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FEDERAL RESERVE SYSTEM

12 CFR Part 248

[Docket No. R-1643]

RIN 7100-AF33

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 351

RIN 3064-AE88

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 75

RIN 3038-AE72

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 255

[Release No. BHCA-6; File No. S7-30-18]

RIN 3235-AM43

Revisions to Prohibitions and Restrictions on Proprietary Trading and Certain Interests in, and Relationships With, Hedge Funds and Private Equity Funds

AGENCY: Board of Governors of the Federal Reserve System (Board); Federal Deposit Insurance Corporation (FDIC); Securities and Exchange Commission (SEC); and Commodity Futures Trading Commission (CFTC), collectively, the Agencies.

ACTION: Final rule; correction.

SUMMARY: The Agencies published a final rule in the **Federal Register** on July 22, 2019, that adopted final rules to amend regulations implementing Section 13 of the Bank Holding Company Act (the Volcker Rule) in a manner consistent with the statutory amendments made pursuant to certain sections of the Economic Growth, Regulatory Relief, and Consumer Protection Act. This document corrects

errors in amendatory instructions in the rule.

DATES: Effective August 6, 2019.

FOR FURTHER INFORMATION CONTACT:

Board: Flora Ahn, Special Counsel, (202) 452-2317, Gregory Frischmann, Senior Counsel, (202) 452-2803, Kirin Walsh, Attorney, (202) 452-3058, or Sarah Podrygula, Attorney, (202) 912-4658, Legal Division, Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551.

FDIC: Michael B. Phillips, Counsel, mphillips@fdic.gov, Benjamin J. Klein, Counsel, bklein@fdic.gov, or Annmarie H. Boyd, Counsel, aboyd@fdic.gov, Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SEC: Andrew R. Bernstein, Senior Special Counsel, Sam Litz, Attorney-Adviser, Aaron Washington, Special Counsel, Office of Derivatives Policy and Trading Practices, Division of Trading and Markets, U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

CFTC: Cantrell Dumas, Special Counsel, (202) 418-5043, cdumas@cftc.gov; Mark Fajfar, Assistant General Counsel, (202) 418-6636, mfajfar@cftc.gov, Office of the General Counsel; Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

SUPPLEMENTARY INFORMATION: This document corrects errors in amendatory instructions in a final rule published on July 22, 2019, affecting 12 CFR 248.11, 12 CFR 351.11, 17 CFR 75.11, and 17 CFR 255.11 of the Agencies' regulations.

Correction

■ In final rule FR Doc. 2019-15019 published in the **Federal Register** on July 22, 2019 (84 FR 35008), beginning on page 35020, make the following corrections:

■ 1. On page 35020, in the third column, correct amendatory instruction 11 to read as follows:

“11. Revise paragraph (a)(6) to read as follows:”

■ 2. On page 35021, in the second column, correct amendatory instruction 16 to read as follows:

“16. Revise paragraph (a)(6) to read as follows:”

■ 3. On page 35022, in the first column, correct amendatory instruction 21 to read as follows:

“21. Revise paragraph (a)(6) to read as follows:”

■ 4. On page 35022, in the second column, correct amendatory instruction 26 to read as follows:

“26. Revise paragraph (a)(6) to read as follows:”

Board of Governors of the Federal Reserve System, July 26, 2019.

Ann E. Mishback,

Secretary of the Board.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on July 23, 2019, by the Commission.

Valerie J. Best,

Assistant Executive Secretary.

Issued in Washington, DC, on July 23, 2019, by the Commission.

Christopher Kirkpatrick,

Secretary of the Commission.

By the Securities and Exchange Commission

Dated: July 23, 2019.

J. Lynn Taylor,

Assistant Secretary.

[FR Doc. 2019-16634 Filed 8-5-19; 8:45 am]

BILLING CODE 8011-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA-2018-1016; Special Conditions No. 25-753-SC]

Special Conditions: The Boeing Company Model 777-9 Airplane; Electronic Flight-Control System and Control-Surface-Position Awareness

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions.

SUMMARY: These special conditions are issued for The Boeing Company (Boeing) Model 777-9 airplane. This airplane 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 electronic flight-control system requiring control-surface-position awareness. The applicable airworthiness regulations do not contain adequate or

appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: Effective September 5, 2019.

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

SUPPLEMENTARY INFORMATION:

Background

On December 6, 2013, Boeing applied for an amendment to Type Certificate No. T00001SE to include the new 777-9 airplane. This airplane, which is a derivative of the Boeing Model 777 airplane currently approved under Type Certificate No. T00001SE, is a twin-engine, transport-category airplane with seating for 495 passengers and a maximum takeoff weight of 775,000 pounds.

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 airplane meets 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 the Boeing Model 777-9 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, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special

conditions, the Boeing Model 777-9 airplane must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34, and the noise-certification requirements of 14 CFR part 36.

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

Novel or Unusual Design Features

The Boeing Model 777-9 airplane will incorporate the following novel or unusual design feature:

An electronic flight-control system requiring control-surface-position awareness.

Discussion

With a response-command type of flight-control system and no direct coupling from the cockpit controller to control surface, such as on the Boeing Model 777 and 787 airplanes, the pilot is not aware of the actual surface-deflection position during flight maneuvers. This feature of this design is novel and unusual when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. These special conditions are intended to contain the additional safety standard.

Some unusual flight conditions, arising from atmospheric conditions, or airplane or engine failures, or both, may result in full or nearly full control-surface deflection. Unless the flightcrew is made aware of excessive deflection or impending control-surface deflection limiting, piloted or the automated flight-control system control of the airplane could be inadvertently continued in a way that would cause loss of control, or other unsafe handling or performance situations.

The special conditions require that suitable annunciation be provided to the flightcrew when a flight condition exists in which nearly full control-surface deflection occurs. Suitability of such an annunciation must take into account that some pilot-demanded maneuvers, such as a rapid roll, are necessarily associated with intended full or nearly full control-surface deflection. Simple alerting systems, which would function in both intended and unexpected control-limiting situations, must be properly balanced between providing needed crew awareness and avoiding nuisance warnings.

The special conditions are derived initially from standardized requirements the Aviation Rulemaking Advisory Committee (ARAC) developed, a committee comprising representatives of

the FAA, Europe's Joint Aviation Authorities (now replaced by the European Aviation Safety Agency), and industry representatives. In the case of some of these requirements, a draft notice of proposed rulemaking has been prepared but no final rule has been issued.

The 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.

Discussion of Comments

The FAA issued Notice of Proposed Special Conditions No. 25-19-06-SC for the Boeing Model 777-9 airplane, which was published in the **Federal Register** on May 8, 2019 (84 FR 20053). No comments were received, and the special conditions are adopted as proposed.

Applicability

As discussed above, these special conditions are applicable to the Boeing Model 777-9 airplane. 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 a certain novel or unusual design feature on one model of 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 Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Boeing Model 777-9 airplanes.

In addition to compliance with §§ 25.143, 25.671, and 25.672, the following special conditions apply.

(1) The system design must ensure that the flightcrew is made suitably aware whenever the primary control means nears the limit of control authority. This indication should direct the pilot to take appropriate action to avoid the unsafe condition in

accordance with appropriate airplane flight manual instructions. Depending on the application, suitable annunciations may include flight-deck control position, annunciator light, or surface position indicators. Furthermore, this requirement applies at limits of control authority, not necessarily at limits of any individual surface travel.

(2) Suitability of such a display or alerting must take into account that some pilot-demanded maneuvers are necessarily associated with intended full performance, which may require full surface deflection. Therefore, simple alerting systems, which would function in both intended or unexpected control-limiting situations, must be properly balanced between needed flightcrew awareness and nuisance factors. A monitoring system, which might compare airplane motion, surface deflection, and pilot demand, could be useful for eliminating nuisance alerting.

Issued in Des Moines, Washington, on July 31, 2019.

Victor Wicklund,

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

[FR Doc. 2019-16729 Filed 8-5-19; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF COMMERCE

International Trade Administration

15 CFR Part 315

[Docket No. 180223210-8210-01]

RIN 0625-AB14

Elimination of Regulations Implementing the Automotive Products Trade Act of 1965

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Final rule.

SUMMARY: Through this final rule, the International Trade Administration (ITA), U.S. Department of Commerce, removes the regulations implementing the Automotive Products Trade Act of 1965 (Act). That statute implemented the 1965 Canada-United States Automotive Products Agreement (Auto Pact). Since the North American Free Trade Agreement (NAFTA) came into effect in 1994, trade in automotive products between the United States and Canada is no longer governed by the Auto Pact or the Act. Implementing regulations for the Act are thus obsolete and unnecessary.

DATES: This rule is effective August 6, 2019.

FOR FURTHER INFORMATION CONTACT:

Scott Kennedy, Office of Transportation and Machinery, U.S. Department of Commerce, 1401 Constitution Avenue NW, Room 38032, Washington, DC 20230; telephone: (202) 482-1474.

SUPPLEMENTARY INFORMATION:

Background

In 1965, the United States and Canada entered into the Auto Pact concerning trade between Canada and the United States in automotive parts. Under the Auto Pact, the United States agreed to accord duty-free treatment to imports of certain automotive products of Canada. Specifically, Annex B of the Auto Pact listed certain kinds of motor vehicles and fabricated components that would receive duty-free treatment upon entry into the United States, subject to a limitation relating to non-Canadian content. Annex B limited the duty-free treatment of automotive parts upon entry into the United States to those “for use as original equipment in the manufacture of motor vehicles” described in Annex B.

The United States implemented the Auto Pact through the Automotive Products Trade Act of 1965, Public Law 89-283 (the Act). The Act gave the President the authority to proclaim modifications to the Tariff Schedules of the United States (tariff schedules), as provided in the Auto Pact. Section 404 of the Act defined the term “original motor vehicle equipment” as an imported Canadian article “which has been obtained from a supplier in Canada under or pursuant to a written order, contract or letter of intent from a bona fide motor-vehicle manufacturer in the United States, and which is a fabricated component intended for use as original equipment in the manufacture in the United States of a motor vehicle.” The Act directed the Secretary of Commerce to publish periodically in the **Federal Register** a list of bona fide motor-vehicle manufacturers. In 1980, the Department of Commerce promulgated regulations to establish a procedure by which a person could apply to be determined to be a bona fide motor-vehicle manufacturer (15 CFR part 315).

Trade in automobiles and automotive products between the United States and Canada is now governed by the NAFTA, which went into effect on January 1, 1994. Imports of the products described in the Auto Pact and the Act now enter the United States duty-free, with no distinction based on the nature of the importer. The amendments to the tariff schedules proclaimed by the President

on October 21, 1965, regarding bona fide motor-vehicle manufacturers, ceased to be relevant when the NAFTA went into effect. Since that date, no person has applied to be determined to be a bona fide motor-vehicle manufacturer, and the Secretary has published no listing in the **Federal Register** of bona fide motor-vehicle manufacturers. As a result, the regulations found at 15 CFR part 315 are obsolete and unnecessary.

Classification

This final rule was drafted in accordance with Executive Orders 12866, 13563, and 13771. OMB has determined that this rule is not significant for purposes of Executive Orders 12866. This final rule to eliminate 15 CFR part 315 is a deregulatory action under Executive Order 13771. Since the regulation has not been utilized in almost 25 years, there are no cost savings associated with this elimination.

Administrative Procedure Act and Regulatory Flexibility Act

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and opportunity for public comment on this action, as notice and comment are unnecessary. This rule removes obsolete regulations that were superseded by the implementation of the NAFTA, and that will remain obsolete under the new United States-Mexico-Canada Agreement (USMCA), once that agreement is implemented. Therefore, public comment would serve no purpose and is unnecessary. There is also good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in the date of effectiveness for this final rule. Because this rule does not alter the rights or responsibilities of any party, delaying implementation of this rule would serve no purpose.

Because prior notice and opportunity for public comment are not required pursuant to 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. Therefore, a regulatory flexibility analysis has not been prepared.

Congressional Review Act

This final rule is not major under the Congressional Review Act (5 U.S.C. 801 *et seq.*).

Executive Order No. 13132

This final rule does not contain policies that have federalism implications.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA) requires that a Federal agency consider the impact of paperwork and other information collection burdens imposed on the public and obtain approval from OMB for each collection of information it conducts, sponsors, or requires through regulations. Notwithstanding any other provision of 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 PRA unless that collection displays a currently valid OMB Control Number. This final rule does not require the collection of any information.

List of Subjects in 15 CFR Part 315

Canada, Customs duties and inspection, Imports, Motor vehicles.

Dated: July 22, 2019.

Bart Meroney,

Senior Advisor to the Deputy Assistant Secretary for Manufacturing, International Trade Administration, U.S. Department of Commerce.

PART 315—[REMOVED AND RESERVED]

■ For the reasons set out in the preamble, and under the authority of 5 U.S.C. 301, we remove and reserve part 315 of title 15 of the Code of Federal Regulations.

[FR Doc. 2019-16699 Filed 8-5-19; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic Atmospheric Administration

15 CFR Part 923

[Docket No. 080416573-8999-03]

RIN 0648-AW74

Coastal Zone Management Act Program Change Procedures

AGENCY: Office for Coastal Management, National Ocean Service, National Oceanic Atmospheric Administration (NOAA), Department of Commerce (Commerce).

ACTION: Final rule.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA) is providing states and NOAA with a more efficient process for making changes to state coastal management programs ("management programs"). The final rule revises the Coastal Zone

Management Act (CZMA) program change regulations and alleviates the need for previous associated guidance (Program Change Guidance (July 1996) and Addendum (November 2013)); the 1996 Guidance and 2013 Addendum no longer apply. Under the CZMA, a coastal state may not implement any amendment, modification, or other change as part of its approved management program unless the amendment, modification, or other change is approved by the Secretary of Commerce under the regulations. Once NOAA approves the incorporation of a change into a management program, any new or amended management program enforceable policies are applied to Federal actions through the CZMA Federal consistency provision. The final rule addresses the objectives raised in NOAA's May 2008 Advance Notice of Proposed Rulemaking (ANPR) and November 2016 Proposed Rule. These objectives include: Provide a more efficient process for states and NOAA to make changes to state management programs; remove unnecessary requirements in the current regulations; establish program change documentation that all states would adhere to; continue to ensure that Federal agencies and the public have an opportunity to comment to NOAA on a state's proposed change to its management program; and comply with the requirements of the CZMA and other applicable Federal law. The final rule also addresses comments submitted on the proposed rule.

DATES: *Effective:* September 5, 2019.

FOR FURTHER INFORMATION CONTACT: Mr. Kerry Kehoe, Federal Consistency Specialist, Office for Coastal Management, NOAA, at 240-533-0782 or kerry.kehoe@noaa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Unless otherwise specified, the term "NOAA" refers to the Office for Coastal Management, within NOAA's National Ocean Service. The Office for Coastal Management formed in 2014 through the merger of the former Office of Ocean and Coastal Resource Management and the Coastal Services Center.

The CZMA (16 U.S.C. 1451-1466) was enacted on October 27, 1972, to encourage coastal states, Great Lake states, and United States territories and commonwealths (collectively referred to as "coastal states" or "states") to be proactive in managing the uses and resources of the coastal zone for their benefit and the benefit of the Nation. The CZMA recognizes a national interest in the uses and resources of the

coastal zone and in the importance of balancing the competing uses of coastal resources. The CZMA established the National Coastal Zone Management Program, a voluntary program for states. If a state decides to participate in the program, it must develop and implement a comprehensive management program pursuant to Federal requirements. *See* CZMA § 306(d) (16 U.S.C. 1455(d)); 15 CFR part 923. Of the thirty-five coastal states that are eligible to participate in the National Coastal Zone Management Program, thirty-four have federally-approved management programs. Alaska is currently not participating in the program.

An important component of the National Coastal Zone Management Program is that state management programs are developed with the full participation of state and local agencies, industry, the public, other interested groups and Federal agencies. *See e.g.*, 16 U.S.C. 1451(i) and (m), 1452(2)(H) and (I), 1452(4) and (5), 1455(d)(1) and (3)(B), and 1456. The comprehensive state management programs must address the following areas pursuant to 15 CFR part 923:

1. Uses Subject to Management (Subpart B);
2. Special Management Areas (Subpart C);
3. Boundaries (Subpart D);
4. Authorities and Organization (Subpart E); and
5. Coordination, Public Involvement and National Interest (Subpart F).

NOAA approval is required for the establishment of a state management program. Once approved, changes to one or more of the program management areas listed above, including new or revised enforceable policies, must be submitted to NOAA for approval through the program change process.

Program changes are important for several reasons: The CZMA requires states to submit changes to their programs to NOAA for review and approval (16 U.S.C. 1455(e)); state programs are not static—laws and issues change, requiring continual operation of the CZMA state-Federal partnership; and the CZMA "Federal consistency" provisions require that Federal actions that have reasonably foreseeable coastal effects be consistent with the enforceable policies of federally-approved management programs. The state-Federal partnership is a cornerstone of the CZMA. The primacy of state decisions under the CZMA and compliance with the CZMA Federal consistency provision is balanced with adequate consideration of the national interest in CZMA objectives; the

opportunity for Federal agency input into the content of state management programs; NOAA evaluation of management programs; and NOAA review and approval of changes to management programs.

In establishing and maintaining their federally-approved management programs, states must consider national interest objectives of the CZMA in addition to state and local interests. These national interest objectives are contained in CZMA §§ 302 and 303 (16 U.S.C. 1451 and 1452). NOAA must also evaluate whether a state program change would meet these national interest objectives. As part of NOAA's national interest evaluation, by statute and regulations NOAA also determines whether a state's management program if changed would continue to give "priority consideration to coastal-dependent uses and orderly processes for siting major facilities related to national defense, energy, fisheries, recreation, and ports and transportation." 16 U.S.C. 1452(2)(D). Further, states, in developing and implementing their management programs, must provide for adequate consideration of the national interest involved in planning for, and managing the coastal zone, including the siting of facilities such as energy facilities which are of greater than local significance. In the case of energy facilities, the Secretary shall find that the State has given consideration to any applicable national or interstate energy plan or program. (16 U.S.C. 1455(d)(8), *see* 15 CFR 923.52 (Consideration of the national interest in facilities)). These CZMA national interest requirements for the development and implementation of state management programs are further described in NOAA's CZMA regulations. *See* 15 CFR 923.52.

Some of the important issues NOAA must consider when evaluating program changes include whether the change would: (1) Conflict with CZMA national interest objectives; (2) attempt to regulate Federal agencies, lands or waters, or areas outside state jurisdiction; (3) be preempted by Federal law; (4) discriminate against particular coastal users or Federal agencies; (5) include policies that are enforceable under state law; and (6) raise issues under the National Environmental Policy Act (NEPA), Endangered Species Act (ESA), Marine Mammal Protection Act (MMPA), National Historic Preservation Act (NHPA), or Magnuson Stevens Fisheries Conservation and Management Act (MSFCMA).

NOAA review and approval of program changes is also important because the CZMA provides for Federal agency and public participation in the content of a state's management program. NOAA can only approve management programs and changes to management programs after Federal agencies and the public have an opportunity to comment on the content of the program change. Within the context of the CZMA Federal consistency provisions, an enforceable policy is a state policy that has been incorporated into a state's federally-approved management program, is legally binding under state law (*e.g.*, through constitutional provisions, laws, regulations, land use plans, ordinances, or judicial or administrative decisions), and by which a state exerts control over private and public coastal uses and resources. *See* 16 U.S.C. 1453(6a) and 15 CFR 930.11(h) (enforceable policy). This means that enforceable policies must be given legal effect by state law and cannot apply to Federal lands, Federal waters, Federal agencies or other areas or entities outside a state's jurisdiction, unless authorized by Federal law. Also, the CZMA section 307 Federal consistency provision requires that state enforceable policies are the standards that apply to Federal agency activities, Federal license or permit activities, outer continental shelf plans and Federal financial assistance activities. (16 U.S.C. 1456; *see also* 15 CFR 930.11(h)). Therefore, Federal agencies and the public must have an opportunity to review proposed substantive changes to a state's enforceable policies.

Program changes are also important because the CZMA Federal consistency provision applies only if the Federal action has reasonably foreseeable coastal effects and a state has applicable policies approved by NOAA that are legally enforceable under state law. It is therefore important for states to submit to NOAA for approval timely updates to state management program enforceable policies.

II. Need for Revised Program Change Regulations

The previous program change regulations, 15 CFR part 923, subpart H, were in place since the late 1970s. The CZMA was revised in 1990, in part, to place greater emphasis on state management program enforceable policies. This has led to an increase in the number of program changes submitted to NOAA and the workload for state and Federal staff. States and NOAA have, therefore, recognized the need to clarify the program change

procedures and to provide a more administratively efficient submission and review process. In 1996, NOAA made minor revisions to the regulations and also issued program change guidance that further described program change requirements. In 2013, NOAA issued an addendum to the 1996 program change guidance for added clarification. Over the years, states and NOAA have, at times, found the regulations difficult to interpret. For example, there has been confusion about determining: When a program change is "routine" versus an "amendment;" when a program change is "substantial;" what level of state analysis is required; what level of detail is needed for a policy to be enforceable; and what can be approved as an enforceable policy. The final rule addresses these points of confusion by revising the regulations at 15 CFR part 923, subpart H, and alleviating the need for the 1996 program change guidance and the 2013 addendum; the 1996 guidance and 2013 addendum no longer apply. The final rule addresses the objectives raised in NOAA's May 2008 Advance Notice of Proposed Rulemaking, 73 FR 29093 (May 20, 2008) (ANPR) and November 2016 Proposed Rule, 81 FR 78514 (Nov. 8, 2016).

III. Objectives of the Final Rule

NOAA's objectives in revising the program change regulations are to:

1. Establish a clear, efficient and transparent process for program change review;
2. Describe approval criteria and how these apply;
3. Use terminology from the CZMA, including time lines and extensions;
4. Eliminate the distinction between "routine program changes (RPCs)" and "amendments." This removes the program change analysis currently done by states to determine if a change is substantial, and therefore an amendment, and instead requires states to describe the nature of the program change and indicate whether the state believes the program change would impact CZMA program approvability areas, national interest objectives, or compliance with other Federal laws. The distinction between RPCs and amendments, and the substantiality analyses by states were administrative and paperwork burdens with little or no benefit;
5. Continue to determine on a case-by-case basis the appropriate level of NEPA analysis warranted. With over 35 years of reviewing program changes, NOAA has determined that the vast majority of program changes do not, for purposes of

NEPA, significantly affect the human environment;

6. Encourage states to use underline/strikeout documents for program change submissions to show changes to previously approved policies;

7. Create a program change form that all states must use to submit changes to NOAA, easing state and NOAA paperwork burdens, promoting more consistent submissions and NOAA analyses, and expediting NOAA's review;

8. Use the NOAA "Program Change website" through which NOAA will electronically post program changes and public comments received, and notify Federal agencies and the public of the status of program changes, <http://coast.noaa.gov/czmprogramchange>; and

9. Require states to post program change public notices on the state's management program website.

In addition, the previous regulations at 15 CFR part 923, subpart H, included "termination of approved management programs." However, sanctions to and termination of management programs are described in detail in Subpart L—Review of Performance. Therefore, the final rule no longer includes termination of approved management programs under subpart H.

Changes Between the Proposed Rule and Final Rule

In general, the final rule has the same overall provisions, requirements, and structure as the proposed rule. The final rule does not introduce major new requirements. There are various minor changes and clarifications in the final rule preamble and regulatory text in response to comments and to ensure that NOAA's new Program Change website is consistent with the final rule. This final rule also provides further explanation and clarification of CZMA national interest considerations, public notice for state program change submissions to NOAA, and how NOAA applies the Federal preemption doctrine to its review of state CZMA program change submissions.

NOAA describes the changes from the proposed rule for each of the five regulation sections (923.80, 923.81, 923.82, 923.83, 923.84, and 923.85) in the preamble below under section IV. Explanation of Changes to the CZMA Program Change Regulations.

Comments on the Proposed Rule

NOAA received comments on the proposed rule from the state coastal management programs from California (from both the California Coastal Commission and San Francisco Bay Conservation and Development

Commission), Hawaii, Maine, New York, Oregon, and Virginia. The Coastal States Organization and the National Ocean Policy Coalition also submitted comments. In addition, NOAA discussed some of the proposed changes with the U.S. Navy. NOAA addresses general comments below. NOAA addresses comments on specific sections in section IV. Explanation of Changes to the CZMA Program Change Regulations. The comments on the proposed rule can be viewed in their entirety and downloaded at <https://www.regulations.gov/docket?D=NOAA-NOS-2016-0137>.

General Comments on the Proposed Rule

Comment 1 (Hawaii, Maine, California, Oregon, Coastal States Organization): We support the purposes of the rulemaking to provide a more effective and efficient process for states and NOAA to make changes to state coastal management programs.

Response: NOAA appreciates the comment.

Comment 2 (Oregon): We support doing away with the concepts of "routine" changes or "amendments" and removing the need to provide an analysis of whether a change is "substantial."

Response: NOAA appreciates the comment.

Comment 3 (Virginia): We have no comments or concerns with the proposed rule.

Response: NOAA appreciates the comment.

Comment 4 (National Ocean Policy Coalition): The proposed rule refers to proposed revisions to the associated guidance and Addendum within NOAA regulations, such revisions were not included in the proposed rule and the Coalition requests that the proposed guidance and Addendum revisions be provided for public comment before being finalized.

Response: NOAA was not proposing any changes to the 1996 program change guidance and addendum to the guidance. Rather NOAA is removing the guidance and addendum and replacing them with the final rulemaking; the program change guidance and addendum are no longer effective.

IV. Explanation of Changes to the CZMA Program Change Regulations

§ 923.80 General

This section describes the general requirements for program changes. Paragraph (a) states that the term "program changes" includes all terms used in the statute, CZMA § 306(e), and

identifies the Office for Coastal Management as the NOAA office that administers these regulations. Paragraph (b), derived from CZMA § 306(e), states that a coastal state may not implement a change as part of its management program until NOAA approves the program change. Similarly, a coastal state may not use a state or local government policy or requirement as an "enforceable policy" for purposes of Federal consistency unless NOAA has approved the state or local policy or requirement as an "enforceable policy." State or local government law not approved by NOAA as part of a state's management program remain legal requirements for state and local government purposes, but will not be part of a state's management program and, therefore, cannot be used for CZMA Federal consistency purposes.

Paragraph (d) states that the term "enforceable policies" has the same definition as that included in NOAA's CZMA Federal consistency regulations at 15 CFR 930.11(h). NOAA has added enforceable policy decision criteria in § 923.84. These criteria have been included in NOAA guidance and information documents and have been part of long-standing NOAA implementation of program changes and enforceable policies. *See, e.g.,* NOAA's former Program Change Guidance (July 1996) (<http://coast.noaa.gov/czm/consistency/media/guidanceappendices.pdf>) and NOAA's Federal Consistency Overview document (http://www.coast.noaa.gov/czm/consistency/media/FC_overview_022009.pdf).

Paragraph (e) notes that the submission of program changes may be required as a necessary action under NOAA's evaluation of management programs under CZMA § 312 and 15 CFR part 923, subpart L. Failure to comply with a necessary action to submit a program change can result in a suspension of CZMA grants pursuant to CZMA § 312 and the subpart L regulations.

Comments on Proposed § 923.80

Comment 5 (New York): Under § 923.80(e), how will NOAA identify which program changes are "necessary actions" under section 312 of the Act and part 923, subpart L (Review of Performance) that will trigger the process for suspending NOAA funding allocations to states or impose new program changes to previously-approved Federal program elements?

Response: NOAA does not have authority to require a state to make a change to state law or its coastal management program, except in limited circumstances if a state is not adhering

to its NOAA-approved coastal management program. *See California Coastal Com'n v. Mack*, 693 F.Supp. 821 (N.D. Cal. 1988). However, if a state makes a change to any part of its NOAA-approved management program that was needed to obtain NOAA approval or that a state uses for Federal consistency purposes, then section 306(e)(1) of the Act requires the state to submit those changes to NOAA for approval. NOAA can find the failure to do so as part of a periodic evaluation of a state's management program pursuant to section 312 of the Act and require submission of the changes to those management program provisions as a necessary action. Failure to meet the section 312 necessary action for the program change could form the basis for enforcement action under 15 CFR 923.135.

Changes from Proposed Rule. NOAA did not make any material changes between the proposed rule and final rule.

§ 923.81 Program Change Procedures, Deadlines, Public Notice and Comment, and Application of Approved Changes

This section sets forth various procedures for submitting program changes.

Paragraph (a). Program changes must be submitted by the Governor of a coastal state, the head of the single state agency designated under the management program to be the lead state agency for administering the CZMA, or the head of an office within the designated single state agency if the state has authorized that person to submit program changes.

NOAA will no longer require states to mail hard copies of program changes. Rather, states must submit all program changes through the new Program Change website or through an alternative method, agreed to by the state and NOAA, if an electronic submission through the website is not possible.

All deadlines and timeframes will start on the first full business day after NOAA receives a program change (Day 1). For example, if NOAA receives a submission on a Thursday, Day 1 for timeline purposes would be Friday. If the day of receipt is Friday and Monday is a Federal holiday, Day 1 would be Tuesday. All days, starting with Day 1, are included in the calculation of total time for a deadline, including weekends and Federal holidays, except for the last day (e.g., Day 30 or Day 120). The day that NOAA's decision is due must also end on a full business day. For example, if Day 30 is a Saturday, then NOAA's decision would be due the next

Monday, or if Monday is a Federal holiday, on Tuesday. States may request that the official start date occur at a later time; this is an administrative convenience NOAA has allowed states to use in the past to account for various state administrative purposes.

Paragraph (b). NOAA shall confirm receipt of all program changes and future deadlines. During NOAA's review of a program change, NOAA may request additional information that it needs to make its decision.

Paragraph (c). This paragraph sets forth the deadlines NOAA must follow in responding to state program change requests. The deadlines in paragraph (c) are the same as NOAA's current practice and clarify a discrepancy that exists in the current program change regulations and the CZMA. NOAA is required by the Act to respond within 30 calendar days of receipt of a program change request. The 30-day period starts on Day 1 (the first full business day after receipt of a program change request). If NOAA does not respond within the 30-day period, then NOAA's approval is presumed. NOAA may extend its review period up to 120 days after receipt of a program change request, if NOAA so notifies the state during the 30-day period. NOAA can extend its review period beyond 120 days for NEPA compliance; NOAA must notify the state of the NEPA extension during the 120-day review period.

Paragraph (d). This paragraph codifies the current practice of pre-submission consultation with NOAA to identify any potential approval issues prior to submitting a program change submission. States are encouraged to submit draft program changes to NOAA for informal review and to consult with NOAA, to the extent practicable, prior to state adoption of new or revised laws, policies and other provisions that the state intends to submit as a program change.

Paragraph (e). Given the reliance on electronic means of communication and the demise of hard copy notices in newspapers and other formats, all states must post a public notice of its program change on the state management program's website and directly email or mail the notice to applicable local and regional offices of relevant Federal agencies, Federal agency headquarter contacts, affected local governments and state agencies, and any individuals or groups requesting direct notice. NOAA will also post the state notice on its Program Change website and directly notify via email Federal agency headquarter contacts and any other individual or group requesting direct notice. The state's public notice will

describe the program change, any new or modified enforceable policies, and indicate that any comments on the incorporation of the program change into the state's management program shall be submitted to NOAA through NOAA's Program Change website. NOAA will post the program change and all NOAA decisions on its website and notify Federal agency headquarter contacts and other individuals or groups requesting notification. NOAA may extend the public comment period.

State program change approval requests will be submitted electronically by the state through the Program Change website. The timing of the state's public notice will occur in the following manner. States will draft a public notice of a submission, which shall be included as part of the contents of the program change submission form. When NOAA posts the program change submission on its Program Change website, NOAA will notify the state management program via email. The state will then post its public notice on the state web page providing a link to the submission on NOAA's Program Change website. The state shall send the public notice and link to the state and local agencies, Federal agency contacts, and others who have requested the state's public notice. Day 1 for NOAA review purposes will be the first business day after the state submits to NOAA the program change request. However, the 21-day comment period will not start until the state posts its public notice on the state web page. If a state fails to post its public notice, then NOAA would either determine the program change submission is not complete and the review period has not started or deny the program change request.

Paragraph (f). This paragraph states that program changes to enforceable policies can only be applied for CZMA Federal consistency review purposes on or after the date NOAA approves the changes. The effective date for the approved changes will be the date on NOAA's approval letter. NOAA will post its program change decision letters on its Program Change website. This section codifies in regulation NOAA's long-standing position that a state enforceable policy cannot apply retroactively to previously proposed Federal actions; proposed Federal actions are only subject to the management program enforceable policies approved at the time the Federal action is proposed under the various subparts of 15 CFR part 930. Applying newly approved program changes retroactively to proposed Federal actions would be contrary to

Congressional intent that Federal consistency apply in an expeditious and timely manner, and could impose unfair retroactive requirements on applicants and Federal agencies.

Comments on Proposed § 923.81

Comment 6 (Hawaii, Coastal States Organization): We support § 923.81(a) that program changes may be submitted on a cyclical basis or as changes occur giving states flexibility.

Response: NOAA appreciates the comment.

Comment 7 (Hawaii): The proposed rules should change “§ 923.81 Program change procedures, deadlines, public notice and comment and application of Federal consistency” to “§ 923.81 Program change procedures, deadlines, public notice and comment and application of approved changes.”

Response: NOAA agrees that the phrase “application of approved changes” would be more appropriate to match the title of Subpart H—Changes to Approved Management Programs, and maintain the title consistency from § 923.81 to § 923.84.

Comment 8 (Hawaii): The proposed rule should include a deadline under § 923.81(b) for NOAA to determine and notify the state whether its submission is complete.

Response: NOAA agrees with the comment and has added to § 923.81(b) five- and ten-day timeframes, respectively, for responding to the receipt of a program change and notifying the state if a program change submission is incomplete. This timeframe does not preclude NOAA from requesting additional information from the state on the submission.

Comment 9 (Hawaii): A state’s public notice is required by § 923.81(e)(2)(iii) to indicate that any comments on the content of the program change shall be submitted to NOAA through NOAA’s Program Change website within 21 calendar days of the date NOAA’s review period starts. However, as required by § 923.81(e)(1), when the state posts its public notice prior to, or on the same date as, the date the state submits the electronic program change to NOAA, the state does not know the date when NOAA’s review period will start. Therefore, when a state posts its public notice on the state’s management program website, the deadline for comment submitted to NOAA has to be left as “to be determined,” which shall be updated when the day one of NOAA’s review period is available from NOAA.

Response: NOAA agrees that this could be confusing and has modified § 923.81(e)(2)(iii) to state that comments

shall be submitted within 21 days of the date of the state’s notice.

Comment 10 (National Ocean Policy Coalition): NOAA must publish notice and provide public comment opportunities in the **Federal Register** for any changes that are not editorial, non-substantive, and/or minor in scope, including but not limited to any proposed changes or additions to state Federal consistency lists or geographic location descriptions, any major changes requiring analysis for their justification, and any changes that may require analysis under NEPA, rather than rely solely on website notices and communications to individuals who opt-in to receive such announcements.

Response: The CZMA establishes a 30-day timeframe for reviewing program changes that are further detailing of state programs. Preparation and publication of a public notice in the **Federal Register** while providing a meaningful opportunity for public comment cannot be accomplished within a 30-day timeframe. Nonetheless, public notice and an opportunity for public comment is provided through state management program websites and email list serves as well as NOAA’s Program Change website and list serve. Furthermore, additional public notice and an enhanced opportunity to submit comments will be provided through the NOAA’s new Program Change website with direct notifications sent to interested parties. Where changes are so substantial as to bring into question the continued approvability of a state program and when NOAA needs additional time for NEPA compliance, NOAA’s practice has been to extend its review timeframe in order to provide for notice and comment in the **Federal Register**. NOAA will continue to follow that practice.

Comment 11 (National Ocean Policy Coalition): NOAA should provide for at least 45 days of public comment on proposed changes to management programs that are not editorial, non-substantive, and/or minor in scope, including but not limited to any proposed changes or additions to state Federal consistency lists or geographic location descriptions, any major changes requiring analysis for their justification, and any changes that may require analysis under NEPA.

Response: NOAA disagrees. NOAA is required by statute to respond to the state within 30 days of receipt of a program change. Therefore, NOAA retains the 21-day comment period. However, both the proposed rule and final rule, in § 923.81(e)(4), allow NOAA to extend a public notice period at

NOAA’s discretion. *See* 16 U.S.C. 1455(e)(2).

Comment 12 (New York, Oregon): Please clarify how this rule will relate to the new NOAA Revised National Environmental Policy Act Implementing Procedures in its draft Companion Manual for NOAA Administrative Order 216–6A containing policy and procedures for implementing NEPA. What standards will OCM use to determine “on a case by case basis” the appropriate level of NEPA analysis to be applied?

