliance with Order EA–12–049, Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events,'' Revision 1, January 22, 2016.	ML15357A163
JLD–ISG–2012–01, ''Compliance with Order EA–12–049, Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events,'' Draft Revision 2, November 4, 2016.	ML16277A617
JLD–ISG–2012–03, ''Compliance with Order EA–12–051, Reliable Spent Fuel Pool Instrumentation,'' Revision 0, August 29, 2012.	ML12221A339
''Kewaunee Power Station—60-Day Response to March 12, 2012, Information Request Regarding Recommendation 2.1, Seismic Reevaluations,'' April 29, 2013.	ML13123A004
''Kewaunee Power Station—Rescission of Order EA–12–049, 'Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond Design Basis External Events' (TAC No. MF2774)'' June 10, 2014.	ML14059A411
''Kewaunee Power Station—Response to Request for Relief from Responding Further to the March 2012 Request for Information Letter for Recommendation 9.3,'' January 22, 2014.	ML13322B255
Letter from Anne T. Boland, NRC, to J.W. Shea, TVA, ''Watts Bar Nuclear Plant, Unit 2—Request for Tennessee Valley Authority's Consent to Imposition of New Requirement Related to Mitigation of Beyond-Design-Basis Events,'' February 15, 2017.	ML17040A353
Letter from Anthony R. Pietrangelo, NEI, to Mark A. Satorius, NRC, ''Use of Qualitative Factors in Regulatory Decision Making,'' May 11, 2015.	ML15217A314
Letter from Eric J. Leeds to Holders of Licenses for Operating Power Reactors as Listed in the Enclosure, ''Rescission or Partial Rescission of Certain Power Reactor Security Orders Applicable to Nuclear Power Plants,'' November 28, 2011.	ML111220447
Letter from J. E. Dyer, NRC, to Holders of Licenses for Operating Power Reactors Listed in the Enclosure, ''Order Requiring Compliance with Key Radiological Protection Mitigation Strategies,'' August 28, 2006.	ML062300304
Letter from J. Sam Armijo, ACRS Chairman, to Mr. R. W. Borchardt, ''Response to February 27, 2012 Letter Regarding Final Disposition of Fukushima-Related ACRS Recommendations in Letters Dated October 13, 2011, and November 8, 2011,'' March 13, 2012.	ML12072A197
Letter from J. W. Shea to NRC Document Control Desk, ''Watts Bar Nuclear Plant, Unit 2—Response to NRC Request for TVA's Consent to Imposition of New Requirement Related to Mitigation of Beyond-Design-Basis Events,'' March 1, 2017.	ML17061A121
Letter from John W. Stetkar, ACRS Chairman, to Chairman Stephen G. Burns, NRC, ''Draft SECY Paper Proposed Rulemaking: Mitigation of Beyond-Design-Basis Events (RIN 3150–AJ49),'' April 22, 2015.	ML15111A271
Letter from Mark A. Satorius to John W. Stetkar, ACRS, ''Draft SECY Paper 'Proposed Rulemaking: Mitigation of Beyond-Design-Basis Events (RIN 3150–AJ49)','' May 15, 2015.	ML15125A485
Letter from Said Abdel-Khalik, ACRS Chairman, to Chairman Gregory B. Jaczko, NRC, ''Initial ACRS Review of: (1) the NRC Near-Term Task Force Report on Fukushima and (2) Staff's Recommended Actions To Be Taken Without Delay,'' October 13, 2011.	ML11284A136
Memorandum from R. W. Borchardt to J. Sam Armijo, ACRS Chairman, ''Final Disposition of the Advisory Committee on Reactor Safeguards' Review of (1) the U.S. Nuclear Regulatory Commission Near-Term Task Force Report on Fukushima, (2) Staff's Recommended Actions To Be Taken Without Delay (SECY-11-0124), and (3) Staff's Prioritization of Recommended Actions To Be Taken in Response to Fukushima Lessons-Learned (SECY–11–0137),'' February 27, 2012.	ML12030A198
NEI 06–12, ''B.5.b Phase 2 & 3 Submittal Guideline,'' Revision 2, December 2006	ML070090060