Response: All program changes are now subject to NOAA’s Companion Manual for NOAA Administrative Order 216–6A, Appendix E, Categorical Exclusion A6, effective January 13, 2017. *See* <http://www.nepa.noaa.gov/>. NOAA will evaluate each program change submitted by a coastal state on a case-by-case basis pursuant to the Administrative Record for Categorical Exclusion A6 to determine if the magnitude of the difference between the current NOAA approved management program and the management program as changed would no longer be covered under this Categorical Exclusion (CE) and would require an environmental assessment or environmental impact statement. Factors NOAA will consider when determining if the CE applies include, but are not limited to, the following. The presence of any of these factors in a program change does not necessarily mean the change is not covered by the CE; rather, NOAA will consider the magnitude of the change to the management program for these factors. Factors considered prior to applying the CE:

- Whether the program change is further detailing of existing: Uses subject to the management program; enforceable policies; organizational structure; coastal zone boundaries; special area management plans; national interest objectives; geographic location descriptions; or Federal consistency lists.
- Whether the program change contains new: Uses subject to the management program; enforceable policies; organizational structure; coastal zone boundaries; special area management plans; national interest objectives; geographic location descriptions; or Federal consistency lists.
- Whether the approval of a program change may be controversial.
- Whether the program change may have a potentially significant effect on tribal resources or sovereignty, threatened or endangered species, historic properties, essential fish habitat, or marine mammals.

• Whether the program change may trigger any informal or formal consultations for tribal or other Federal law purposes. Not all tribal or other Federal law consultations would necessarily trigger the need for an environmental assessment; rather, NOAA would determine the magnitude of the issues and whether the CE would still apply.

Comment 13 (Oregon): We support the use of the language in the statute for establishing NOAA's review periods and extensions.

Response: NOAA appreciates the comment.

Comment 14 (New York, Maine): Please clarify the time limits NOAA will have to review and approve program changes and for extensions and public hearings. It is unclear how long of an extension "beyond 120 days" NOAA can make based on the language under § 923.81(c) (see Page 78523 column 1). Can the extension be indefinite?

Response: The CZMA requires NOAA to respond within 30 days of receipt of a program change request. Determining the 30 days is described in this preamble and in § 923.81(a), (b), and (c). The Act authorizes NOAA to extend the 30-day response period to 120 days. 16 U.S.C. 1455(e)(2). Whether NOAA extends the 30-day time period will depend on the complexity or issues raised by a program change, including whether NOAA will hold a public hearing. NOAA can extend beyond 120 days if NOAA needs that time to comply with NEPA and the length of time NOAA extends beyond 120 days will depend on the time needed to produce additional NEPA documents.

Comment 15 (New York): Will the public be able to comment on every program change submitted to the NOAA Program Change website, and what will be the process for states responding to those comments? What type of comments will be accepted during the public comment period under this new rule?

Response: The public and Federal agencies will be able to respond to any program change that NOAA determines is complete and is under NOAA review. This applies to all program changes that states submit to NOAA through the Program Change website and that NOAA has made publicly available on the Program Change website. NOAA has modified § 923.81(e)(3) to state that NOAA will not accept and will not consider any comments received after NOAA issues its decision. If a state responds to a public comment before NOAA issues its decision, then NOAA will consider the state's response and may post the state's response on the

Program Change website. A state's response to a comment would be sent directly to NOAA via email or mail and not through the Program Change website. NOAA has modified § 923.81(e)(2)(iii) to state that any public comments on a state's request to incorporate the program changes into the state's management program may be submitted to NOAA.

Comment 16 (New York): Please clarify the time requirements or limits for submitting program changes "as the changes occur" or "on a cyclical basis." Will the states get to choose the option they prefer ("as the changes occur" or "on a cyclical basis")?

Response: There is no requirement for a state to submit program changes within a specified time period, unless the submission of program changes is a necessary action in a CZMA section 312 finding and that 312 finding has a specified time frame that would have been discussed between NOAA and the state. Section 923.81(a) gives states choices on submitting program changes as they occur or on some cyclical basis. When a state submits a program change may also depend on whether the state wants NOAA to approve a program change so the state can use the change for Federal consistency reviews.

Comment 17 (New York): Under § 923.81(e)(4) how will NOAA determine if a proposed program change is elevated to a "controversial" status that would necessitate a public hearing? How would NOAA weigh the information gathered during a public hearing in its decision making regarding whether or not to approve the proposed program change?

Response: NOAA will evaluate the magnitude of the proposed change to the management program and the totality of any issues raised on any particular program change submission to determine if any controversy over a request for approval of a program change warrants a public hearing. If NOAA conducts a public hearing, public comments become part of NOAA's decision record and NOAA will evaluate the usefulness of the comments submitted when applying NOAA's decision criteria.

Comment 18 (New York): When will the new proposed regulations take effect, and how will program changes happen while the Program Change Form and website are being developed, tested, and finalized?

Response: The final regulations will take effect 30 days after publication in the **Federal Register**. The Program Change website described in § 923.81(a)(1) has been developed, tested, and finalized concurrently with

development of this rulemaking. Any program change submitted after the effective date identified in the **Federal Register** notice for the final rule must apply these regulations and use the Program Change website.

Comment 19 (Maine, Coastal States Organization): Under § 923.81(e)(1), allowing a coastal state to provide public notice and opportunity for comment on proposed program changes by publishing a notice on its website seems like a sensible change that, in today's world, provides notice in a forum likely to reach interested parties and reduces administrative costs related to publication of newspaper notices.

Response: NOAA appreciates the comment.

Comment 20 (Maine, Coastal States Organization): Under § 923.81(e)(3), NOAA would notify and solicit comments from Federal agencies regarding all proposed program changes and provide access to information on such changes on its website. Section 923.81(e)(1) appears to require coastal states to provide the same notice to the same Federal agencies. NOAA should revise these provisions to avoid duplicative notice and consider clarifying that it will assume sole responsibility for notifying Federal agencies via its website as outlined in proposed § 923.81(e)(3).

Response: NOAA disagrees with the comment. States have a wider set of local, regional, and sometimes headquarter Federal agency contacts. In addition, Federal agencies should have the full 21 days to provide comments, which starts from when the state provides notice. It is the state's notice that solicits comments; NOAA's notice via the Program Change website alerts Federal agency headquarter contacts and anyone else asking for direct notification that the program change is available for viewing on the Program Change website.

Comment 21 (Maine, Coastal States Organization): Section 923.81(f) clarifies that enforceable policies become effective on the date of NOAA's letter to a coastal state providing its decision on proposed program changes. This seems helpful and well-aligned with rules regarding web-based notice of approved program changes.

Response: NOAA appreciates the comment.

Changes from the Proposed Rule. NOAA modified the title of the section by replacing "Federal consistency" with "approved changes." NOAA added to § 923.81(b) five- and ten-day timeframes, respectively, for responding to the receipt of a program change and notifying the state if a program change

submission is incomplete. NOAA modified § 923.81(e)(2)(iii) to state that comments shall be submitted within 21 days of the date of the state's notice. NOAA modified § 923.81(e)(3) to state that NOAA will not accept and will not consider any comments received after NOAA issues its decision. If a state responds to a public comment before NOAA issues its decision, then NOAA will consider the state's response and may post the state's response on the Program Change website. NOAA modified § 923.81(e)(2)(iii) to state that any public comments on a state's request to incorporate the program changes into the state's management program may be submitted to NOAA.

§ 923.82 Program Change Submissions

Section 923.82 identifies the type of changes that a state would submit to NOAA. Paragraph (a) reflects the statutory requirement that states may not implement changes to their management programs unless the changes are approved by NOAA. Paragraph (b) identifies the five CZMA management program approval areas; all changes to a state management program would fall under one or more of these five areas. The changes described in § 923.82(c) are editorial, non-substantive, or are minor in scope, both procedurally and substantively. The distinction between paragraph (c) (editorial, non-substantive, or minor in scope) and paragraph (d) (substantive changes) does not re-introduce "routine" changes and "substantial" changes from the previous regulations. Rather, paragraph (c) changes that are editorial, non-substantive, or minor in scope are not controversial and pose little or no impact on Federal agencies or the public. Therefore, NOAA's review of changes under § 923.82(c) would be expedited.

Paragraphs (c)(1) through (4) describe program changes that are either editorial in nature or are minor in scope, both procedurally and substantively. Paragraph (c)(1) addresses editorial or non-substantive changes to state laws, regulations, enforceable policies, local government coastal programs or plans that contain enforceable policies, and other authorities. Paragraph (c)(2) covers changes to special area management plans that do not change a state's coastal zone boundary, enforceable policies, or geographic location descriptions, and are not otherwise used by the state for Federal consistency review. Paragraph (c)(3) covers most organizational changes where the primary structure and responsibilities of the management remain intact. NOAA will closely monitor organizational changes to

ensure that major overhauls of a state's management program structure would not weaken a coastal program.

Most program changes, even those that result in some substantive change to enforceable policies, have historically been minor and non-controversial, and have not posed any approval issues or resulted in any comments from Federal agencies or the public. Under paragraph (c)(4), NOAA's review of these types of program changes should be expedited so long as these minor substantive changes would only apply to revised enforceable policies, not wholly new enforceable policies, and the changes are consistent with the scope and application of the previously approved enforceable policy.

The types of program changes under § 923.82(d) are self-explanatory and include: Any changes that are not covered under § 923.82(c) and would be used for Federal consistency purposes (new or revised enforceable policies, changes to state lists of Federal actions subject to Federal consistency review, geographic location descriptions outside the coastal zone, necessary data and information); new or revised coastal uses; changes in the coastal zone boundary; program approval authorities; and special area management plans.

Paragraph (d)(4) recognizes that for some states with local coastal programs or plans, the state can respond to Federal consistency reviews without having to refer to the local programs or plans. In such cases, while the local programs and plans are important implementing mechanisms for coastal management in the states, states do not need to submit updates to the local programs or plans if they do not contain enforceable policies for Federal consistency purposes. This removes the substantial administrative burden for states and NOAA to submit and review local coastal programs.

Paragraph (e) addresses changes to state Clean Air Act (CAA) and Clean Water Act (CWA) Pollution Control Requirements. CZMA section 307(f) states that CAA and CWA requirements established by the Federal Government or by any state or local government pursuant to the CWA and CAA shall be incorporated in state management programs and shall be the water pollution control and air pollution control requirements applicable to such management program. NOAA's long-standing interpretation of 307(f) has been that these CWA and CAA pollution control requirements are automatically enforceable policies of the state management programs and, therefore, states are not required to submit as program changes any changes to state CAA and CWA provisions. NOAA

notes, however, that changes to state CWA or CAA pollution control requirements must be consistent with the Acts and not seek to circumvent or supersede exemptions provided for specified military activities. For example, state CWA and CAA requirements must not attempt to regulate or prohibit discharges from vessels of the armed forces that are permissible as a matter of law under the CWA.

Comments on Proposed § 923.82

Comment 22 (Hawaii): We support § 923.82(c)(4) [now (d)(4)] that the states are not required to submit program changes for local government coastal management programs or plans that do not contain enforceable policies for Federal consistency review.

Response: NOAA appreciates the comment.

Comment 23 (Hawaii, Maine, Coastal States Organization): We support § 923.82(d) [now (e)] that the states are not required to submit as program changes, any changes to state Clean Air Act (CAA) and Clean Water Act (CWA) provisions. The CZMA itself expressly makes such requirements applicable under NOAA-approved state coastal management programs.

Response: NOAA appreciates the comment.

Comment 24 (Oregon, Coastal States Organization): Section 923.82(c)(3) [now (d)(3)] concerns changes to provisions that are not enforceable policies but that help determine whether an enforceable policy applies. Please clarify which provisions would fall under this category.

Response: In their program, some states include guidance documents and explanatory text for enforceable policies to help interpret and apply the policies. While such guidance or explanatory text may explain how a Federal agency or license or permit applicant may demonstrate consistency with the policies, the actual guidance or explanatory text cannot be treated as enforceable policies and cannot serve as the basis for a state's finding of inconsistency or objection.

Changes from the Proposed Rule. NOAA made minor wording changes to clarify program change submission types. In the preamble, NOAA further explained the incorporation of Clean Air Act and Clean Water Act provisions into management programs and that state CWA and CAA provisions cannot circumvent or supersede exemptions provided for specified military activities.

§ 923.83 Program Change Materials

Section 923.83 describes all the program change information a state must submit to NOAA. NOAA has transformed these paragraphs into a form that will, to the greatest extent practicable, use check-boxes or “radio-buttons,” and require minimal text input. While the same form will be used for all program changes, there will be less information needed for those changes that fall under § 923.82(b).

Paragraph (a)(1) is a brief general overview of the entire program change submission. Paragraph (a)(2) is a more detailed overview requiring states to briefly describe each authority or policy included in a program change. For example, if a program change submission contains changes to two state statutes and three different state regulatory programs, then the state would briefly describe the changes in each of the two statutes and three regulations. The brief description would also describe the effect of the change on the management program, that is, the “delta”—how the management program as changed is different than the previously approved management program.

Paragraph (a)(3) requires states to indicate which of the five program approval areas the program change applies to.

Paragraph (a)(4) is the table states will fill out for each change within a state statute, regulation, or other program change authority. This is similar to the table format states previously used to fill out, but NOAA has eliminated some of the columns.

Paragraph (a)(4)(vi) codifies NOAA interpretation and long-standing practice of the term “enforceable mechanism.” An enforceable mechanism is the state legal authority that makes a state policy enforceable under state law. In order to be an “enforceable policy,” CZMA § 304(6a) requires that the policies be legally binding under state law. NOAA has interpreted this to mean that the enforceable policy must be incorporated into the state’s NOAA-approved management program, but the underlying enforceable mechanism does not necessarily have to be incorporated into a state’s management program or submitted for NOAA approval. Some enforceable mechanisms are integral parts of the management program or are needed for NOAA approval of a state’s management program and changes to these enforceable mechanisms would be submitted to NOAA as program changes (e.g., core management program statutes, regulatory permit programs that

implement a part of a management program). States need to identify the enforceable mechanism for each enforceable policy. This is needed not only so NOAA can concur that a state policy is legally binding under state law, but an enforceable mechanism may be changed in such a way that makes an enforceable policy no longer legally binding under state law. In such cases, that policy, while previously approved by NOAA as part of the state’s management program, would no longer be an enforceable policy that could be used for Federal consistency purposes.

Paragraph (a)(5) applies to changes to state Federal consistency lists or geographic location descriptions under 15 CFR 930.53.

Paragraph (a)(6) applies to necessary data and information under 15 CFR 930.58.

Paragraph (a)(7) requires states to indicate whether they believe that NOAA’s decision criteria are met.

Paragraph (a)(8) requires states to describe any impacts related to other Federal laws. This does not require states to develop new information or to consult with Federal agencies or tribes. Rather, NOAA needs any information a state may have regarding requirements of other Federal laws.

Paragraph (a)(9) requires states to identify their websites where the public notices and program change submissions are located.

Paragraph (a)(10) requires states to provide any correspondence they have with Federal agencies regarding the program change.

Paragraph (a)(11) requires states to specify whether a program change is responding to a CZMA § 312 evaluation necessary action.

States are encouraged to show the changes, additions and deletions to enforceable policies using an underline/strikeout format or other similar format. If a state uses an underline/strikeout format, the state should only show the changes from the version of the policy last approved by NOAA and the most current version that is being submitted to NOAA.

States are also encouraged to post comprehensive lists of the enforceable policies to the state’s coastal management program website.

Comments on Proposed § 923.83

Comment 25 (Hawaii, New York): NOAA should provide the states an opportunity to review and comment on the Program Change Form and website before it is finalized for use.

Response: The Program Change website and web-based form that states will have to use to submit program

changes once these regulations are final and will not be available for public review and comment. The website and form are directly tied to these regulations and do not contain any requirements that are in addition to these regulations. The website and form were developed by NOAA’s in-house web designers and NOAA did conduct testing of the web-based form with three states (Maine, North Carolina, Oregon).

Comment 26 (National Ocean Policy Coalition, Oregon, Coastal States Organization): We oppose, are concerned with, or have questions on proposed § 923.83(a)(3)(iii), which would have allowed use of a Regional Planning Body (RPB) process to replace the program change requirements in the regulations for notifications to Federal agencies and the public for the development of geographic location descriptions and changes to state lists of Federal license or permit activities that describe general concurrences for minor Federal license or permit activities resulting from state and Federal agency agreements as part of an RPB’s regional ocean plan, and agreed to by NOAA through the RPB process.

Response: NOAA has deleted § 923.83(a)(3)(iii) from the final rule, regarding establishment of geographic location descriptions and changes to state Federal consistency lists by states as part of a regional ocean plan by an RPB. NOAA’s intent was that the public process used by an RPB when developing a regional ocean plan would suffice for meeting public notice and comment for changes to state CZMA programs. However, neither the Northeast RPB nor the Mid-Atlantic RPB proposed geographic locations descriptions or changes to state Federal consistency lists and, while there was public discussion at the RPBs of the concept, there was no discussion of any proposed geographic location description. NOAA agrees that now that these two regional ocean plans are final, any further RPB or other regional process should not suffice for the CZMA’s and NOAA’s public participation requirements. In addition, Executive Order 13840 (Ocean Policy to Advance the Economic, Security, and Environmental Interests of the United States) revokes and replaces the 2010 ocean policy Executive Order 13547 and disbands the RPBs. States could discuss and coordinate on geographic location descriptions and other changes to a state’s management program through regional discussions, but any changes to a state’s management program would need to follow all requirements of 15 CFR part 923, subpart H, including public notice requirements.

Comment 27 (New York): One of NOAA's objectives in revising the program change regulations is for the states to "indicate whether the state believes the program change would impact CZMA program approvability areas." (82 FR at 78515). Would this new analysis require a state to defend the entirety of NOAA's prior program approval(s) when just one program component is being updated?

Response: This is not a new requirement. The comment refers to §§ 923.83(a)(3) and 923.82(b), which is the requirement for the state to identify which of, and assess the impact to, the five program approvability areas the program change applies to: Uses Subject to Management (subpart B); Special Management Areas (subpart C); Boundaries (subpart D); Authorities and Organization (subpart E); and Coordination, Public Involvement and National Interest (subpart F). Neither the state nor NOAA assess the approvability of a state's entire program when submitting and reviewing program changes. If a program change raises an approvability issue, NOAA addresses that particular issue and not the entire management program.

Comment 28 (New York): What standards will OCM use to determine that "enforceable mechanisms" are inadequate for making enforceable policies legally binding?

Response: As described in § 923.83(a)(2)(v) and in this preamble for subpart H, NOAA relies on a state's identification of the state statutes, regulations, or other state legal requirements that can be shown to compel compliance with the policy. In reviewing state program change submissions NOAA, in consultation with the state, may identify policies that are no longer supported by an enforceable mechanism, e.g., the enforceable mechanism was repealed by the state or changed in such a manner that it no longer supports the enforceable policy.

Comment 29 (New York): Please clarify and describe how the "Coastal Effects Analysis" will be applied. Will states be able to create their own "Coastal Effects Analysis" tools, and what standards will be acceptable? For the "causal connection," will probabilistic (Bayesian) statistics methods and tools be allowable?

Response: For the coastal effects analyses described in § 923.83(a)(5) and § 923.84(d), NOAA will determine whether the state has demonstrated that there will be reasonably foreseeable effects to uses or resources of a state's coastal zone for a new item on a state's Federal consistency list or from listed

activities in a proposed geographic location description. NOAA has provided the steps for states to use in making a coastal effects analysis in § 923.84(d) and states may use a variety of tools that help them address these steps. For example, there are new ocean-related data portals for the Northeast and Mid-Atlantic Regional Ocean Plans, as well as the Federal Marine Cadastre that can provide substantial information on resources, uses, and economic information, related to coastal effects analyses. At this time, NOAA is not speculating on what tools may or may not be persuasive in making a coastal effects analysis.

Comment 30 (New York): Related to § 923.83(a)(4)(vi), after this proposed rule is adopted, how will NOAA carry out its review process for state coastal programs to identify which, if any, state coastal policies are no longer enforceable for lack of standards?

Response: In reviewing state program change submissions that include previously approved enforceable policies, NOAA, in consultation with the state, may identify policies submitted in a program change request that were approved many years ago, but do not contain a sufficient standard for Federal consistency. NOAA will work with the state to revise the policy or to determine that it is no longer enforceable.

Comment 31 (Maine, Coastal States Organization): Section 923.83(a)(4)(i) raises a technical issue. Use of the citation to the pertinent public law section(s) is an accurate way to reference a proposed program change. Use of the popular name or citation to the codified law may prove confusing. The same section of codified law may be amended multiple times over the years. In Maine, not all public laws are codified. This section may be improved by asking that states not provide just public law citations but reference to the codified law as well, to the extent practicable.

Response: NOAA agrees with the comment and has modified § 923.83(a)(4)(i) to include state code, public law number, state regulation, and other official state formats.

Comment 32 (Maine): Section 923.83(a)(4) requires coastal states to submit to NOAA information that it presumably already has. Accordingly, for efficiency's sake, it should be deleted.

Response: NOAA has determined that the only date needed for program change submissions is the date the state policy became effective in the state. NOAA has deleted the other dates, including date last approved by NOAA.

Comment 33 (Oregon): We support creating a program change form that states would submit to ease state and NOAA paperwork burdens and promote consistent submissions and NOAA analyses.

Response: NOAA appreciates the comment.

Comment 34 (Oregon): We believe providing underline/strikeout documents showing changes to previously approved policies is an unnecessary and overly burdensome requirement. There may be instances where such a technique is employed to clearly explain a program change, but this should be an available tool, not a strict requirement.

Response: The regulation does not contain a requirement for states to submit underline/strikeout documents. However, the preamble to the final rule does encourage states to submit underline/strikeout documents as these documents can be very useful in reviewing the changes to management programs and help expedite NOAA's review and approval.

Changes from the Proposed Rule. NOAA made minor wording and organization changes to § 923.83. NOAA removed from the final rule a provision, included in the proposed rule as § 923.83(a)(3)(iii), that would have allowed use of the Regional Planning Body process to replace some of the program change requirements for the development of geographic location descriptions and changes to state Federal consistency lists that describe general concurrences for minor Federal license or permit activities. NOAA made this change after considering the public comments, the current status of the Northeast and Mid-Atlantic regional ocean plans, and Executive Order 13840 (June 19, 2018—Ocean Policy to Advance the Economic, Security, and Environmental Interests of the United States), which revokes and replaces the 2010 ocean policy Executive Order 13547 and disbands the Regional Planning Bodies. NOAA modified § 923.83(a)(4)(i) to include state code, public law number, state regulation, and other official state formats. NOAA modified § 923.83(a)(4) so that the only date a state needs to include for program change submissions is the date the state policy became effective in the state. NOAA deleted the other dates that were in the proposed rule, including date last approved by NOAA.

§ 923.84 Program Change Decision Criteria

The decision criteria in this section are taken from the previous Program Change Guidance (1996) and NOAA's

Federal Consistency Overview document. NOAA has applied these criteria since at least 1996 when reviewing program change requests. These criteria are generally self-explanatory, and states will use NOAA's program change form to assess whether these criteria are satisfied. For enforceable policies under paragraph (b) of this section, a policy must contain a standard; if a provision of a state law or regulation merely directs a state agency to develop standards, then that provision would not be an enforceable policy as it does not contain a standard. An enforceable policy should contain terms such as "shall," "must," or other terms interpreted under state law that mandate some action or compliance. Paragraph (b) also clarifies that it does not always make sense to parse out the enforceable policies within a statute or regulation that also contain parts that are necessary details for applying enforceable policies even though not enforceable themselves. This includes definitions, procedures, and information requirements that are essential elements of interpreting the substantive standards and determining consistency with the standards. Therefore, in some cases NOAA may designate a statute or regulation as an enforceable policy; however, this designation only applies to the substantive standards within the statute or regulation. Procedural requirements are not considered to be enforceable policies for CZMA review purposes.

Paragraph (b) also clarifies that enforceable policies must: Apply to areas and entities within state jurisdiction; not assert regulatory authority over Federal agencies, lands or waters unless Federal law authorizes such jurisdiction; not be preempted by Federal law; not attempt to incorporate by reference other state or local mandatory requirements not submitted to, reviewed, and approved by NOAA; not discriminate against a particular activity or entity; and not adversely affect the national interest in the CZMA objectives.

State review under the CZMA is contingent upon a Federal action having coastal effects. State enforceable policies must relate to the particular effects of a Federal action. NOAA will not approve proposed enforceable policies that arbitrarily discriminate against a particular type of Federal action. There must be a sufficient justification for discriminatory policies. NOAA would determine if a discriminatory policy is reasonable and also whether a prohibition of an activity would violate the national interest objectives of the CZMA.

State enforceable policies must apply equally to private and public entities, and for Federal consistency purposes states cannot apply enforceable policies differently to Federal agencies. This is derived from requirements in the CZMA for states to "exert control over private and public land and water uses and natural resources in the coastal zone" (16 U.S.C. 1453(6a), definition of enforceable policy), and for management programs to contain "standards to guide public and private uses. . . ." (16 U.S.C. 1453(12), definition of management program).

NOAA evaluates whether a program change would adversely affect the national interests in the CZMA because states are required to consider the national interest in numerous activities and activities that have a regional or national benefit. The primary national interest requirements for program change considerations are set forth in 16 U.S.C. 1452(2)(D) and 1455(d)(8), and 15 CFR 923.52. *See above* discussion of national interest requirements under Background. If a state policy adversely affects these national interests, then NOAA will not approve the state policy as part of a state's management program.

For example, if a state is concerned about having policies that would apply to offshore oil and gas activities, the state would need to develop policies that would apply to any activity or industry that would have similar coastal effects; the state could not single out and discriminate against offshore oil and gas unless there are specific activities or coastal effects that only apply to the offshore oil and gas industry. Likewise, if a state wants to promote marine renewable energy in its enforceable policies, it may do so, but could not at the same time prohibit other forms of energy development without sufficient justification. Blanket prohibitions are generally not approved by NOAA as part of a state's management program unless a state provides sufficient justification. These examples have both discrimination and national interest issues. Not only is energy one of the national interests in the CZMA, but states also have to give priority consideration to energy siting and must have energy facility siting processes as part of their management program.

In addition, NOAA will not approve a proposed enforceable policy if Federal law expressly preempts the state policy. For example, NOAA could not approve a state proposed policy that regulates the siting of onshore liquefied natural gas (LNG) terminals regulated by the Federal Energy Regulatory Commission (FERC) under the Natural Gas Act, since

FERC has exclusive jurisdiction over the siting of onshore LNG terminals and states are federally preempted from regulating the siting of LNG terminals. Such a policy could not be legally binding under state law, as required by the CZMA definition of enforceable policy in CZMA section 304(6a). States can still apply enforceable policies of general applicability to address coastal effects from the siting of an LNG terminal.

Paragraph (c) codifies long-standing NOAA practice and guidance when enforceable policies previously approved by NOAA are no longer enforceable for purposes of Federal consistency review. If an underlying enforceable mechanism, e.g., a state law, is repealed or changed in such a way that an enforceable policy is no longer legally enforceable under state law, then that policy can no longer be used for Federal consistency purposes. The same applies if a policy previously approved by NOAA is subsequently preempted by Federal law.

Paragraph (d) describes NOAA criteria for states to amend their lists of Federal actions subject to Federal consistency review and to propose geographic location descriptions (GLDs) to review Federal actions outside the coastal zone, either landward or seaward. This paragraph focuses on the need for a state to make an adequate justification based on reasonably foreseeable effects to the state's coastal uses or resources. For NOAA to find that an activity in a proposed GLD outside the coastal zone may have coastal effects, a state must show that the impact from an activity will have a reasonably foreseeable effect to coastal uses or resources of the state. A state's burden to demonstrate coastal effects means that a mere assertion that an activity in Federal waters will have an impact is insufficient to make a finding of reasonably foreseeable coastal effects. Moreover, a state's effects analysis must provide more than general assertions. A persuasive coastal effects analysis should identify, to the extent practicable, each of the following:

1. The affected uses (e.g., commercial and recreational fishing, boating, tourism, shipping, energy facilities) and resources (e.g., fish, marine mammals, reptiles, birds, landmarks).

2. Where and in what densities the uses and resources are found.

3. How the state has a specific interest in the resource or use. Be specific in showing their connection to the coastal zone of the state (e.g., economic values, harvest amounts, vulnerabilities, seasonal information relevant to the proposed activity).

4. Where the proposed activity overlaps with these resources, uses and values.

5. Impacts to the resources or uses from the proposed activity.

6. A reasonable showing of a causal connection to the proposed activity, including how any impacts from the activity results in reasonably foreseeable effects on the state's coastal uses or resources.

7. Why any required mitigation may be inadequate. While there may be mitigation considerations while reviewing Federal consistency list additions or geographic location descriptions, NOAA expects that the mitigation analysis would mostly be used case-by-case for state requests to review an unlisted activity under the Federal consistency regulations (15 CFR 930.54), and not for program change requests for state-Federal consistency lists or state geographic location descriptions.

8. Empirical data and information that supports the effects analysis and: Can be shown to be reliable; visualizes the affected area, resources and uses with maps; and shows values, trends and vulnerabilities.

Comments on Proposed § 923.84.

Comment 35 (New York): Please further clarify, define and provide examples of “standards” to be used in policies. How does this new requirement comport with the definition of an “enforceable policy?” Will standards allow probabilistic (Bayesian) statistics methods and tools in cases of future uncertainties?

Response: NOAA is not adding a new requirement for the content of enforceable policies and will use the definition of an enforceable policy under 15 CFR 930.11(h). NOAA is not providing further specificity to the regulatory requirement that enforceable policies must be some form of a directive or other standard for compliance, but “need not establish detailed criteria such that a proponent of an activity could determine the consistency of an activity without interaction with the State agency.” 15 CFR 930.11(h). A state may propose any manner of criteria for an enforceable policy and NOAA would determine whether in the specific context a probabilistic statistical method for an enforceable policy is a sufficient standard for compliance.

Comment 36 (Maine, Oregon, Coastal States Organization): Section 923.83(a)(8) calls on coastal states to “describe whether and how the program change will impact” the interests of federally-recognized tribes and natural

and cultural resources managed under a host of Federal laws. This provision, which appears related to coastal states’ consideration of the national interest, imposes a new and potentially significant and burdensome requirement on coastal states. We suggest that NOAA should continue to bear the burden of conducting the assessments called for by this provision if such assessments are needed. Federally-recognized tribes are the best ones to articulate whether and how a given proposed change may affect their interests. The trust responsibility for consideration of tribal interests and for compliance with consultation requirements of other Federal laws is NOAA’s responsibility. Federal agencies responsible for administration of the laws referenced in this section are best positioned to provide comments to NOAA on how a proposed change may relate to those laws.

Response: NOAA recognizes that it has responsibility for conducting potential government-to-government consultation with tribes as well as compliance for various consultations that may be needed under other Federal statutes. Section 923.85 describes NOAA’s responsibilities. However, when submitting a program change, NOAA needs the state’s assessment of whether it believes any tribal or other Federal law interests are impacted given a state’s local knowledge. NOAA is not asking the state to gather additional information or to reach out to tribes or to initiate and consult under other Federal statutes. Rather, NOAA is merely asking for information that a state may have for these consultation processes.

Comment 37 (California, Coastal States Organization, Maine): The commenters assert that, under § 923.84(b)(5), Federal preemption should not apply to state CZMA enforceable policies, because the state policies are implemented through a Federal statute, the CZMA. Further, they comment that NOAA should not make a determination of whether an enforceable policy is federally preempted and, therefore, not approvable. Rather, the determination should be made by state attorneys general or the courts. In making these comments, the commenters assert that NOAA’s application of the Federal preemption doctrine to the definition of enforceable policy in CZMA section 304(6a) is incorrect.

Response: Federal preemption of state law arises from the Supreme Court’s interpretation of the Supremacy Clause which states that the “Constitution, and the Laws of the United States . . . shall be the supreme Law of the land.” U.S.

Const., Art. VI, cl. 2. There are two main types of Federal preemption, both of which result in the invalidation of state law: Express preemption and implied preemption. Express preemption occurs when a Federal law explicitly conveys Congress’ intent to preempt state law or regulation. Implied preemption occurs when a state law conflicts with a Federal law, or Congress intends to “occupy the field” in a particular area of law. If a Federal law preempts a state policy, the policy is not legally binding under state law and shall not be an enforceable policy under 16 U.S.C. 1453(6a). NOAA will not approve for incorporation into a state’s management program a state policy that is expressly preempted by Federal law. NOAA also recognizes that situations may arise in which an approved enforceable policy is not expressly preempted by Federal law, but could be impliedly preempted by Federal law. In such situations, NOAA encourages states to coordinate with the applicable Federal agency to determine whether Federal law preempts application of the state’s enforceable policy.

Even though states review Federal actions under the CZMA Federal consistency authority (a Federal law requirement), the states apply their CZMA enforceable policies, which are based on state law, to review Federal actions. NOAA does not believe that the CZMA Federal consistency authority or NOAA’s approval of state enforceable policies for incorporation into state management programs, removes the application of Federal preemption to the state enforceable policies. The application of the Federal preemption doctrine to the CZMA and state enforceable policies as described in the proposed rule and in this final rule is NOAA’s long-standing position and does not represent a change in NOAA’s view or how NOAA would review state CZMA program changes under the revised regulations. NOAA believes that its application of Federal preemption to state CZMA enforceable policies is required by the definition of “enforceable policy” in CZMA section 304(6a) (must be legally binding under state law).

The Federal preemption doctrine results in the invalidation of state law, not Federal law. Therefore, even if a Federal law preempts a state’s enforceable policy, CZMA Federal consistency review still applies to Federal actions. For example, under the CZMA Federal consistency authority, states have routinely reviewed Federal actions that are regulated by a Federal law that preempts certain state law, such as: Onshore liquefied natural gas

terminals or oil and gas pipelines regulated by the Federal Energy Regulatory Commission (FERC) under the Natural Gas Act; hydroelectric facilities regulated by FERC under the Federal Power Act; abandonment of railway lines regulated by the Surface Transportation Board under the Revised Interstate Commerce Act; and impacts to marine mammals regulated by NOAA's National Marine Fisheries Service under the Marine Mammal Protection Act. In such instances, states conduct CZMA Federal consistency reviews by applying their enforceable policies of general applicability to address coastal effects of the proposed Federal actions.

NOAA has removed the phrase "on its face," from § 923.84(b)(5) as this term could be misinterpreted and is not needed when discussing Federal preemption.

Comment 38 (Maine, Coastal States Organization): Section 923.84(d)(6) is problematic and raises concerns about how it may be interpreted and applied to frustrate coastal states' efforts to address the potential effects of ocean-based activities on coastal resources. In order to secure jurisdiction to review an extra-territorial or unlisted activity or establish a "geographic location description" (GLD) under NOAA's rules, a coastal state need only show that a coastal effect is "reasonably foreseeable." As this term is typically used that refers to a level of knowledge or information that an average person may have based on experience. The basic problem with this provision is that, as applied, it may put the cart well before the horse by asking coastal states to prove too much, too soon. This provision appears to require a coastal state to make a significant factual showing establishing a direct causal link between such activities and foreseeable effect(s) simply in order to secure jurisdiction to review such activities for consistency with its enforceable policies. As a consequence, it has the potential to inappropriately shift the burden of coming forward with information regarding coastal effects to coastal states as opposed to Federal agencies or Federal applicants. Whereas subparts (1)–(4) call for factual information that may be reasonably available to a coastal state, subparts (5) and (6) in effect state core issues which a coastal state may want to examine in detail in light of the factual information called for by subparts (1)–(4).

Response: NOAA disagrees with the comment. Paragraphs 5 (impacts from the activity) and 6 (causal connection to coastal effects) have always been essential to NOAA's analysis when reviewing a change to a state's list of

Federal license or permit activities for Federal consistency review and state requests to add a geographic location description outside a state's coastal zone for Federal consistency purposes. (In addition, while not related to this rulemaking these have also been essential to NOAA review of state requests to review unlisted activities under the Federal consistency regulations at 15 CFR 930.54.)

Paragraphs 5 and 6 explain how a state makes the "reasonably foreseeable effects" argument. Paragraphs 1–4 and 8 have been developed to assist states in better understanding how to show effects under paragraphs 5 and 6, especially by using new geospatial tools such as the data portals for the Northeast and Mid-Atlantic Regional Ocean Plans and the Marine Cadastre developed by the Bureau of Ocean Energy Management (BOEM) and NOAA. In addition, while states should address all of the paragraphs 1–8 to make the most persuasive effects argument, the precursor language to paragraphs 1–8 includes the phrase "to the extent practicable," and NOAA has added to paragraph 6 the phrase "A reasonable showing of a causal connection"

Comment 39 (Maine, Coastal States Organization): Section 923.84(d)(7) would authorize NOAA to reject a coastal state's attempt to assert Federal consistency review authority through establishment of a geographic location description or a change in its list of Federal license and permit actions subject to consistency review based on NOAA's assessment of whether mitigation that may be proposed in the future would effectively eliminate the "coastal effect" necessary for such extensions of state review authority. This provision is problematic. Mitigation proposed to ameliorate adverse effects of a development or other activity cannot reliably be known or presumed until an actual proposal, such as a Federal permit application, has been filed. Accordingly, it is not clear how NOAA could conclude that mitigation which has not actually been proposed may eliminate a coastal effect. The question of whether and how the proposed mitigation may ameliorate the effect is best examined following detailed review of the proposed action and based on the understanding of project-specific effects that must be mitigated.

Response: NOAA believes that mitigation information may be relevant to determining reasonably foreseeable coastal effects. When mitigation is included as part of the programmatic requirements for a Federal activity a

state is requesting to add to its Federal consistency list or a geographic location description, the mitigation measures may be relevant in determining effects. NOAA understands that additional mitigation measures may ultimately be required for a project beyond those proposed and that these cannot be considered in determining effects if they are unknown at the time of NOAA's review.

NOAA agrees with the comment, in part, related to changes to state Federal consistency lists and state geographic location description proposals. NOAA has added language to the preamble description of paragraph 7 explaining that NOAA expects that the mitigation analysis would be used mostly for state case-by-case requests to review an unlisted activity, but still may be relevant for additions to state Federal consistency lists or state geographic location descriptions.

Comment 40 (Oregon): We are concerned with the last sentence of section 923.84(c) (Effect of Prior Program Change Approvals) regarding a previously approved enforceable policy that may become unenforceable if subsequent Federal law preempts state regulation of a particular activity. We are concerned with situations where a state has regulated an activity based on similar coastal effects. It is not clear how that would interplay with the "particular activity" preemption.

Response: This sentence has been revised to clarify that a previously approved enforceable policy will no longer be legally enforceable under state law if subsequent Federal law preempts the state policy. For example, if a state policy that NOAA previously approved as part of the state's management program has text that determines where someone can "site liquefied natural gas (LNG) terminals," that requirement would no longer be enforceable for CZMA purposes as states are federally preempted from siting LNG terminals, because the Energy Policy Act of 2005 amended the Natural Gas Act to give FERC exclusive authority for the siting of LNG terminals. States would still review applications to FERC for LNG terminals under the CZMA Federal consistency provision and apply its relevant enforceable policies that address coastal effects.

Comment 41 (Oregon): It would be helpful if NOAA identified what criteria were not met when they do not approve a portion of a plan or statute as enforceable.

Response: The criteria NOAA uses to approve or not to approve an enforceable policy are discussed in this

preamble and are contained in 15 CFR 930.11(h) and 15 CFR 923.84(b) and (c).

Comment 42 (Oregon): Regarding NOAA's decision criteria, we believe that the only applicable criteria are first, the program continues to meet the standards set forth in CZMA § 306(d), and second, the revised program does not place an unacceptable burden on a Federal agency operating in the coastal zone. Absent either of those circumstances, NOAA should approve any change to a coastal program.

Response: NOAA decision criteria must include the program approval standards in 16 U.S.C. 1455(d) and in corresponding program approval regulations in 15 CFR part 923, the program change requirements in 16 U.S.C. 1455(e), and criteria established for determining enforceable policies under 16 U.S.C. 1453(6a), 15 CFR 930.11(h), and as further described in 15 CFR part 923, subpart H. These criteria have been part of NOAA regulations and guidance for decades. NOAA is not making substantial changes to program change decision criteria in this final rule.

Changes from the Proposed Rule. NOAA modified the preamble language to further clarify how the Federal preemption doctrine applies to the CZMA. NOAA removed the phrase “on its face,” from § 923.84(b)(5) as this term could be misinterpreted and is not needed when discussing Federal preemption. NOAA revised § 923.84(c) to clarify that a previously approved enforceable policy will no longer be legally enforceable under state law if subsequent Federal law preempts the state policy. NOAA added to § 923.84(d)(6) the phrase “A reasonable showing of a causal connection to the proposed activity” This further emphasizes that the information described in § 923.84(d) does not require states to provide absolute proof of coastal effects, but to provide information to the “extent practicable” that supports a reasonable causal connection of coastal effects to the proposed activity.

§ 923.85 Procedural Requirements of Other Federal Law

This section describes compliance and consultations under other Federal law such as ESA, NHPA, MSFCMA or MMPA and also coordination with federally-recognized Indian Tribes. A “federally-recognized Indian Tribe” is an Indian or Alaska Native Tribe, Band, Nation, Pueblo, Village, or Community that the Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally Recognized

Indian Tribe List Act. *See* 82 FR 4915 (Jan. 17, 2017).

NOAA's action in approving a program change may require NOAA to coordinate with tribes or with other Federal agencies to determine if NOAA needs to consult under other Federal statutes. In some circumstances NOAA may need to conduct government-to-government consultation with tribes pursuant to applicable executive orders and Federal case law.

However, it is important to understand the nature of NOAA's discretion for the review and approval of program changes when informally or formally consulting on Endangered Species Act, other Federal consultations and addressing tribal concerns. NOAA can approve or deny a program change, but cannot affect the state's ability to enact a law and implement it at the state level. NOAA's approval of any state or local provisions as enforceable policies of the state's management program means those provisions can be used during a state's CZMA Federal consistency review.

The CZMA is a voluntary program and if a state chooses to participate it develops a management program unique to its state, based on state laws and policies pursuant to general program requirements in the CZMA and NOAA's regulations. As such, the national coastal zone management program is not a federally delegated program and if a state chooses not to participate NOAA does not implement a coastal management program in the state. Once NOAA approves a state's management program, NOAA cannot require a state to change its program. NOAA can, through periodic evaluations of a state's management program under CZMA section 312, establish necessary actions if NOAA finds a state is not adhering to its NOAA-approved program, but NOAA can only recommend that a state change its program to create a different state standard or to address emerging issues. If NOAA finds that a state is not adhering to its management program and the state does not remedy the issue, NOAA's only recourse is to impose financial sanctions by withholding a part of a state's annual CZMA implementation grant until the state remedies the issue or ultimately NOAA could decertify a state's management program.

If a state submits a program change, NOAA can approve or disapprove that program change. When NOAA reviews a program change, NOAA has a limited ability to require a state to make changes to state policies. If NOAA disapproves, this does not require a state to change state law. Therefore, there is no effect

from NOAA's denial on the implementation of state law at the state (or local government) level. NOAA's denial means the disapproved state policy is not part of the state's NOAA approved management program and cannot be used for CZMA Federal consistency purposes. NOAA cannot use a program change to require changes to other parts of a state's management program.

Changes from the Proposed Rule. NOAA made minor wording changes to § 923.85.

V. Miscellaneous Rulemaking Requirements

Executive Order 12372: Intergovernmental Review

This program is subject to Executive Order 12372.

Executive Order 13132: Federalism Assessment

NOAA has concluded that this regulatory action is consistent with federalism principles, criteria, and requirements stated in Executive Order 13132. The proposed changes in the program change regulations are intended to facilitate Federal agency coordination with coastal states, and ensure compliance with CZMA requirements. The CZMA and these revised implementing regulations promote the principles of federalism articulated in Executive Order 13132 by granting the states a qualified right to amend their federally-approved management programs to address activities that affect the land and water uses or natural resources of state coastal zones and to apply these amended management programs to Federal actions through the CZMA Federal consistency provision. CZMA section 307 and NOAA's implementing regulations (15 CFR part 930) balance responsibilities between Federal agencies and state agencies whenever Federal agencies propose activities, or applicants for a required Federal license or permit propose to undertake activities, affecting state coastal uses or resources. Through the CZMA, Federal agencies are required to carry out their activities in a manner that is consistent to the maximum extent practicable with federally-approved state management programs while licensees and permittees are to be fully consistent with the state programs. The CZMA and these implementing regulations provide a mechanism for states to object to Federal actions that are not consistent with the state's management program. A state objection prevents the issuance of the Federal permit or license, unless the

Secretary of Commerce overrides the objection. Because the CZMA and these regulations promote the principles of federalism and enhance state authorities, no federalism assessment need be prepared.

Executive Order 12866: Regulatory Planning and Review

This final rule is not significant for purposes of Executive Order 12866.

Regulatory Flexibility Act

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received that would change the certification that this action will not have a significant economic impact on a substantial number of small entities regarding this certification. As a result, a final regulatory flexibility analysis and not required and none was prepared.

Paperwork Reduction Act

This rule contains no additional collection-of-information requirement subject to review and approval by the Office of Management and Budget under the Paperwork Reduction Act; rather it changes the manner in which states provide information to NOAA and, in some cases, eliminates or reduces information currently required.

National Environmental Policy Act

NOAA has concluded that this action does not have the potential to pose significant impacts on the quality of the human environment. Further, NOAA has concluded that this final rule would not result in any changes to the human environment and that no extraordinary circumstances exist. Therefore, NOAA has concluded that this rulemaking does not have a significant impact on the human environment and is categorically excluded from the need to prepare an environmental impact statement pursuant to the requirements of NEPA in accordance with NAO 216–6A, Categorical Exclusion G7: Preparation of policy directives, rules, regulations, and guidelines of an administrative, financial, legal, technical, or procedural nature, or for which the environmental effects are too broad, speculative or conjectural to lend themselves to meaningful analysis and will be subject later to the NEPA process, either collectively or on a case-by-case basis.

See also the description above on NEPA compliance for program changes.

List of Subjects in 15 CFR Part 923

Administrative practice and procedure, Coastal zone, Reporting and record keeping requirements.

Nicole R. LeBoeuf,

Acting Assistant Administrator, for Ocean Services and Coastal Zone Management, National Oceanic and Atmospheric Administration.

For the reasons stated in the preamble, 15 CFR part 923 is amended as follows:

PART 923—COASTAL ZONE MANAGEMENT PROGRAM REGULATIONS

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

Authority: 16 U.S.C. 1451 *et seq.*; 31 U.S.C. 6506; 42 U.S.C. 3334; Sections 923.92 and 923.94 are also issued under E.O. 12372, July 14, 1982, 3 CFR 1982 Comp. p. 197, as amended by E.O. 12416, April 8, 1983, 3 CFR 1983 Comp. p. 186.

■ 2. Revise subpart H to read as follows:

Subpart H—Changes to Approved Management Programs

Sec.

923.80 General.

923.81 Program change procedures, deadlines, public notice and comment, and application of approved changes.

923.82 Program change submissions.

923.83 Program change materials.

923.84 Program change decision criteria.

923.85 Procedural requirements of other Federal law.

Subpart H—Changes to Approved Management Programs

§ 923.80 General.

(a) This subpart establishes the criteria and procedures by which any proposed change to approved management programs shall be made. The term “program change” includes all terms used in section 306(e) of the Act, including amendment, modification or other program change. Draft program changes submitted to NOAA for informal review and comment are not subject to these requirements. Unless otherwise specified, the term “NOAA” refers to the Office for Coastal Management, within NOAA’s National Ocean Service. (The Office for Coastal Management was formerly known as the Office of Ocean and Coastal Resource Management and the Coastal Services Center.)

(b) Pursuant to section 306(e) of the Act, a coastal state may not implement any change to a management program as part of its management program unless

the state submits, and NOAA approves, the change for incorporation into the state’s federally-approved management program. A state shall not use a state or local government policy or requirement as an “enforceable policy” under 16 U.S.C. 1453(6a) and § 930.11(h) of this subchapter for purposes of Federal consistency under 16 U.S.C. 1456 and part 930 of this subchapter, unless NOAA has approved the incorporation of, and subsequent changes to, the state or local policy into the state’s management program under this subpart. State or local government law not approved by NOAA as part of a state’s management program remain legal requirements for state and local government purposes, but not for CZMA Federal consistency purposes.

(c) For purposes of this subpart, program changes include changes to enforceable policies as well as changes to one or more of the following management program areas under part 923: Uses Subject to Management (Subpart B); Special Management Areas (Subpart C); Boundaries (Subpart D); Authorities and Organization (Subpart E); and Coordination, Public Involvement and National Interest (Subpart F).

(d) The phrase “enforceable policies” used in this subpart is described in 16 U.S.C. 1453(6a) and § 930.11(h) of this subchapter. Enforceable policies are the only policies states can use to determine whether a Federal action is consistent with its management program under section 307, the Federal Consistency provision, of the Act (16 U.S.C. 1456 and part 930 of this subchapter).

(e) Pursuant to section 306(e)(1) of the Act and § 923.135, NOAA may suspend all or part of any grant or cooperative agreement made under section 306 of the Act if the state has failed to submit a program change identified as a necessary action under section 312 of the Act and part 923, subpart L (Review of Performance) and pursuant to the requirements for NOAA to notify the Governor of a state under the enforcement provisions of § 923.135.

§ 923.81 Program change procedures, deadlines, public notice and comment, and application of approved changes.

(a) Pursuant to section 306(d)(6) of the Act and § 930.11(o) of this subchapter, all program changes shall be submitted to NOAA by: The Governor of a coastal state with an approved management program; the head of the single state agency designated under the management program to be the lead state agency for administering the CZMA; or the head of an office within the designated single state agency if the

state has authorized that person to submit program changes. Program changes may be submitted to NOAA on a cyclical basis (*e.g.*, quarterly, twice a year, annually) or as the changes occur.

(1) One (1) copy shall be submitted electronically using the Program Change Form on NOAA's Program Change website, <http://coast.noaa.gov/czmprogramchange>.

(i) If a state is not able to electronically send all or part of a program change to NOAA through NOAA's Program Change website, the state and NOAA shall agree to an alternative method (*e.g.*, email, electronic CD, or a state website). In such instances, NOAA will, to the extent practicable, post the program change to NOAA's Program Change website.

(ii) [Reserved]

(2) All deadlines and timeframes under this subpart shall start on the first full business day after the day NOAA receives a program change (Day 1). For example, if a submission is received on a Thursday, day one of NOAA's review period would be Friday; if the day of receipt is Friday and Monday is a Federal holiday, Day 1 would be Tuesday. All days, starting with Day 1, are included in the calculation of total time for a deadline, including weekends and Federal holidays, except for the last day (*e.g.*, Day 30 or Day 120). The day that NOAA's decision is due shall also end on a full business day. For example, if Day 30 is a Saturday, then NOAA's decision will be due the next Monday, or if Monday is a Federal holiday, on Tuesday. A state may request that NOAA's review period begin on a specified date following receipt by NOAA.

(b) Within 5 days of receipt of a program change submission, NOAA shall notify the state (via email or letter) of the date the program change was received and NOAA's expected decision deadline. NOAA will also notify the state within 10 days of receipt of a program change submission if NOAA determines the submission is incomplete. If NOAA determines a submission is incomplete, NOAA shall inform the state that the program change review timeline shall not start until the missing information is submitted. During NOAA's review of a program change request, NOAA may request additional information that NOAA needs to make its decision.

(c) NOAA's program change review period shall start on Day 1 pursuant to paragraph (a)(2) of this section, unless NOAA determines the submission is incomplete pursuant to paragraph (b) of this section. NOAA shall respond to the

state (via email or letter) within 30 calendar days after the date NOAA receives a program change. NOAA's approval is presumed if NOAA does not respond or extend its review period within the 30-day period. NOAA may extend its review period up to 120 days after receipt of a program change request, if NOAA so notifies the state during the 30-day period. NOAA can extend beyond 120 days only as necessary to meet the requirements of the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*). NOAA shall inform the state via email or letter whether NOAA approves, approves in part, approves with qualifications or denies the incorporation of the program change into the state's management program.

(d) States shall, to the extent practicable, consult with NOAA prior to state adoption of new or revised state laws, policies, regulations, and other changes the state intends to submit to NOAA as a program change. States are encouraged to submit draft program changes to NOAA for informal review and comment prior to submitting a program change. If consulted, NOAA shall review draft submissions to identify issues that would need to be addressed in the formal submission.

(e)(1) A state shall post a public notice of its program change on the state's management program website in a conspicuous manner, and email or mail the public notice to local and regional offices of relevant Federal agencies, Federal agency CZMA headquarter contacts identified on NOAA's Federal consistency website, affected local governments and state agencies, and to individuals requesting direct notice. To meet the requirement for direct public notice (via email or mail), states are encouraged to maintain a coastal management listserv or mailing list. In addition to posting the public notice on the state's website and notifying the parties described above, states may, but are not required to, publish the notice in any state bulletin or newspaper. The timing of the state's public notice. States will draft a public notice of a submission, which shall be included as part of the contents of the program change submission form. When NOAA posts the program change submission on its Program Change website, NOAA will notify the state management program via email. The state will then post its public notice on the state web page providing a link to the submission on NOAA's Program Change website. The state shall send the public notice and link to the state and local agencies, Federal agency contacts, and others who have requested the state's public notice.

Day 1 for NOAA review purposes will be the first business day after the state submits to NOAA the program change request. However, the 21-day comment period shall not start until the state posts its public notice on the state web page. If a state fails to post its public notice, then NOAA may either determine the program change submission is not complete and the review period has not started or deny the program change request.

(2) A state's public notice shall:

(i) Describe the changes to the management program;
(ii) If applicable, identify any new, modified or deleted enforceable policies of the management program;
(iii) Indicate that any comments on the incorporation of the program change into the state's management program shall be submitted to NOAA through NOAA's Program Change website within 21 calendar days of the date of the state's public notice; and

(3) NOAA shall post all program changes on its Program Change website where any interested party may review or download materials. NOAA shall also post on its Program Change website deadlines, extensions and any comments received. For each program change posted on NOAA's website, NOAA shall notify the Federal agency CZMA headquarter contacts (identified on NOAA's Federal consistency website) via email. In addition, any party may request through the Program Change website that NOAA notify them via email when program changes are submitted by one or more state(s). NOAA's email shall also state that any party may, through NOAA's Program Change website, submit comments to NOAA on a state's request to incorporate a program change into the state's management program within 21 calendar days from the date of the state's public notice. NOAA shall only consider public and Federal agency comments for program change requests that are pending for a NOAA decision; no comments shall be accepted or considered for program changes once NOAA issues its decision. If a state, during or after the public comment period, submits directly to NOAA a response to a comment before NOAA issues a decision, NOAA shall consider the state's response and post the state's response on the Program Change website.

(4) NOAA may, at its discretion, extend the public comment period or hold a public hearing. NOAA shall only consider holding a public hearing for a program change that would substantially change a management program and/or be controversial.

(5) NOAA shall post its program change decisions on its CZMA Program Change website and shall notify, by email, Federal agency CZMA headquarter contacts and individuals requesting such notice. A state shall post NOAA's decision regarding a state's program change on the state agency's website.

(f) Application of approved program changes for Federal consistency purposes under section 307 of the Act (16 U.S.C. 1456) and part 930 of this subchapter. The effective date for the approved changes will be the date on NOAA's approval letter. NOAA will post its program change decision letters on its Program Change website. Changes to a state's management program and enforceable policies shall apply for Federal consistency purposes to Federal actions proposed on or after the date NOAA approves the changes. Approved program changes shall not apply retroactively to state Federal consistency reviews under 15 CFR part 930 initiated prior to the date NOAA approved the changes, except as allowed by part 930 (*e.g.*, a Federal action was finalized or authorized and there is a substantial change, amendment or renewal proposed for the Federal action on or after the date of NOAA's approval of a program change, pursuant to the applicable subpart of part 930).

§ 923.82 Program change submissions.

(a) As required by CZMA section 306(e)(3)(A), coastal states may not implement a change as part of its approved management program unless the change is approved by NOAA. In accordance with §§ 923.81 and 923.83, states shall submit program changes to NOAA for approval using the Program Change Form on NOAA's Program Change website.

(b) All state program changes shall identify the program approval area(s) that apply to the program change. The five program approval areas are: Uses Subject to Management (subpart B of this part); Special Management Areas (subpart C of this part); Boundaries (subpart D of this part); Authorities and Organization (subpart E of this part); and Coordination, Public Involvement and National Interest (subpart F of this part).

(c) Program changes that are editorial, non-substantive, or minor in scope. The types of program changes in paragraphs (c)(1) through (4) of this section shall be approved by NOAA and need less review as long as they satisfy the decision criteria in § 923.84 and do not raise issues under any Federal laws, as described in § 923.85:

(1) Editorial or non-substantive changes (*e.g.*, citation changes, minor technical changes, or changes to state agency name) to state laws, regulations, enforceable policies, local government coastal management programs, special area management plans, and other authorities;

(2) Changes that do not change a state's coastal zone boundary or geographic location description(s), and are not otherwise used by the state for Federal consistency review;

(3) Changes to the organization of a state's management program if the management program's structure and responsibilities will remain intact; and

(4) Changes to enforceable policies previously approved by NOAA that make minor substantive revisions consistent with the scope and application of the previously approved enforceable policy. If the proposed changes are not consistent with the scope and application of the previously approved enforceable policy, then NOAA shall more closely review the changes under paragraph (d) of this section to ensure they satisfy the decision criteria.

(d) Any program change that is not described in paragraph (c) of this section shall be reviewed by NOAA to ensure the state's management program will remain approvable if the proposed program change is approved. These changes include:

(1) Changes to the five program approval areas, including: Uses Subject to Management (subpart B of this part); Special Management Areas (subpart C of this part); Boundaries (subpart D of this part); Authorities and Organization (subpart E of this part); and Coordination, Public Involvement and National Interest (subpart F of this part);

(2) Changes to enforceable policies, including modifications, additions and deletions;

(3) Changes to provisions that are not enforceable policies, but which a state may use to evaluate the scope or applicability of an enforceable policy (*e.g.*, definitions, advisory statements);

(4) Changes to local government coastal management programs or plans if those local programs or plans contain enforceable policies that the state uses for Federal consistency review. States are not required to submit program changes for local government coastal management programs or plans that do not contain enforceable policies for Federal consistency review;

(5) Changes or additions to the state's Federal consistency list or geographic location descriptions (part 930 of this subchapter); and

(6) Changes or additions to Necessary Data and Information (§ 930.58 of this subchapter).

(e) Changes to state Clean Air Act (CAA) and Clean Water Act (CWA) Pollution Control Requirements. Pursuant to section 307(f) of the Act, requirements established by the CWA (33 U.S.C. 1251–1387) and the CAA (42 U.S.C. 7401–7671), or established by the Federal Government or by any state or local government pursuant to the CWA and CAA shall be incorporated in state management programs and shall be the water pollution control and air pollution control requirements applicable to such management program. Therefore, states are not required to submit as program changes any changes to state CAA and CWA provisions.

§ 923.83 Program change materials.

(a) All program changes submitted to NOAA shall be submitted in accordance with § 923.81. States shall use the Program Change website Form and Table to provide the following.

(1) A brief general overview description of the proposed program change(s) and a current version of the document(s) containing the program change (*e.g.*, text of the revised statute, regulation, policy, map). The general overview description shall identify the law, regulation, policy, or other type of program provision contained in the program change submission.

(2) A brief summary of the changes of each authority or policy identified in paragraph (a)(1) of this section, and how the management program as changed is different than the previously approved management program.

(3) Indicate which of one or more of the five management program approval areas under this part apply to the program change:

(i) Uses Subject to Management (subpart B);

(ii) Special Management Areas (subpart C);

(iii) Boundaries (subpart D);

(iv) Authorities and Organization (subpart E); or

(v) Coordination, Public Involvement and National Interest (subpart F).

(4) States shall use the Program Change Table provided by NOAA through the Program Change website to provide:

(i) The State legal citation for the policy (state code, public law number, state regulation, other official state format);

(ii) The title of the policy, section, or other descriptor;

(iii) Whether the change or policy is new, revised, or deleted;

(iv) The date the change was effective in the state;

(v) Identification of each enforceable policy submitted as part of the program change; and

(vi) The state enforceable mechanism citation that makes the policy enforceable under state law. The phrase “enforceable mechanism” means a state authority that makes an enforceable policy legally binding under state law, as described in this subpart and § 930.11(h) of this subchapter. Examples of an enforceable mechanism include state statutes, regulations, permitting programs, local government ordinances or court decisions. If an enforceable mechanism is changed so that an enforceable policy is no longer legally binding under state law, then the enforceable policy shall be submitted as a program change with a new underlying state enforceable mechanism; otherwise the policy is no longer enforceable for purposes of state CZMA Federal consistency reviews under part 930 of this subchapter.

(5) Changes or additions to the state’s Federal consistency list or geographic location descriptions.

(i) For each new or revised listed Federal action, states shall describe the:

(A) Type of Federal action;

(B) Specific Federal statutory authority;

(C) Responsible Federal agency; and

(D) Reasonably foreseeable effects to the uses and resources of the state’s coastal zone (§ 923.84(d)).

(ii) For each new or revised geographic location description, states shall describe the:

(A) Geographic location description, using specific geographic boundaries;

(B) Listed Federal actions to be included within a geographic location description; and

(C) Reasonably foreseeable effects to the uses and resources of the state’s coastal zone (§ 923.84(d)).

(6) States shall describe any changes or additions to Necessary Data and Information approved by NOAA in accordance with § 930.58 of this subchapter and explain why such information is necessary in order for the state to commence its Federal consistency review period.

(7) The state shall indicate that the program change meets each of NOAA’s decision criteria in § 923.84.

(8) The state shall describe whether and how the program change will impact the following:

(i) Resources or interests of any federally-recognized Indian Tribe.

(ii) Threatened or endangered species listed under the Federal Endangered Species Act (ESA);

(iii) Historic properties designated under the National Historic Preservation Act (NHPA);

(iv) Essential fish habitat designated under the Magnuson Stevens Fishery Conservation and Management Act (MSFCMA); and

(v) Marine mammals managed under the Marine Mammal Protection Act (MMPA).

(9) The state shall identify the state’s website where the public notices for the notification and submission requests are, or will be, located and where, if applicable, state documents related to the request may be viewed.

(10) The state shall submit to NOAA any substantive correspondence between the state and Federal agencies (not including NOAA’s Office for Coastal Management) concerning the development of the changes that are the subject of the program change request.

(11) The state shall indicate if the program change was developed as a necessary action pursuant to section 312 of the Act (16 U.S.C. 1458—Review of performance) and, if so, shall briefly describe the necessary action.

(b) [Reserved]

§ 923.84 Program change decision criteria.

(a) NOAA shall review all program changes on a case-by-case basis. NOAA shall determine whether a management program, if changed, would continue to satisfy the applicable program approval criteria of CZMA section 306(d) and subparts B through F of this part and the requirements of this subpart (subpart H).

(b) Enforceable policies. In order for NOAA to approve the incorporation of a new or revised enforceable policy into a state’s management program, the policy shall:

(1) Be legally binding under state law;

(2) Contain standards of sufficient specificity to guide public and private uses. A policy is not enforceable if it merely directs a state agency to develop regulations or standards.

(i) Definitions and information requirements are essential elements of determining compliance with regulatory and permit standards. As such, a state law or regulation that contains numerous standards, definitions, and information requirements may be considered enforceable in its entirety after consultation with NOAA. If NOAA determines that a law or regulation may be considered enforceable in its entirety, a state shall still need to apply only the substantive standards within the statute or regulation as enforceable policies for CZMA Federal consistency reviews. Procedural requirements are not considered to be enforceable policies for CZMA review purposes.

(ii) [Reserved]

(3) Apply only to areas and/or entities under state jurisdiction;

(4) Not refer to or otherwise purport to apply to Federal agencies, Federal lands or Federal waters. The Act does not authorize states to establish regulatory standards for Federal agencies or for Federal lands or waters. A state policy that would regulate or otherwise establish standards for Federal agencies or Federal lands or waters shall not meet the Act’s definition of “enforceable policy” (*i.e.*, legally binding under state law) under 16 U.S.C. 1453(6a). States apply their NOAA-approved enforceable policies to Federal actions, regardless of location, through CZMA Federal consistency reviews under 16 U.S.C. 1456 and part 930 of this subchapter;

(5) Not be preempted by Federal law. If a state policy is preempted by Federal law, the policy is not legally binding under state law and shall not be an enforceable policy under 16 U.S.C. 1453(6a). Policies previously approved by NOAA as enforceable policies shall no longer be enforceable if Federal law enacted after NOAA’s approval preempts the state policy;

(6) Not incorporate by reference other state or local requirements that are not identified, described and evaluated as part of the program change request. Any state or local requirements incorporated by reference shall not be applicable for Federal consistency review purposes unless separately approved by NOAA as enforceable policies;

(7) Not discriminate against a particular type of activity or entity. Enforceable policies shall be applied to all relevant public and private entities that would have similar coastal effects. Enforceable policies may be specific to a particular type of activity or entity if NOAA agrees that a state has demonstrated that the activity or entity present unique circumstances; and

(8) Not adversely affect the national interest in the CZMA objectives described in 16 U.S.C. 1451 and 1452.

(c) If enforceable policies previously approved by NOAA become obsolete or unenforceable through application of subsequently enacted state or Federal law, such policies will no longer be enforceable for purposes of CZMA Federal consistency review. For example, a state law change may repeal a previous policy or may change the policy in a manner that changes the scope and application of the policy. In such cases, the previously approved enforceable policy is no longer applicable under state law and the new or substantially revised policy is not applicable for Federal consistency

purposes until that policy has been submitted by the state as a program change and approved by NOAA. A previously approved enforceable policy will no longer be legally enforceable under state law if subsequent Federal law preempts the state policy.

(d) Changes to a management program's Federal consistency list or a new or revised geographic location description under part 930 of this subchapter, subparts C, D, E, F or I. For changes to a management program's list of Federal actions or a new or revised geographic location description, the state's effects analysis shall be based on information that would allow NOAA to find that the listed activity, either within the state's coastal zone or within a geographic location described outside the state's coastal zone, would have reasonably foreseeable effects on the uses or resources of the state's coastal zone. A state's analysis asserting impacts to uses or resources outside of the coastal zone shall not, by itself, demonstrate a coastal effect; rather, the state shall describe a causal connection of how an impact outside the coastal zone could result in a coastal effect. A state's effects analysis shall not be based on unsupported conclusions, speculation or the mere existence of coastal uses or resources within a geographic location. A state's coastal effects analysis shall, to the extent practicable, identify:

(1) The affected uses (*e.g.*, commercial and recreational fishing, boating, tourism, shipping, energy facilities) and resources (*e.g.*, fish, marine mammals, reptiles, birds, landmarks).

(2) Where and in what densities the uses and resources are found.

(3) How the state has a specific interest in the resource or use. States should be specific in showing the connection to the coastal zone of the state (*e.g.*, economic values, harvest amounts, vulnerabilities, seasonal information relevant to the proposed activity).

(4) Where the proposed activity overlaps with these resources, uses and values.

(5) Impacts to the resources or uses from the proposed activity.

(6) A reasonable showing of a causal connection to the proposed activity, including how the impacts from the activity results in reasonably foreseeable effects on the state's coastal uses or resources.

(7) Why any required mitigation may be inadequate.

(8) Empirical data and information that supports the effects analysis and: Can be shown to be reliable; visualizes the affected area, resources and uses

with maps; and shows values, trends and vulnerabilities.

§ 923.85 Procedural requirements of other Federal law.

NOAA shall determine on a case-by-case basis whether each program change requires NOAA to take additional actions under any other Federal requirements.

(a) If a state's program change will affect the resources or interests of any federally-recognized Indian Tribe (tribe), NOAA shall contact the affected tribe(s) and determine if Government-to-Government consultation is desired under Executive Order 13175 (Nov. 6, 2000).

(b) If, for the purposes of ESA, NHPA, MSFCMA or MMPA compliance, NOAA determines that a state's program change will have effects on listed threatened or endangered species, historic properties, essential fish habitat or marine mammals, then NOAA shall determine if consultation is needed with the applicable Federal agency under the ESA, NHPA, MSFCMA and MMPA.

(c) When NOAA determines whether to consult under other Federal statutes or tribal executive orders, NOAA's ability to require changes to a state's proposed program change are limited by the following:

(1) Once NOAA approves a state's management program, NOAA cannot require a state to change its program. NOAA can, through periodic evaluations of a state's management program under section 312 of the Act, establish necessary actions if NOAA finds a state is not adhering to its NOAA-approved program, but NOAA can only recommend that a state change its program to create a different state standard or to address emerging issues; and

(2) NOAA can approve or disapprove a program change request. When NOAA reviews a program change, NOAA has a limited ability to require a state to make changes to state policies. If NOAA disapproves a program change request, this does not require a state to change state law. Therefore, there is no effect from NOAA's denial on the implementation of state law at the state (or local government) level. NOAA's denial means the disapproved state policy is not part of the state's NOAA-approved management program and cannot be used for CZMA Federal consistency purposes. NOAA cannot use a program change to require changes to other parts of a state's management program.

[FR Doc. 2019-16513 Filed 8-5-19; 8:45 am]

BILLING CODE 3510-08-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2019-0213]

RIN 1625-AA87

Security Zone; Burke Lakefront Airport, Lake Erie, Cleveland, OH

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a security zone for certain navigable waters of Lake Erie, Cleveland, OH. This action is necessary to protect the public and surrounding waterways from terrorist acts, sabotage, or other subversive acts, accidents, or other causes of a similar nature. This regulation prohibits persons and vessels from being in the security zone unless specifically authorized by the Captain of the Port (COTP) Buffalo or a designated representative.

DATES: This rule is effective September 5, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2019-0213 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, contact LT Sean Dolan, Chief Waterways Management Division at 716-843-9322 or email D09-SMB-SECBuffalo-WWM@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

Previously, COTP Buffalo implemented emergent security zones around Burke Lakefront Airport, Cleveland, OH, whenever Senior Government Officials or foreign dignitaries utilized the airport. On April 29, 2019, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Security Zone; Burke Lakefront Airport, Lake Erie, Cleveland, OH (84 FR 17981). There we stated why we issued the NPRM, and invited

comments on our proposed regulatory action related to this security zone. During the comment period that ended June 28, 2019, we received one comment.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70051. The purpose of the rulemaking is to ensure the safety and security of vessels, the public, and navigable waters within the security zone before, during, and after the arrival and departure of certain individuals. The COTP Buffalo determined that a security zone is necessary to protect those within the security zone and surrounding area from terrorist acts, sabotage, or other subversive acts, accidents, or other causes of a similar nature.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received one comment on our NPRM published April 29, 2019. The comment stated based upon our listed coordinates that we had the wrong distance contained within the zone. The comment also requested that we include a statement about the datum of the coordinates. In response to the comment we updated the distance from the shore covered by the security zone, and included a statement about the datum of the coordinates. There are no other changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a security zone that will be enforced only upon notice by the COTP Buffalo. The COTP Buffalo will provide notice of enforcement of the security zone established by this section, including publication in the **Federal Register** as practicable, in accordance with 33 CFR 165.7(a). Such means of notification may also include, but are not limited to Broadcast Notice to Mariners or Local Notice to Mariners. The COTP Buffalo will also issue a Broadcast Notice to Mariners notifying the public when enforcement of the security zone is established by this section is suspended.

The security zone will encompass all waters in Lake Erie within a line connecting the following geographical positions: 41°31'45" N, 081°39'20" W; then extending northwest to 41°32'23" N, 081°39'46" W; then extending southwest to 41°31'02" N, 081°42'10" W; then extending southwest to the shoreline at 41°30'38" N, 081°41'53" W (NAD 83); then following the shoreline back to the point of origin.

The Captain of the Port Buffalo determined that the security zone in this rule is necessary to protect Senior

Government Officials or foreign dignitaries. No vessel or person is permitted to enter the security zone without obtaining permission from the COTP or a designated representative. The Captain of the Port or his or her designated representative may be contacted via VHF Channel 16 or at 716-843-9525.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the need to protect individuals, personnel, vessels, the public, and surrounding waterways from terrorist acts, sabotage, or other subversive acts, accidents or other causes of a similar nature. We conclude that this rule will have a minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The security zone created by this rule will be relatively small, effective only during the time necessary to protect individuals, personnel, vessels, the public, and surrounding waterways, and is designed to minimize its impact on navigable waters. Furthermore, the security zone has been designed to allow vessels to transit around it. Thus restrictions on vessel movement within that particular area are expected to be minimal. Under certain conditions, moreover, vessels may still transit through the security zone when permitted by the Captain of the Port.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601-612, as amended,

requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the

various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves establishing a security zone that encompasses all waters in Lake Erie within a line connecting the following geographical positions: 41°31'45" N, 081°39'20" W; then extending northwest to 41°32'23" N, 081°39'46" W; then extending southwest to 41°31'02" N, 081°42'10" W; then extending southwest to the shoreline at 41°30'38" N, 081°41'53" W (NAD 83); then following the shoreline back to the point of origin. It is categorically excluded from further review under paragraph L[60](a) in Table 3–1 of U.S. Coast Guard Environmental Planning Implementing Procedures 5090.1. A Record of Environmental Consideration supporting this determination is

available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

- 2. Add § 165.913 to read as follows:

§ 165.913 Security Zone; Burke Lakefront Airport, Lake Erie, Cleveland, OH.

(a) *Location.* This security zone includes all waters extending from the surface to the sea floor within approximately 650 yards seaward from the shoreline of the Burke Lakefront Airport and encompasses all waters in Lake Erie within a line connecting the following geographical positions: 41°31'45" N, 081°39'20" W; then extending northwest to 41°32'23" N, 081°39'46" W; then extending southwest to 41°31'02" N, 081°42'10" W; then extending southwest to the shoreline at 41°30'38" N, 081°41'53" W (NAD 83); then following the shoreline back to the point of origin.

(b) *Definitions.* (1) Designated representative means any Coast Guard commissioned, warrant, or petty officers designated by the Captain of the Port Buffalo to monitor a security zone, permit entry into a security zone, give legally enforceable orders to persons or vessels within a security zone, and take other actions authorized by the Captain of the Port Buffalo.

(2) Public vessel means a vessel that is owned, chartered, or operated by the United States, or by a State or political subdivision thereof.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.33 of this part, entry into, transiting, or

anchoring within this security zone is prohibited unless authorized by the Captain of the Port Buffalo or her designated on-scene representative.