Document	ADAMS accession No./ web link/**Federal Register** citation
NEI 10–05, ''Assessment of On-Shift Emergency Response Organization Staffing and Capabilities,'' Revision 0, June 2011.	ML111751698
NEI 12–01, ''Guideline for Assessing Beyond Design Basis Accident Response Staffing and Communications Capabilities,'' Revision 0, May 2012.	ML12125A412
NEI 12–02, ''Industry Guidance for Compliance with NRC Order EA-12-051, 'To Modify License with Regard to Reliable Spent Fuel Pool Instrumentation','' Revision 1, August 2012.	ML122400399
NEI 12–06, ''Diverse and Flexible Coping Strategies (FLEX) Implementation Guide,'' Revision 0, August 2012	ML12242A378
NEI 12–06, ''Diverse and Flexible Coping Strategies (FLEX) Implementation Guide,'' Revision 1A, October 2015 ...	ML15279A426
NEI 12–06, ''Diverse and Flexible Coping Strategies (FLEX) Implementation Guide,'' Revision 2, December 2015	ML16005A625
NEI 12–06, ''Diverse and Flexible Coping Strategies (FLEX) Implementation Guide,'' Revision 3, September 2016	ML16267A274
NEI 13–06, ''Enhancements to Emergency Response Capabilities for Beyond Design Basis Events and Severe Accidents,'' Revision 0, September 2014.	ML14269A230
NEI 13–06, ''Enhancements to Emergency Response Capabilities for Beyond Design Basis Events and Severe Accidents,'' Revision 1, February 2016.	ML16224A618
NEI 14–01, ''Emergency Response Procedures and Guidelines for Beyond Design Basis Events and Severe Accidents,'' Revision 0, September 2014.	ML14269A236
NEI 14–01, ''Emergency Response Procedures and Guidelines for Beyond Design Basis Events and Severe Accidents,'' Revision 1, February 2016.	ML16224A619
NEI 91–04, ''Severe Accident Issue Closure Guidelines,'' Revision 1, December 1994	ML072850981
Non-concurrence NCP–2015–003	ML15091A646
Non-concurrence NCP–2016–018	ML16312A020
NUREG–0654/FEMA–REP–1, ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants,'' Revision 1, November 1980.	ML040420012
NUREG–0660, Vol. 1, ''NRC Action Plan Developed as a Result of the TMI–2 Accident,'' May 1980	ML072470526
NUREG–0660, Vol. 2, ''NRC Action Plan Developed as a Result of the TMI–2 Accident,'' May 1980	ML072470524
NUREG–0711, ''Human Factors Engineering Program Review Model,'' Revision 3, November 2012	ML12324A013
NUREG–0737, ''Clarification of TMI Action Plan Requirements,'' November 1980	ML102560051
NUREG–0737, ''Clarification of TMI Action Plan Requirements,'' Supplement 1, January 1983	ML102560009
NUREG–0800, ''Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,'' Section 19.4, ''Strategies and Guidance To Address Loss-of-Large Areas of the Plant Due to Explosions and Fires,'' June 2015.	ML13316B202
NUREG–1935, ''State-of-the-Art Reactor Consequence Analyses (SOARCA) Report,'' November 2012	ML12332A057
''Omaha Public Power District's Overall Integrated Plan in Response to March 12, 2012, Commission Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond Design Basis External Events (Order Number EA–12–049,'' February 28, 2013.	ML13116A208
Order EA–02–026, ''Order for Interim Safeguards and Security Compensatory Measures,'' February 25, 2002	ML020510635
Order EA–06–137, ''Order Modifying Licenses,'' June 20, 2006	ML061600076
Order EA–12–049, ''Order Modifying Licenses With Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events,'' (Mitigation Strategies Order), March 12, 2012.	ML12054A735
Order EA–12–051, ''Order Modifying Licenses with Regard to Reliable Spent Fuel Pool Instrumentation'' (SFPI Order), March 12, 2012.	ML12056A044
Order EA–13–109, ''Order Modifying Licenses with Regard to Reliable Hardened Containment Vents Capable of Operation under Severe Accident Conditions,'' June 6, 2013.	ML13130A067
''Preliminary Proposed Rule Language for Mitigation of Beyond-Design-Basis Events Rulemaking,'' August 15, 2014.	ML14218A253
''Preliminary Proposed Rule Language for Mitigation of Beyond-Design-Basis Events Rulemaking,'' made available to the public on November 13, 2014, and December 8, 2014, to support public discussion with the ACRS.	ML14336A641
PRM–50–96, ''Petition for Rulemaking Submitted by Thomas Popik on Behalf of the Foundation for Resilient Societies To Adopt Regulations that Would Require Facilities Licensed by the NRC under 10 CFR Part 50 To Assure Long-Term Cooling and Unattended Water Makeup of Spent Fuel Pools,'' March 14, 2011.	ML110750145
PRM–50–97, ''NRDC's Petition for Rulemaking To Require Emergency Preparedness Enhancements for Prolonged Station Blackouts,'' July 26, 2011.	ML11216A237
PRM–50–98, ''NRDC's Petition for Rulemaking To Require Emergency Preparedness Enhancements for Multiunit Events,'' July 26, 2011.	ML11216A238
PRM–50–100, ''NRDC's Petition for Rulemaking To Require Licensees to Improve Spent Nuclear Fuel Pool Safety,'' July 26, 2014.	ML11216A240
PRM–50–101, ''NRDC's Petition for Rulemaking To Revise 10 CFR § 50.63,'' July 26, 2011	ML11216A241
PRM–50–102, ''NRDC's Petition for Rulemaking To Require More Realistic Training on Severe Accident Mitigation Guidelines,'' July 26, 2011.	ML11216A242
Regulatory Issue Summary 2009–13, ''Emergency Response Data System Upgrade from Modem to Virtual Private Network Appliance,'' September 28, 2009.	ML092670124
''Request for Information Pursuant to Title 10 of the *Code of Federal Regulations* 50.54(f) Regarding Recommendations 2.1, 2.3, and 9.3, of the Near-Term Task Force Review of Insights from the Fukushima Dai-Ichi Accident,'' March 12, 2012.	ML12053A340
San Onofre Nuclear Generating Station Units 2 and 3, ''Final Response to the March 12, 2012 Information Request Regarding Near-Term Task Force Recommendations 2.1, 2.3, and 9.3 and Corresponding Commitments San Onofre Nuclear Generating Station (SONGS) Units 2 and 3,'' September 30, 2013.	ML13276A020
''San Onofre Nuclear Generating Station, Units 2 and 3—NRC Response to Southern California Edison's Final Response to the March 2012 Request for Information Letter,'' January 22, 2014.	ML13329A826
''San Onofre Nuclear Generating Station, Units 2 and 3—Rescission of Order EA–12–049, 'Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond Design Basis External Events' (TAC Nos. MF2657 and MF2658),'' June 30, 2014.	ML14113A572