(2) All persons and vessels must comply with the instructions of the Coast Guard Captain of the Port Buffalo or a designated representative. Upon being hailed by the U.S. Coast Guard by siren, radio, flashing light or other means, the operator of a vessel shall proceed as directed.

(3) All vessels must obtain permission from the Captain of the Port Buffalo or a designated representative to enter, move within, or exit the security zone established in this section when the security zone is enforced. Vessels and persons granted permission to enter the security zone shall obey all lawful orders or directions of the Captain of the Port Buffalo or a designated representative. While within the security zone, all vessels shall operate at the minimum speed necessary to maintain a safe course.

(d) *Notice of Enforcement or Suspension of Enforcement.* The security zone established by this section will be enforced only upon notice of the Captain of the Port Buffalo. The Captain of the Port Buffalo will cause notice of enforcement of the security zone established by this section to be made by all appropriate means to the affected segments of the public including publication in the **Federal Register** as practicable, in accordance with 33 CFR 165.7(a). Such means of notification may also include, but are not limited to Broadcast Notice to Mariners or Local Notice to Mariners. The Captain of the Port Buffalo will issue a Broadcast Notice to Mariners notifying the public when enforcement of the security zone established by this section is suspended.

(e) *Exemption.* Public vessels as defined in paragraph (b) of this section are exempt from the requirements in this section.

(f) *Waiver.* For any vessel, the Captain of the Port Buffalo or a designated representative may waive any of the requirements of this section, upon finding that operational conditions or other circumstances are such that application of this section is unnecessary or impractical for the purposes of safety or environmental safety.

(g) *Authority.* In addition to 46 U.S.C. 70034 and 46 U.S.C. 70051, the authority for this section includes 46 U.S.C. 70116.

Dated: July 29, 2019.

L.M. Littlejohn,

Captain, U.S. Coast Guard, Captain of the Port Buffalo.

[FR Doc. 2019-16730 Filed 8-5-19; 8:45 am]

BILLING CODE 9110-04-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0140; FRL-9996-79]

Fluoxastrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluoxastrobin in or on cotton, undelinted seed and cotton, gin byproducts. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 6, 2019. Objections and requests for hearings must be received on or before October 7, 2019 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2018-0140, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDfRNNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2018-0140 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before October 7, 2019. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2018-0140, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the online

instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001.

- **Hand Delivery:** To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of June 14, 2018 (83 FR 27744) (FRL-9978-29), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7F8649) by Bayer CropScience, 2 T.W. Alexander Drive, P.O. Box 12014, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.609 be amended by establishing tolerances for residues of the fungicide fluoxastrobin, (1E)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl][5,6-dihydro-1,4,2-dioxazin-3-yl]methanone O-methylxime, in or on cotton, undelinted seed and cotton, gin byproducts at 0.01 parts per million (ppm). There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from

aggregate exposure to the pesticide chemical residue”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fluoxastrobin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluoxastrobin follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

In mammals, the liver and kidney were the main target organs. Liver effects (cholestasis) were observed in dogs following subchronic and chronic oral exposures. Dogs were the more sensitive species, with liver effects occurring at a 35-fold lower dose than elicited adverse effects in other species. Kidney effects were observed in rats and dogs following subchronic exposures but not following chronic exposures. In rats, effects were also observed in the adrenal glands, urinary bladder, and urethra. There were dose-related changes in the liver and kidneys of

mice; however, the changes were not considered to be adverse.

There was no evidence of increased quantitative or qualitative fetal or offspring susceptibility in the developmental toxicity study in the rats or rabbits and two-generation reproduction toxicity study in rats. In the two-generation reproduction study in rats, the only effects observed were in both the offspring and the parental animals at the same dose. No developmental effects were observed in the rat and rabbit developmental studies.

Fluoxastrobin has low acute toxicity via the oral, dermal, and inhalation routes of exposure. Overall, it is mildly irritating to the eyes, but is neither a dermal irritant nor a dermal sensitizer. Fluoxastrobin has been classified by the Cancer Assessment Review Committee (CARC) as “not likely to be carcinogenic to humans” based on the absence of treatment-related tumors in two adequate rodent carcinogenicity studies. There was no concern for mutagenicity.

Specific information on the studies received and the nature of the adverse effects caused by fluoxastrobin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document, “Human Health Risk Assessment in Support of Application to Avocado, Barley, Rapeseed subgroup 20A, and Dried Shelled Pea and Bean on pages 14 and 15 in docket ID number EPA-HQ-OPP-2015-0727”.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints for fluoxastrobin used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUOXASTROBIN FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All Populations)	No appropriate toxicological effect attributable to a single dose was observed. Therefore, a dose and endpoint were not identified for this risk assessment.		
Chronic dietary (All populations)	NOAEL= 1.5 mg/kg/day UF _A = 10X UF _H = 10X FQPA SF = 1X	Chronic RfD = 0.015 mg/kg/day cPAD = 0.015 mg/kg/day.	Chronic Toxicity Study in Dogs. LOAEL = M/F 8.1/7.7 mg/kg/day based on body weight reductions and hepatocytomegaly and cytoplasmic changes associated with increased serum liver alkaline phosphatase indicative of cholestasis.
Incidental oral short-term (1–30 days) and Intermediate-term (1–6 months).	NOAEL= 3.0 mg/kg/day UF _A = 10X UF _H = 10X FQPA SF = 1X	LOC for MOE = <100.	90-Day Toxicity in Dogs. LOAEL = 24 mg/kg/day based on reductions in body-weight gain and food efficiency, liver effects (cholestasis), and kidney effects (increased relative weights in females, degeneration of proximal tubular epithelium in males).
Dermal short-term (1–30 days) and intermediate-term (1–6 months).	Oral study NOAEL = 3.0 mg/kg/day (dermal absorption rate = 2.3%) UF _A = 10X UF _H = 10X FQPA SF = 1X	Residential LOC for MOE = <100 Occupational LOC for MOE = <100.	90 Day Toxicity in Dogs. LOAEL = 24 mg/kg/day based on reductions in body-weight gain and food efficiency, liver effects (cholestasis), and kidney effects (increased relative weights in females, degeneration of proximal tubular epithelium in males).

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUOXASTROBIN FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Inhalation short and Intermediate-Term.	Oral study NOAEL = 3.0 mg/kg/day (inhalation toxicity is considered equivalent to oral toxicity) UF _A = 10X UF _H = 10X FQPA SF = 1X	Residential LOC for MOE = <100 Occupational LOC for MOE = <100.	90-Day Toxicity in Dogs. LOAEL = 24 mg/kg/day based on reductions in body-weight gain and food efficiency, liver effects (cholestasis), and kidney effects (increased relative weights in females, degeneration of proximal tubular epithelium in males).
Cancer (Oral, dermal, inhalation).	Classification: Fluoxastrobin is classified as “not likely to be carcinogenic to humans” based on the absence of treatment-related tumors in two adequate rodent carcinogenicity studies.		

Note: FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fluoxastrobin, EPA considered exposure under the petitioned-for tolerances as well as all existing fluoxastrobin tolerances in 40 CFR 180.609. EPA assessed dietary exposures from fluoxastrobin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for fluoxastrobin; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM-FCID, Version 3.16, food consumption data from the 2003–2008 U.S. Department of Agriculture’s (USDA’s) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance-level residues for livestock commodities, average field-trial residues for some crop commodities, and percent crop treated (PCT) and percent crop treated for new use (PCT_n) estimates for some commodities. DEEM version 7.81 default processing factors were assumed, except for tolerances that were established for processed commodities or when processing studies showed no concentration.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fluoxastrobin does not pose a cancer risk to humans. Therefore,

a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may

require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows: Corn, 1.0%; peanuts, 1.0%; peppers, 1.0%; potatoes, 1.0%; soybeans, 1.0%; and wheat, 2.5%. In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figures for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding up to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the most recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

The Agency estimated the PCT for new uses as follows: Avocado, 12%; barley, 16%; canola, 9%; and dry beans/peas, 15%. EPA estimates PCT_n of fluoxastrobin based on the PCT of the dominant pesticide (*i.e.*, the one with the greatest PCT) used on that crop over

the three most recent years of available data. Comparisons are only made among pesticides of the same pesticide types (*i.e.*, the dominant fungicide on the crop is selected for comparison with a new fungicide). The PCTs included in the analysis may be for the same pesticide or for different pesticides since the same or different pesticides may dominate for each year. Typically, EPA uses USDA/NASS as the source for raw PCT data because it is publicly available and does not have to be calculated from available data sources. When a specific use site is not surveyed by USDA/NASS, EPA uses proprietary market research data or other publicly available state data when 80% or more of the crop acreage is grown in that state and calculates the PCTn. This estimated PCTn, based on the average PCT of the market leader, is appropriate for use in the chronic dietary risk assessment. This method of estimating a PCT for a new use of a registered pesticide or a new pesticide produces a high-end estimate that is unlikely, in most cases, to be exceeded during the initial five years of actual use. The predominant factors that bear on whether the estimated PCTn could be exceeded are (1) the extent of pest pressure on the crops in question; (2) the pest spectrum of the new pesticide in comparison with the market leaders as well as whether the market leaders are well-established for this use; and (3) resistance concerns with the market leaders. EPA has examined the relevant data and determined that it is unlikely that the actual PCT with fluoxastrobin on avocado, barley, canola (rapeseed subgroup 20A) and dried shelled pea and bean (crop subgroup 6C) will exceed the PCTn within the next five years.

The Agency believes that the three conditions discussed in Unit III.C.1.iv have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no

regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which fluoxastrobin may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for fluoxastrobin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluoxastrobin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

The estimated drinking water concentrations (EDWCs) in surface water resulting from the proposed fluoxastrobin uses were calculated using the pesticide water calculator (PWC). Groundwater EDWCs for fluoxastrobin were derived for the proposed and existing uses using PRZM-Groundwater (PRZM GW).

Based on PRZM GW, the EDWCs of fluoxastrobin for chronic exposures for non-cancer assessments are estimated to be 53.1 parts per billion (ppb) for surface water and 163 ppb for ground water. The more conservative modeled estimate of drinking water concentrations (163 ppb) was directly entered into the dietary exposure model to assess the contribution to drinking water and chronic dietary risk.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (*e.g.*, for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Fluoxastrobin is currently registered for the following uses that could result in residential exposures: Turf and ornamentals. EPA assessed residential exposure using the following assumptions:

i. *Residential Handler Exposure:* All registered fluoxastrobin product labels with residential use sites (*e.g.*, turf and ornamentals) require that handlers wear specific clothing (*e.g.*, long sleeve shirt/long pants) and/or use personal-protective equipment (PPE). Therefore, the Agency has made the assumption that these products are not intended for homeowner use and has not conducted a quantitative residential handler assessment.

ii. *Residential Post-Application Exposure:* Adults and children performing physical activities on turf and ornamentals during post-application activities (*e.g.*, high-contact lawn activities, mowing, and gardening) may receive dermal exposure to fluoxastrobin residues. Young children 1 to <2 years old may also receive incidental oral post-application exposure to fluoxastrobin from treated turf. Residential post-application exposure is expected to be short-term in duration. Intermediate-term exposures are not likely because of the intermittent nature of exposure to homeowners. Post-application dermal and hand-to-mouth exposure scenarios were combined for children 1 to <2 years old. This combination was considered a protective estimate of children's exposure. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found fluoxastrobin to share a common mechanism of toxicity with any other substances, and fluoxastrobin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fluoxastrobin does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different

margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* As discussed in Unit III.A., there is no evidence of quantitative or qualitative fetal or offspring susceptibility in the developmental toxicity studies in rats or rabbits nor in two-generation reproduction studies in rats.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for fluoxastrobin is complete.

ii. There is no indication that fluoxastrobin is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.

iii. There is no evidence that fluoxastrobin results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. A partially refined chronic aggregate dietary (food and drinking water) exposure and risk assessments were conducted. The assumptions of this dietary assessment include tolerance-level residues for livestock and some crop commodities, average field-trial residues for some crop commodities, and PCT plus PCTn estimates for some commodities.

EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluoxastrobin in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by fluoxastrobin.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the

estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, fluoxastrobin is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fluoxastrobin from food and water will utilize 28% of the cPAD for the general U.S. population and 71% of the cPAD for all infants <1-year-old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of fluoxastrobin is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fluoxastrobin is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to fluoxastrobin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 160 for adults and 100 for children (1–2 years old). Because EPA's level of concern for fluoxastrobin is an MOE below 100, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk

assessment for evaluating intermediate-term risk for fluoxastrobin.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fluoxastrobin is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to fluoxastrobin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology liquid chromatography methods with tandem mass-spectroscopy detection (LC/MS/MS) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for fluoxastrobin in/on cotton.

V. Conclusion

Therefore, tolerances are established for residues of fluoxastrobin, (1E)-2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl][5,6-dihydro-1,4,2-dioxazin-3-yl]methanone O-methylxime, in or on cotton, undelinted seed and cotton, gin byproducts at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR

67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 23, 2019.

Donna Davis,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.609(a)(1), amend the table by adding alphabetically the commodities “Cotton, gin byproducts” and “Cotton, undelinted seed” to read as follows:

§ 180.609 Fluoxastrobin; tolerances for residues.

(a) * * *

(1) * * *

Commodity				Parts per million
*	*	*	*	*
Cotton, gin byproducts				0.01
Cotton, undelinted seed				0.01
*	*	*	*	*

* * * * *

[FR Doc. 2019-16322 Filed 8-5-19; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 180117042-8884-02]

RIN 0648-XT010

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

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

ACTION: Temporary rule; inseason quota transfer.

SUMMARY: NMFS is transferring 15 metric tons (mt) of Atlantic bluefin tuna (BFT) quota from the Reserve category to the Harpoon category. With this transfer, the adjusted Harpoon category quota for the 2019 fishing season is 91 mt. The 2019 Harpoon category fishery is open until November 15, 2019, or until the Harpoon category quota is reached, whichever comes first. The action is based on consideration of the regulatory determination criteria regarding inseason adjustments, and applies to Atlantic tunas Harpoon category (commercial) permitted vessels.

DATES: Effective August 1, 2019, through November 15, 2019.

FOR FURTHER INFORMATION CONTACT: Sarah McLaughlin, 978-281-9260, or Larry Redd, 301-427-8503.

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) and as implemented by the United States among the various domestic fishing categories, per the allocations established in Amendment 7 to the 2006 Consolidated Atlantic Highly Migratory Species Fishery Management Plan (2006 Consolidated HMS FMP) (Amendment 7) (79 FR 71510, December 2, 2014), and in accordance with implementing regulations. NMFS is required under ATCA and the Magnuson-Stevens Act to provide U.S. fishing vessels with a reasonable opportunity to harvest the ICCAT-recommended quota.

The current baseline quotas for the Harpoon and Reserve categories are 46 mt and 29.5 mt, respectively. See § 635.27(a). To date for 2019, NMFS has published three actions that have adjusted the available 2019 Reserve category quota to 113 mt, including a recent action that adjusted the Harpoon category quota to 76 mt (84 FR 3724, February 13, 2019; 84 FR 6701, February 28, 2019; and 84 FR 35340, July 23, 2019). The 2019 Harpoon category fishery opened June 1 and is open through November 15, 2019, or until the Harpoon category quota is reached, whichever comes first.

Quota Transfer

Under § 635.27(a)(9), NMFS has the authority to transfer quota among fishing categories or subcategories, after considering regulatory determination criteria provided under § 635.27(a)(8). NMFS has considered the relevant determination criteria and their applicability to the Harpoon category fishery. These considerations include, but are not limited to, the following:

Regarding the usefulness of information obtained from catches in the particular category for biological sampling and monitoring of the status of the stock (§ 635.27(a)(8)(i)), biological samples collected from BFT landed by Harpoon category fishermen and provided by BFT dealers continue to provide valuable data for ongoing scientific studies of BFT age and growth, migration, and reproductive status. Additional opportunity to land BFT in the Harpoon category would support the continued collection of a broad range of data for these studies and for stock monitoring purposes.

NMFS also considered the catches of the Harpoon category quota to date and the likelihood of closure of that segment of the fishery if no adjustment is made (§ 635.27(a)(8)(ii) and (ix)). As of July 30, 2019, the Harpoon category has landed 71.1 mt. Commercial-size BFT are currently readily available to vessels fishing under the Harpoon category quota. Without a quota transfer at this time, Harpoon category participants would have to stop BFT fishing activities with very short notice, while commercial-sized BFT remain available in the areas Harpoon category permitted vessels operate. Transferring 15 mt of BFT quota from the Reserve category would result in a total of 91 mt being available for the Harpoon category for the 2019 Harpoon category fishing season.

Regarding the projected ability of the vessels fishing under the particular category quota (here, the Harpoon category) to harvest the additional

amount of BFT before the end of the fishing year (§ 635.27(a)(8)(iii)), NMFS considered Harpoon category landings over the last several years. Landings are highly variable and depend on access to commercial-sized BFT and fishing conditions, among other factors. NMFS anticipates that the Harpoon category could harvest the transferred 15 mt prior to the end of the Harpoon category season, subject to weather conditions and BFT availability. NMFS may transfer unused Harpoon category quota to other quota categories, as appropriate. NMFS also anticipates that some underharvest of the 2018 adjusted U.S. BFT quota will be carried forward to 2019 and placed in the Reserve category, in accordance with the regulations. Thus, this quota transfer would allow fishermen to take advantage of the availability of fish on the fishing grounds, consider the expected increases in available 2019 quota, and provide a reasonable opportunity to harvest the full U.S. BFT quota.

NMFS also considered the estimated amounts by which quotas for other gear categories of the fishery might be exceeded (§ 635.27(a)(8)(iv)) and the ability to account for all 2019 landings and dead discards. In the last several years, total U.S. BFT landings have been below the available U.S. quota such that the United States has carried forward the maximum amount of underharvest allowed by ICCAT from one year to the next. NMFS will need to account for 2019 landings and dead discards within the adjusted U.S. quota, consistent with ICCAT recommendations, and anticipates having sufficient quota to do that.

NMFS also considered the effects of the adjustment on the BFT stock and the effects of the transfer on accomplishing the objectives of the FMP (§ 635.27(a)(8)(v) and (vi)). This transfer would be consistent with the current quotas, which were established and analyzed in the 2018 BFT quota final rule (83 FR 51391, October 11, 2018), and with objectives of the 2006 Consolidated HMS FMP and amendments and is not expected to negatively impact stock health or to affect the stock in ways not already analyzed in those documents. Another principal consideration is the objective of providing opportunities to harvest the full annual U.S. BFT quota without exceeding it based on the goals of the 2006 Consolidated HMS FMP and amendments, including to achieve optimum yield on a continuing basis and to optimize the ability of all permit categories to harvest their full BFT

quota allocations (related to § 635.27(a)(8)(x)).

Based on the considerations above, NMFS is transferring 15 mt of the available 113 mt of Reserve category quota to the Harpoon category. Therefore, NMFS adjusts the Harpoon category quota to 91 mt for the 2019 Harpoon category fishing season (*i.e.*, through November 15, 2019, or until the Harpoon category quota is reached, whichever comes first), and adjusts the Reserve category quota to 98 mt.

Monitoring and Reporting

NMFS will continue to monitor the BFT fishery 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 adjustments and closures, and may result in enforcement actions. Additionally, and separate from the dealer reporting requirement, Harpoon category vessel owners are required to report their own 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 action (*i.e.*, quota and/or daily retention limit adjustment, or closure) is necessary to ensure available quota is 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 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. Affording prior notice and opportunity for public comment to implement the quota transfer for the remainder of 2019

is also contrary to the public interest as such a delay would likely result in closure of the Harpoon fishery when the baseline quota is met and the need to re-open the fishery, with attendant administrative costs and costs to the fishery. The delay would preclude the fishery from harvesting BFT that are available on the fishing grounds and that might otherwise become

unavailable during a delay. 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 these reasons, there also is good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness.

This action is being taken under § 635.27(a)(9), and is exempt from review under Executive Order 12866.

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

Dated: July 31, 2019.

Alan D. Risenhoover,

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

[FR Doc. 2019-16733 Filed 8-1-19; 4:15 pm]

BILLING CODE 3510-22-P

Proposed Rules

Federal Register

Vol. 84, No. 151

Tuesday, August 6, 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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2019-0566; Product Identifier 2018-CE-035-AD]

RIN 2120-AA64

Airworthiness Directives; Pacific Aerospace Limited Airplanes

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for Pacific Aerospace Limited Model 750XL airplanes. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as ineffective firewall sealing for firewall wiring penetrations. The FAA is issuing this proposed AD to require actions to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by September 20, 2019.

ADDRESSES: You may send comments by any of the following methods:

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

For service information identified in this proposed AD, contact Pacific Aerospace Limited, Airport Road, Hamilton, Private Bag 3027, Hamilton 3240, New Zealand; phone: +64 7843 6144; fax: +64 843 6134; email: pacific@aerospace.co.nz; internet: www.aerospace.co.nz. You may review this referenced service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

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-2019-0566; 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 proposed AD, 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:

Mike Kiesov, Aerospace Engineer, FAA, Small Airplane Standards Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4144; fax: (816) 329-4090; email: mike.kiesov@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2019-0566; Product Identifier 2018-CE-035-AD" at the beginning of your comments. The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. The FAA will consider all comments received by the closing date and may amend this proposed AD because of those comments.

The FAA will post all comments the FAA receives, 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 Civil Aviation Authority (CAA), which is the aviation authority for New Zealand, has issued AD DCA/750XL/31, dated July 5, 2018 (referred to after this as "the MCAI"), to correct an unsafe condition for Pacific Aerospace Limited Model 750XL airplanes. The MCAI states:

During a review of the installation of the aircraft main loom [part number] P/N 11-81021, possible ineffective sealing was identified for firewall wiring penetrations. DCA/750XL/31 is issued to mandate the instructions in Pacific Aerospace Mandatory Service Bulletin (MSB) PACSB/XL/101 issue 1, dated 9 May 2018, or later approved revision to improve the firewall sealing by installing new components (firewall penetration tubes, firesleeve and hose clips).

The CAA advised the design is non-compliant with regard to the fireproof requirements for firewalls. Ineffective sealant may fail to prevent fire propagation through the firewall, which could result in smoke or fire in the cockpit. The CAA issued the MCAI to correct this unsafe condition. You may examine the MCAI on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0566.

Related Service Information Under 14 CFR Part 51

Pacific Aerospace Limited has issued Pacific Aerospace Service Bulletin PACSB/XL/101, Issue 1, dated May 9, 2018. The service information provides instructions for installing improved firewall sealing for wiring penetration looms and correcting any damaged or chafed looms. 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 and Requirements of the Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI and service information referenced above. The FAA is proposing

this AD because the FAA evaluated all information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Costs of Compliance

The FAA estimates that this proposed AD will affect 22 products of U.S. registry. The FAA also estimates that it would take about 8 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is \$85 per work-hour. Required parts would cost about \$385 per product.

Based on these figures, the FAA estimates the cost of the proposed AD on U.S. operators to be \$23,430, or \$1,065 per product.

According to the manufacturer, some 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 costs in our cost estimate.

Authority for This Rulemaking

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

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

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to small airplanes, gliders, balloons, airships, domestic business jet transport airplanes, and associated appliances to the Director of the Policy and Innovation 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):

Pacific Aerospace Limited: Docket No. FAA–2019–0566; Product Identifier 2018–CE–035–AD.

(a) Comments Due Date

The FAA must receive comments by September 20, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Pacific Aerospace Limited Model 750XL airplanes, serial numbers up to and including 221, certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 71: Power Plant.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe

condition on an aviation product. The FAA is issuing this AD to prevent fire propagation through the firewall because of ineffective sealant, which could result in smoke or fire in the cockpit.

(f) Actions and Compliance

Unless already done, within 3 months after the effective date of this AD or within 300 hours time-in-service after the effective date of this AD, whichever occurs first, install new sealant components into the main loom firewall penetration hole and the ADAS or DAAM firewall penetration holes if installed by following the Accomplishment Instructions in Pacific Aerospace Mandatory Service Bulletin PACSB/XL/101, Issue 1, dated May 9, 2018, except you are not required to contact PAL if there is any chafing or damage on a loom. Instead, your repair must be accomplished before further flight using a method approved by the Manager, Small Airplane Standards Branch, FAA, using the contact information in paragraph (g) of this AD, or approved by the Civil Aviation Authority of New Zealand (CAA). For a repair method to be approved as required by this paragraph, the FAA or CAA approval letter must specifically refer to this AD.

(g) Alternative Methods of Compliance (AMOCs)

The Manager, Small Airplane Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Mike Kiesov, Aerospace Engineer, FAA, Small Airplane Standards Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4144; fax: (816) 329–4090; email: mike.kiesov@faa.gov. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(h) Related Information

Refer to MCAI CAA AD DCA/750XL/31, dated July 5, 2018, for related information. You may examine the MCAI on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2019–0566. For service information related to this AD, contact Pacific Aerospace Limited, Airport Road, Hamilton, Private Bag 3027, Hamilton 3240, New Zealand; phone: +64 7843 6144; fax: +64 843 6134; email: pacific@aerospace.co.nz; internet: www.aerospace.co.nz. You may review this referenced service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on July 19, 2019.

Melvin J. Johnson,

Aircraft Certification Service, Deputy Director, Policy and Innovation Division, AIR–601.

[FR Doc. 2019–16574 Filed 8–5–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 1**

[REG–118425–18]

RIN 1545–BO90

Section 199A Rules for Cooperatives and Their Patrons; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking; withdrawal of notice of proposed rulemaking; correction.

SUMMARY: This document contains a correction to a notice of proposed rulemaking; withdrawal of notice of proposed rulemaking (REG–118425–18) that was published in the **Federal Register** on June 19, 2019 (84 FR 28668). The proposed regulations provide guidance to cooperatives to which sections 1381 through 1388 of the Internal Revenue Code (Code) apply (Cooperatives) and their patrons regarding the deduction for qualified business income (QBI) under section 199A(a) of the Code as well as guidance to specified agricultural or horticultural cooperatives (Specified Cooperatives) and their patrons regarding the deduction for domestic production activities under section 199A(g) of the Code.

DATES: Written or electronic comments and requests for a public hearing are still being accepted and must be received by August 19, 2019.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, James Holmes at (202) 317–4137; concerning submission of comments or to request a public hearing, Regina Johnson, (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:**Background**

The proposed regulations that are the subject of this correction are under sections 199A and 1388 of the Internal Revenue Code.

Need for Correction

As published, the notice of proposed rulemaking; withdrawal of notice of proposed rulemaking (REG–118425–18) contains errors which may prove to be misleading and need to be clarified.

Correction of Publication

Accordingly, the notice of proposed rulemaking; withdrawal of notice of proposed rulemaking (REG–118425–18) that was the subject of FR Doc. 2019–

11501, published at 84 FR 28668 (June 19, 2019), is corrected to read as follows:

1. On page 28668, in the preamble, second column, under caption **ADDRESSES**, third line from the bottom of the paragraph, the language “118425–18” is corrected to read “118425–18”.

2. On page 28670, in the preamble, first column, the sixth line from the bottom of the last paragraph, the language “defined under section” is corrected to read “defined under”.

3. On page 28670, in the preamble, second column, the third line from the bottom of the last partial paragraph, the language “deduction and” is corrected to read “deduction, and”.

4. On page 28671, in the preamble, first column, the twelfth line from the bottom of the page, the language “deduction and” is corrected to read “deduction, and”.

5. On page 28671, in the preamble, second column, under the paragraph heading “*D. Determination of W–2 Wages and UBI of Qualified Property*”, the first line of the paragraph, the language “Section §” is corrected to read “Section”.

6. On page 28676, in the preamble, second column, under the paragraph V. Proposed § 1.199A–11, Wage Limitation, the sixth line of the paragraph, the language “2019–16” is corrected to read “2019–31”.

§ 1.99A–8 [Corrected]

■ 7. On page 28689, column 3, paragraph (d)(7), the fourth line, the language “applicable) by” is corrected to read “applicable, by”.

§ 1.99A–12 [Corrected]

■ 8. On page 28705, column 2, paragraph (h) *Example 2* (i), the seventh line, the language, “All of X,” is corrected to read “All of X’s,”.

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2019–16378 Filed 8–5–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 100**

[Docket Number USCG–2019–0631]

RIN 1625–AA08

Special Local Regulation; Atlantic Ocean, Key West, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a temporary special local regulation for the RWO Offshore World Championship on November 6, 8, and 10, 2019. This action is necessary to ensure safety of life on navigable waters on the waters of the Key West Main Ship Channel, Key West Turning Basin, and Key West Harbor Entrance in Key West, FL. This proposed rulemaking would prohibit persons and vessels from entering, transiting through, anchoring in, or remaining within the regulated area without permission from the Captain of the Port Key West or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before September 5, 2019.

ADDRESSES: You may submit comments identified by docket number USCG–2019–0631 using the Federal eRulemaking Portal at <https://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Ensign Vera Max, Sector Key West Waterways Management Division, Coast Guard; telephone (305) 292–8768, email SKWWaterways@uscg.mil.

SUPPLEMENTARY INFORMATION:**I. Table of Abbreviations**

CFR Code of Federal Regulations
COTP Captain of the Port
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

On May 20, 2019, Race World Offshore notified the Coast Guard that it will be conducting a high speed boat race from 9:30 a.m. to 4:30 p.m. on

November 6, 8, and 10, 2019.

Approximately 50 participants and 200 spectator craft will attend the event, which will take place in the Atlantic Ocean, off the tip of Key West, Florida, on the waters of the Key West Main Ship Channel, Key West Turning Basin, and Key West Harbor Entrance in Key West, FL. The Captain of the Port Key West has determined the potential hazards associated with the high speed boat race would be a safety concern for the participants, participant vessels, and the general public.

The purpose of this rulemaking is to protect event participants, spectators, and vessels on the navigable waters of the Key West Main Ship Channel, Key West Turning Basin, and Key West Harbor Entrance before, during, and after the scheduled event. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70041.

III. Discussion of Proposed Rule

The COTP Key West proposes to establish a temporary special local regulation from 9:30 a.m. through 4:30 p.m. on November 6, 8, and 10, 2019. The proposed special local regulation would consist of two regulated areas: (1) A race and safety buffer area and (2) a spectator area. These areas would prohibit persons and vessels from entering, transiting through, anchoring in, or remaining within the race area or buffer zone and prohibits vessels from transiting at speeds that cause wake within the spectator area, unless authorized by the Captain of the Port Key West or a designated representative. The special local regulation would cover all navigable waters in the Atlantic Ocean, off the tip of Key West, Florida, on the waters of the Key West Main Ship Channel, Key West Turning Basin, and Key West Harbor Entrance. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This NPRM has not

been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the location, duration, and time-of-day of the regulated area. Although persons and vessels may not enter, transit through, anchor in, or remain within the area without authorization from the COTP or a designated representative, they will be able to safely transit around the area. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the area, and the rule would allow vessels to seek permission to enter the area between race heats.

B. Impact on Small Entities

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

While some owners or operators of vessels intending to transit the regulated area may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small

entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132 (Federalism), if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01 and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this

action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a temporary special local regulation for a 7 hour duration on 3 days that would prohibit entry into the race area or buffer zone, and prohibit vessels from transiting at speeds that cause wake within the spectator area. Normally such actions are categorically excluded from further review under paragraph L61 in Table 3–1 of U.S. Coast Guard Environmental Planning Implementing Procedures 5090.1. A preliminary Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

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

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at <https://www.regulations.gov>. If your material cannot be submitted using <https://www.regulations.gov>, call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to <https://www.regulations.gov> and will include any personal information you have provided. For more about privacy and the docket, visit <https://www.regulations.gov/privacyNotice>.

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online

docket at <https://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 100

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

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 46 U.S.C. 70041; 33 CFR 1.05–1.

■ 2. Add a temporary § 100.799–0631 to read as follows:

§ 100.799–0631 Special Local Regulation; RWO World Championship, Key West, FL.

(a) *Locations*. The following regulated areas are established as special local regulations. All coordinates are North American Datum 1983.

(1) *Race and Safety Buffer Area*. Waters of the Atlantic Ocean of Key West, FL that are encompassed within the following points: Starting at Point 1 in position 24°32.506' N, 81°49.984' W; thence southwest to Point 2 in position 24°32.455' N, 81°49.040' W; thence northwest to Point 3 in position 24°32.559' N, 81°49.584' W; thence northwest to Point 4 in position 24°32.608' N, 81°49.628' W; thence northwest to Point 5 in position 24°33.095' N, 81°49.265' W; thence northeast to Point 6 in position 24°33.518' N, 81°48.902' W; thence northeast to Point 7 in position 24°33.908' N, 81°48.448' W; thence east to Point 8 in position 24°33.898' N, 81°48.364' W; thence southeast back to origin.

(2) *Spectator Area*. All waters of the Atlantic Ocean in Key West, FL that are encompassed within the following points: Starting at Point 1 in position 24°33.123' N, 81°49.290' W; thence northeast to Point 2 in position 24°33.545' N, 81°48.923' W; thence east to Point 3 in position 24°33.518' N, 81°48.902' W thence southwest to point 4 in position 24°33.095' N, 81°49.265' W thence west back to origin.

(b) *Definition*. As used in this section, the term “designated representative” means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a

Federal, State, and local officer designated by or assisting the Captain of the Port Key West in the enforcement of the safety zone.

(c) *Regulations*. (1) All non-participant persons and vessels, except those persons and vessels participating in the high-speed boat races, are prohibited from entering, transiting through, anchoring in, or remaining within the regulated areas described in paragraph (a) of this section unless authorized by the Captain of the Port Key West or their designated representative.

(2) All persons are prohibited from entering the water or swimming in the spectator area described in paragraph (a)(2) of this section.

(3) All vessels are prohibited from transiting at speeds that cause wake within the spectator area described in paragraph (a)(2) of this section.

(4) To seek permission to enter, contact the Captain of the Port Key West or a designated representative by telephone at (305) 433–0954, or via VHF radio on channel 16. If authorization is granted by the Captain of the Port Key West or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Key West or a designated representative.

(5) The Coast Guard will provide notice of the regulated area by Broadcast Notice to Mariners and on-scene designated representatives.

(d) *Enforcement Period*. This section will be enforced from 9:30 a.m. until 4:30 p.m. on November 6, 8, and 10, 2019.

Dated: July 31, 2019.

A.A. Chamie,

Captain, U.S. Coast Guard, Captain of the Port Key West.

[FR Doc. 2019–16740 Filed 8–5–19; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[EPA–HQ–OW–2015–0174; FRL–9997–42–OW]

RIN 2040–AF94

Withdrawal of Certain Federal Water Quality Criteria Applicable to Washington

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) proposes to amend the

federal regulations to withdraw certain human health criteria applicable to waters in Washington because Washington adopted, and the EPA approved, human health criteria that the EPA determined are protective of Washington's designated uses for its waters. The EPA is providing an opportunity for public comment on this proposed withdrawal of certain federally promulgated human health criteria. The withdrawal will enable Washington to implement its EPA-approved human health criteria, submitted on August 1, 2016, and approved on May 10, 2019, as applicable criteria for Clean Water Act (CWA or the Act) purposes.

DATES: Comments must be received on or before October 7, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OW-2015-0174, at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www2.epa.gov/dockets/commenting-epa-dockets>.

The EPA is offering two public hearings so that interested parties may also provide oral comments on this proposed rulemaking. For more details on the public hearings and to register to attend the hearings, please visit <https://www.epa.gov/wqs-tech/water-quality-standards-regulations-washington>.

FOR FURTHER INFORMATION CONTACT:

Erica Fleisig, Office of Water, Standards and Health Protection Division (4305T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 566-1057; email address: fleisig.eric@epa.gov.

SUPPLEMENTARY INFORMATION: This proposed rule is organized as follows:

- I. General Information
 - Does this action apply to me?
- II. Background
 - A. What are the applicable federal statutory and regulatory requirements?
 - B. What are the applicable federal water quality criteria that the EPA is proposing to withdraw?
- III. Statutory and Executive Order Reviews
 - A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
 - B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs
 - C. Paperwork Reduction Act (PRA)
 - D. Regulatory Flexibility Act (RFA)
 - E. Unfunded Mandates Reform Act (UMRA)
 - F. Executive Order 13132: Federalism
 - G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
 - H. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks
 - I. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use
 - J. National Technology Transfer and Advancement Act of 1995
 - K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

I. General Information

Does this action apply to me?

This proposed action is proposing to withdraw certain federal human health criteria that are no longer needed due to the EPA's approval of corresponding state human health criteria on May 10, 2019. Entities discharging in Washington waters, citizens, as well as the state of Washington may be interested in this rulemaking, as after the completion of this rulemaking Washington's EPA-approved human health criteria, rather than the federal human health criteria, will be the applicable water quality standards in Washington waters for CWA purposes. If you have questions regarding the applicability of this action to a particular entity, consult the person identified in the preceding **FOR FURTHER INFORMATION CONTACT** section.

II. Background

A. What are the applicable federal statutory and regulatory requirements?

Consistent with the CWA, the EPA's water quality standards (WQS) program assigns to states and authorized tribes the primary authority for adopting

WQS.¹ After states adopt WQS, they must be submitted to the EPA for review and action in accordance with the CWA. The Act authorizes the EPA to promulgate federal WQS following the EPA's disapproval of state WQS or an Administrator's determination that new or revised WQS are "necessary to meet the requirements of the Act."²

On September 14, 2015, the EPA proposed a federal rule to establish updated human health criteria in Washington based on an Administrator's determination that new or revised WQS were necessary to meet the requirements of the Act. Specifically, in its 2015 proposed rulemaking, the EPA considered data representing regional and local fish consumption that reflected consumption levels much higher than the National Toxics Rule (NTR) fish consumption rate of 6.5 grams/day, and accordingly "determined that the federal human health criteria in the NTR as applied to Washington no longer protect the relevant designated uses of Washington's waters."³ To address the Administrator's determination pursuant to its section 303(c) authority, the EPA's proposed rulemaking established human health criteria using a fish consumption rate of 175 grams/day.⁴ As explained in the EPA's May 10, 2019, letter, the EPA also used all of the inputs from the EPA's recently updated 2015 CWA section 304(a) recommendations to calculate the proposed federal criteria.⁵

Following the EPA's 2015 proposed rulemaking, on August 1, 2016, Washington submitted human health criteria for the EPA's review.⁶ Washington's criteria were based on a fish consumption rate of 175 grams/day and incorporated most of the components of the EPA's updated 2015 CWA section 304(a) recommendations.⁷ By using a fish consumption rate of 175 grams/day which is consistent with the EPA's proposed rulemaking,

¹ 33 U.S.C. 1313(a), (c).

² 33 U.S.C. 1313(c)(4).

³ *Revision of Certain Water Quality Standards Applicable to Washington*, 80 FR 55063, 55066 (September 14, 2015).

⁴ *Id.* at 55066–55067.

⁵ May 10, 2019. Letter and enclosed Technical Support Document from Chris Hladick, Regional Administrator, EPA Region 10 to Maia Bellon, Director, Department of Ecology, Re: The EPA's Reversal of the November 15, 2016 Clean Water Act Section 303(c) Partial Disapproval of Washington's Human Health Water Quality Criteria and Decision to Approve Washington's Criteria, at 7.

⁶ Department of Ecology. *Washington State Water Quality Standards: Human health criteria and implementation tools, Overview of key decisions in rule amendment*. August 2016. Ecology Publication no. 16–10–025.

⁷ *Id.*

Washington's human health criteria addressed the basis for the EPA's 2015 Administrator's determination—that it is necessary to adopt new or revised human health criteria based on a higher fish consumption rate.

For the reasons explained in the EPA's 2016 disapproval letter and final federal rule, the EPA partially disapproved certain human health criteria that Washington submitted to the EPA.⁸ The EPA's final federal rule was issued concurrent with its partial disapproval letter.⁹ In explaining the rationale underlying the partial disapproval of Washington's August 1, 2016, submittal, the EPA "agree[d] with Washington's decision to derive the human health criteria using a FCR of 175 g/day," noting that that value was consistent with the EPA's final federal rule,¹⁰ however the EPA disagreed with the risk management decisions the State made during the development of its human health criteria and its decision not to incorporate all components of the updated 2015 CWA section 304(a) recommendations.¹¹

Although the EPA promulgated human health criteria for Washington in the NTR, and subsequently in November 2016, the EPA prefers that states maintain primary responsibility and establish their own WQS. In response to a February 21, 2017, petition from several entities asking the EPA to reconsider the partial disapproval of Washington's August 2016 human health criteria,¹² the EPA issued a letter

on August 3, 2018 stating its intent to reconsider its partial disapproval of Washington's human health criteria and its subsequent promulgation of federal criteria.¹³ After a thorough review of the State's 2016 submittal and applicable provisions of the CWA, implementing regulations and longstanding EPA guidance, on May 10, 2019, the EPA reconsidered its partial disapproval of Washington's human health criteria and approved all but two of the criteria that the EPA previously disapproved.¹⁴

As provided in 40 CFR 131.21(c), federally promulgated WQS that are more stringent than EPA-approved state WQS remain applicable for purposes of the CWA until the EPA withdraws the federal standards. Accordingly, the EPA is proposing to amend the federal regulations to withdraw those federally promulgated human health criteria for which the EPA has approved Washington's criteria and is providing an opportunity for public comment on this proposed action.

The EPA's proposal to withdraw federal criteria following approval of state criteria is consistent with the federal and state roles contemplated by the CWA. Consistent with the cooperative federalism structure of the CWA, once the EPA approves state WQS addressing the same pollutants for which the EPA has promulgated federal WQS, it is incumbent on the EPA to withdraw the federal WQS to enable the EPA-approved state WQS to become the applicable WQS for CWA purposes. That is what the EPA is proposing to do in this proposed rulemaking. This proposal is consistent with the EPA's withdrawal of other federally promulgated WQS following the EPA's

Quality Criteria and Implementation Tools, and Repeal of the Final Rule Revision of Certain Federal Water Quality Standards Applicable to Washington, 81 Fed. Reg. 85,417 (Nov. 28, 2016) submitted by Northwest Pulp & Paper Association, American Forest and Paper Association, Association of Washington Business, Greater Spokane Incorporated, Treated Wood Council, Western Wood Preservers Institute, Utility Water Act Group and Washington Farm Bureau.

¹³ August 3, 2018. Letter from David P. Ross, Assistant Administrator, Office of Water, EPA to Penny Shamblin, Counsel for Utility Water Act Group, Re: Petition for Reconsideration of the Environmental Protection Agency's (EPA) Partial Disapproval of Washington's Human Health Water Quality Criteria and Implementation Tools submitted by the State of Washington on August 1, 2016, and Repeal of the Final Rule Revision of Certain Federal Water Quality Standards Applicable to Washington.

¹⁴ May 10, 2019. Letter and enclosed Technical Support Document from Chris Hladick, Regional Administrator, EPA Region 10 to Maia Bellon, Director, Department of Ecology, Re: The EPA's Reversal of the November 15, 2016 Clean Water Act Section 303(c) Partial Disapproval of Washington's Human Health Water Quality Criteria and Decision to Approve Washington's Criteria.

approval of state-adopted WQS.¹⁵ Further, although the state of Washington opposes the EPA withdrawing the 2016 federal human health criteria, the State remains free to promulgate the federal standards into state law if it so chooses.¹⁶

Shortly before taking its action to approve Washington's human health criteria, the EPA received several letters expressing concerns about the EPA revising or repealing the federal criteria and the EPA's authority under the CWA to "propose new standards" for a state.¹⁷ As described herein, the EPA reconsidered the human health criteria that Washington submitted to the EPA in 2016 and approved the majority of those criteria. In light of that approval, the EPA proposes to amend federal regulations to withdraw the federal criteria the EPA previously promulgated for Washington. Thus, in this proposed rulemaking, the EPA is not proposing to promulgate any new or revised federal criteria for Washington. The EPA's authority to promulgate new or revised federal criteria is not at issue in this proposal to withdraw the federal criteria.

B. What are the applicable federal water quality criteria that the EPA is proposing to withdraw?

This action proposes to amend federal regulations to withdraw all federal human health criteria promulgated for Washington in November 2016 at 40 CFR 131.45,¹⁸ with the exception of

¹⁵ See e.g., *Withdrawal of Certain Federal Water Quality Criteria Applicable to California: Lead, Chlorodibromomethane, and Dichlorobromomethane*, 83 FR 52163 (Oct. 16, 2018); *Water Quality Standards for the State of Florida's Lakes and Flowing Waters; Withdrawal*, 79 FR 57447 (Sept. 25, 2014); *Withdrawal of Certain Federal Water Quality Criteria Applicable to California, New Jersey and Puerto Rico*, 78 FR 20252 (Apr. 4, 2013).

¹⁶ See May 7, 2019. Letter from Maia D. Bellon, Director, Washington Department of Ecology, to Hon. Andrew R. Wheeler, Administrator, EPA, Re: EPA's Intention to Reconsider Washington State's Water Quality Standards for Human Health Criteria.

¹⁷ May 8, 2019. Letter from Bob Ferguson, Attorney General, Washington, to Hon. Andrew R. Wheeler, Administrator, EPA; see also May 7, 2019. Letter from Maia D. Bellon, Director, Washington Department of Ecology, to Hon. Andrew R. Wheeler, Administrator, EPA, Re: EPA's Intention to Reconsider Washington State's Water Quality Standards for Human Health Criteria; May 7, 2019. Letter from Frances G. Charles, Chairwoman, to Hon. Andrew R. Wheeler, Administrator, EPA, Re: Washington State Water Quality Standards (Human Health Criteria); May 3, 2019. Letter from Justin Parker, Executive Director, Northwest Indian Fisheries Commission, to Hon. Andrew R. Wheeler, Administrator, and Mr. David Ross, Assistant Administrator, Office of Water, EPA, Re: EPA Action Regarding Washington's Human Health Water Quality Criteria.

¹⁸ *Revision of Certain Water Quality Standards Applicable to Washington*, 81 FR 85417 (November 28, 2016).

⁸ November 15, 2016. Letter (EPA Partial Disapproval Letter) and enclosed Technical Support Document (Partial Disapproval TSD) from Daniel D. Opalski, Director, Office of Water and Watersheds, EPA Region 10 to Maia Bellon, Director, Department of Ecology, Re: EPA's Partial Approval/Disapproval of Washington's Human Health Water Quality Criteria and Implementation Tools; 81 FR at 85417 ("Concurrent with this final rule, EPA is taking action under CWA 303(c) to approve in part, and disapprove in part, the human health criteria submitted by Washington.").

⁹ *Revision of Certain Water Quality Standards Applicable to Washington*, 81 FR 85417 (November 28, 2016). Contrary to at least one comment letter EPA received prior to its May 10, 2019 Decision to Approve Washington's criteria, the EPA did not provide the State with 90 days to remedy the partial disapproval, as envisioned in section 303(c)(3) of the Act. See May 7, 2019 Letter from the Lower Elwha Klallam Tribe to Administrator Andrew Wheeler, EPA, Re: Washington State Water Quality Standards at 4.

¹⁰ Partial Disapproval TSD at 16.

¹¹ May 10, 2019. Letter and enclosed Technical Support Document from Chris Hladick, Regional Administrator, EPA Region 10 to Maia Bellon, Director, Department of Ecology, Re: The EPA's Reversal of the November 15, 2016 Clean Water Act Section 303(c) Partial Disapproval of Washington's Human Health Water Quality Criteria and Decision to Approve Washington's Criteria, at 7–9.

¹² February 21, 2017. *Petition for Reconsideration of EPA's Partial Disapproval of Washington's August 1, 2016 submission on Human Health Water*

criteria for arsenic, methylmercury, and bis(2-chloro-1-methylethyl) ether. For arsenic, on May 10, 2019, the EPA reaffirmed its November 2016 disapproval of the two criteria Washington submitted for arsenic (water + organism and organism only), and therefore the federal arsenic criteria for Washington at 40 CFR 131.45 will remain in place.¹⁹ For methylmercury and bis(2-chloro-1-methylethyl) ether, Washington did not submit criteria for those pollutants and therefore the federally promulgated criteria are the only criteria in effect for those pollutants in the State. Although the EPA is proposing to maintain the federally promulgated criteria for these pollutants, the EPA is also soliciting comment on whether to withdraw the federally promulgated criteria for methylmercury and bis(2-chloro-1-methylethyl) ether.

1. Washington Human Health Criteria That the EPA Approved on May 10, 2019

On May 10, 2019, the EPA revised its disapproval of 141 of Washington's human health criteria and approved

those criteria. In addition, the EPA approved four criteria for two pollutants (thallium and 2,3,7,8-TCDD [dioxin]) that the EPA previously deferred action on in November 2016.²⁰

Because Washington now has 145 additional human health criteria approved by the EPA for CWA purposes, the EPA has determined that the 141 corresponding federally promulgated human health criteria are no longer needed in Washington. As noted in the EPA's May 10, 2019, action, the EPA determined upon reconsideration that Washington's 2016 human health criteria are scientifically sound and protective of the applicable designated uses in the state.²¹ More information on the EPA's action to approve Washington's human health criteria upon reconsideration, including the EPA's approval letter and associated Technical Support Document, can be accessed at <https://www.epa.gov/wqs-tech/water-quality-standards-regulations-washington> and in the docket for this proposed rulemaking.

As explained above, the EPA seeks public comment before withdrawing the federally promulgated criteria. Although

the EPA has determined that these state criteria are scientifically sound and protective of the applicable designated uses for waters in the state and otherwise meet the requirements of the CWA and EPA's implementing regulations at 40 CFR 131, the EPA recognizes that many of Washington's human health criteria are less stringent than the EPA's federally promulgated criteria which are based on the EPA's CWA section 304(a) criteria (see Table 1). However, as explained in the EPA's May 10, 2019, approval and Technical Support Document, the EPA's CWA section 304(a) criteria are national recommendations and states retain discretion to adopt different criteria, that may be less stringent, if the state's criteria are based on sound science and protect the designated use. In issuing the May 10, 2019, approval, the EPA determined that Washington's human health criteria meet the requirements of the CWA and the EPA's regulations because the State's inputs are based on sound science and the resulting criteria protect the designated uses.

TABLE 1—COMPARISON OF FEDERALLY PROMULGATED CRITERIA AND EPA-APPROVED WASHINGTON CRITERIA

Chemical	CAS No.	Washington's criteria that EPA approved on May 10, 2019		EPA Federally promulgated criteria at 40 CFR 131.45 that EPA is proposing to withdraw	
		Water & organisms (µg/L)	Organisms only (µg/L)	Water & organisms (µg/L)	Organisms only (µg/L)
1. 1,1,1-Trichloroethane	71556	47000	160000	20000	50000.
2. 1,1,2,2-Tetrachloroethane	79345	0.12	0.46	0.1	0.3.
3. 1,1,2-Trichloroethane	79005	0.44	1.8	0.35	0.90.
4. 1,1-Dichloroethylene	75354	1200	4100	700	4000.
5. 1,2,4-Trichlorobenzene	120821	0.12	0.14	0.036	0.037.
6. 1,2-Dichlorobenzene	95501	2000	2500	700	800.
7. 1,2-Dichloroethane	107062	9.3	120	8.9	73.
8. 1,2-Dichloropropane	78875	(*)	(*)	(*)	(*).
9. 1,2-Diphenylhydrazine	122667	0.015	0.023	0.01	0.02.
10. 1,2-Trans-Dichloroethylene	156605	600	5800	200	1000.
11. 1,3-Dichlorobenzene	541731	13	16	2	2.
12. 1,3-Dichloropropene	542756	0.24	2.0	0.22	1.2.
13. 1,4-Dichlorobenzene	106467	460	580	200	200.
14. 2,3,7,8-TCDD (Dioxin)	1746016	0.000000064	0.000000064	0.000000013	0.000000014.
15. 2,4,6-Trichlorophenol	88062	(*)	(*)	(*)	(*).
16. 2,4-Dichlorophenol	120832	25	34	10	10.
17. 2,4-Dimethylphenol	105679	(*)	(*)	(*)	(*).
18. 2,4-Dinitrophenol	51285	60	610	30	100.
19. 2,4-Dinitrotoluene	121142	(*)	(*)	(*)	(*).
20. 2-Chloronaphthalene	91587	170	180	100	100.
21. 2-Chlorophenol	95578	(*)	(*)	(*)	(*).
22. 2-Methyl-4,6-Dinitrophenol	534521	7.1	25	3	7.
23. 3,3'-Dichlorobenzidine	91941	(*)	(*)	(*)	(*).
24. 3-Methyl-4-Chlorophenol	59507	(*)	(*)	(*)	(*).
25. 4,4'-DDD	72548	0.000036	0.000036	0.0000079	0.0000079.

¹⁹ May 10, 2019. Letter and enclosed Technical Support Document from Chris Hladick, Regional Administrator, EPA Region 10 to Maia Bellon, Director, Department of Ecology, Re: The EPA's Reversal of the November 15, 2016 Clean Water Act Section 303(c) Partial Disapproval of Washington's Human Health Water Quality Criteria and Decision to Approve Washington's Criteria.

²⁰ May 10, 2019. Letter and enclosed Technical Support Document from Chris Hladick, Regional Administrator, EPA Region 10 to Maia Bellon, Director, Department of Ecology, Re: The EPA's Reversal of the November 15, 2016 Clean Water Act Section 303(c) Partial Disapproval of Washington's Human Health Water Quality Criteria and Decision to Approve Washington's Criteria.

²¹ May 10, 2019. Letter and enclosed Technical Support Document from Chris Hladick, Regional Administrator, EPA Region 10 to Maia Bellon, Director, Department of Ecology, Re: The EPA's Reversal of the November 15, 2016 Clean Water Act Section 303(c) Partial Disapproval of Washington's Human Health Water Quality Criteria and Decision to Approve Washington's Criteria.

TABLE 1—COMPARISON OF FEDERALLY PROMULGATED CRITERIA AND EPA-APPROVED WASHINGTON CRITERIA—
Continued

Chemical	CAS No.	Washington's criteria that EPA approved on May 10, 2019		EPA Federally promulgated criteria at 40 CFR 131.45 that EPA is proposing to withdraw	
		Water & organisms (µg/L)	Organisms only (µg/L)	Water & organisms (µg/L)	Organisms only (µg/L)
26. 4,4'-DDE	72559	0.000051	0.000051	0.00000088	0.00000088.
27. 4,4'-DDT	50293	0.000025	0.000025	0.0000012	0.0000012.
28. Acenaphthene	83329	110	110	30	30.
29. Acrolein	107028	(*)	(*)	(*)	(*).
30. Acrylonitrile	107131	(*)	(*)	(*)	(*).
31. Aldrin	309002	0.0000057	0.0000058	0.000000041	0.000000041.
32. alpha-BHC	319846	0.0005	0.00056	0.000048	0.000048.
33. alpha-Endosulfan	959988	9.7	10	6	7.
34. Anthracene	120127	3100	4600	100	100.
35. Antimony	7440360	12	180	6	90.
36. Arsenic	7440382	Disapproved	Disapproved	N/A	N/A.
37. Asbestos	1332214	(*)	(*)	(*)	(*).
38. Benzene	71432	(*)	(*)	(*)	(*).
39. Benzidine	92875	(*)	(*)	(*)	(*).
40. Benzo(a) Anthracene	56553	0.014	0.021	0.00016	0.00016.
41. Benzo(a) Pyrene	50328	0.0014	0.0021	0.000016	0.000016.
42. Benzo(b) Fluoranthene	205992	0.014	0.021	0.00016	0.00016.
43. Benzo(k) Fluoranthene	207089	0.014	0.21	0.0016	0.0016.
44. beta-BHC	319857	0.0018	0.002	0.0013	0.0014.
45. beta-Endosulfan	33213659	(*)	(*)	(*)	(*).
46. Bis(2-Chloroethyl) Ether	111444	(*)	(*)	(*)	(*).
47. Bis(2-Chloro-1-Methylethyl) Ether ^a	108601	Not submitted	Not submitted	See explanation below.	See explanation below.
48. Bis(2-Ethylhexyl) Phthalate ...	117817	0.23	0.25	0.045	0.046.
49. Bromoform	75252	5.8	27	4.6	12.
50. Butylbenzyl Phthalate	85687	0.56	0.58	0.013	0.013.
51. Carbon Tetrachloride	56235	(*)	(*)	(*)	(*).
52. Chlordane	57749	0.000093	0.000093	0.000022	0.000022.
53. Chlorobenzene	108907	380	890	100	200.
54. Chlorodibromomethane	124481	0.65	3	0.60	2.2.
55. Chloroform	67663	260	1200	100	600.
56. Chrysene	218019	1.4	2.1	0.016	0.016.
57. Copper	7440508	(*)	(*)	(*)	(*).
58. Cyanide	57125	19	270	9	100.
59. Dibenzo(a,h) Anthracene	53703	0.0014	0.0021	0.000016	0.000016.
60. Dichlorobromomethane	75274	0.77	3.6	0.73	2.8.
61. Dieldrin	60571	0.0000061	0.0000061	0.000000070	0.000000070.
62. Diethyl Phthalate	84662	4200	5000	200	200.
63. Dimethyl Phthalate	131113	92000	130000	600	600.
64. Di-n-Butyl Phthalate	84742	450	510	8	8.
65. Endosulfan Sulfate	1031078	9.7	(*)	9	(*).
66. Endrin	72208	0.034	0.035	0.002	0.002.
67. Endrin Aldehyde	7421934	(*)	(*)	(*)	(*).
68. Ethylbenzene	100414	200	270	29	31.
69. Fluoranthene	206440	16	16	6	6.
70. Fluorene	86737	420	610	10	10.
71. Gamma-BHC; Lindane	58899	15	17	0.43	0.43.
72. Heptachlor	76448	0.0000099	0.00001	0.00000034	0.00000034.
73. Heptachlor Epoxide	1024573	0.0000074	0.0000074	0.0000024	0.0000024.
74. Hexachlorobenzene	118741	0.000051	0.000052	0.0000050	0.0000050.
75. Hexachlorobutadiene	87683	0.69	4.1	0.01	0.01.
76. Hexachlorocyclopentadiene ..	77474	150	630	1	1.
77. Hexachloroethane	67721	0.11	0.13	0.02	0.02.
78. Indeno(1,2,3-cd) Pyrene	193395	0.014	0.021	0.00016	0.00016.
79. Isophorone	78591	(*)	(*)	(*)	(*).
80. Methyl Bromide	74839	520	(*)	300	(*).
81. Methylene Chloride	75092	16	250	10	100.
82. Methylmercury	22967926	(Not submitted)	(Not submitted)	See explanation below.	See explanation below.
83. Nickel	7440020	150	190	80	100.
84. Nitrobenzene	98953	55	320	30	100.
85. N-Nitrosodimethylamine	62759	(*)	(*)	(*)	(*).
86. N-Nitrosodi-n-Propylamine ...	621647	(*)	(*)	(*)	(*).
87. N-Nitrosodiphenylamine	86306	(*)	(*)	(*)	(*).
88. Pentachlorophenol (PCP)	87865	0.046	0.1	0.002	0.002.
89. Phenol	108952	18000	200000	9000	70000.

TABLE 1—COMPARISON OF FEDERALLY PROMULGATED CRITERIA AND EPA-APPROVED WASHINGTON CRITERIA—Continued

Chemical	CAS No.	Washington's criteria that EPA approved on May 10, 2019		EPA Federally promulgated criteria at 40 CFR 131.45 that EPA is proposing to withdraw	
		Water & organisms (µg/L)	Organisms only (µg/L)	Water & organisms (µg/L)	Organisms only (µg/L)
90. Polychlorinated Biphenyls (PCBs).	PCB	0.00017	0.00017	0.000007	0.000007.
91. Pyrene	129000	310	460	8	8.
92. Selenium	7782492	120	480	60	200.
93. Tetrachloroethylene	127184	4.9	7.1	2.4	2.9.
94. Thallium	7440280	0.24	0.27	1.7	6.3.
95. Toluene	108883	180	410	72	130.
96. Toxaphene	8001352	(*)	(*)	(*)	(*).
97. Trichloroethylene	79016	0.38	0.86	0.3	0.7.
98. Vinyl Chloride	75014	(*)	0.26	(*)	0.18.
99. Zinc	7440666	2300	2900	1000	1000.

^a Bis(2-Chloro-1-Methylethyl) Ether was previously listed as Bis(2-Chloroisopropyl) Ether.

^{*} EPA approved Washington's criteria for these pollutants in November 2016 and therefore did not promulgate corresponding federal criteria.

2. Methylmercury and bis(2-chloro-1-methylethyl) ether

Washington did not submit human health criteria for methylmercury or bis(2-chloro-1-methylethyl) ether in August 2016. For methylmercury, Washington explained in its August 2016 submittal documents that it “decided to defer state adoption of [human health criteria] for methylmercury at this time, and plans to schedule adoption of methylmercury criteria and develop a comprehensive implementation plan after the current rulemaking is completed and has received EPA Clean Water Act approval.”²² To date, the EPA is not aware of any efforts Washington has undertaken since 2016 to adopt methylmercury criteria or develop associated implementation materials, likely because the EPA promulgated a federal criterion. For bis(2-chloro-1-methylethyl) ether (which was previously named ‘bis(2-chloroisopropyl) ether’ in the NTR), Washington explained its position that “bis(2-chloroisopropyl) ether does not have a [CWA section] 304(a) national recommended criteria associated with it, thus the proposed criteria for this chemical were deleted from the [state’s] final rule. Ecology has determined that the older NTR criteria for bis(2-chloroisopropyl) ether were incorrect, and were not developed for that particular priority pollutant. Ecology is adopting criteria only for the priority

pollutants for which EPA has published 304(a) criteria documents.”²³

CWA section 303(c)(2)(B) requires states to adopt numeric criteria for all toxic pollutants listed pursuant to CWA section 307(a)(1) for which the EPA has published 304(a) criteria, as necessary to protect the states’ designated uses. In 1992, the EPA promulgated the NTR at 40 CFR 131.36, establishing chemical-specific numeric criteria for 85 priority toxic pollutants for 14 states and territories (states), including Washington, that were not in compliance with the requirements of CWA section 303(c)(2)(B). In the proposed NTR, the EPA provided states three options for demonstrating compliance with section 303(c)(2)(B).²⁴

- Option 1: Adopt statewide numeric criteria in state WQS for all section 307(a) toxic pollutants for which the EPA has developed criteria guidance, regardless of whether the pollutants are known to be present.

- Option 2: Adopt chemical-specific numeric criteria for priority toxic pollutants that are the subject of the EPA’s section 304(a) criteria guidance, where the state determines based on available information that the pollutants are present or discharged and can reasonably be expected to interfere with designated uses.

- Option 3: Adopt a procedure to be applied to a narrative WQS provision prohibiting toxicity in receiving waters. Such procedures would be used by the

state in calculating derived numeric criteria which must be used for all purposes under section 303(c) of the CWA. At a minimum, such criteria need to be developed for section 307(a) toxic pollutants, as necessary to support designated uses, where these pollutants are discharged or present in the affected waters and could reasonably be expected to interfere with designated uses.

For the NTR in Washington, the EPA applied Option 1, explaining that Washington “has not adopted numeric criteria for any human health based criteria for priority pollutants, and EPA has reason to believe that at least some additional criteria are necessary to comply with section 303(c)(2)(B).”²⁵ The EPA further explained that it did not attempt “to determine the specific priority pollutants and water bodies that require criteria. However, EPA has determined that at least some Federal criteria are necessary to protect designated uses. This determination is supported by information in the record which demonstrates that priority toxic pollutants are discharged or present in surface waters at levels that can reasonably be expected to interfere with State designated uses. For some priority toxic pollutants, available data clearly demonstrate use impairment and the need for toxics criteria. For most priority toxic pollutants, however, available data on the discharge and presence of priority toxic pollutants are spatially and temporally limited. Nevertheless, EPA believes that the data for many of these pollutants are sufficient to satisfy the ‘reasonable

²³ *Id.*

²⁴ EPA. 1991. *Amendments to the Water Quality Standards Regulation to Establish the Numeric Criteria for Priority Toxic Pollutants Necessary to Bring All States Into Compliance With Section 303(c)(2)(B)*. 56 FR 58420, November 19, 1991. <https://www.epa.gov/sites/production/files/2015-06/documents/ntr-proposal-1991.pdf>.

²⁵ *Id.*

²² Department of Ecology. *Washington State Water Quality Standards: Human health criteria and implementation tools, Overview of key decisions in rule amendment*. August 2016. Ecology Publication no. 16–10–025. Page 80.

expectation' test established in section 303(c)(2)(B).''²⁶

In 2016, Washington explained in its submittal that it was following Option 1 outlined in the NTR by adopting human health criteria for all CWA section 307(a) priority toxic pollutants (except mercury/methylmercury) for which the EPA has developed national recommended CWA section 304(a) criteria, regardless of whether the pollutants are known to be present in the state.²⁷ The EPA followed this same approach in 2016 when promulgating federal human health criteria for Washington.²⁸ However, while Washington concluded in 2016 that it wanted to retain the 1992 federally promulgated NTR criteria for mercury and adopt methylmercury criteria in the future, the EPA determined that revised criteria for all priority pollutants were necessary in Washington and therefore promulgated a fish tissue methylmercury criterion (replacing the NTR water column mercury criteria) for Washington in 2016. Also, as explained in a memo to the file in the docket for the 2016 rulemaking,²⁹ the EPA disagreed with Washington's conclusion that bis(2-chloro-1-methylethyl) ether was not a CWA section 307(a) priority pollutant with associated CWA section 304(a) criteria, and therefore the EPA promulgated criteria for bis(2-chloro-1-methylethyl) ether at 40 CFR 131.45. Because the EPA followed the same Option 1 approach in 2016 as it used in the NTR and as Washington used for its submittal in 2016, the EPA did not specifically conduct a search for available information indicating that any of the priority pollutants, including methylmercury and bis(2-chloro-1-methylethyl) ether, are present or discharged in Washington and can reasonably be expected to interfere with Washington's designated uses.

However, as Washington noted in its 2016 submittal, mercury contamination is widespread across all 50 states, and Washington has listed waters as impaired and issued fish advisories due to mercury.³⁰ Additionally,

Washington's 2016 cost-benefit analysis for its human health criteria rulemaking identified mercury as one of the five most detected chemicals in three discharger categories (wastewater treatment plants, pulp and paper mills, and resource extraction).³¹ For its final rulemaking in 2016, the EPA identified reasonable potential for certain industrial dischargers in the state to cause or contribute to exceedances of the federally promulgated methylmercury criterion.³² Therefore, the available evidence indicates that mercury is present and discharged in Washington and can reasonably be expected to interfere with Washington's designated uses.

The available data on bis(2-chloro-1-methylethyl) ether are more limited. The EPA did not identify reasonable potential for any dischargers in Washington to cause or contribute to exceedances of the federally promulgated criteria for bis(2-chloro-1-methylethyl) ether. Washington did not evaluate bis(2-chloro-1-methylethyl) ether in its cost-benefit analysis because it did not include this pollutant in the state rulemaking. Therefore, the EPA is not aware of evidence on whether bis(2-chloro-1-methylethyl) ether is present or discharged in Washington and can reasonably be expected to interfere with Washington's designated uses.

Given the information outlined above, the EPA proposes to retain (*i.e.*, not withdraw) the methylmercury and bis(2-chloro-1-methylethyl) ether human health criteria promulgated for Washington at 40 CFR 131.45 (81 FR 85417, November 28, 2016). This is consistent with the Option 1 approach and will ensure that Washington has CWA-effective human health criteria for these two pollutants that may be present in Washington's waters. The EPA specifically solicits any additional information on whether mercury/methylmercury and/or bis(2-chloro-1-methylethyl) ether are present or discharged in Washington and can reasonably be expected to interfere with Washington's designated uses. Based on the public comments received, the EPA may consider withdrawing the federally promulgated criteria for one or both of these pollutants. If the EPA withdraws the federal criteria for methylmercury and/or bis(2-chloro-1-methylethyl) ether, there would be no applicable

numeric criteria for CWA purposes. Washington may, at any time adopt and submit to the EPA human health criteria for either pollutant, consistent with CWA section 303(c) and the EPA's implementing regulations at 40 CFR part 131.

III. Statutory and Executive Order Reviews

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

It has been determined that this proposed rule is not a "significant regulatory action" under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is, therefore, not subject to review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011). The proposed rule does not establish any requirements directly applicable to regulated entities or other sources of toxic pollutants.

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

This action is expected to be an Executive Order 13771 deregulatory action.

C. Paperwork Reduction Act (PRA)

This action does not impose any new information-collection burden under the Paperwork Reduction Act (PRA) because it is administratively withdrawing federal requirements that are no longer needed in Washington. It does not include any information collection, reporting, or recordkeeping requirements. The Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the existing regulations 40 CFR part 131 and has assigned OMB control number 2040-0286.

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 Regulatory Flexibility Act (RFA). This action will not impose any requirements on small entities. Small entities, such as small businesses or small governmental jurisdictions, are not directly regulated by this rule.

E. Unfunded Mandates Reform Act (UMRA)

This action contains no unfunded federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. As

²⁶ *Id.*

²⁷ Department of Ecology. *Washington State Water Quality Standards: Human health criteria and implementation tools, Overview of key decisions in rule amendment*. August 2016. Ecology Publication no. 16-10-025. Page 20.

²⁸ *Revision of Certain Water Quality Standards Applicable to Washington*, 81 FR 85417 (November 28, 2016).

²⁹ EPA. 2016. Bis chem CAS 108-60-1 Memo to File clean. <https://www.regulations.gov/document?D=EPA-HQ-OW-2015-0174-0301>.

³⁰ Department of Ecology. *Washington State Water Quality Standards: Human health criteria and implementation tools, Overview of key decisions in rule amendment*. August 2016. Ecology Publication no. 16-10-025. Page 80.

³¹ Department of Ecology. *Final Cost-Benefit and Least-Burdensome Alternative Analyses*. July 2016. Ecology Publication no. 16-10-019. Page 27.

³² Abt Associates. *Economic Analysis for Water Quality Standards Applicable to the State of Washington*. October 21, 2016. <https://www.regulations.gov/document?D=EPA-HQ-OW-2015-0174-0300>.

this action proposes to withdraw certain federally promulgated criteria, 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. This rule imposes no regulatory requirements or costs on any state or local governments. Thus, Executive Order 13132 does not apply to this action.

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

This action may have tribal implications. However, it will neither impose substantial direct compliance costs on federally recognized tribal governments, nor preempt tribal law. In the state of Washington, there are 29 federally recognized Indian tribes.

The EPA initiated consultation with federally recognized tribal officials under the EPA's Policy on Consultation and Coordination with Indian tribes early in the process of developing this proposed rule to allow meaningful and timely input into its development. The EPA initially offered tribal consultation on this rule making on May 21, 2019. EPA staff then offered two informational calls for tribal staff on June 4 and 5, 2019, to assist tribes with the consultation process, including the tribes' decisions on whether to accept the offer to consult. Many tribes have expressed dissatisfaction that EPA did not offer consultation prior to its May 10, 2019, decision and have questioned how meaningful the EPA's offer for consultation is on this rule making as a result. To the extent tribes have been interested in consulting on this rulemaking, they have emphasized the importance of consultation occurring prior to publication of a proposed rule.

A number of tribes expressed the need for more time prior to the proposed rule publication to conduct consultation, for more information provided in advance to prepare for and engage in consultation and for the actual EPA decision-maker to be present.

Input received from tribes during consultation, meetings and through letters received thus far, indicates tribes are opposed to this proposed action. Tribes have raised health, economic and implementation concerns, as well as the EPA's trust responsibility, treaty obligations and consultation practices. While the EPA acknowledges it may not satisfy the tribal consultation expectations of each tribe, the EPA will continue to offer the opportunity to consult up to the point of finalizing this rule and will evaluate the input received before making a final decision.

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

This rule is not subject to Executive Order 13045, because it is not economically significant as defined in Executive Order 12866, and because the environmental health or safety risks addressed by this action do not present a disproportionate risk to children.

I. Executive Order 13211: Actions 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.

J. National Technology Transfer and Advancement Act of 1995

This proposed rulemaking does not involve technical standards.

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

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs

federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. The EPA concludes 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 has previously determined that Washington's adopted and EPA-approved criteria are protective of human health.

List of Subjects in 40 CFR Part 131

Environmental protection, Indians-lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water pollution control.

Dated: July 23, 2019.

Andrew R. Wheeler,
Administrator.

For the reasons set forth in the preamble, the EPA proposes to amend 40 CFR part 131 as follows:

PART 131—WATER QUALITY STANDARDS

- 1. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 *et seq.*

Subpart D—Federally Promulgated Water Quality Standards

- 2. Amend § 131.45 by revising paragraph (b) to read as follows:

§ 131.45 Revision of certain Federal water quality criteria applicable to Washington.

* * * * *

(b) *Criteria for priority toxic pollutants in Washington.* The applicable human health criteria are shown in Table 1 to paragraph (b).

TABLE 1 TO PARAGRAPH (b)—HUMAN HEALTH CRITERIA FOR WASHINGTON

A		B					C	
Chemical	CAS No.	Cancer Slope factor, CSF (per mg/kg-d)	Relative source contribution, RSC (-)	Reference dose, RfD (mg/kg-d)	Bio-accumulation factor (L/kg tissue)	Bio-concentration factor (L/kg tissue)	Water & organisms (µg/L)	Organisms only (µg/L)
		(B1)	(B2)	(B3)	(B4)	(B5)	(C1)	(C2)
1. Arsenic**	7440382	1.75				44	^a 0.018	^a 0.14.
2. Bis(2-Chloro-1-Methylethyl) Ether*.	108601	0.50		0.04	10		400	900.
3. Methylmercury	22967926		2.7E-05	0.0001				^b 0.03 (mg/kg).

^a This criterion refers to the inorganic form of arsenic only.

^b This criterion is expressed as the fish tissue concentration of methylmercury (mg methylmercury/kg fish). See *Water Quality Criterion for the Protection of Human Health: Methylmercury* (EPA-823-R-01-001, January 3, 2001) for how this value is calculated using the criterion equation in the EPA's 2000 Human Health Methodology rearranged to solve for a protective concentration in fish tissue rather than in water.

* Bis(2-Chloro-1-Methylethyl) Ether was previously listed as Bis(2-Chloroisopropyl) Ether.