Document	ADAMS accession No./ web link/**Federal Register** citation
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SECY–11–0093, "Near-Term Report and Recommendations for Agency Actions Following the Events in Japan," July 12, 2011.	ML11186A950
SECY–11–0124, "Recommended Actions To Be Taken Without Delay from the Near-Term Task Force Report," September 9, 2011.	ML11245A127
SECY–11–0137, "Prioritization of Recommended Actions To Be Taken in Response to Fukushima Lessons Learned," October 3, 2011.	ML11272A111
SECY–12–0025, "Proposed Orders and Requests for Information in Response to Lessons Learned from Japan's March 11, 2011, Great Tōhoku Earthquake and Tsunami," February 17, 2012.	ML12039A103
SECY–13–0132, "Plan for Updating the U.S. Nuclear Regulatory Commission's Cost Benefit Guidance," January 2, 2014.	ML13274A495
SECY–14–0046, "Fifth 6-Month Status Update on Response to Lessons Learned from Japan's March 11, 2011, Great Tōhoku Earthquake and Subsequent Tsunami," April 17, 2014.	ML14064A523
SECY–15–0050, "Cumulative Effects of Regulation Process Enhancements and Risk Prioritization Initiative," April 1, 2015.	ML15034A360
SECY–15–0065, "Proposed Rulemaking: Mitigation of Beyond-Design-Basis Events (RIN 3150–AJ49)," April 30, 2015.	ML15049A201
SECY–15–0085, "Evaluation of the Containment Protection & Release Reduction for Mark I and Mark II Boiling Water Reactors Rulemaking Activities (10 CFR Part 50) (RIN–3150–AJ26)," enclosure entitled, "Containment Protection and Release Reduction (CPRR) Rulemaking: Draft Regulatory Basis," June 18, 2015.	ML15005A079
SECY–16–0142, "Draft Final Rule—Mitigation of Beyond-Design-Basis Events (RIN 3150–AJ49)," December 15, 2016.	ML16301A005
SECY–89–012, "Staff Plans for Accident Management Regulatory and Research Programs," January 18, 1989	ML19126A278
SECY–97–132, "Status of the Integration Plan for Closure of Severe Accident Issues and the Status of Severe Accident Research," June 23, 1997.	ML992930144
SECY–98–131, "Status of the Integration Plan for Closure of Severe Accident Issues and the Status of Severe Accident Research," June 8, 1998.	ML992880008
SRM–COMSECY–13–0002, "Consolidation of Japan Lessons Learned Near-Term Task Force Recommendations 4 and 7 Regulatory Activities," March 4, 2013.	ML13063A548
SRM–COMSECY–14–0037, "Integration of Mitigating Strategies for Beyond-Design-Basis External Events and The Reevaluation of Flooding Hazards," March 30, 2015.	ML15089A236
SRM–SECY–11–0093, "Near-Term Report and Recommendations for Agency Actions Following the Events in Japan," August 19, 2011.	ML112310021
SRM–SECY–11–0124, "Recommended Actions To Be Taken Without Delay From the Near-Term Task Force Report," October 18, 2011.	ML112911571
SRM–SECY–11–0137, "Prioritization of Recommended Actions To Be Taken in Response to Fukushima Lessons Learned," December 15, 2011.	ML113490055
SRM–SECY–13–0132, "U.S. Nuclear Regulatory Commission Staff Recommendation for the Disposition of Recommendation 1 of the Near-Term Task Force Report," May 19, 2014.	ML14139A104
SRM–SECY–15–0065, "Proposed Rulemaking: Mitigation of Beyond-Design-Basis Events (RIN 3150–AJ49)," August 27, 2015.	ML15239A767
SRM–M190124A: Affirmation Session-SECY–16–0142: Final Rule: Mitigation of Beyond-Design-Basis Events (RIN 3150–AJ49), January 24, 2019.	ML19023A038
Temporary Instruction 2515/191, "Inspection of the Licensee's Responses to Mitigation Strategies Order EA–12–049, Spent Fuel Pool Instrumentation Order EA–12–051 and Emergency Preparedness Information Requested in NRC March 12, 2012," March 12, 2012.	ML14273A444
"Vermont Yankee Nuclear Power Station—Rescission of Order EA-12-049, 'Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond Design Basis External Events' (TAC No. MF4763)," March 2, 2015.	ML14321A685
"Vermont Yankee Nuclear Power Station—Rescission of Order EA-12-051, 'Order Modifying Licenses with Regard to Reliable Spent Fuel Pool Instrumentation' (TAC No. MF4764)," March 2, 2015.	ML14321A696

The NRC may post documents related to this rulemaking, including public comments, on the Federal rulemaking website at *http://www.regulations.gov* under Docket ID NRC–2014–0240. The Federal rulemaking website allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder (NRC–2014–0240); (2) click the "Sign up for Email Alerts" link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

List of Subjects

10 CFR Part 50

Administrative practice and procedure, Antitrust, Backfitting, Classified information, Criminal penalties, Education, Fire prevention, Fire protection, Incorporation by reference, Intergovernmental relations, Nuclear power plants and reactors, Penalties, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements, Whistleblowing.

10 CFR Part 52

Administrative practice and procedure, Antitrust, Backfitting, Combined license, Early site permit, Emergency planning, Fees, Incorporation by reference, Inspection, Limited work authorization, Nuclear power plants and reactors, Penalties, Probabilistic risk assessment, Prototype, Reactor siting criteria, Redress of site, Reporting and recordkeeping requirements, Standard design, Standard design certification.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 50 and 52:

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

■ 1. The authority citation for 10 CFR part 50 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 101, 102, 103, 104, 105, 108, 122, 147, 149, 161, 181, 182, 183, 184, 185, 186, 187, 189, 223, 234 (42 U.S.C. 2014, 2131, 2132, 2133, 2134, 2135, 2138, 2152, 2167, 2169, 2201, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, sec. 306 (42 U.S.C. 10226); National Environmental Policy Act of 1969 (42 U.S.C. 4332); 44 U.S.C. 3504 note; Sec. 109, Pub. L. 96–295, 94 Stat. 783.

§ 50.8 [Amended]

■ 2. In § 50.8(b), add the number ''50.155,'' sequentially.

■ 3. In § 50.34, remove the word ''stationary'' from paragraphs (a)(13) and (b)(12), and revise paragraph (i).

The revision reads as follows:

§ 50.34 Contents of applications; technical information.

* * * * *

(i) *Mitigation of beyond-design-basis events.* Each application for a power reactor operating license under this part must include the applicant's plans for implementing the requirements of § 50.155, including a schedule for achieving full compliance with these requirements and a description of the equipment upon which the strategies and guidelines required by § 50.155(b)(1) rely, including the planned locations of the equipment and how the equipment meets the requirements of § 50.155(c).

■ 4. In § 50.54, remove paragraph (hh)(2), redesignate paragraph (hh)(3) as (hh)(2) and revise it.

The revision reads as follows:

§ 50.54 Conditions of licenses.

* * * * *

(hh) * * *

(2) Paragraph (hh)(1) of this section does not apply to a licensee that has submitted the certifications required under § 50.82(a)(1) or § 52.110(a) of this chapter.

* * * * *

■ 5. Add § 50.155 to read as follows:

§ 50.155 Mitigation of beyond-design-basis events.

(a) *Applicability.* (1) Each holder of an operating license for a nuclear power reactor under this part and each holder of a combined license under part 52 of this chapter for which the Commission has made the finding under § 52.103(g) of this chapter shall comply with the requirements of this section until submittal of the license holder's certifications described in § 50.82(a)(1) or § 52.110(a) of this chapter.

(2)(i) Once the certifications described in § 50.82(a)(1) or § 52.110(a) of this chapter have been submitted by a licensee subject to the requirements of this section, that licensee need only comply with the requirements of paragraphs (b) through (d) and (f) of this section associated with spent fuel pool cooling capabilities.

(ii) Holders of operating licenses or combined licenses for which the certifications described in § 50.82(a)(1) or § 52.110(a) of this chapter have been submitted need not meet the requirements of this section except for the requirements of paragraph (b)(2) of this section associated with spent fuel pool cooling capabilities once the decay heat of the fuel in the spent fuel pool can be removed solely by heating and boiling of water within the spent fuel pool and the boil-off period provides sufficient time for the licensee to obtain off-site resources to sustain the spent fuel pool cooling function indefinitely, as demonstrated by an analysis performed and retained by the licensee.

(iii) The holder of the license for Millstone Power Station, Unit 1, is not subject to the requirements of this section.

(iv) Holders of operating licenses or combined licenses for which the certifications described in § 50.82(a)(1) or § 52.110(a) of this chapter have been submitted need not meet the requirements of this section once all irradiated fuel has been permanently removed from the spent fuel pool(s).

(b) *Strategies and guidelines.* Each applicant or licensee shall develop, implement, and maintain:

(1) Mitigation strategies for beyond-design-basis external events—Strategies and guidelines to mitigate beyond-design-basis external events from natural phenomena that are developed assuming a loss of all ac power concurrent with either a loss of normal access to the ultimate heat sink or, for passive reactor designs, a loss of normal access to the normal heat sink. These strategies and guidelines must be capable of being implemented site-wide and must include the following:

(i) Maintaining or restoring core cooling, containment, and spent fuel pool cooling capabilities; and

(ii) The acquisition and use of offsite assistance and resources to support the functions required by paragraph (b)(1)(i) of this section indefinitely, or until sufficient site functional capabilities can be maintained without the need for the mitigation strategies.

(2) Extensive damage mitigation guidelines—Strategies and guidelines to maintain or restore core cooling, containment, and spent fuel pool cooling capabilities under the circumstances associated with loss of large areas of the plant impacted by the event, due to explosions or fire, to include strategies and guidelines in the following areas:

(i) Firefighting;

(ii) Operations to mitigate fuel damage; and

(iii) Actions to minimize radiological release.

(c) *Equipment.* (1) The equipment relied on for the mitigation strategies and guidelines required by paragraph (b)(1) of this section must have sufficient capacity and capability to perform the functions required by paragraph (b)(1) of this section.

(2) The equipment relied on for the mitigation strategies and guidelines required by paragraph (b)(1) of this section must be reasonably protected from the effects of natural phenomena that are equivalent in magnitude to the phenomena assumed for developing the design basis of the facility.

(d) *Training requirements.* Each licensee shall provide for the training of personnel that perform activities in accordance with the capabilities required by paragraphs (b)(1) and (2) of this section.

(e) *Spent fuel pool monitoring.* In order to support effective prioritization of event mitigation and recovery actions, each licensee shall provide reliable means to remotely monitor wide-range water level for each spent fuel pool at its site until 5 years have elapsed since all of the fuel within that spent fuel pool was last used in a reactor vessel for power generation. This provision does not apply to General Electric Mark III upper containment pools.

(f) *Documentation of changes.* (1) A licensee may make changes in the implementation of the requirements in this section without NRC approval, provided that before implementing each such change, the licensee demonstrates that the provisions of this section continue to be met and maintains documentation of changes until the

requirements of this section no longer apply.

(2) Changes in the implementation of requirements in this section subject to change control processes in addition to paragraph (f) of this section must be processed via their respective change control processes, unless the changes being evaluated impact only the implementation of the requirements of this section.

(g) *Implementation.* Each holder of an operating license for a nuclear power reactor under this part on September 9, 2019, and each holder of a combined license under part 52 of this chapter for which the Commission made the finding specified in 10 CFR 52.103(g) as 10 CFR 52.103(g) as of September 9, 2019, shall continue to comply with the provisions of paragraph (b)(2) of this section, and shall comply with all other provisions of this section no later than September 9, 2022, for licensees that received NRC Order EA–13–109 or September 9, 2021, for all other applicable licensees.

(h) *Withdrawal of orders and removal of license conditions.* (1) On September 9, 2022, Order EA–12–049, ''Order Modifying Licenses With Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events,'' and Order EA–12–051, ''Order Modifying Licenses With Regard to Reliable Spent Fuel Pool Instrumentation,'' are withdrawn for each licensee or construction permit holder that was issued those Orders.

(2) On September 9, 2019, Enrico Fermi Nuclear Plant Unit 3, License No. NPF–95, license conditions 2.D(12)(h), ''Reliable Spent Fuel Pool/Buffer Pool Level Instrumentation,'' 2.D(12)(i), ''Emergency Planning Actions,'' and 2.D(12)(g), ''Mitigation Strategies for Beyond-Design-Basis External Events,'' except for 2.D(12)(g)1, are deemed removed from that license.

(3) On September 9, 2019, William States Lee III Nuclear Station, Unit 1, License No. NPF–101, license conditions 2.D(12)(d)11 regarding reliable spent fuel pool instrumentation, 2.D(12)(g), ''Emergency Planning Actions,'' and 2.D(12)(j), ''Mitigation Strategies for Beyond-Design-Basis External Events,'' except for 2.D(12)(j)1, and William States Lee III Nuclear Station, Unit 2, License No. NPF–102, license conditions 2.D(12)(d)11 regarding reliable spent fuel pool instrumentation, 2.D(12)(g), ''Emergency Planning Actions,'' and 2.D(12)(j), ''Mitigation Strategies for Beyond-Design-Basis External Events,'' except for 2.D(12)(j)1, are deemed removed from those licenses.