** These criteria were promulgated for Washington in the National Toxics Rule at 40 CFR 131.36, and are moved into 40 CFR 131.45 to have one comprehensive human health criteria rule for Washington.

* * * * *

[FR Doc. 2019-16700 Filed 8-5-19; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2019-0359; FRL-9996-62]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances (19-2.F)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 31 chemical substances which were the subject of premanufacture notices. 7 of these chemical substances are subject to Orders issued by EPA pursuant to TSCA section 5(e). This action would require persons who intend to manufacture (defined by statute to include import) or process any of these 31 chemical substances for an activity that is proposed as a significant new use to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the use, under the conditions of use for that chemical substance, within the applicable review period. Persons may not commence manufacture or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required by that determination.

DATES: Comments must be received on or before September 5, 2019.

ADDRESSES: Submit your comments, identified by docket identification (ID)

number EPA-HQ-OPPT-2019-0359, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- **Mail:** Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001.

- **Hand Delivery:** To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-9232; email address: moss.kenneth@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this proposed rule. The following list of North American

Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to final SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after September 5, 2019 are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see 40 CFR 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. What should I consider as I prepare my comments for EPA?

1. **Submitting CBI.** Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or

CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. Background

A. What action is the Agency taking?

EPA is proposing these SNURs under TSCA section 5(a)(2) for chemical substances that were the subject of PMNs and an MCAN. These proposed SNURs would require persons to notify EPA at least 90 days before commencing the manufacture or processing of a chemical substance for any activity proposed as a significant new use. Receipt of such notices would allow EPA to assess risks and, if appropriate, to regulate the significant new use before it may occur. Additional background regarding SNURs is more fully set out in the preamble to EPA's first direct final SNUR published in the **Federal Register** issue of April 24, 1990 (55 FR 17376). Consult that preamble for further general information on the objectives, rationale, and procedures for SNURs and on the basis for significant new use designations, including provisions for developing test data.

B. What is the Agency's authority for taking this action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)(i)). TSCA furthermore prohibits such manufacturing or processing from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required

in association with that determination (15 U.S.C. 2604(a)(1)(B)(ii)).

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the proposed rule, recordkeeping requirements, and exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. Pursuant to § 721.1(c), persons subject to SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A) (15 U.S.C. 2604(a)(1)(A)). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1) (15 U.S.C. 2604(b) and 2604(d)(1)), the exemptions authorized by TSCA sections 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the use is not likely to present an unreasonable risk of injury under the conditions of use for the chemical substance or take such regulatory action as is associated with an alternative determination before the manufacture or processing for the significant new use can commence. In the case of a determination other than not likely to present unreasonable risk, the applicable review period must also expire before manufacturing or processing for the new use may commence. If EPA determines that the use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register**, a statement of EPA's findings.

III. Significant New Use Determination

TSCA section 5(a)(2) states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing,

processing, distribution in commerce, and disposal of a chemical substance.

In determining significant new use for the 31 chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances and potential human exposures and environmental releases that may be associated with the conditions of use for the substances, in addition to the factors in TSCA section 5(a)(2). Note that when the Agency issues an order under TSCA section 5(e), TSCA section 5(f)(4) requires that the Agency consider whether to promulgate a SNUR for any use not conforming to the restrictions of the order or publish a statement describing the reasons for not initiating the rulemaking.

IV. Substances Subject to This Proposed Rule

EPA is proposing significant new use and recordkeeping requirements for 31 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
- Basis for the SNUR or basis for the TSCA 5(e) Order.
- Information identified by EPA that would help characterize the potential health and/or environmental effects of the chemical substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use designated by the SNUR. This information may include testing required in a TSCA section 5(e) Order to be conducted by the PMN submitter, as well as testing not required to be conducted but which would also help characterize the potential health and/or environmental effects of the PMN substance. Any recommendation for information identified by EPA was made based on EPA's consideration of available screening-level data, if any, as well as other available information on appropriate testing for the chemical substance. Further, any such testing identified by EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models. EPA also recognizes that whether testing/further information is needed will depend on the specific

exposure and use scenario in the SNUN. EPA encourages all SNUN submitters to contact EPA to discuss any potential future testing. See Unit VII. for more information.

- CFR citation assigned in the regulatory text section of the proposed rule. The regulatory text section of each proposed rule specifies the activities that would be designated as significant new uses. Certain new uses, including exceedance of production volume limits (*i.e.*, limits on manufacture volume) and other uses designated in this proposed rule, may be claimed as CBI.

These proposed rules include 7 PMN substances that are subject to Orders issued under TSCA section 5(e)(1)(A), as required by the determinations made under TSCA section 5(a)(3)(B). Those Orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The proposed SNURs would identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying Orders, consistent with TSCA section 5(f)(4).

Where EPA determined that the PMN substance may present an unreasonable risk of injury to human health via inhalation exposure, the underlying TSCA section 5(e) Order usually requires, among other things, that potentially exposed employees wear specified respirators unless actual measurements of the workplace air show that air-borne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL) that is established by EPA to provide adequate protection to human health. In addition to the actual NCEL concentration, the comprehensive NCELs provisions in TSCA section 5(e) Orders, which are modeled after Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs) provisions, include requirements addressing performance criteria for sampling and analytical methods, periodic monitoring, respiratory protection, and recordkeeping. However, no comparable NCEL provisions currently exist in 40 CFR part 721, subpart B, for SNURs. Therefore, for these cases, the individual SNURs in 40 CFR part 721, subpart E, will state that persons subject to the SNUR who wish to pursue NCELs as an alternative to the 40 CFR 721.63 respirator requirements may request to do so under 40 CFR 721.30. EPA expects that persons whose 40 CFR 721.30 requests to use the NCELs approach for SNURs that are approved by EPA will be required to comply with NCELs

provisions that are comparable to those contained in the corresponding TSCA section 5(e) Order for the same chemical substance.

These proposed rules also include 24 PMN substances that received “not likely to present an unreasonable risk” determination in TSCA section 5(a)(3)(c). However, during the course of these reviews, EPA identified concerns for certain health and/or environmental risks if the chemicals were not used following the limitations identified by the submitters in the notices but the TSCA section 5(a)(3)(C) determinations did not deem those uses as reasonably foreseen. The proposed SNURs would identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to those same protection measures.

The chemicals subject to these proposed SNURs are as follows:

PMN Number: P-16-400

Chemical Name: Alkanes, C11-16-branched and linear.

CAS Number: 1809170-78-2.

Basis for action: The PMN states that the use of the PMN substance will be as a chemical intermediate, in cured coatings, cleaning fluids, metalworking fluids/rolling oils, and in agrochemicals. Based on the estimated physical chemical properties of the PMN substance and analogy to structurally similar substances, EPA has identified concerns for lung effects and dermal irritation if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No manufacture, processing, or use of the PMN substance other than for the uses stated in the PMN; and

2. No manufacture, processing, or use of the PMN substance for consumer use.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health effects of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of irritation and pulmonary effects testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11300.

PMN Number: P-17-119

Chemical Name: Alkyl alkenoic acid, alkoxyalkyl ester, polymer with alkyl alkenoate, alkyl alkyl alkenoate and triis alkyl silyl alkyl alkenoate (generic).

CAS Number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be as a component of industrial coatings. Based on the estimated physical chemical properties of the PMN substance and test data on the PMN substance, EPA has identified concerns for lung effects and irritation to the eyes, skins, lung, and mucous membranes if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No domestic manufacture of the PMN substance; and

2. No manufacture, processing, or use of the PMN substance that results in inhalation exposures.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health effects of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of pulmonary effects testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11301.

PMN Number: P-17-191

Chemical Name: Alkyldiamine, aminoalkyl dimethylaminoalkyl dimethyl-, reaction products with propylene oxide (generic).

CAS Number: Not available.

Basis for action: The PMN states that the use of the PMN substance will be as a polyurethane catalyst. Based on the estimated physical chemical properties of the PMN substance and data on analogous compounds, EPA has identified concerns for skin, eye, and lung corrosion, neurotoxicity, and systemic effects if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measure:

- No manufacture, processing, or use of the PMN substance that would generate a spray, mist, or aerosol.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health effects of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of skin irritation/corrosion and neurotoxicity testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11302.

PMN Number: P-17-220

Chemical Name: 2-Oxepanone, reaction products with alkylenediamine-alkyleneimine polymer, 2-[[[(2-alkyl)oxy]alkyl]oxirane and tetrahydro-2H-pyran-2-one (generic).

CAS Number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be as an additive, open, non-dispersive use. Based on the estimated physical chemical properties of the PMN substance, comparison with structurally analogous chemical substances, and Structure Analysis Relationships (SAR) analysis of test data on polycationic polymers, EPA has identified hazards for irritation to the eye, lung, and mucous membranes, lung effects, and aquatic toxicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No domestic manufacture of the PMN substance;
2. No manufacture or import of the PMN substance other than in liquid form; and
3. No manufacture, processing, or use of the PMN substance other than for the confidential use stated in the PMN.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health and environmental effects of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of aquatic toxicity and pulmonary effects testing would help characterize the potential health and environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.11303.

PMN Numbers: P-17-387 and P-17-388

Chemical Name: Dicarboxylic acids, polymers with alkanolic acid, alkanediol, substituted-alkylalkanoic acid, substituted alkyl carbomonocycle, alkanedioic acid, alkanolamine blocked compds with alkanolamine (P-17-387 and P-17-388) (generic).

CAS Numbers: Not available.

Basis for action: The PMNs state that the generic (non-confidential) use of the substances will be as paint. Based on the estimated physical/chemical properties of the PMN substances and available PMN data, EPA has identified developmental and reproductive effects, lung toxicity, and nasal and ocular irritation if the chemical substances are not used following the limitations noted. The conditions of use of the PMN substances as described in the PMNs include the following protective measures:

1. No manufacture (including import) of the PMN substances that results in amine counter ions greater than 4% by weight;
2. No manufacture (including import) of the PMN substances that results in isocyanate residuals greater than 0.1% by weight;
3. No manufacture (including import) of the PMN substances that results in a proportion of the acid group greater than 20% by weight; and
4. No manufacture (including import) of the PMN substances that results in the average molecular weight smaller than the confidential molecular weight specified in the PMNs or proportion of the low molecular weight species greater than the confidential values specified in the PMNs for the 500 and 1000 dalton species.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health effects of the PMN substances may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of developmental/reproductive and pulmonary effects testing would help characterize the potential health effects of the PMN substances.

CFR Citation: 40 CFR 721.11304.

PMN Number: P-17-419

Chemical name: Unsaturated polycyclic hydrocarbon (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: February 6, 2019.

Basis for TSCA section 5(e) Order:

The PMN states that the generic (non-confidential) use of the substance will be as a cyclic hydrocarbon building block. Based on physical/chemical properties of the PMN substance (as described in the New Chemical Program's PBT category at 64 FR 60194; November 4, 1999) and test data on structurally similar substances, the PMN substance is a potentially persistent, bioaccumulative, and toxic (PBT) chemical. EPA estimates that the PMN substance will persist in the environment more than 2 months and estimates a bioaccumulation factor of greater than or equal to 1,000. EPA has also identified concern for skin irritation, reproductive and developmental toxicity based on analog data and concern for sensitization based on Safety Data Sheet (SDS) information. Based on SAR analysis of test data on analogous neutral organics, EPA has identified concern for aquatic toxicity. The Order was issued under 5(a)(3)(B)(i) and 5(e)(1)(A)(i), based on a finding that the available information is insufficient to permit a reasoned evaluation of the human health and environmental effects of the PMN substance. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Submit to EPA certain toxicity testing within 9 months from the effective date of the Order.
2. Submit to EPA certain toxicity testing for within 12 months from EPA's direction to proceed with that testing.
3. Refrain from manufacturing (including import) more than the confidential annual production volume limit specified in the Order.
4. Use of the PMN substance only for the confidential use allowed by the Order.
5. No release of the PMN substance to surface waters.
6. Use of personal protective equipment to its workers to prevent dermal exposure where there is potential for dermal exposure.
7. Use of a National Institute for Occupational Safety and Health (NIOSH) certified respirator with an Assigned Protection Factor (APF) of at least 50 where there is a potential for inhalation exposure.
8. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The SNUR designates as a “significant new use” the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health and environmental effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. The submitter has agreed to perform certain acute aquatic toxicity testing within 9 months of the effect of the Order, and certain chronic aquatic toxicity testing within 12 months of EPA’s direction to proceed. The Agency has determined that specific target organ toxicity, reproductive and developmental toxicity, sensitization, and fate information would help EPA determine the potential health effects of the PMN substance. Although the Order does not require this information, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citation: 40 CFR 721.11305.

PMN Numbers: P-18-7 and P-18-8

Chemical Names: Glycerides, soya mono- and di-, epoxidized, acetates (P-18-7) and Glycerides, C16-18 and C18-unsatd. mono- and di-, epoxidized, acetates (P-18-8).

CAS Numbers: 2097734-14-8 (P-18-7) and 2097734-15-9 (P-18-8).

Basis for action: The PMNs state that the use of the substances will be as plasticizers/stabilizers for flexible polyvinyl chloride. Based on the estimated physical/chemical properties of the PMN substances and comparison with structurally analogous chemical substances, EPA has identified skin irritation and kidney and liver hazards if the chemical substances are not used following the limitations noted. The conditions of use of the PMN substances as described in the PMNs include the following protective measures:

1. No manufacture, processing, or use that results in inhalation exposures; and
2. No release of a manufacturing, processing, or use stream associated with any use of the PMN substances into the waters of the United States exceeding a surface water concentration of 9,000 parts per billion (ppb).

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human effects of the PMN substances may be potentially useful if

a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of specific target organ toxicity and skin irritation testing would help characterize the potential health effects of the PMN substances.

CFR Citations: 40 CFR 721.11306 (P-18-7) and 40 CFR 721.11307 (P-18-8).

PMN Number: P-18-55

Chemical Name: Mixed metal oxide (generic).

CAS Number: Not Available.

Effective date of TSCA section 5(e)

Order: April 2, 2019.

Basis for TSCA section 5(e) Order: The PMN states that the generic use of the PMN substance will be as a catalyst. EPA identified concerns for lung effects including cancer, and respiratory and dermal sensitization based on the estimated physical/chemical properties, available PMN data, and by comparison to structurally analogous chemical substances. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. Use of personal protective equipment where there is a potential for dermal exposure;
2. Use of a NIOSH-certified respirator with an APF of at least 1,000 where there is a potential for inhalation exposure or compliance with a NCEL of 0.04 mg/m³ as an 8-hour time-weighted average to prevent inhalation exposure;
3. Use of the PMN substance only for the confidential use allowed by the Order; and
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The SNUR designate as a “significant new use” the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. EPA has also determined that specific pulmonary toxicity and sensitization effects testing of the PMN substance would be useful in determining the health effects of the

PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citation: 40 CFR 721.11308.

PMN Number: P-18-77

Chemical Name: Urea, reaction products with N-butylphosphorothioic triamide and formaldehyde.

CAS Number: 2093385-47-6.

Basis for action: The PMN states that the use of the PMN substance will be as an additive for urea-containing fertilizer. Based on physical-chemical properties, available test data, and test data on analogous chemical substances for the PMN substance, EPA has identified concerns for neurotoxicity, reproductive toxicity, kidney toxicity, irritation and sensitization if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No manufacture, processing, or use of the substance that results in inhalation exposure; and
2. No use of the substance in a consumer product.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of neurotoxicity, specific target organ toxicity, irritation, sensitization, and reproductive/developmental toxicity testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11309.

PMN Number: P-18-85

Chemical Name: Fatty acid reaction products with ethyleneamines and dialkyl ester (generic).

CAS Number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be for industrial use in oilfields. Based on the estimated physical chemical properties of the PMN substance and comparison with structurally analogous chemical substances, EPA has identified irritation to the eyes, lungs, and skin, and lung effects if the chemical substance is not used following the limitation noted. The

condition of use of the PMN substance as described in the PMN includes the following protective measure:

- No manufacture, processing, or use that results in inhalation exposures.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of pulmonary effects testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11310.

PMN Number: P-18-101

Chemical Name: Pentaerythritol, mixed esters with linear and branched fatty acids (generic).

CAS Number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be for industrial use. Based on the estimated physical chemical properties of the PMN substance and comparison with structurally analogous chemical substances, EPA has identified concerns for developmental effects, blood and thyroid effects, and skin and eye irritation if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measure:

- No manufacturing, processing, or use involving an application method that generates a vapor, mist, or aerosol.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of specific organ toxicity and reproductive/developmental testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11311.

PMN Number: P-18-107

Chemical Name: Alcohol capped polycarbodiimide from diethyldiisocyanatobenzene (generic).

CAS Number: Not available.

Basis for action: The PMN states that the use of the PMN substance will be as a hydrolysis stabilizer. Based on the physical chemical properties of the PMN substance and comparison with structurally analogous chemical substances, EPA has identified concerns for systemic toxicity and developmental toxicity if the chemical substance is not used following the limitation noted. The conditions of use of the PMN substance as described in the PMN include the following protective measure:

- No manufacture (including import) of the PMN substances that results in isocyanate residuals greater than 0.1% by weight.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of reproductive/development toxicity testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11312.

PMN Numbers: P-18-118 and P-18-119

Chemical Names: Oxirane, 2-methyl-, polymer with methoxirane homopolymer, 1,1'-methylenebis[4-isocyanatobenzene], and glycerol-propylene oxide polymer (generic) (P-18-118) and Oxirane, 2-methyl-, polymer with methoxirane homopolymer, 1,1'-methylenebis[isocyanatobenzene], and glycerol-propylene oxide polymer (generic) (P-18-119).

CAS Numbers: Not available.

Basis for action: The PMNs state that the generic (non-confidential) use of the substances will be as industrial adhesives. Based on the estimated physical chemical properties of the PMN substances and comparison with structurally analogous chemical substances, EPA has identified concerns for lung effects, irritation, and sensitization if the chemical substances are not used following the limitations noted. The conditions of use of the PMN substances as described in the PMNs include the following protective measures:

1. No manufacturing, processing, or use that results in inhalation exposures;
2. No manufacturing, processing, or use of the PMN substances with isocyanate residuals greater than 0.1%; and

3. Refrain from using the PMN substance for consumer use.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substances may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of skin sensitization testing would help characterize the potential health effects of the PMN substances.

CFR Citations: 40 CFR 721.11313 (P-18-118) and 40 CFR 721.11314 (P-18-119).

PMN Numbers: P-18-123 and P-18-124

Chemical Name: Lithium nickel hydride oxide (P-18-123) and Lithium nickel potassium oxide (P-18-124).

CAS Numbers: 2081933-92-6 (P-18-123) and 210352-95-7 (P-18-124).

Effective date of TSCA section 5(e)

Order: December 7, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the use of the PMN substances will be as a chemical intermediate used in the production of battery electrodes (P-18-123) and a cathode material for standard and premium (P-18-124). Based on physical/chemical properties and on test data submitted with the PMN, EPA identified concerns for pulmonary effects, neurotoxicity, developmental toxicity, kidney toxicity, carcinogenicity, skin and respiratory sensitization, and irritation to the eye, skin, and respiratory tract. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(I)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation the substances may present an unreasonable risk of injury to human health and the environment. The Order was also issued under TSCA section 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the substances are or will be produced in substantial quantities and that the substances either enter or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substances. To protect against these risks, the Order requires:

1. Use of personal protective equipment where there is a potential for dermal exposure.
2. Use a NIOSH-certified respirator with an APF of at least 50 where there is potential for inhalation exposure or

compliance with a NCEL of 0.05 mg/m³ as an 8-hour time-weighted average to prevent inhalation exposure.

3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

4. Submit to EPA certain environmental and health hazard testing within six months and four years of the first manufacture (including import), respectively on P-18-124.

5. No release of the PMN substances resulting in surface water concentrations that exceed 32 ppb.

The SNUR designate as a "significant new use" the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health and environmental effects of the PMN substances may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. The submitter has agreed to submit an algal toxicity test 6 months after the date of first manufacture and a specific organ toxicity test 4 years after the date of first manufacture on PMN substance P-18-124. EPA has also determined that information on specific target organ toxicity and reproductive/developmental toxicity would help characterize the potential health effects of the PMN substances. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR Citations: 40 CFR 721.11315 (P-18-123) and 40 CFR 721.11316 (P-18-124).

PMN Number: P-18-152

Chemical Name: Hydrolyzed functionalized di-amino silanol polymer (generic).

CAS Number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be as an intermediate. Based on the estimated physical chemical properties of the PMN substance, data on the PMN substance, comparison with structurally analogous chemical substances, and Structure Analysis Relationships (SAR) analysis of test data on analogous aliphatic amines, EPA has identified irritation and corrosion to all tissues, sensitization, lung toxicity, and aquatic toxicity at surface water concentrations exceeding 3 parts per billion (ppb) if the chemical substance is not used

following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No manufacturing, processing, or use of the PMN substance in any manner that results in inhalation exposure; and
2. No release of a manufacturing, processing, or use stream associated with any use of the PMN substance exceeding a surface water concentration of 3 ppb.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health and environmental effects of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of skin toxicity, sensitization, and aquatic toxicity testing of would help characterize the potential health and environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.11317.

PMN Number: P-18-169

Chemical Name: Propanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl-, polymer with dimethyl carbonate, 1,6-hexanediol, diamine and 1,1'-methylenebis[4-isocyanatocyclohexane], pentaerythritol, triacrylate-blocked, compds. with triethylamine (generic).

CAS Number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be as a protective coating. Based on estimated physical chemical properties of the PMN substance and comparison with structurally analogous acrylates/methacrylates, EPA has identified dermal and respiratory irritation and sensitization, developmental toxicity, and neurotoxicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. Use of personal protective equipment including impervious gloves where there is a potential for dermal exposure;
2. Use of a NIOSH certified respirator with an APF of at least 1,000 for spray applications and 50 for non-spray applications; and
3. No manufacture (including import) of the PMN substance with triethylamine concentrations greater

than the confidential concentration described in the PMN.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of composition of Low Molecular Weight (LMW) species and specific organ toxicity testing for the LMW species would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11318.

PMN Numbers: P-18-200 and P-18-201

Chemical names: Waste plastics, poly(ethylene terephthalate), polymers with diethylene glycol, glycerol, polyerythritol, triethylene glycol, trimethylolalkane and polypropylene glycol (P-18-200) (generic) and Waste plastics, poly(ethylene terephthalate), polymers with diethylene glycol, glycerol, polyerythritol glycol, trimethylolalkane and polypropylene glycol (P-18-201) (generic).

CAS numbers: Not available.

Effective date of TSCA section 5(e) Order: January 20, 2019.

Basis for TSCA section 5(e) Order: The PMNs state that the generic (non-confidential) use of the substances will be as insulation components. Based on analogue data for low molecular weight components and metabolites of high molecular weight components, EPA identified concerns for bladder and kidney effects. . Based on SAR predictions for nonionic polymers EPA also identified concerns for aquatic toxicity at concentrations that exceed 280 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the substances are or will be produced in substantial quantities and that the substances either enter or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substances. To protect against these risks, the Order requires:

1. Use of personal protective equipment involving impervious gloves where there is a potential for dermal exposure;

2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;

3. Use of a NIOSH-certified respirator with an APF of at least 10 where there is a potential for inhalation exposure;

4. Refrain from using the PMN substances for consumer use; and

5. No release of the PMN substances resulting in surface water concentrations that exceed 280 ppb.

The SNUR would designate as a “significant new use” the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human and environmental health effects of the PMN substances may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. A toxicokinetics test, a specific target organ toxicity test, and a chronic aquatic organism toxicity test would help EPA determine the potential health and environmental effects of the PMN substances. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citations: 40 CFR 721.11319 (P–18–200) and 40 CFR 721.11320 (P–18–201).

PMN Number: P–18–235

Chemical Name: Naphtha oils (generic).

CAS Number: Not Available.

Effective date of TSCA section 5(e)

Order: April 10, 2019.

Basis for TSCA section 5(e) Order: The PMN states that the generic use of the PMN substance will be as a component in automotive gasoline and transportation fuel for consumer use. EPA identified concerns for neurological, liver, kidney, developmental, immunological, carcinogenic, mutagenic and irritation effects based on estimated physical/chemical properties and analysis of test data on structurally analogous chemical substances. In addition, based on SAR analysis of test data on analogous neutral organics, EPA predicts acute and chronic toxicity to aquatic organisms may occur at concentrations greater than 88 ppb and 3 ppb respectively. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation the substance may

present an unreasonable risk of injury to human health and the environment. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. To protect against these risks, the Order requires:

1. No domestic manufacture of the PMN substance (import only).

2. Processing and use of the PMN substance only for the confidential use specified in the PMN.

The SNUR designate as a “significant new use” the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health and environmental effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. EPA has also determined that specific product composition testing of the PMN substance would be useful in determining the health and environmental effects of the PMN substance. Although the Order does not require this test, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citation: 40 CFR 721.11321.

PMN Number: P–18–238

Chemical Name: Saccharide reaction products with acid anhydride, etherified (generic).

CAS Number: Not available.

Basis for action: The PMN states that the use of the PMN substance will be as a binder for wood panels. Based on the estimated physical chemical properties of the PMN substance, structural alerts, data on an analogue of a potential metabolites, and test data on analogous esters, EPA has identified skin and respiratory sensitization, germ cell mutagenicity, carcinogenicity, reproductive/developmental, liver, and kidney toxicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include this protective measure:

• No manufacturing, processing, or use that results in inhalation exposures.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of absorption, specific target organ toxicity, sensitization, genetic toxicology, and reproductive/developmental toxicity testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11322.

PMN Number: P–18–307

Chemical Name: Alkyl alkenoic acid, alkyl ester, telomer with alkyl alkenoate, substituted alkyl alkyl alkenoate, alkylthiol, substituted carbomonocycle, hydroxyalkyl alkyl alkenoate and alkyl alkyl alkenoate (generic).

CAS Number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be as a binder resin in coatings. Based on the estimated and measured physical chemical properties of the PMN substance, data submitted on the new chemical substance, and comparison with structurally analogous chemical substances, EPA has identified concerns for systemic effects if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measure:

• No manufacture (including import) of the PMN substance with more than 5% of the molecular weight content less than 1,000 Daltons.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of toxicokinetic and specific target organ toxicity testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11323.

PMN Number: P–18–312

Chemical Name: Formaldehyde, polymer with 2-phenoxyalkanol and .alpha.-phenyl-.omega.

hydroxypoly(oxy-1,2-alkylenediyl), dihydrogen phosphate 2-phenoxyalkyl hydrogen phosphate, alkaline salt (generic).

CAS Number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be as a dispersing agent. Based on the estimated physical chemical properties of the PMN substance and hazard data on chemically analogous substances, EPA has identified concerns for lung effects, eye irritation, and systemic (blood/kidney) effects, if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No manufacturing, processing, or use that results in inhalation exposures; and

2. No manufacture of the PMN substance with greater than 20% (weight percent) components with molecular weight below 500 Daltons.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of composition of low molecular weight (LMW) species and specific organ toxicity testing for the LMW species would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11324.

PMN Number: P-19-8

Chemical Name: Substituted polyalkylenepolycarbomonocycle ester, polymer with dialkanolamine, [(hydroxyalkoxy)carbonyl] derivs., (alkoxyalkoxy) alkanol-blocked (generic).

CAS Number: Not available.

Basis for action: The PMN states that the use of the PMN substance will be as a component in coating resin products that are applied by cathodic electrodeposition and used as additives for corrosion protection. Based on the estimated physical chemical properties of the PMN substance and comparison with structurally analogous chemical substances, EPA has identified concerns for irritation, lung effects, immunotoxicity, and blood effects if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance

as described in the PMN include the following protective measures:

1. No manufacture (including import) or processing the PMN substance in the forms of a powder or solid; and

2. No use of the PMN substance involving application methods that generate inhalation exposures.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of pulmonary effects and specific target organ toxicity testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11325.

PMN Number: P-19-9

Chemical Name: Carbonmonocycles, polymer with haloalkyl substituted heteromonocycle and hydro-hydroxypoly[oxy(alkyl-alkanediyl)], dialkyl-alkanediamineterminated, hydroxyalkylated, acetates (salts) (generic).

CAS Number: Not available.

Basis for action: The PMN states that the use of the PMN substance will be as a corrosion protection additive in resin for cathodic electrodeposition dip coating for metal substrates. Based on the estimated physical chemical properties of the PMN substance and comparison with structurally analogous chemical substances, EPA has identified concerns for lung effects and irritation if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No manufacturing (including import), processing, or use that results in inhalation exposures; and

2. No manufacture beyond an annual production volume of 85,000 kg.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of pulmonary effects and skin irritation testing would help characterize the

potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11326.

PMN Number: P-19-26

Chemical Name: Alkanoic acid, compds. with substituted carbomonocycle-dialkyl-alkanediamine-halosubstituted heteromonocycle-polyalkylene glycol polymerdialkanolamine reaction products (generic).

CAS Number: Not available.

Basis for action: The PMN states that the use of the PMN substance will be as a component in coating resin products that are applied by cathodic electrodeposition and as an additive for corrosion protection. Based on the estimated physical chemical properties of the PMN substance, comparison with structurally analogous chemical substances, and Structure Analysis Relationships (SAR) analysis of test data on cationic polymers, EPA has identified concerns for irritation, lung effects, and aquatic toxicity at concentrations greater than 15 ppb if the chemical substance is not used following the limitation noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No manufacturing (including import), processing, or use that results in inhalation exposures to vapor, particulate, mist or aerosols; and

2. No release of a manufacturing, processing, or use stream associated with any use of the PMN substance exceeding a surface water concentration of 15 ppb.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health and environmental effects of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of pulmonary effects, skin irritation, and aquatic toxicity testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11327.

PMN Number: P-19-27

Chemical Name: Substituted carbomonocycle, polymer with haloalkyl substituted heteromonocycle, dialkyl-alkanediamine and hydro-hydroxypoly[oxy(alkylalkanediyl)], reaction products with metal oxide and dialkanolamine, acetates (salt) (generic).

CAS Number: Not available.

Basis for action: The PMN states that the use of the PMN substance will be as an isolated intermediate incorporated as a component in coating resin products that are applied by cathodic electrodeposition and used as additives for corrosion protection. Based on the estimated physical chemical properties of the PMN substance, comparison with structurally analogous chemical substances, and Structure Analysis Relationships (SAR) analysis of test data on analogous cationic polymers, EPA has identified lung effects and aquatic toxicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No manufacturing, processing, or use that results in inhalation exposures to vapor, particulate, mist or aerosols; and

2. No manufacture (including import) of an annual production volume of the PMN substance greater than 95,600 kg.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health and environmental effects of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of pulmonary effects and aquatic toxicity testing would help characterize the potential health and environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.11328.

PMN Number: P-19-45

Chemical Name: Non-metal tetrakis (hydroxyalkyl)-, halide, polymer with amide oxidized (generic).

CAS Number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be as a component of a textile coating. Based on the estimated physical chemical properties of the PMN substance and comparison with structurally analogous chemical substances, EPA has identified effects concerns for irritation to the skin and eyes, skin sensitization, and reproductive and developmental toxicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No manufacturing, processing, or use that results in inhalation exposures;

2. No manufacturing that results in unbound formaldehyde residuals greater than 0.1%; and

3. No manufacturing, processing, or use other than the confidential use described in the PMN.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of skin and eye irritation, skin sensitization, and developmental toxicity testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11329.

V. Rationale and Objectives of the Proposed Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these proposed SNURs, EPA concluded that for 7 chemical substances regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) Orders requiring the use of appropriate exposure controls were negotiated with the PMN/MCAN submitters. The SNURs would identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying Orders, consistent with TSCA section 5(f)(4).

During review of the other 24 chemical substances that are the subject of these SNURs and as further discussed in Unit IV, EPA identified circumstances different from the intended conditions of use identified in the PMNs that raised potential risk concerns. EPA determined that deviations from the protective measures identified in the submissions could result in changes in the type or form of exposure to the chemical substances and/or increased exposures to the chemical substances and/or changes in the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of the chemical substances, and

therefore warranted SNURs. The SNURs would identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the protection measures in the submission.

B. Objectives

EPA is proposing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants to achieve the following objectives with respect to the significant new uses that would be designated in this proposed rule:

- EPA would receive notice of any person's intent to manufacture or process a listed chemical substance for the described significant new use before that activity begins.

- EPA would be required to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.

- EPA would be required to either determine that the prospective manufacture or processing is not likely to present an unreasonable risk, or to take necessary regulatory action associated with any other determination, before the described significant new use of the chemical substance occurs.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the internet at <http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html>.

VI. Applicability of the Proposed Significant New Use Designation

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which a NOC has not been submitted EPA concludes that the designated significant new uses are not ongoing.

When chemical substances identified in this proposed rule are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use.

However, TSCA section 5(e) Orders have been issued for 7 of the 31 chemical substances, and the PMN submitters are prohibited by the TSCA section 5(e) Orders from undertaking activities which would be designated as significant new uses. The identities of 25 of the 31 chemical substances subject to this proposed rule have been claimed as confidential (per §§ 720.85 and 725.85) for a chemical substance covered by this action. Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this proposed rule are ongoing.

Therefore, EPA designates August 6, 2019 as the cutoff date for determining whether the new use is ongoing. The objective of EPA's approach is to ensure that a person cannot defeat a SNUR by initiating a significant new use before the effective date of the final rule.

Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified as of that date would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and wait until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

VII. Development and Submission of Information

EPA recognizes that TSCA section 5 does not require developing any particular new information (e.g., generating test data) before submission of a SNUN. There is an exception: Development of test data is required where the chemical substance subject to the SNUR is also subject to a rule, order or consent agreement under TSCA section 4 (see TSCA section 5(b)(1)).

In the absence of a TSCA section 4 test rule covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to or reasonably ascertainable by them (see 40 CFR 720.50 and 725.155). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit IV. lists potentially useful information identified by EPA that would help characterize the potential health and/or environmental effects of the PMN/SNUN substance for all of the listed SNURs. EPA recognizes that the 2016 Lautenberg Amendments have led to modifications in our approach to testing requirements,

including an increased consideration of alternatives to vertebrate testing. Descriptions of tests/information needs are provided for informational purposes only and EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. Pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the potentially useful information. EPA encourages dialogue with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h). To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines." The Organisation for Economic Co-operation and Development test guidelines are available from the OECD Bookshop at <http://www.oecdbookshop.org> or SourceOECD at <http://www.sourceoecd.org>.

The potentially useful information listed in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.

VIII. SNUN Submissions

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN or MCAN, including submission of test data on health and environmental effects as described in 40 CFR 720.50 or 725.160. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and 721.25 (or 40 CFR 725.25 and § 725.27). E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

IX. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this proposed rule. EPA's complete economic analysis is available in the docket under docket ID number EPA-HQ-OPPT-2019-0359.

X. Statutory and Executive Order Reviews

A. Executive Order 12866

This proposed rule would establish SNURs for several new chemical substances that were the subject of PMNs and TSCA section 5(e) Orders. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993).

B. Paperwork Reduction Act (PRA)

According to PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection requirements related to this proposed rule have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Regulatory Support Division, Office of Mission Support (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence,

but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of this proposed SNUR would not have a significant adverse economic impact on a substantial number of small entities. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule as a “significant new use.” Because these uses are “new,” based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA’s experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was seven in Federal fiscal year (FY) 2013, 13 in FY2014, six in FY2015, 10 in FY2016, 14 in FY2017, and 18 in FY2018 and only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from \$16,000 to \$2,800. This lower fee reduces the total reporting and recordkeeping of cost of submitting a SNUN to about \$10,116 for qualifying small firms. Therefore, the potential economic impacts of complying with this proposed SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** of June 2, 1997 (62 FR 29684) (FRL–5597–1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA’s experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal

government will be impacted by this action. As such, EPA has determined that this proposed rule would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 11632

This proposed rule would not have a substantial direct effect on 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, as specified in Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999).

F. Executive Order 13175

This proposed rule would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This proposed rule would not significantly nor uniquely affect the communities of Indian Tribal governments, nor would it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this action.

G. Executive Order 13045

This proposed rule is not subject to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211

This proposed rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), because this proposed rule is not expected to affect energy supply, distribution, or use and because this proposed rule is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this proposed rule would not involve any technical standards, NTTAA section 12(d) (15

U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898

This proposed rule does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Parts 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: July 26, 2019.

Tala Henry,

Deputy Director, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PARTS 721—[AMENDED]

■ 1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, 2613, and 2625(c).

■ 2. Add §§ 721.11300 through 721.11329 to subpart E to read as follows:

Subpart E—Significant New Uses for Specific Chemical Substances

Sec.

- | | | | | |
|-----------|--|---|---|---|
| * | * | * | * | * |
| 721.11300 | Alkanes, C11–16-branched and linear. | | | |
| 721.11301 | Alkyl alkenoic acid, alkoxyalkyl ester, polymer with alkyl alkenoate, alkyl alkyl alkenoate and tris alkyl silyl alkyl alkenoate (generic). | | | |
| 721.11302 | Alkyldiamine, aminoalkyl dimethylaminoalkyl dimethyl-, reaction products with propylene oxide (generic). | | | |
| 721.11303 | 2-Oxepanone, reaction products with alkylenediamine-alkyleneimine polymer, 2-[[[(2-alkyl)oxy]alkyl]oxirane and tetrahydro-2H-pyran-2-one (generic). | | | |
| 721.11304 | Dicarboxylic acids, polymers with alkanolic acid, alkanediol, substituted-alkylalkanoic acid, substituted alkyl carbomonocycle, alkanedioic acid, alkanolamine blocked compds with alkanolamine (generic). | | | |
| 721.11305 | Unsaturated polycyclic hydrocarbon (generic). | | | |
| 721.11306 | Glycerides, soya mono- and di-, epoxidized, acetates. | | | |
| 721.11307 | Glycerides, C16-18 and C18-unsatd. mono- and di-, epoxidized, acetates. | | | |
| 721.11308 | Mixed metal oxide (generic). | | | |
| 721.11309 | Urea, reaction products with N-butylphosphorothioic triamide and formaldehyde. | | | |
| 721.11310 | Fatty acid reaction products with ethyleneamines and dialkyl ester (generic). | | | |

- 721.11311 Pentaerythritol, mixed esters with linear and branched fatty acids (generic).
- 721.11312 Alcohol capped polycarbodiimide from diethyldiisocyanatobenzene (generic).
- 721.11313 Oxirane, 2-methyl-, polymer with methoxirane homopolymer, 1,1'-methylenebis[4-isocyanatobenzene], and glycerol-propylene oxide polymer (generic).
- 721.11314 Oxirane, 2-methyl-, polymer with methoxirane homopolymer, 1,1'-methylenebis[isocyanatobenzene], and glycerol-propylene oxide polymer (generic).
- 721.11315 Lithium nickel hydride oxide.
- 721.11316 Lithium nickel potassium oxide.
- 721.11317 Hydrolyzed functionalized diamino silanol polymer (generic).
- 721.11318 Propanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl-, polymer with dimethyl carbonate, 1,6-hexanediol, diamine and 1,1'-methylenebis[4-isocyanatocyclohexane], pentaerythritol, triacrylate-blocked, compds. with triethylamine (generic).
- 721.11319 Waste plastics, poly(ethylene terephthalate), polymers with diethylene glycol, glycerol, polyerythritol, triethylene glycol, trimethylolalkane and polypropylene glycol (generic).
- 721.11320 Waste plastics, poly(ethylene terephthalate), polymers with diethylene glycol, glycerol, polyerythritol glycol, trimethylolalkane and polypropylene glycol (generic).
- 721.11321 Naphtha oils (generic).
- 721.11322 Saccharide reaction products with acid anhydride, etherified (generic).
- 721.11323 Alkyl alkenoic acid, alkyl ester, telomere with alkyl alkenoate, substituted alkyl alkyl alkenoate, alkylthiol, substituted carbomonocycle, hydroxyalkyl alkyl alkenoate and alkyl alkyl alkenoate (generic).
- 721.11324 Formaldehyde, polymer with 2-phenoxyalkanol and .alpha.-phenyl-.omega.hydroxypoly(oxy-1,2-alkylenediyl), dihydrogen phosphate 2-phenoxyalkyl hydrogen phosphate, alkaline salt (generic).
- 721.11325 Substituted polyalkylenepolycarbomonocycle ester, polymer with dialkanolamine, (hydroxyalkoxy)carbonyl] derivs., (alkoxyalkoxy) alkanol blocked (generic).
- 721.11326 Carbonmonocycles, polymer with haloalkyl substituted heteromonocycle and hydro-hydroxypoly[oxy(alkyl-alkanediyl)], dialkyl-alkanediamineterminated, hydroxyalkylated, acetates (salts) (generic).
- 721.11327 Alkanoic acid, compds. with substituted carbomonocycle-dialkyl-alkanediamine-halosubstituted heteromonocycle-polyalkylene glycol polymerdialkanolamine reaction products (generic).
- 721.11328 Substituted carbomonocycle, polymer with haloalkyl substituted heteromonocycle, dialkyl-alkanediamine and hydro-hydroxypoly[oxy(alkylalkanediyl)], reaction products with metal oxide and dialkanolamine, acetates (salt) (generic).

- 721.11329 Non-metal tetrakis (hydroxyalkyl)-, halide, polymer with amide oxidized (generic).

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Subpart E—Significant New Uses for Specific Chemical Substances

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§ 721.11300 Alkanes, C11–16-branched and linear.

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance identified as alkanes, C11–16-branched and linear (PMN P–16–400, CAS No. 1809170–78–2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is a significant new use to use the substance other than as a chemical intermediate, in cured coatings, cleaning fluids, metalworking fluids/rolling oils, and in agrochemicals.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i), are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11301 Alkyl alkenoic acid, alkoxyalkyl ester, polymer with alkyl alkenoate, alkyl alkyl alkenoate and tris alkyl silyl alkyl alkenoate (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as alkyl alkenoic acid, alkoxyalkyl ester, polymer with alkyl alkenoate, alkyl alkyl alkenoate and tris alkyl silyl alkyl alkenoate (PMN P–17–119) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f). It is a significant new use to manufacture, process, or use the PMN substance in any manner that results in inhalation exposures.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part

apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i), are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11302 Alkyldiamine, aminoalkyl dimethylaminoalkyl dimethyl-, reaction products with propylene oxide (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified alkyldiamine, aminoalkyl dimethylaminoalkyl dimethyl-, reaction products with propylene oxide (PMN P–17–191) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the PMN substance in any manner that generates a spray, mist, or aerosol.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i), are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11303 2-Oxepanone, reaction products with alkylenediamine-alkyleneimine polymer, 2-[[[(2-alkyl)oxy]alkyl]oxirane and tetrahydro-2H-pyran-2-one (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as 2-oxepanone, reaction products with alkylenediamine-alkyleneimine polymer, 2-[[[(2-alkyl)oxy]alkyl]oxirane and tetrahydro-2H-pyran-2-one (PMN P–17–220) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f) and (j). It is a significant new use to manufacture or import the PMN substance other than in liquid form.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11304 Dicarboxylic acids, polymers with alkanolic acid, alkanediol, substituted-alkylalkanoic acid, substituted alkyl carbomonocycle, alkanedioic acid, alkanolamine blocked compds with alkanolamine (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substances generically identified as dicarboxylic acids, polymers with alkanolic acid, alkanediol, substituted-alkylalkanoic acid, substituted alkyl carbomonocycle, alkanedioic acid, alkanolamine blocked compds with alkanolamine (P-17-387 and P-17-388) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the PMN substances resulting in amine counter ions greater than 4% by weight, isocyanate residuals greater than 0.1% by weight, or a proportion of the acid group greater than 20% by weight. It is a significant new use to manufacture, process, or use the PMN substances that results in the average molecular weight smaller than the molecular weight specified in the PMNs or proportion of the low molecular weight species greater than the values specified in the PMNs for the 500 and 1000 dalton species.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of these substances.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11305 Unsaturated polycyclic hydrocarbon (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as unsaturated polycyclic hydrocarbon (PMN P-17-419) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.*

Requirements as specified in § 721.63(a)(1), (2)(i), (3), (4), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (5) respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50, (6)(v), (vi), (b)(concentration set at 1.0%), and (c).

(ii) *Hazard communication.*

Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(i), (ii), (vi), (ix), (skin sensitization), (specific target organ toxicity), (2)(i), (ii), (iv), (v), (3)(i), (ii), (4)(iii), and (5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) and (t). It is a significant new use to manufacture the substance for more than 9 months.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions

of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

§ 721.11306 Glycerides, soya mono- and di-, epoxidized, acetates.

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance identified as glycerides, soya mono- and di-, epoxidized, acetates (P-18-7, CAS No. 2097734-14-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposures.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=9,000.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11307 Glycerides, C16-18 and C18-unsatd. mono- and di-, epoxidized, acetates.

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance identified as glycerides, C16-18 and C18-unsatd. mono- and di-, epoxidized, acetates (P-18-8, CAS No. 2097734-15-9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposures.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=9,000.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11308 Mixed metal oxide (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as mixed metal oxide (PMN P-18-55) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.*

Requirements as specified in § 721.63(a)(1), (2), (3), (4) when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (5)(respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000), (6)(particulate), (b)(concentration set at 0.1%), and (c).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) Order for this substance. The NCEL is 0.04 mg/m³ as an 8-hour time weighted average. Persons who wish to pursue NCELs as an alternative to § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELs approach are approved by the EPA will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) Order.

(B) [Reserved]

(ii) [Reserved]

(ii) *Hazard communication.*

Requirements as specified in § 721.72(a) through (d) (e)(concentration set at 0.1%), (f), (g)(1)(ii), (vii), (allergic skin reaction), (respiratory sensitization), (germ cell mutagenicity), (2)(i), (ii), (iii), (iv) (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.04 mg/m³), (v), and (5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k).

(b) *Specific requirements.* The provisions of subpart A of this part

apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) Determining whether a specific use is subject to this section. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

§ 721.11309 Urea, reaction products with N-butylphosphorothioic triamide and formaldehyde.

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance identified as urea, reaction products with N-butylphosphorothioic triamide and formaldehyde (P-18-77, CAS No. 2093385-47-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (o). It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposures.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (f) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11310 Fatty acid reaction products with ethyleneamines and dialkyl ester (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as fatty acid reaction products with ethyleneamines and dialkyl ester (P-18-85) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11311 Pentaerythritol, mixed esters with linear and branched fatty acids (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as pentaerythritol, mixed esters with linear and branched fatty acids (PMN P-18-101) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (y)(1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11312 Alcohol capped polycarbodiimide from diethyldiisocyanatobenzene (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as alcohol capped polycarbodiimide from diethyldiisocyanatobenzene (PMN P-18-107) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance with a residual isocyanate level greater than 0.1%.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11313 Oxirane, 2-methyl-, polymer with methoxirane homopolymer, 1,1'-methylenebis[4-isocyanatobenzene], and glycerol-propylene oxide polymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as oxirane, 2-methyl-, polymer with methoxirane homopolymer, 1,1'-methylenebis[4-isocyanatobenzene], and glycerol-propylene oxide polymer (P-18-118) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (o). It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposures. It is a significant new use to manufacture, process, or use the substance with isocyanate residuals greater than 0.1%.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11314 Oxirane, 2-methyl-, polymer with methoxirane homopolymer, 1,1'-methylenebis[isocyanatobenzene], and glycerol-propylene oxide polymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as oxirane, 2-methyl-, polymer with methoxirane homopolymer, 1,1'-methylenebis[isocyanatobenzene], and glycerol-propylene oxide polymer (P-18-119) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as

specified in § 721.80 (o). It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposures. It is a significant new use to manufacture, process, or use the substance with isocyanate residuals greater than 0.1%.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11315 Lithium nickel hydride oxide.

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance identified as lithium nickel hydride oxide (P-18-123, CAS No. 2081933-92-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.*

Requirements as specified in § 721.63(a)(1), (2), (3), (4), (5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (6) (particulate), and (c).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) consent order for this substance. The NCEL is 0.05 mg/m³ as an 8-hour time weighted average. Persons who wish to pursue NCELs as an alternative to § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELs approach are approved by EPA will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) consent order.

(B) [Reserved]

(ii) *Hazard communication.*

Requirements as specified in § 721.72(a) through (d), (f), (g)(1)(i), (ii), (iii), (iv), (vii), (viii), (ix), (eye irritation), (2)(i), (ii), (iii), (iv) (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.05 mg/m³), (v), (skin irritation), (3)(ii), (4)(i), (5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance for more than six months.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=32.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k), are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11316 Lithium nickel potassium oxide.

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance identified as lithium nickel potassium oxide (P-18-124, CAS No. 210352-95-7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.*

Requirements as specified in § 721.63(a)(1), (2), (3), (4), (5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (6) (particulate), and (c).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) consent order

for this substance. The NCEL is 0.05 mg/m³ as an 8-hour time weighted average. Persons who wish to pursue NCEs as an alternative to § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCEs approach are approved by EPA will be required to follow NCEs provisions comparable to those contained in the corresponding TSCA section 5(e) consent order.

(B) [Reserved]

(ii) *Hazard communication.*

Requirements as specified in § 721.72(a) through (d), (f), (g)(1)(i), (ii), (iii), (iv), (vii), (viii), (ix), (eye irritation), (2)(i), (ii), (iii), (iv) (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.05 mg/m³), (v), (skin irritation), (3)(ii), (4)(i), (5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance for more than six months.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=32.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k), are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11317 Hydrolyzed functionalized di-amino silanol polymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as hydrolyzed functionalized di-amino silanol polymer (PMN P-18-152) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the PMN substance in any manner that results in inhalation exposure.

(ii) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) where N=3.

(b) *Specific requirements.* The provisions of subpart A of this part

apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11318 Propanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl-, polymer with dimethyl carbonate, 1,6-hexanediol, diamine and 1,1'-methylenebis[4-isocyanatocyclohexane], pentaerythritol, triacrylate-blocked, compds. with triethylamine (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as propanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl-, polymer with dimethyl carbonate, 1,6-hexanediol, diamine and 1,1'-methylenebis[4-isocyanatocyclohexane], pentaerythritol, triacrylate-blocked, compds. with triethylamine (PMN P-18-169) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.*

Requirements as specified in § 721.63(a)(2)(i), (3), (4) and (5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000 for spray applications and of at least 50 for non-spray applications). When determining which persons are reasonably likely to be exposed as required for in § 721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture (including import) the PMN substance with triethylamine concentration no greater than the confidential concentration described in the PMN.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (e) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

§ 721.11319 Waste plastics, poly(ethylene terephthalate), polymers with diethylene glycol, glycerol, polyerythritol, triethylene glycol, trimethylolalkane and polypropylene glycol (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as waste plastics, poly(ethylene terephthalate), polymers with diethylene glycol, glycerol, polyerythritol, triethylene glycol, trimethylolalkane and polypropylene glycol. (PMN P-18-200) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.*

Requirements as specified in § 721.63(a)(1), (2), (3), (4), (5) (respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 10), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), (4) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (6)(particulate), (b)(concentration set at 1.0%), and (c).

(ii) *Hazard communication.*

Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(iv), (2)(i), (iv), (v), (avoid eye contact), (use eye protection), (3)(i), (ii), (4)(water releases restrictions apply), and (5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=280.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are

applicable to manufacturers and processors of this substance.

(2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§ 721.11320 Waste plastics, poly(ethylene terephthalate), polymers with diethylene glycol, glycerol, polyerythritol glycol, trimethylolalkane and polypropylene glycol (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as waste plastics, poly(ethylene terephthalate), polymers with diethylene glycol, glycerol, polyerythritol glycol, trimethylolalkane and polypropylene glycol (P-18-201) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.*

Requirements as specified in § 721.63(a)(1), (2), (3), (4), (5) (respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 10), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), (4) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (6) (particulate), (b) (concentration set at 1.0%), and (c).

(ii) *Hazard communication.*

Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(iv), (2)(i), (iv), (v), (avoid eye contact), (use eye protection), (3)(i), (ii), (4) (water releases restrictions apply), and (5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(iv) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) where N=280.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The

provisions of § 721.185 apply to this section.

§ 721.11321 Naphtha oils (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as naphtha oils (PMN P-18-235) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (f) and (j).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11322 Saccharide reaction products with acid anhydride, etherified (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as saccharide reaction products with acid anhydride, etherified (PMN P-18-238) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11323 Alkyl alkenoic acid, alkyl ester, telomere with alkyl alkenoate, substituted alkyl alkyl alkenoate, alkylthiol, substituted carbomonocycle, hydroxyalkyl alkyl alkenoate and alkyl alkyl alkenoate (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as alkyl alkenoic acid, alkyl ester, telomere with alkyl alkenoate, substituted alkyl alkyl alkenoate, alkylthiol, substituted carbomonocycle, hydroxyalkyl alkyl alkenoate and alkyl alkyl alkenoate (PMN P-18-307) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture (including import) the PMN substance with more than 5% of the molecular weight content less than 1,000 Daltons.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11324 Formaldehyde, polymer with 2-phenoxyalkanol and .alpha.-phenyl-.omega. hydroxypoly(oxy-1,2-alkylenediyl), dihydrogen phosphate 2-phenoxyalkyl hydrogen phosphate, alkaline salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as formaldehyde, polymer with 2-phenoxyalkanol and .alpha.-phenyl-.omega. hydroxypoly(oxy-1,2-alkylenediyl), dihydrogen phosphate 2-phenoxyalkyl hydrogen phosphate, alkaline salt (PMN P-18-312) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure. It is a significant new use to manufacture the PMN substance with greater than 20% (weight percent) components with molecular weight below 500 Daltons.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part

apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11325 Substituted polyalkylenepolycarbomonocycle ester, polymer with dialkanolamine, (hydroxyalkoxy)carbonyl derivs., (alkoxyalkoxy) alkanol blocked (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as substituted polyalkylenepolycarbomonocycle ester, polymer with dialkanolamine, [(hydroxyalkoxy)carbonyl] derivs., (alkoxyalkoxy) alkanol-blocked (PMN P-19-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(w)(1)(2), (x)(1)(2), and (y)(1)(2).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11326 Carbonmonocycles, polymer with haloalkyl substituted heteromonocycle and hydro-hydroxypoly[oxy(alkyl-alkanediyl)], dialkyl-alkanediamineterminated, hydroxyalkylated, acetates (salts) (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as carbonmonocycles, polymer with haloalkyl substituted heteromonocycle and hydro-hydroxypoly[oxy(alkyl-alkanediyl)], dialkyl-alkanediamineterminated, hydroxyalkylated, acetates (salts) (PMN P-19-9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant

new use to manufacture, process, or use the substance in any manner that results in inhalation exposure to vapor, particulate, mist or aerosols. It is a significant new use to manufacture the PMN substance beyond an annual production volume of 85,000 kg.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11327 Alkanoic acid, compds. with substituted carbomonocycle-dialkyl-alkanediamine-halosubstituted heteromonocycle-polyalkylene glycol polymerdialkanolamine reaction products (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as alkanic acid, compds. with substituted carbomonocycle-dialkyl-alkanediamine-halosubstituted heteromonocycle-polyalkylene glycol polymerdialkanolamine reaction products (PMN P-19-26) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure to vapor, particulate, mist or aerosols.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=15.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11328 Substituted carbomonocycle, polymer with haloalkyl substituted heteromonocycle, dialkyl-alkanediamine and hydro-hydroxypoly[oxy(alkylalkanediyl)], reaction products with metal oxide and dialkanolamine, acetates (salt) (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as substituted carbomonocycle, polymer with haloalkyl substituted heteromonocycle, dialkyl-alkanediamine and hydro-hydroxypoly[oxy(alkylalkanediyl)], reaction products with metal oxide and dialkanolamine, acetates (salt) (PMN P-19-27) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the PMN substance in any manner that results in inhalation exposure to vapor, particulate, mist or aerosols. It is a significant new use to manufacture the PMN substance beyond an annual production volume of 95,600 kg.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11329 Non-metal tetrakis (hydroxyalkyl)-, halide, polymer with amide oxidized (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as non-metal tetrakis (hydroxyalkyl)-, halide, polymer with amide oxidized (PMN P-19-45) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j). It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure. It is a significant new use to manufacture the substance that results in unbound formaldehyde residuals greater than 0.1%.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

42 CFR Part 88

[NIOH Docket 094]

World Trade Center Health Program; Petition 022—Monoclonal Gammopathy of Undetermined Significance; Finding of Insufficient Evidence

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Denial of petition for addition of a health condition.

SUMMARY: On March 11, 2019, the Administrator of the World Trade Center (WTC) Health Program received a petition (Petition 022) to add “monoclonal gammopathy of undetermined significance (MGUS)” to the List of WTC-Related Health Conditions (List). Upon reviewing the scientific and medical literature, including information provided by the petitioner, the Administrator has determined that the available evidence does not have the potential to provide a basis for a decision on whether to add MGUS to the List. The Administrator also finds that insufficient evidence exists to request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee (STAC), to publish a proposed rule, or to publish a determination not to publish a proposed rule.

DATES: The Administrator of the WTC Health Program is denying this petition for the addition of a health condition as of August 6, 2019.

ADDRESSES: Visit the WTC Health Program website at [https://](https://www.cdc.gov/wtc/received.html)

www.cdc.gov/wtc/received.html to review Petition 022.

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Program Analyst, 1090 Tusculum Avenue, MS: C-48, Cincinnati, OH 45226; telephone (855) 818-1629 (this is a toll-free number); email NIOHSHregs@cdc.gov.

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A. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111-347, as amended by Pub. L. 114-113), added Title XXXIII to the Public Health Service (PHS) Act,¹ establishing the WTC Health Program within the Department of Health and Human Services (HHS). The WTC Health Program provides medical monitoring and treatment benefits for health conditions on the List to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001, or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

All references to the Administrator of the WTC Health Program (Administrator) in this document mean the Director of the National Institute for Occupational Safety and Health (NIOSH) or his designee.

Pursuant to section 3312(a)(6)(B) of the PHS Act, interested parties may petition the Administrator to add a health condition to the List in 42 CFR 88.15. Within 90 days after receipt of a valid petition to add a condition to the List, the Administrator must take one of the following four actions described in

section 3312(a)(6)(B) of the PHS Act and § 88.16(a)(2) of the Program regulations: (1) Request a recommendation of the STAC; (2) publish a proposed rule in the **Federal Register** to add such health condition; (3) publish in the **Federal Register** the Administrator's determination not to publish such a proposed rule and the basis for such determination; or (4) publish in the **Federal Register** a determination that insufficient evidence exists to take action under (1) through (3) above.

B. Procedures for Evaluating a Petition

In addition to the regulatory provisions, the WTC Health Program has developed policies to guide the review of submissions and petitions,² as well as the analysis of evidence supporting the potential addition of a non-cancer health condition to the List.³

A valid petition must include sufficient medical basis for the association between the September 11, 2001, terrorist attacks and the health condition to be added; in accordance with WTC Health Program policy, reference to a peer-reviewed, published, epidemiologic study about the health condition among 9/11-exposed populations or to clinical case reports of health conditions in WTC responders or survivors may demonstrate the required medical basis.⁴ Studies linking 9/11 agents or hazards⁵ to the petitioned health condition may also provide sufficient medical basis for a valid petition.

After the Program has determined that a petition is valid, the Administrator must direct the Program to conduct a review of the scientific literature to determine if the available scientific information has the potential to provide

² See WTC Health Program [2014], *Policy and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions*, May 14, 2014, <http://www.cdc.gov/wtc/pdfs/WTCHPPPPetitionHandlingProcedures14May2014.pdf>.

³ See WTC Health Program [2017], *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions*, February 14, 2017, https://www.cdc.gov/wtc/pdfs/policies/WTCHPP_Padding_NonCancers_14_February_2017-508.pdf.

⁴ See *supra* note 2.

⁵ 9/11 agents are chemical, physical, biological, or other hazards reported in a published, peer-reviewed exposure assessment study of responders, recovery workers, or survivors who were present in the New York City disaster area, or at the Pentagon site, or the Shanksville, Pennsylvania site, as those locations are defined in 42 CFR 88.1, as well as those hazards not identified in a published, peer-reviewed exposure assessment study, but which are reasonably assumed to have been present at any of the three sites. See WTC Health Program [2018], *Development of the Inventory of 9/11 Agents*, July 17, 2018, https://www.cdc.gov/ResearchGateway/Content/pdfs/Development_of_the_Inventory_of_9-11_Agents_20180717.pdf.

¹ Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm-61. Those portions of the James Zadroga 9/11 Health and Compensation Act of 2010 found in Titles II and III of Public Law 111-347 do not pertain to the WTC Health Program and are codified elsewhere.

a basis for a decision on whether to add the health condition to the List.⁶ The literature review is a keyword search of relevant scientific databases; peer-reviewed, published, epidemiologic studies (including direct observational studies in the case of health conditions such as injuries) about the health condition among 9/11-exposed populations are then identified from the initial search results. The Program evaluates the scientific quality of each peer-reviewed, published, epidemiologic study of the health condition identified in the literature search; the Program then compiles the scientific results of each study to assess whether a causal relationship between 9/11 exposures and the health condition is supported, and evaluates whether the results of the studies are representative of the 9/11-exposed population of responders and survivors. A health condition may be added to the List if peer-reviewed, published, epidemiologic studies provide support that the health condition is substantially likely⁷ to be causally associated with 9/11 exposures. If the evaluation of evidence provided in peer-reviewed, published, epidemiologic studies of the health condition in 9/11 populations demonstrates a high, but not substantial, likelihood of a causal association between the 9/11 exposures and the health condition, then the Administrator may consider additional highly relevant scientific evidence regarding exposures to 9/11 agents from sources using non-9/11-exposed populations. If that additional assessment establishes that the health condition is substantially likely to be causally associated with 9/11 exposures among 9/11-exposed populations, the health condition may be added to the List.

C. Petition 022

On March 11, 2019, the Administrator received a petition (Petition 022) requesting the addition of “monoclonal gammopathy of undetermined significance (MGUS)” to the List.⁸ The petition included a 2018 study by Landgren *et al.*,⁹ which provided

sufficient medical basis for the petition to be considered valid because it is a peer-reviewed, published, epidemiologic study about the health condition among 9/11-exposed populations; Landgren *et al.* is a scientific source that demonstrates a potential link between exposure to a 9/11 hazard (in this case, the identified 9/11 agents polychlorinated biphenyl (PCB), dioxins, polycyclic aromatic hydrocarbons (PAHs), and asbestos)¹⁰ and the requested health condition, MGUS.

D. Review of Scientific and Medical Information and Administrator Determination

The Program policy on the addition of non-cancer health conditions to the List directs the Program to conduct a literature review of the health condition(s) petitioned.¹¹ Petition 022 requested the addition of MGUS, an asymptomatic condition characterized by the presence of a monoclonal immunoglobulin (Ig), also called an M-protein, in the blood without any evidence of multiple myeloma or another lymphoproliferative disorder. MGUS is not a cancer, and the vast majority of people with MGUS never develop the types of cancer for which it is a precursor. Immunoglobulin subtypes involved may be IgM, non-IgM (e.g., IgA and IgG), or light-chain.¹² All pose a slight risk of progression (1–2 percent per year) to a malignant disorder. Typically, IgG and IgA MGUS are the precursors of multiple myeloma, IgM MGUS is the precursor of Waldenstrom macroglobulinemia or other lymphoproliferative conditions, and light-chain MGUS is the precursor of light-chain multiple myeloma.¹³

In response to Petition 022, the Program conducted a review of the scientific literature on MGUS to identify peer-reviewed, published, epidemiologic studies of the health condition in the 9/11-exposed population.¹⁴ Only one study meeting

the Program’s criteria for further evaluation was identified in this literature review, Landgren *et al.* [2018], referenced above.

Landgren *et al.* [2018] reported on two analyses conducted on 9/11-exposed firefighters from the New York City Fire Department (FDNY). One was a case series (a descriptive report) of 16 multiple myeloma cases identified among white male WTC-exposed FDNY firefighters. Since this analysis does not provide dispositive evidence linking 9/11 exposures to MGUS, it is not relevant to this petition and will not be further described.

The second analysis was a prevalence screening study of 781 9/11-exposed FDNY white male firefighters aged 50 to 79 years. Patients with MGUS, light-chain MGUS, and overall MGUS (*i.e.*, MGUS and light-chain MGUS combined) were diagnosed using a serum immunoglobulin assay. 9/11 exposure was assessed based on initial arrival time at Ground Zero and five exposure groups were recognized (*i.e.*, arriving the morning of 9/11 [most highly exposed]; arriving the afternoon of September 11, 2001; arriving on September 12, 2001; arriving between September 13 and 24, 2001; and arriving between September 25, 2001 and July 24, 2002 [least exposed]). 9/11 exposure was also assessed by length of time worked at Ground Zero (months in which a participant worked at least 1 day at Ground Zero).

Findings in this study were compared to those of a population-based cohort of 7,612 white male residents of Olmsted County, Minnesota, aged 50 years and older, previously assembled to estimate MGUS prevalence.¹⁵ Among FDNY firefighters, the age-standardized prevalence rate (ASR) of overall MGUS (*i.e.*, MGUS and light-chain MGUS combined) was 7.63 per 100 persons (95% CI, 5.45–9.81). The ASR of light-chain MGUS was 3.08 per 100 persons (95% CI, 1.66–4.50), and for MGUS was 4.55 per 100 persons (95% CI, 2.90–6.21). The relative rate of overall MGUS (*i.e.*, MGUS and light-chain MGUS combined) was 1.76 (95% CI, 1.34–2.29) when comparing FDNY firefighters with the Olmsted County reference population; the relative rate was 3.13 for light-chain MGUS (95% CI, 1.99–4.93) and 1.35 for MGUS (95% CI, 0.96–1.91).

proliferative disorder, monoclonal gammopathy, monoclonal gammopathies. The literature search was conducted in English-language journals on April 25, 2019.

¹⁵ Dispenzieri A, Katzmann JA, Kyle RA, et al. [2010], *Prevalence and Risk of Progression of Light-Chain Monoclonal Gammopathy of Undetermined Significance: A Retrospective Population-Based Cohort Study*, *Lancet* 375(9727):1721–8.

Among Firefighters Exposed to the World Trade Center Disaster, *JAMA Oncol* 4(6):821–827.

¹⁰ See *supra* note 5.

¹¹ *Supra* note 3.

¹² “Light-chain” refers to the antibody components made by malignant plasma cells in patients with multiple myeloma.

¹³ Fanning SR, Hussein MA [2018], *Monoclonal Gammopathies of Undetermined Significance*, Medscape, <https://emedicine.medscape.com/article/204297-overview>.

¹⁴ Databases searched include: CINAHL, Embase, NIOSHTIC-2, ProQuest Health & Safety, PsycINFO, Ovid MEDLINE, Scopus, Toxicology Abstracts/TOXLINE, and WTC Health Program Bibliographic Database. Keywords used to conduct the search include: MGUS, monoclonal gammopathy of undetermined significance, premalignant clonal plasma cell disorder, lymphoplasmacytic

⁶ See *supra* note 3.

⁷ The “substantially likely” standard is met when the scientific evidence, taken as a whole, demonstrates a strong relationship between the 9/11 exposures and the health condition.

⁸ See Petition 022, *WTC Health Program: Petitions Received*, <http://www.cdc.gov/wtc/received.html>.

⁹ Landgren O, Zeig-Owens R, Giricz O, Goldfarb D, Murata K, Thoren K, Ramanathan L, Hultcrantz M, Dogan A, Nwankwo G, Steidl U, Pradhan K, Hall CB, Cohen HW, Jaber N, Schwartz T, Crowley L, Crane M, Irby S, Webber MP, Verma A, Prezant DJ [2018], *Multiple Myeloma and its Precursor Disease*

The researchers evaluated the risk of overall MGUS (*i.e.*, MGUS and light-chain MGUS combined) by 9/11 exposure; for each of the arrival times described above, the ASRs for the 9/11-exposed FDNY firefighters were greater than in the Olmsted County reference population, although the authors did not find an exposure gradient and did not provide risk estimates for these findings. Additionally, the authors reported that there were no statistically significant differences in ASRs when length of time worked at Ground Zero was included in the analyses (the authors did not report a risk estimate for this finding). In addition, the authors did not report the results of the association between 9/11 exposures, expressed by time of arrival or duration of work at Ground Zero, and light-chain MGUS, nor for MGUS overall.

Among the strengths of Landgren *et al.* [2018] is that this is the first study to present the age-specific prevalence of MGUS or light-chain MGUS in 9/11-exposed responders, and show an excess age-standardized prevalence when compared to an unexposed reference population.¹⁶ Health outcomes were objectively assessed, since diagnosis was determined in all study participants by testing serum samples, collected between December 2013 and October 2015, in the laboratory.

However, Landgren *et al.* [2018] is subject to a number of limitations. The prevalence study design limits the interpretation and generalizability of findings. IgM MGUS and non-IgM MGUS were lumped together as “MGUS” and not reported separately. Risk estimates of the association between 9/11 exposure and MGUS were not reported. A temporal relationship between 9/11 exposure and the first occurrence of MGUS could also not be established; because MGUS is asymptomatic, it is possible that some FDNY members with MGUS had the condition prior to September 11, 2001 (no baseline samples were collected prior to September 11, 2001 to ascertain date of onset). Another limitation suggested by the authors is inadequate statistical power to detect a statistically significant exposure-response relationship. Landgren *et al.* [2018] addressed confounding by race, gender, and age by limiting the analysis to white men and standardizing the rates by age. However, family history of MGUS and

other occupational exposures were not controlled for. A major limitation of this study is the use of the Olmsted County reference group,¹⁷ which is a general population selected from a mixed rural-urban setting and not comparable to the FDNY population, a predominantly urban working population. The authors acknowledged that a comparison group composed of firefighters with no 9/11 exposure or a truly random sample of the U.S. (or the New York City) population would be desirable. Finally, the authors reported that they were unable to control for all of the potential confounders between the study and reference populations.

Evaluation of Study Using Select Bradford Hill Criteria

Landgren *et al.* [2018] was assessed to determine whether a causal relationship between 9/11 exposures and MGUS is supported. As described in the policy on the addition of non-cancer health conditions to the List,¹⁸ the WTC Health Program uses the following Bradford Hill criteria to evaluate studies of 9/11-exposed populations: strength of association, precision of the risk estimate, consistency of association, biological gradient, and plausibility and coherence.¹⁹

Strength of association:²⁰ Landgren *et al.* [2018] found a relatively strong association between being a 9/11-exposed FDNY member and an increased prevalence of MGUS, especially light-chain MGUS. However, Landgren *et al.* [2018] did not report risk estimates for the association between their measures of 9/11 exposure (initial arrival time and length of time worked at Ground Zero); the WTC Health Program would need such risk estimates in order to evaluate the strength of the association between 9/11 exposure and MGUS.

Precision of risk estimate:²¹ Landgren *et al.* [2018] reported reasonably precise risk estimates when comparing FDNY

members with the Olmsted County reference population.²² Because Landgren *et al.* [2018] did not report risk estimates and their confidence intervals for the association between 9/11 exposure and MGUS, the WTC Health Program is unable to evaluate the precision of such risk estimates.

Consistency of association:²³ Multiple studies are not available to ascertain consistency. Only the Landgren *et al.* [2018] study is available.

Biological gradient:²⁴ The exposure-response (biological gradient) information provided in Landgren *et al.* [2018] does not demonstrate an exposure gradient between 9/11 exposure and MGUS. In other words, the study does not provide evidence that the risk of MGUS increases with increasing levels of exposure.

Plausibility and coherence:²⁵ The findings of Landgren *et al.* [2018] do not demonstrate a basis for a potential relationship between 9/11 exposure and MGUS. Some FDNY members with MGUS may have had the condition prior to September 11, 2001. This lack of temporal information severely limits an evaluation of the plausibility of an association between 9/11 exposure and MGUS.

Evaluation of Representativeness of Study

Landgren *et al.* [2018] was reviewed to determine whether both the WTC responder cohort studied is representative of the entire 9/11-exposed population and whether the results can be extrapolated. MGUS screening study subjects were a subset of FDNY members who were exposed to 9/11 agents on or in the aftermath of September 11, 2001 until the Ground Zero site closed in July 2002. All study subjects were white males between the ages of 50 and 79 who had serum samples taken by the FDNY WTC Health Program from December 2013 through October 2015. The findings of this study represent only a subset of white male FDNY responders and may not be

¹⁷ Wi C, St Sauver JL, Jacobson DJ, *et al.* [2016], Ethnicity, Socioeconomic Status, and Health Disparities in a Mixed Rural-Urban US Community—Olmsted County, Minnesota, Mayo Clinic Proceedings 91(5):612–622.

¹⁸ *Supra* note 3.

¹⁹ Aschengrau A, Seage GR [2018], *Essentials of Epidemiology in Public Health*, 4th Edition, (Burlington, MA: Jones & Bartlett).

²⁰ It is generally thought that strong associations are more likely to be causal than weak associations; however, a weak association does not rule out a causal relationship. *See supra* note 19.

²¹ The uncertainty inherent in estimating the strength of association between exposure and health effect (effect size) from observational data is expressed as a confidence interval, illustrating a range of values that contains the true effect size. A narrow confidence interval indicates a more precise measure of the effect size and a wider interval indicates greater uncertainty. *See supra* note 19.

²² *See supra* note 16.

²³ Consistent findings are demonstrated when they have been repeatedly reported by multiple studies. *See supra* note 19.

²⁴ Studies establish an exposure-response relationship by demonstrating that increases in exposure (*i.e.*, exposures of greater intensity and/or longer duration) are associated with a greater incidence of disease. A thorough evaluation of exposure-response requires analysis of multiple levels of exposure such that the investigator can demonstrate that the risk increases with increasing levels of exposure. *See supra* note 19.

²⁵ Study findings demonstrate a basis in scientific theory that supports the relationship between the exposure and the health effect and do not conflict with known facts about the biology of the health condition. *See supra* note 19.

¹⁶ Among FDNY firefighters, the ASR of overall MGUS was 7.63 per 100 persons (95% CI, 5.45–9.81) versus the ASR of overall MGUS among the Olmsted County reference population of 4.34 per 100 persons (95% CI, 3.88–4.81 per 100 persons and RR, 1.76; 95% CI, 1.34–2.29).

generalizable to other 9/11-exposed groups.