(4) On September 9, 2019, North Anna Unit 3, License No. NPF–103, license conditions 2.D(12)(g), ''Reliable Spent Fuel Pool/Buffer Pool Level Instrumentation,'' 2.D(12)(h), ''Emergency Planning Actions,'' and 2.D(12)(f), ''Mitigation Strategies for Beyond-Design-Basis External Events,'' except for 2.D(12)(f)1, are deemed removed from the license.

(5) On September 9, 2019, Turkey Point, Unit 6, License No. NPF–104, license conditions 2.D(12)(e)11 regarding reliable spent fuel pool instrumentation, 2.D(12)(g), ''Emergency Planning Actions,'' and 2.D(12)(h), ''Mitigation Strategies for Beyond-Design-Basis External Events,'' except for 2.D(12)(h)1, and Turkey Point, Unit 7, License No. NPF–105, license conditions 2.D(12)(e)11 regarding reliable spent fuel pool instrumentation, 2.D(12)(g), ''Emergency Planning Actions,'' and 2.D(12)(h), ''Mitigation Strategies for Beyond-Design-Basis External Events,'' except for 2.D(12)(h)1, are deemed removed from those licenses.

■ 6. In appendix E to part 50 revise paragraphs IV.F.2.j and VI.3.c to read as follows:

Appendix E to Part 50—Emergency Planning and Preparedness for Production and Utilization Facilities

* * * * *

IV. * * *

F. * * *

2. * * *

j. The exercises conducted under paragraph 2 of this section by nuclear power reactor licensees must provide the opportunity for the ERO to demonstrate proficiency in the key skills necessary to implement the principal functional areas of emergency response identified in paragraph 2.b of this section. Each exercise must provide the opportunity for the ERO to demonstrate key skills specific to emergency response duties in the control room, TSC, OSC, EOF, and joint information center. Additionally, in each 8-calendar-year exercise cycle, nuclear power reactor licensees shall vary the content of scenarios during exercises conducted under paragraph 2 of this section to provide the opportunity for the ERO to demonstrate proficiency in the key skills necessary to respond to the following scenario elements: hostile action directed at the plant site, no radiological release or an unplanned minimal radiological release that does not require public protective actions, an initial classification of or rapid escalation to a Site Area Emergency or General Emergency, implementation of strategies, procedures, and guidance under § 50.155(b)(2), and integration of offsite resources with onsite response. The licensee shall maintain a record of exercises conducted during each 8-year exercise cycle that documents the content of scenarios used to comply with the requirements of this paragraph. Each licensee shall conduct a hostile action exercise for each of its sites no later than December 31, 2015. The first 8-year exercise cycle for a site will begin in the calendar year in which the first hostile action exercise is conducted. For a site licensed under 10 CFR part 52, the first 8-year exercise cycle begins in the calendar year of the initial exercise required by section IV.F.2.a of this appendix.

* * * * *

VI. * * *

3. * * *

c. In the event of a failure of NRC-supplied equipment, a replacement will be furnished by the NRC for licensee installation.

* * * * *

PART 52—LICENSES, CERTIFICATIONS, AND APPROVALS FOR NUCLEAR POWER PLANTS

■ 7. The authority citation for part 52 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 103, 104, 147, 149, 161, 181, 182, 183, 185, 186, 189, 223, 234 (42 U.S.C. 2133, 2134, 2167, 2169, 2201, 2231, 2232, 2233, 2235, 2236, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); 44 U.S.C. 3504 note.

■ 8. In § 52.80, revise paragraph (d) to read as follows:

§ 52.80 Contents of applications; additional technical information.

* * * * *

(d) The applicant's plans for implementing the requirements of § 50.155 of this chapter including a schedule for achieving full compliance with these requirements, and a description of the equipment upon which the strategies and guidelines required by § 50.155(b)(1) of this chapter rely, including the planned locations of the equipment and how the equipment meets the requirements of § 50.155(c) of this chapter.

Dated at Rockville, Maryland, this 30th day of July, 2019.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

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

Views of the Commission

Following the Fukushima Dai-ichi accident in Japan, the NRC embarked on a program of work that has taken eight years and involved a wide variety of people from the agency, from the regulated industry and from our interested stakeholders. The Commission's action on this final rule provides a holistic conclusion to a large portion of this work, which has already resulted in undeniable safety improvements throughout the operating power reactor fleet in the United States. Other work continues outside of the

rulemaking context; there is some analysis to determine whether additional safety improvements are appropriate and further evaluation is ongoing of the actual risk posed by external hazards needed to make such determinations. This work is being performed and will continue in the disciplined, site-specific processes that are in use and are appropriate for resolving these issues. The Commission's action on the final rule does not undermine, stop, or modify these risk-informed, site-specific activities.

As our colleagues note, the final rule omits many provisions of the draft final rule; we did not arrive at this result lightly. Rather, as discussed in our votes and fully explained over the course of the lengthy revisions to this document, after carefully considering whether imposition of the underlying requirements would comply with our existing regulations, specifically the Backfit Rule in 10 CFR 50.109, we supported only those provisions for which such compliance was substantiated by the staff's analysis in the decision record. In that consideration, we primarily analyzed whether the new requirements were necessary for adequate protection or provided a cost-justified, substantial safety benefit. In general, we concluded that the requirements already imposed by the Commission by the Mitigation Strategies Order following the Fukushima Dai-ichi accident are sufficient and no new information in the record before us, including information developed by the staff or submitted by the public, indicates otherwise.

Our colleagues also claim that the Staff Requirements Memorandum (SRM) on COMSECY–14–0037, ''Integration of Mitigating Strategies for Beyond-Design-Basis External Events and the Reevaluation of Flooding Hazards,'' established that it is necessary that the mitigation strategies under this final rule address the reevaluated seismic and flooding hazards to ensure adequate protection of public health and safety. To the extent our colleagues suggest that SRM–COMSECY–14–0037 redefined the requirements needed for adequate protection stated in the March 2012 Mitigation Strategies Order, that suggestion is inconsistent with the agency's long standing practice and with applicable procedural and safety requirements.

Staff Requirements Memoranda provide direction to the agency staff from the Commission and are not appropriate vehicles for imposing requirements on licensees and applicants. Under the Administrative Procedure Act, such vehicles are generally regulations and orders. Subsequent to COMSECY–14–0037, neither the Commission nor the staff undertook any additional action to modify and re-issue the March 2012 Mitigation Strategies Order or to issue a new order as was done for the hardened containment venting system orders when the NRC concluded venting systems should be capable of use in a severe accident. It would be inappropriate and without precedent for the agency to establish with finality what is required of our licensees in a process lacking either the hearing rights of our process for issuing orders or the public notice and comment of our deliberative rulemaking process.

Moreover, our colleagues' suggestion regarding adequate protection finds no support within the four corners of the SRM. As noted in our underlying votes, seeking clear direction within the plain text of that document is difficult. The SRM did not approve the entirety of the staff's planned approach and in our view should not be read to approve the staff's bases for their plan. Indeed, COMSECY–14–0037 itself did not address the issue of the reevaluation of seismic hazards.

Most importantly, the assertion that the Commission made an adequate protection determination in its action on COMSECY–14–0037 is inconsistent with the Commission's conduct in the wake of the issuance of the SRM. Under long-standing agency policy, when the NRC identifies a need to impose a new or revised requirement to maintain a reasonable assurance of adequate protection, the agency must next determine whether an ''imminent threat'' to public health and safety exists. If so, the agency must implement the requirement immediately. In this case, the record surrounding SRM–COMSECY–14–0037 does not contain any evidence that the Commission or staff conducted such an imminent threat assessment. The lack of such an assessment severely undercuts any suggestion that the SRM somehow expanded the requirements in our March 2012 Mitigation Strategies Order to maintain a reasonable assurance of adequate protection.

Moreover, to the extent our colleagues observe that SRM–COMSECY–14–0037 directed the staff to include certain provisions in a draft rule, the absence of those provisions in the final rule is not surprising or problematic. Rather, this absence is a normal part of the rulemaking process. As the Supreme Court has observed, ''Since [a] proposed rule [is] simply a proposal, its presence mean[s] that the [regulator is] *considering* the matter; after that consideration the [regulator] might choose to adopt the proposal or to withdraw it'' *Long Island Care at Home, Ltd.* v. *Coke,* 551 U.S. 158, 175 (2007) (emphasis in the original). We certainly have the option, as we have exercised here, to adopt certain aspects of a proposal and to reject others.

Our colleagues appear to suggest that we are ignoring the actual flooding and earthquake hazards that our licensees have determined could occur at our nation's nuclear power plants. This is not the case; we are simply choosing to complete the Commission-directed site-specific process already underway rather than to enact additional requirements on a generic basis. The hazard reevaluations conducted by licensees at the Commission's request under 10 CFR 50.54(f) have been developed using the best available methods for siting nuclear power plants and include conservative assumptions and margin sufficient to show that the reevaluated hazards will not affect the plants. Work continues on the assessment of the results of these reevaluations to determine just what the actual hazards to the plants are on a site-specific basis. To facilitate these assessments, the Commission specifically directed the staff, in the course of determining what regulatory actions are appropriate, to ''introduce more realism for the purpose of identifying potential safety enhancements for operating reactors'' (SRM–COMSECY–14–0037) and ''continue to look for additional opportunities to address any over conservatism in the flood hazard evaluations and to streamline the process as additional lessons are learned'' (SRM–COMSECY–15–0019). The staff continues to make good progress in this area as it completes its work under § 50.54(f) to determine whether individual licenses ''should be modified, suspended, or revoked.'' These efforts are, in our view, sufficient to provide reasonable assurance of adequate protection at each facility.

Finally, our colleagues note the lack of specific requirements in this final rule for items that have already been resolved in the nuclear industry's response to the Mitigation Strategies Order. This is, however, in keeping with our regulatory processes. Our Backfit Rule itself provides that ''[i]f there are two or more ways to achieve compliance with a license or the rules or orders of the Commission, or with written licensee commitments, or there are two or more ways to reach a level of protection which is adequate, then ordinarily the applicant or licensee is free to choose the way which best suits its purposes'' (10 CFR 50.109(a)(7)). Although we may certainly constrain the manner in which applicants or licensees develop their mitigation strategies to comply with this final rule, we will not do so absent a sufficiently documented basis. We have not been provided in the record before us—or anywhere else—a basis for artificially constraining the means and methods of future compliance as our colleagues would have us do. We have confidence that all of the nation's currently operating power reactors are capable of complying with the requirements of this final rule using industry-developed and NRC-approved guidance because they have been able to achieve compliance with the Mitigation Strategies Order, which is made generically applicable by this Commission action.

Chairman Kristine L. Svinicki,
Commissioners Annie Caputo and David A. Wright

Separate Views of Commissioner Baran

This rule was meant to be the capstone of the agency's response to the Fukushima Dai-ichi accident in Japan. The draft final rule presented to the Commission by the NRC staff in December 2016 was the culmination of years of work to establish new requirements for the mitigation of beyond-design-basis events at nuclear power plants. The draft final rule would have responded to Near-Term Task Force (NTTF) recommendations 2 and 4 by requiring licensee strategies to mitigate beyond-design-basis events to address each plant's re-evaluated seismic and flooding hazards. The rule also would have responded to NTTF recommendations 8 and 9 by requiring an integrated emergency response capability and ''sufficient staffing, command and control, training, drills, communications capability, and documentation of changes to support the integrated response capability.'' To address NTTF recommendations 10 and 11, the rule

would have set requirements for enhanced onsite emergency response capabilities.

I strongly support requiring these updated standards and critical safety improvements, which are necessary to provide adequate protection of public health and safety. But the majority of the Commission has decided to gut this key post-Fukushima safety rule.

In the aftermath of Fukushima, licensees and the NRC staff spent years using the latest science and modern methods to determine the present-day flooding and earthquake hazards for the nation's nuclear power plants. Now, the majority of the Commission has decided that licensees can ignore these reevaluated hazards with their strategies to mitigate beyond-design-basis events. Instead of requiring nuclear power plants to be prepared for the actual flooding and earthquake hazards that could occur at their sites, NRC will allow them to be prepared only for the old, outdated hazards typically calculated decades ago when the science of seismology and hydrology was far less advanced than it is today. This decision is nonsensical.

The requirement for licensees to develop and maintain mitigating strategies for beyond-design-basis events based on the modern, reevaluated hazards was at the core of this rulemaking, and the majority of the Commission has voted to jettison it. Under the final rule written by the majority, the FLEX equipment at nuclear power plants is not required to be reasonably protected from the up-to-date flooding and earthquake hazards. Other vital safety protections were completely excised from the rule. Licensees will not be required to have sufficient staffing or communications capabilities to implement the mitigating strategies. And there will be no requirement for drills and exercises to test licensees' ability to respond to these kinds of extreme events. Instead of establishing these commonsense and non-controversial safety standards, the majority of the Commission has opted to require only what was already required in the Commission's March 2012 Mitigation Strategies Order. That order was supposed to be a first step towards improved safety, not the last. But the majority's version of this rule does nothing to enhance the safety of nuclear power plants.

This outcome is a complete U-turn for NRC. In the 2012 order, the Commission made it clear that mitigating strategies for beyond-design-basis events were necessary to ensure adequate protection of public health and safety. The Commission did not require the mitigating strategies to account for the reevaluated hazards at that time because the seismic and flooding analyses had not yet been performed. But the NRC staff clearly understood that the mitigating strategies would ultimately need to address the reevaluated hazards. In 2014, the staff recommended that ''licensees' mitigating strategies address the reevaluated flooding hazards as part of the [mitigating beyond-design-basis-events] rulemaking.'' [5] The Commission unanimously approved that recommendation.[6] As a result, the proposed rule was written to ''resolve and clarify the necessary actions a licensee must take to continue to show adequate protection of public health and safety, in light of the reevaluated hazards.'' [7] This central aspect of the proposed rule was likewise unanimously approved by the Commission. In the comments submitted on the proposed rule, no stakeholder disagreed that these requirements should be included in the rule or disputed that they were necessary for adequate protection of public health and safety. Thus, the majority of the Commission has now voted for a final rule that bears no resemblance to the proposed rule or any of the public comments submitted to the agency in response to the proposed rule. Despite the fact that the Commission had repeatedly and unanimously found that updated safety standards were necessary to adequately protect the public, those safety standards have now been abruptly dropped from the final rule at the last minute, without any warning or notice to stakeholders.

The guidance that has been developed by the NRC staff and industry was intended to facilitate compliance with the requirements included in the draft final rule. Licensees have been preparing for years to implement mitigating strategies that account for the reevaluated flooding and earthquake hazards at nuclear power plant sites. This guidance is not a substitute for a regulation. It is not a legally binding requirement.

This rule was always intended to be the agency's response to several key Near-Term Task Force recommendations. Instead of following through on these planned safety improvements, critical aspects of those recommendations to enhance mitigation and strengthen emergency preparedness are simply left unaddressed. As a result, the rule fails to confront a fundamental lesson of the Fukushima accident—that nuclear power plants must be fully prepared for the natural hazards that could threaten their safe operation. The majority of the Commission has chosen to leave this important safety work for a future Commission. The unfortunate reality is that this hollow shell of a rule does nothing beyond what the Commission already did more than six years ago. Nuclear power plants will be no safer with this rule than they are today.

Separate Views of Commissioner Burns

The version of the final rule supported by the majority of the Commission will, in my view, significantly weaken what will be the agency's most enduring action as a result of lessons learned from the Fukushima Daiichi accident. In doing so, the Commission will have systematically and inexplicably unraveled a framework for addressing beyond-design-basis external events carefully crafted as a collaborative effort between the NRC staff and our external stakeholders in the years since the accident occurred in March 2011.

I am chiefly concerned with the position the Commission majority has taken with respect to the reevaluated hazard analyses performed by licensees. This position is particularly disconcerting given that the accident at Fukushima was a direct result of the operator and regulator failing to take action to account for new scientific knowledge related to natural hazards, especially flooding hazards. In this regard, I believe that the majority has undermined the Commission's past position on these issues. In their edits to the statements of consideration for the final rule as well as to the supporting backfitting assessment, the majority has mischaracterized the Commission decision on COMSECY–14–0037. In its March 2015 Staff Requirements Memorandum on COMSECY–14–0037, the Commission approved the staff's recommendation ''that licensees for operating nuclear power plants need to address the reevaluated flooding hazards within their mitigation strategies for beyond-design-basis external events.'' The staff was explicit in COMSECY–14–0037 about what it was asking of the Commission:

The NRC staff is asking the Commission to support the planned approach by affirming that the MBDBE rulemaking needs to require mitigating strategies that are able to address the reevaluated flooding hazards developed in response to the § 50.54(f) letters *in order to ensure reasonable assurance of adequate protection of the public health and safety.* (emphasis added)

The staff followed the Commission's unequivocal direction when it presented the proposed rulemaking on the Mitigation of Beyond-Design Basis Events to the Commission in April 2015. In the draft proposed rule, the staff clearly stated that the proposed rulemaking would apply to power reactor applicants and licensees and include proposed ''requirements for the reasonable protection of mitigation equipment for beyond-design-basis external events that reflect the reevaluated hazards determined through regulatory efforts stemming from the 10 CFR 50.54(f) request issued on March 12, 2012.'' In the Commission paper transmitting the proposed rule (SECY–15–0065), the staff highlighted the fact that the proposed rule would ''resolve and clarify the necessary actions a licensee must take to continue to show adequate protection of public health and safety, in light of the reevaluated hazards, as directed in SRM–COMSECY–14–0037.'' The Commission unanimously approved publication of the draft proposed rule and noted only two exceptions it was taking to the staff's proposals, neither of which involved the need for mitigation strategies to reflect the reevaluated hazards.

We should recall that, in the SRM for SECY–11–0124, ''Recommended Actions to

[5] COMSECY–14–0037 at 6–7. There was no ambiguity on this point. The staff paper also stated: ''The NRC staff is asking the Commission to support the planned approach by affirming that the MBDBE rulemaking needs to require mitigating strategies that are able to address the reevaluated flooding hazards developed in response to the § 50.54(f) letters in order to ensure reasonable assurance of adequate protection of the public health and safety.'' *Id.* at 7. The paper further stated: ''The results of the reevaluation of the flooding hazard are important to define the necessary attributes of the mitigating strategies equipment and actions to adequately protect against external events. The NRC staff plans to include this requirement in the pending MBDBE rulemaking. As such, the strategies required by the MBDBE rulemaking cannot be completed without information about the site-specific reevaluated flooding hazards.'' *Id.* at 6.

[6] Staff Requirements Memorandum for COMSECY–14–0037.

[7] SECY–15–0065 at 7. *See also* Proposed Rule Draft **Federal Register** Notice at 22, 69, 71, 102, 118–119, 124–125.

be Taken Without Delay from the Near-Term Task Force Report,'' the Commission approved the staff's intent to issue a request for information to all operating reactor licensees to address, among other things, reevaluations of seismic and flooding hazards in accordance with Near-Term Task Force (NTTF) Recommendation 2.1. The request for information, issued under the provisions of 10 CFR 50.54(f) on March 12, 2012, (§ 50.54(f) letter) stated that the hazard evaluation developed consistent with Recommendation 2.1 would be implemented in two phases. The first phase involved the reevaluation of the seismic and flooding hazards at all sites. In the second phase, the NRC staff was to determine, based upon the results of Phase 1, whether additional regulatory actions were necessary (*e.g.,* updating the design basis and SSCs important to safety) to provide additional protection against the updated hazards.

As former Commissioner Apostolakis pointed out in his 2011 vote on the NTTF Report, ''there is growing evidence that the historical record of tsunamis had not been used properly to determine the design basis at Fukushima Daiichi and, consequently, the protection of the plants was not sufficient.'' In the United States, there exists incontrovertible evidence that the current design bases for some plants do not address a flood hazard identified by the licensees' own analyses. Had the final rule been approved as proposed by the staff, the Commission's carefully crafted strategy would have dealt with this situation appropriately and effectively by requiring that the mitigation strategies for all sites be able to address the reevaluated hazards developed in response to the § 50.54(f) letters as a matter of adequate protection of the public health and safety. For plants with the most extreme exceedances from their current design basis, additional actions may have been necessary, but those decisions would only be made once their final flooding and/or seismic evaluations (*e.g.,* integrated assessments or seismic PRAs) were completed. Absent a requirement in the MBDBE final rule to protect the mitigation strategies from the reevaluated hazard, the process for closing out NTTF Recommendation 2.1 and the § 50.54(f) letter for all plants will be made much more burdensome for both licensees and the NRC staff and the outcome with respect to protecting plants from beyond-design-basis external events much more uncertain.

In addition, the majority's approach calls into question the degree to which the NRC will be able to give credit for the existence of the mitigation strategies in a number of risk-informed regulatory initiatives like adaptation of alternative treatment requirements for SSCs under 10 CFR 50.69, ''Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors,'' and risk-informed technical specifications. Licensees are also seeking credit for mitigation strategies in the Reactor Oversight Process and have expressed interest in pursuing credit for use of the strategies in the physical security program. The assessment of the degree to which credit for the mitigation strategies is possible will be much more complex now that the mitigation strategies will not be required to address the reevaluated hazards.

Moreover, the decision to strip out the draft final rule requirements for an integrated response capability, as well as requirements for sufficient staffing levels, means of communication, and drills, also ignores primary lessons from the Fukushima Daiichi accident. These requirements were approved by the Commission in the proposed rule, and nothing has occurred in the interceding years to change the need for these requirements to ensure a holistic approach to the response to beyond-design basis accidents.

The decision of the Commission majority to reverse course now, when the lion's share of the actions that would be required under the rule have already been completed by industry, is baffling. It is difficult to understand how the arguments put forth of regulatory over-reach are defensible with anyone who was at the agency when the accident occurred and has followed the activities of the agency, including the decisions made by the Commission, in the intervening years. It is equally baffling that some in the majority should lay the blame on the shoulders of the NRC staff for the perceived misapplication of the backfit rule when the staff was merely following Commission direction in producing the draft final rule.

I would also point out that the changes reflected in the final rule are troubling in two other respects. First, the changes seem to be based in part on a presumption that the orders developed by staff and approved by the Commission in 2012 were a fully informed and complete regulatory solution to the Fukushima Daiichi accident. I do not mean to suggest that the Commission and the staff didn't implement thoughtful and effective solutions given what was known at the time. However, the orders were approved by the Commission just one year after the accident, and significant gaps still remained in the NRC's and industry's knowledge. To now suggest, as the majority has done, that the NRC could not improve upon the requirements of the orders or address these gaps in knowledge through this rulemaking makes little sense. I am also troubled that the final rule eliminates a substantial number of requirements that were included in the proposed rule for which no adverse public comments were received.

Finally, although I have long supported the NRC's pursuit of a rigorous application of its backfitting regulations and adherence to its Principles of Good Regulation, this pursuit must be rational. In defense of this rulemaking proposal, the staff produced appropriate backfitting and regulatory analyses, which were consistent with previous Commission direction. The majority has decided to reverse these previous Commission decisions and takes issue with the staff's supporting analysis based on little more than conclusory statements in Commission votes that some of the requirements in the draft final rule are not ''necessary'' or would not result in a ''substantial increase in the overall protection of the public health and safety.'' Such an approach is entirely inconsistent with the principles of clarity, reliability, and openness that are supposed to drive this agency's work.

In the official report of the National Diet of Japan's Fukushima Nuclear Accident Independent Investigation Commission, Chairman Kiyoshi Kurokawa noted:

The earthquake and tsunami of March 11, 2011 were natural disasters of a magnitude that shocked the entire world. Although triggered by these cataclysmic events, the subsequent accident at the Fukushima Daiichi Nuclear Power Plant cannot be regarded as a natural disaster. It was a profoundly manmade disaster—that could and should have been foreseen and prevented. And its effects could have been mitigated by a more effective human response.

The issuance of the NRC's final rule was meant to be the culmination of the agency's efforts to learn the lessons of the Fukushima Daiichi accident. Given the final form of the rule approved by the Commission majority, it will be difficult to convince others that the agency has learned those lessons well.

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