Summary of Evaluation

The study by Landgren *et al.* [2018] was evaluated to determine whether a causal relationship between 9/11 exposures and MGUS is supported. As described in the policy on the addition of non-cancer health conditions to the List,²⁶ the WTC Health Program uses the Bradford Hill criteria described above to evaluate whether a causal relationship between 9/11 exposures and a health condition is supported. Although Landgren *et al.* [2018] speculated that the study results demonstrate an association between 9/11 exposure and MGUS, the information available in the study is insufficient to support a claim for causation using the Bradford Hill criteria. The study reported a reasonably strong and precise association between being a 9/11-exposed FDNY firefighter and an increased prevalence of MGUS; however, an exposure-response gradient was not found. Furthermore, the temporality of the findings was not established because some FDNY members with MGUS may have had the condition prior to September 11, 2001. Finally, the consistency of an association could not be assessed as Landgren *et al.* [2018] was the only relevant study that was identified. Given the lack of an exposure-response gradient, the questionable plausibility, the lack of other relevant studies, and the other limitations discussed above, the WTC Health Program considers the Landgren *et al.* [2018] study to be preliminary and insufficient to add MGUS to the List.

E. Administrator's Final Decision on Whether To Propose the Addition of Monoclonal Gammopathy of Undetermined Significance to the List

Pursuant to PHS Act, sec. 3312(a)(6)(B)(iv) and 42 CFR 88.16(a)(2)(iv), the Administrator has determined that insufficient evidence is available to take further action at this time, including proposing the addition of MGUS to the List (pursuant to PHS Act, sec. 3312(a)(6)(B)(ii) and 42 CFR 88.16(a)(2)(ii)) or publishing a determination not to publish a proposed rule in the **Federal Register** (pursuant to PHS Act, sec. 3312(a)(6)(B)(iii) and 42 CFR 88.16(a)(2)(iii)). The Administrator has also determined that requesting a recommendation from the STAC (pursuant to PHS Act, sec. 3312(a)(6)(B)(i) and 42 CFR 88.16(a)(2)(i)) is unwarranted.

For the reasons discussed above, the Petition 022 request to add MGUS to the List of WTC-Related Health Conditions is denied.

F. Approval To Submit Document to the Office of the Federal Register

The Secretary, HHS, or his designee, the Director, Centers for Disease Control and Prevention (CDC) and Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), authorized the undersigned, the Administrator of the WTC Health Program, to sign and submit the document to the Office of the Federal Register for publication as an official document of the WTC Health Program. Robert Redfield M.D., Director, CDC, and Administrator, ATSDR, approved this document for publication on July 29, 2019.

John J. Howard,

Administrator, World Trade Center Health Program and Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.

[FR Doc. 2019-16609 Filed 8-5-19; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Part 180

[Docket No. PHMSA-2017-0083 (HM-219B)]

RIN 2137-AF30

Hazardous Materials: Response to an Industry Petition To Reduce Regulatory Burden for Cylinder Requalification Requirements

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: PHMSA is proposing to revise requirements on the requalification period for certain DOT 4-series specification cylinders in non-corrosive gas service in response to a petition for rulemaking submitted by the National Propane Gas Association. This rulemaking proposes regulatory relief and a reduction in the requalification-related costs for propane marketers, distributors, and others in non-corrosive gas service.

DATES: Comments must be received by October 7, 2019. To the extent possible,

PHMSA will consider late-filed comments as a final rule is developed.

ADDRESSES: You may submit comments identified by the Docket Number PHMSA-2017-0083 (HM-219B) by any of the following methods:

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

- **Fax:** 1-202-493-2251.

- **Mail:** Docket Management System; U.S. Department of Transportation, West Building, Ground Floor, Room W12-140, Routing Symbol M-30, 1200 New Jersey Avenue SE, Washington, DC 20590.

- **Hand Delivery:** To the Docket Management System; Room W12-140 on the ground floor of the West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the agency name and Docket Number (PHMSA-2017-0083) or RIN (2137-AF30) for this rulemaking at the beginning of the comment. To avoid duplication, please use only one of these four methods. All comments received will be posted without change to the Federal Docket Management System (FDMS) and will include any personal information you provide.

Docket: For access to the dockets to read background documents or comments received, go to <http://www.regulations.gov> or DOT's Docket Operations Office (see **ADDRESSES**).

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

FOR FURTHER INFORMATION CONTACT:

Shelby Geller, Standards and Rulemaking Division, (202) 366-8553, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590-0001.

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²⁶ *Supra* note 3.

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I. Background

A. History

On January 30, 2015, PHMSA published a notice of proposed rulemaking (NPRM) titled “Hazardous Materials: Adoption of Special Permits (MAP–21) (RRR)” [Docket No. PHMSA–2013–0042 (HM–233F); 80 FR 5339]. The HM–233F NPRM proposed to adopt provisions contained in 98 widely-used or longstanding special permits with an established safety record. Following a 60-day comment period, PHMSA published a final rule on January 21, 2016, that adopted the provisions of 96 of these special permits [81 FR 3635]. The HM–233F final rule became effective on February 22, 2016.

The HM–233F final rule amended § 180.209(e), which details conditions for allowing the requalification period to be longer for DOT 4-series specification cylinders in certain hazardous material service. Prior to publication of the final rule, § 180.209(e) authorized DOT 4B, 4BW, 4BA, or 4E cylinders used exclusively for a specified list of hazardous materials (non-corrosive gases) to be requalified by volumetric expansion every 12 years, instead of every 5 years. Alternatively, these cylinders were authorized to be requalified by the proof pressure test method every 7 years after the first 12-year period. A proof pressure test is a pressurization test without the determination of a cylinder’s expansion, and a volumetric expansion test determines the total and permanent expansion of a cylinder at a given pressure and is conducted by either water jacket or direct expansion test, both of which are conducted with water (see § 180.203).

In the HM–233F NPRM, PHMSA proposed to adopt the provisions of special permit 12084, which was issued

to Honeywell International, Inc.¹ This special permit authorized the requalification of DOT 4B, 4BA, or 4BW cylinders in accordance with § 180.209(e) for 11 additional non-corrosive gases. PHMSA identified this special permit as suitable for adoption into the regulations. In the HM–233F NPRM, PHMSA proposed to revise § 180.209(e) by replacing the list of specific hazardous materials with broader applicability to non-corrosive gases commercially free from corroding components.

PHMSA also proposed to amend the requalification periods of authorized cylinders for both the volumetric expansion and proof pressure tests in § 180.209(e). Specifically, PHMSA proposed to standardize the requalification period to 10 years for both the volumetric expansion test (previously a 12-year period) and the proof pressure test (previously a 7-year period after an initial 12-year period). While this proposed change was not discussed in the preamble of the HM–233F NPRM, PHMSA did propose amended regulatory text. PHMSA received no adverse comments to any of the proposed changes to § 180.209(e)—the adoption of special permit 12084 and 10-year requalification period—and therefore adopted the language as proposed in the final rule. While the effective date of the final rule was February 22, 2016, PHMSA allowed for delayed compliance to begin on January 23, 2017.

B. Petition P–1696

On January 13, 2017, the National Propane Gas Association (NPGA) submitted a petition to PHMSA and the Office of the Secretary of Transportation (OST) titled “Petition for Rulemaking and Emergency Stay Cylinder Requalification Requirements” [PHMSA–2017–0019 (P–1696) ²]. NPGA requested that PHMSA revise the initial timeframe before requalification, revise the requalification period for both the volumetric expansion and proof pressure tests in § 180.209(e) to those authorized prior to the HM–233F final rule, and update the table in § 180.209(a) accordingly. NPGA also requested a Statement of Enforcement Discretion while the rulemaking action was pending.

In the petition, NPGA advised PHMSA and OST that the HM–233F rulemaking created potential impacts and unanticipated costs. Specifically,

NPGA asserted that the regulatory change to the requalification period created confusion in the propane industry because it was unclear whether those cylinders manufactured or requalified by the volumetric expansion test within the last 10 to 12 years had to be immediately requalified, since prior to the final rule they would not have required requalification until the 12-year date. Furthermore, NPGA stated that the requirement to test cylinders following manufacture or volumetric expansion testing more frequently (*i.e.*, every 10 years instead of every 12 years) would increase qualification and training costs. NPGA explained that current industry practice ³ is to mark newly manufactured cylinders, eligible for requalification in accordance with § 180.209(e), with a 12-year requalification mark. Even though this marking is not required by the Hazardous Materials Regulations (HMR; 49 CFR parts 171–180), industry would have to train employees to ignore those markings. Additional training would be required on the revised requalification periods for both volumetric expansion and proof pressure testing.

On March 2, 2017, PHMSA met with NPGA representatives to: (1) Better understand NPGA’s concerns; (2) identify existing industry practice and request data to assess the impact of the revised cylinder requalification periods; and (3) evaluate the merits of a rulemaking and Statement of Enforcement Discretion. During this meeting, NPGA reiterated their petition, in that the change in requalification intervals would impose unanticipated industry costs. Furthermore, NPGA conveyed that a majority of their associate members requalify certain DOT 4-series specification cylinders by volumetric expansion testing. Following these discussions, PHMSA accepted NPGA’s petition for rulemaking.

C. Statement of Enforcement Discretion

On March 17, 2017, PHMSA issued a Statement of Enforcement Discretion stating that it will not take enforcement action against a person who requalifies DOT 4-series specification cylinders using volumetric expansion testing pursuant to a 12-year requalification period while it reviews NPGA’s petition for rulemaking.⁴ This Statement of

³ This is voluntary industry practice and not required by the HMR.

⁴ Pipeline and Hazardous Materials Safety Administration’s Notice Regarding the Requalification Period for Department of Transportation (DOT) Specification Cylinders, issued May 17, 2017, available at: <https://www.regulations.gov/document?D=PHMSA-2017-0083-0001>.

¹ <https://www.phmsa.dot.gov/approvals-and-permits/hazmat/file-serve/offer/SP12084.pdf/offerserver/SP12084>.

² See P–1696: <https://www.regulations.gov/docket?D=PHMSA-2017-0019>.

Enforcement Discretion specified that until further action, DOT 4-series specification cylinders requalified by volumetric expansion in accordance with § 180.209(e) may have a 10- or 12-year requalification period without any enforcement action taken.

II. Overview

PHMSA has reviewed NPGA's petition for rulemaking and agrees that it merits a rulemaking to consider revising the § 180.209(e) requalification period, as accepting the petition is expected to reduce regulatory burden and industry cost. PHMSA does not anticipate that this revision poses any increased safety risk, as historically these cylinders were authorized to be requalified on a 12-year cycle for volumetric expansion testing and on a 7-year cycle (after an initial 12-year period) for proof pressure testing with no known incidents attributable to the requalification timeframe. It should be noted that in accordance with § 180.205(c), even if a cylinder is due for requalification, it may be used until emptied, as long as it was filled prior to the requalification due date. Once emptied and placed into transportation, it must be requalified in accordance with the appropriate test method before being refilled.

In this NPRM, PHMSA is proposing to return the initial and subsequent requalification periods to 12 years for volumetric expansion tests, as proposed in the NPGA petition and authorized prior to HM-233F. PHMSA is proposing to also return the initial requalification period for proof pressure testing to 12 years, but maintain the 10-year period for subsequent proof pressure requalification testing as adopted in HM-233F final rule. The proof pressure test requalification period of 10 years was not proposed in NPGA's petition for rulemaking (proposed as 7 years). We acknowledge that the proposed 10-year requalification period will likely result in one-time industry training costs; however, the allowance to requalify a cylinder by proof pressure test every 10 years, instead of every 7 years, after the initial 12-year requalification period, may outweigh the costs of training because of less frequent cylinder requalification. Thus, PHMSA believes that this could allow for the greatest regulatory relief. PHMSA invites comments on the potential for costs or savings that may result from maintaining a 10-year requalification period following the initial 12-year requalification period for proof pressure testing instead of returning to the 7-year cycle, after the initial 12-year period (as proposed by the NPGA in its petition

and reflective of the requalification period prior to publication of the HM-233F final rule).

Additionally, PHMSA is proposing to revise the title of § 180.209(e) to more appropriately reflect the regulatory provisions in this paragraph. PHMSA is also proposing to revise the table in § 180.209(a) to properly reflect the baseline requalification period and the alternate requalification period allowances for various DOT specification cylinders. The baseline for DOT 4B, 4BA, 4BW, and 4E cylinder requalification is 5-years, but in accordance with the proposed language of § 180.209(e), these cylinders may be requalified every 10 or 12 years, under the specified conditions and dependent on the type of pressure test performed. In addition, PHMSA proposes to add a "7" to the § 180.209(a) table for DOT 4B, 4BA, or 4BW cylinders, as they are authorized for requalification every 7 or 12 years, instead of 5 years, when used as a fire extinguisher in accordance with § 180.209(j). There is no substantive change in adding "7" to the table as this is a conforming amendment for consistency between the table in paragraph (a) and the provisions in paragraph (j), which was inadvertently deleted in the HM-233F final rule.

PHMSA is also proposing to amend the table in § 180.209(a) to remove any reference to paragraph (e) for DOT 3A, 3AA, 3AL, 3AX, 3AAX, 3B, 3BN, and 4AA480 cylinders. Section 180.209(e) does not authorize requalification of these cylinder types. Therefore, this NPRM adjusts for any requalification period that is not currently authorized.

Further, PHMSA is proposing to make editorial corrections to the table for consistency. We propose to: Delete "DOT" preceding 3, 3A, 3AA, 3AL, 3AX, 3AAX, and 4E cylinders because the other entries do not have a similar qualifier; specify "service pressure" in the "Minimum test pressure (psig)" column for DOT 4D, 4DA, and 4DS cylinders to match other entries; and remove a duplicative citation of § 180.209 for DOT 3AL cylinders to be consistent with the other requalification period references.

III. Regulatory Analyses and Notices

A. Statutory/Legal Authority for This Rulemaking

This rulemaking is published under the authority of Federal Hazardous Materials Transportation Law (Federal hazmat law; 49 U.S.C. 5101 *et seq.*), which authorizes the Secretary of Transportation to "prescribe regulations for the safe transportation, including security, of hazardous materials in

intrastate, interstate, and foreign commerce." The Secretary's authority is delegated to PHMSA at 49 CFR 1.97. This rulemaking proposes to amend the requalification periods for certain DOT 4-series specification cylinders under relief provided in § 180.209(e) and to revise the requalification table in § 180.209(a) accordingly.

B. Executive Order 12866 and DOT Regulatory Policies and Procedures

This rulemaking is considered a nonsignificant regulatory action under section 3(f) of Executive Order 12866 ("Regulatory Planning and Review") and was not reviewed by the Office of Management and Budget (OMB). This rulemaking is also considered a nonsignificant rulemaking under the DOT's Policies and Procedures for Rulemakings [DOT Order 2100.6; December 20, 2018].

Executive Order 12866 ("Regulatory Planning and Review")⁵ requires agencies to regulate in the "most cost-effective manner," to make a "reasoned determination that the benefits of the intended regulation justify its costs," and to develop regulations that "impose the least burden on society."

Additionally, Executive Order 12866 requires agencies to provide a meaningful opportunity for public participation, which also reinforces requirements for notice and comment under the Administrative Procedure Act (APA).⁶ Therefore, PHMSA solicits comment on the revised requalification periods for DOT 4-series specification cylinders as proposed in § 180.209(e). PHMSA also seeks comment on the preliminary cost and cost savings analyses, including industry costs or cost savings due to the revised requalification periods for volumetric expansion and proof pressure testing.

Overall, this rulemaking maintains the continued safe transportation of hazardous materials while producing a net cost savings. PHMSA's findings are summarized here and described in further detail in the following 13 sections, which together comprise our preliminary analysis for this NPRM:

1. Summary of preliminary findings
2. Description of the need for the regulatory action
3. Definition of the baseline and rulemaking scenarios
4. The time horizon of analysis
5. Description of the type and number of affected cylinders
6. Description of the type and number of affected entities

⁵ See 58 FR 51735, October 4, 1993 for Executive Order 12866

⁶ See 5 U.S.C. 553.

7. Analysis of requalification cost savings
8. Analysis of training costs and cost savings
9. Analysis of total net cost savings
10. Evaluation of non-quantified and non-monetized impacts
11. Characterization of additional uncertainty in impacts, including estimated costs, cost savings, and net cost savings
12. Supplemental analysis regarding the number of affected cylinders
13. Supplemental analysis regarding possible effects on proof pressure-tested cylinders

Summary of Preliminary Findings

PHMSA's preliminary analysis finds that the proposed changes would result in total net cost savings of approximately \$142.4 million over 10

years, or \$20.3 million annualized, when discounted at 7 percent.

These cost savings are almost entirely based on two effects. The first effect is avoiding the immediate, accelerated requalification of approximately 5 million DOT 4-series specification cylinders that would otherwise be required if the proposed changes of this rulemaking are not adopted. The second effect is an anticipated reduction in the number of cylinders in need of requalification in any given year. The avoidance of accelerated requalification occurs in year one, and the "enduring" effect of reducing the number of cylinders in need of requalification occurs in subsequent years (years 2–10). Our primary analysis focuses on cost savings to entities that requalify cylinders by volumetric expansion

testing. However, this NPRM also proposes to retain the 10-year requalification period for the proof pressure test adopted under the HM–233F final rule, so we assume cylinder marketers require some training to ensure knowledge of the revised requalification timeframes for proof pressure testing. This NPRM would also relieve cylinder manufacturers of training to ensure that voluntary stamping practices align with the initial requalification timeframe, resulting in training-related cost savings for cylinder manufacturers. On net, we estimate training cost savings at approximately \$0.2 million. We add the two types of requalification cost savings to the net cost savings related to training to determine the total net cost savings. See Exhibit 1.

EXHIBIT 1—SUMMARY OF ESTIMATES AND FINDINGS⁷

Number of Cylinders Affected in Year 1	5 million.
Annual Number of Cylinders Affected in Years 2–10	500,000.
Requalification Cost Savings in Year 1	\$86.1 million.
Requalification Cost Savings per Cylinder (weighted average)	\$17.22.
Training Net Cost Savings in Year 1	\$0.2 million.
Requalification Cost Savings in Years 2–10 (7%)	\$56.1 million.
Total Net Cost Savings (7%)	\$142.4 million.

Exhibit 1 shows "year one," monetized cost savings as well as "enduring" cost savings in years 2–10 based on a reduction in the number of cylinders in need of requalification. Please see the section, "Analysis of total net cost savings," for additional tabulation of the total net cost savings of the rule, discounted over 10 years.

If one were to present these cost savings on an indefinite or perpetual time horizon, their net present value would be approximately \$209.3 million at a 7% discount rate, and their annualized value would be \$14.7 million, also at a 7% discount rate.⁸ Please note, to arrive at this calculation, year-one impacts are undiscounted because these impacts are expected to begin occurring soon after the rulemaking is made effective, if it is made effective. On a perpetual horizon, the year-one savings is \$86,338,066 and subsequently, all other years repeat a savings of \$8,610,338.

Description of the Need for Regulatory Action

NPGA petitioned⁹ PHMSA to amend § 180.209(e) because the HM–233F final rule was expected to impose a substantial cost burden on industry. Specifically, NPGA reasoned that, due to confusion about the applicability of the HMR, the requirements in the HM–233F final rule would accelerate the requalification of certain DOT 4-series specification cylinders by 2 years, even though the HMR allows a cylinder filled before the end of the requalification period to remain in service until emptied, as long as it is requalified prior to being refilled and offered back into transportation (see § 180.205(c)). For example, a cylinder tested by volumetric expansion would need to be requalified every 10 years, rather than every 12 years. This 2-year acceleration would effectively force 3 years of cylinder vintages to be requalified in a single year, and thus would have a potential one-time impact on thousands of propane marketers and millions of cylinders. To avoid this substantial cost

burden, PHMSA issued a Statement of Enforcement Discretion on March 17, 2017, and initiated this rulemaking, which proposes to allow affected cylinders to be initially and subsequently requalified over a 12-year period when tested by volumetric expansion.

NPGA also cited confusion stemming from the industry practice of stamping a propane cylinder at the time of manufacture with an indication that the cylinder must be requalified 12 years after the manufacture date. The HMR do not require this stamp. However, this practice means that under current requirements, retraining would be necessary to educate employees on the 10-year requalification period and to ignore the stamp marking.

Further, PHMSA proposes to retain the 10-year period for proof pressure testing requalification, after the initial requalification test at 12 years. Prior to publication of the HM–233F final rule, the HMR required a 7-year timeframe for subsequent requalification by proof pressure. In its petition, NPGA asked that PHMSA return the proof pressure

⁷ Due to rounding, these estimates and findings may differ slightly from those expressed elsewhere in this analysis. Net cost savings is defined as cost savings minus costs, but in Exhibit 1, it is presented equivalently as the sum of (net) cost savings. Year-one effects are undiscounted. Effects related to years two through ten are discounted at 7%. Total

effects, covering the 10-year time period of analysis, include an undiscounted, year-one value, which is added to values discounted at 7% for years two through ten.

⁸ The perpetual, annualized cost savings were calculated by discounting the net present value of

cost savings (\$209,342,894.57) by one year using a 7% discount rate. This is equivalent to multiplying the net present value of cost savings by 0.07. $\$209,342,894.57 \times 0.07 = \$14,654,002.62$.

⁹ See P–1696: <https://www.regulations.gov/docket?D=PHMSA-2017-0019>.

test requalification periods of paragraph (e) to 7 years. However, PHMSA is proposing to maintain the 10-year requirement on the basis that it may add regulatory relief. PHMSA solicits comments regarding this proposal, especially as it differs from the NPGA petition (P-1696). To address possible cost-saving effects on proof pressure-tested cylinders, PHMSA offers a supplemental analysis in the last section of this analysis. Due to data uncertainties, this supplemental cost savings analysis is separate from and secondary to our primary analysis methods and estimates. PHMSA solicits comments to address these data uncertainties, specifically comments regarding the extent of proof pressure testing.

Definition of the Baseline and Rulemaking Scenarios

This rulemaking is expected to have a variety of effects or impacts, some of which result in cost savings, others in costs. We do not estimate benefits in this analysis because PHMSA anticipates that the proposed changes maintain an equivalent level of safety. This section describes the baseline and rulemaking scenarios, which are the basis for determining whether the proposed rule may result in costs or cost savings.

Absent rulemaking action, the existing Statement of Enforcement Discretion relieves cylinder marketers of the HM-233F requirement to requalify cylinders every 10 years. However, the Statement of Enforcement Discretion does not provide regulatory certainty. Therefore, PHMSA uses the HM-233F or current HMR standards as the baseline, and uses this rulemaking action (HM-219B) as the rulemaking scenario and basis for incremental change.

Thus, in the baseline, requalifications are accelerated by 2 years, resulting in costs; in the rulemaking scenario, these accelerated requalifications are avoided, resulting in cost savings. This effect would occur in year one of impacts. In addition, in subsequent years, the pool of cylinders requiring requalification would be larger in the baseline than in the rulemaking scenario. Thus, if this rulemaking becomes effective, PHMSA is also providing “enduring” cost savings due to fewer cylinders being in need of requalification in the rulemaking versus the baseline scenario. These cost saving effects are the main effects of this proposed rulemaking.

Please note that this analysis focuses on the cost and cost-savings impacts of the 2-year acceleration of requalification by volumetric expansion because there is substantial uncertainty regarding the proportion and number of cylinders that are requalified by proof pressure testing. However, in the last section of this cost-savings analysis, we attempt to address this uncertainty by providing a supplemental analysis illustrating possible cost-savings effects on proof pressure-tested cylinders. In the baseline, proof pressure-tested cylinders must be requalified every 7 years after the initial 12-year period; in the rulemaking scenario, these cylinders can be requalified every 10 years after the initial 12-year period. This may enhance regulatory flexibility, and is a possible mechanism for cost savings. To better address these uncertainties in future analyses, PHMSA solicits comment on the proportion and number of cylinders that are proof pressure-tested versus cylinders tested using other methods. Due to data uncertainties, we limit our discussion of these proof-pressure cost savings to the supplemental analysis—they do not

factor into our primary estimates for cost savings.

PHMSA also anticipates another, relatively smaller effect: Cost savings that result from relieving manufacturers of the need to mark cylinders with a revised requalification timeframe. This marking is not an HMR requirement. However, in the baseline scenario, this marking would need to be revised to indicate a 10-year initial requalification timeframe, resulting in costs; in the rulemaking scenario, this marking could continue to indicate a 12-year initial requalification timeframe, resulting in avoided costs or cost savings.

In addition to cost savings, the HM-219B proposal to retain a revised timeframe for subsequent proof pressure requalifications may result in training costs to cylinder marketers. In the baseline, current HMR requirements would necessitate this training and imposition of costs on cylinder marketers. Additionally, the rulemaking scenario will still necessitate this training and imposition of costs, since proof pressure requirements differ from pre-HM-233F conditions.

In summation, this rulemaking may have a variety of cost and cost-savings effects, but the main effects are due to the baseline and rulemaking scenarios for cylinders requalified by volumetric expansion. In the baseline scenario, cylinders must be initially requalified every 10 years. This is the current HMR requirement, as codified in HM-233F. Conversely, in the rulemaking scenario, cylinders tested by volumetric expansion must be requalified every 12 years. This is the change proposed in this rulemaking (HM-219B), which effectively revises the requalification timeframe for volumetric expansion testing back to the standards in place before HM-233F was published. See Exhibit 2.

EXHIBIT 2—IMPACTS OF HM-219B PROVISIONS FOR VOLUMETRIC EXPANSION TESTING

Rulemaking provision	Baseline (no action)	HM-219B amendments
Revise § 180.209(e)	HMR remains as made effective in January 2017, and regulatory text remains the same as in HM-233F. DOT cylinders must be requalified every 10 years ...	PHMSA reverts text in § 180.209(e) to its earlier iteration before HM-233F. DOT cylinders must be requalified every 12 years.

The Time Horizon of Analysis

This analysis assumes that this rulemaking will result in a “one-time” impact occurring in the first year the rulemaking is effective due to accelerated requalifications. After this first year, the rulemaking will also result in a reduction in the number of

cylinders requiring requalification in any one year.

With respect to year-one impacts, we can elaborate further with an example using the baseline and rulemaking scenarios. In the baseline scenario, cylinder marketers need to requalify three different vintages of cylinders in 2019, specifically those cylinders

manufactured or requalified in 2007, 2008, and 2009. This is the direct result of the requirement that these cylinders be requalified on a 10-year timeframe instead of a 12-year timeframe. As such, the HM-233F final rule imposed an accelerated requalification for cylinders manufactured or requalified in 2008 and 2009, whereas the cylinders

manufactured or requalified in 2007 would need to be requalified in 2019 under either the baseline or rulemaking scenario. In the baseline scenario, 3 years' worth of cylinders need to be requalified in a single year, with the 2008 and 2009 cylinders needing requalification earlier than anticipated. Conversely, in the rulemaking scenario,

the 2008 and 2009 cylinders can be requalified in 2020 and 2021, respectively, and the requalification costs that the HM-233F final rule imposed are avoided. To the extent that cylinders are requalified using volumetric expansion, this NPRM proposes a requalification timeframe

that would have occurred were the HM-233F final rule never published.

PHMSA's analysis sees this effect as a "one-time" or "year one" impact. In the baseline, it is a one-time cost imposition; in the rulemaking scenario, it is a one-time avoidance of these costs (cost savings). See Exhibit 3.

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Exhibit 3: Effect of Shortening Requalification Period to 10 Years vs. 12 Years								
	Year in which initial cylinder requalification is performed							
Year of cylinder manufacture	2018	2019		2020	2021	2022	2023	
2006								
2007*								
2008								
2009								
2010								
2011								
2012								
2013								
		12-year requalification (conditions before HM-233F and after adoption of HM-219B)						
		Change to 10-year requalification, per HM-233F (baseline)						
*Industry must requalify the 2007 set of cylinders in 2019 under either scenario								

BILLING CODE 4910-60-C

As evident in Exhibit 3, the baseline scenario (HM 233F; current HMR requirements) primarily affects cylinder requalification in the first year of the rule's effect. Before this first year, there is no difference between the baseline and rulemaking scenario. After this first year of effect (*e.g.*, 2019 onward), the requalification cycle returns to a "normal state," where only one vintage of cylinders are requalified per year, although the number of cylinders in need of requalification in any given year would be smaller in the rulemaking than in the baseline scenario.

Note that we do not have data on the manufacturing and requalification dates for the affected cylinders—this affects how we chose to model the timing of requalification in Exhibit 3 and the

impacts of the baseline and rulemaking scenarios. As evident in Exhibit 3, we assume that each cylinder has a specific manufacturing or requalification year and do not distinguish between the cylinders on a more granular level (*e.g.*, month-to-month). For instance, we do not distinguish between a cylinder from January 2007 and one from June 2007. All 2007 cylinders are assumed to be requalified in 2019, as well as all 2008 and 2009 cylinders in the baseline. We make no further distinction about the timing of the manufacture and requalification of affected cylinders. Further, our analysis does not have a discounting component for avoiding accelerated requalifications because it is assumed to occur in the first year of the rulemaking's implementation, without distinctions between an expenditure

made in January 2019 and one in December 2019, for example. For these reasons, the costs of accelerated requalification (or the avoidance of these costs) are undiscounted, one-time or "year one" impacts.

In addition to "year one" impacts, there is potential for "enduring" effects occurring in subsequent years. In subsequent years, the pool of DOT 4-series specification cylinders that need requalification in a given year may be smaller in the rulemaking scenario than in the baseline scenario. In the baseline scenario, this requalification pool represents effectively 1/10th of cylinders in service since these cylinders would need requalification once every 10 years. In the rulemaking scenario, this requalification pool would represent 1/12th of cylinders in service

since these cylinders would need requalification once every 12 years. This rulemaking scenario reduction in requalification may result in cost savings. We attempt to quantify and monetize this effect as a cost savings, which in tandem with the avoided accelerated requalification costs, may be substantial. PHMSA solicits comment on the “one-time” and “enduring” effects, and on this analysis in general. We also solicit comment on whether

there are additional economic effects that were not foreseen that could be represented in a future, revised analysis.

Description of the Type and Number of Affected Cylinders

According to information provided by NPGA in P-1696, the revisions made in the HM-233F final rule affect nearly 5 million DOT 4-series specification cylinders (e.g., 4B, 4BA, 4BW, and 4E). Furthermore, NPGA estimates that 75 percent of cylinders are 20-lb. cylinders

(used primarily for BBQ grills, patio heaters, construction heat, temporary heat, etc.), and the remaining 25 percent comprise a variety of sizes, e.g., 33.5 lb. (forklift cylinders), 100 lb. (exchange cylinders), and the largest size, 420 lb. propane cylinders (residential/commercial heat). Absent any other data describing the population of affected cylinders, PHMSA uses NPGA’s assumptions for this analysis.¹⁰ See Exhibit 4.

EXHIBIT 4—AFFECTED CYLINDERS ¹¹

Cylinder service sector	Cylinder size categories	Distribution (%)	Number of cylinders requiring accelerated requalification
Residential	20 lbs.	75	3,750,000
Commercial	33–420 lbs.	25	1,250,000
Total	100	5,000,000

Exhibit 4 reiterates that, absent this rulemaking, approximately 5 million cylinders would need to be requalified on an accelerated basis. If this rulemaking is adopted, these 5 million cylinders can be requalified on a 12-year timeframe. As explained previously, this would revert volumetric expansion test requalification back to the timing in place before publication of the HM-233F final rule.

This estimate of the number of affected cylinders is also important to the estimation of “enduring” cost savings. After year one, the difference between the annual number of cylinders in need of requalification in the baseline and rulemaking scenarios is an input to our method for the enduring cost savings. Specifically, NPGA’s estimate of 5 million represents 2 cylinder vintages that would undergo accelerated requalification. This means an estimated 2.5 million cylinders may need requalification in any one year. As such, over 12 years, 30 million cylinders would need requalification (2.5 * 12). If this same number of cylinders were to be requalified instead over 10 years, as the baseline holds, this would mean 3 million cylinders per year, or an increase of 500,000 cylinders per year. In other words, the baseline scenario would require that 20% more cylinders

be requalified each year; in the rulemaking scenario, 20% fewer. This differential is an input to our cost savings method for “enduring” cost savings, which occur after year one.

Based on the accelerated requalifications in year one and the enduring effects thereafter, PHMSA chooses a time period of analysis of 10 years. A different time period of analysis may result in different findings and PHMSA may revise this analysis in the future to reflect different time periods of analysis.

Because PHMSA relies on NPGA assumptions and data, this cost savings analysis includes a supplemental analysis addressing the number of affected cylinders. This is provided in the section, “Supplemental analysis regarding the number of affected cylinders.”

Description of the Type and Number of Affected Entities

This rulemaking affects various entities, specifically cylinder marketers and manufacturers. If this rulemaking is not adopted, cylinder marketers bear the costs of accelerated cylinder requalification; however, if this rulemaking is adopted, cylinder marketers achieve a cost savings because they are relieved of the need to requalify cylinders on an accelerated

basis. Moreover, cylinder marketer employees would require training if this rulemaking is adopted as proposed, since proof pressure requirements would be different. Lastly, if adopted, the rulemaking would relieve cylinder manufacturers of changes to voluntary stamping/marketing practices, resulting in cost savings (avoided training costs). These training costs and cost savings are detailed in the section, “Analysis of training costs and cost savings.”

To describe the type and number of affected cylinder marketers, PHMSA relies on the North American Industrial Classification System (NAICS),¹² specifically sector code *454310 Fuel Dealers*.¹³ This sector is comprised of fuel dealers primarily engaged in retailing heating oil, liquefied petroleum (LP) gas, and other fuels via direct selling to customers. For the purposes of this analysis, we call entities in this sector, “cylinder marketers” or “marketers,” which is used synonymously with “fuel dealers.” There are approximately 8,700 establishments in this sector.¹⁴ The employment estimate for this NAICS sector is approximately 74,000, according to U.S. Census data. This estimate of the number of cylinder marketer employees is used as an input in our estimation of this rulemaking’s training costs. We detail cost and cost-

¹⁰ NPGA does not provide any supporting documentation or other information describing the basis for these estimates.

¹¹ National Propane Gas Association, “RE: Supplement to January 13, 2017 NPGA Petition for Rulemaking and Emergency Stay,” February 13, 2017 [hereinafter NPGA Supplement]: <https://www.regulations.gov/document?D=PHMSA-2017-0083-0003>.

¹² The North American Industry Classification System (NAICS) is the standard used by Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy. The classification framework is updated periodically, and most Federal statistical agencies currently report data using the 2012 version of the NAICS. The NAICS

version—2012—is not related to the year for which statistical data are being published.

¹³ <https://www.census.gov/cgi-bin/sssd/naics/naicsrch?code=454310&search=2012%20NAICS%20Search>.

¹⁴ *Ibid.*

savings methods and calculations in the sections, “Analysis of requalification cost savings” and “Analysis of training costs and cost savings.”

In addition to cylinder marketers, the rulemaking is likely to have an impact on NAICS sector *332420 Metal Tank Manufacturing*,¹⁵ which is the sector primarily engaged in cutting, forming, and joining heavy gauge metal to manufacture tanks, vessels, and other containers. For the purposes of this analysis, we call entities in this sector,

“cylinder manufacturers,” or “manufacturers” for short. During 2014, this sector included 739 establishments and 36,869 employees.¹⁶ It is industry practice—albeit not required by the HMR—that DOT 4-series specification cylinder manufacturers currently place a stamp during manufacture indicating that the cylinder must be requalified 12 years after the manufacture date.¹⁷ If this rulemaking is not adopted (baseline), cylinder manufacturers may need to adjust this stamp to reflect the

10-year requirement, and implement any necessary training or manufacturing process changes to do so. This estimate of the number of cylinder manufacturing employees is used as an input in our estimation of this rule’s training-related cost savings.

See Exhibit 5 for the estimates of the number of establishments and employees on payroll for the NAICS sectors, *454310 Fuel Dealers* and *332420 Metal Tank Manufacturing*.

EXHIBIT 5—POTENTIALLY AFFECTED ENTITIES¹⁸

NAICS code	NAICS code sector	Number of establishments	Employees on payroll
Primarily Affected Industry: 454310	Direct Sales Fuel Dealers	8,677	73,555
Other Relevant Industry Stakeholders: 332420	Metal Tank Manufacturing	739	36,869

Analysis of Requalification Cost Savings

Assuming the rulemaking takes effect in 2019, adoption of this rulemaking would relieve cylinder marketers of the cost to accelerate the requalification of cylinders manufactured in 2008 and 2009. PHMSA believes it would also provide a reduction in the number of cylinders in need of requalification after year one, on an enduring, year-over-year basis. In this section, we estimate the value of these potentially avoided costs.

In the baseline or HM–233F scenario, changes to § 180.209(e) require cylinder marketers to requalify some cylinders on an accelerated basis. Based upon assumptions provided by NPGA, a typical safety inspector can requalify three residential cylinders per hour and two commercial cylinders per hour.¹⁹ We estimate the avoided requalification cost by multiplying the number of residential and commercial cylinders requiring requalification, from Exhibit 4,

by the amount of time needed to requalify a single cylinder, differentiated by type, and the mean hourly labor rate²⁰ for a safety inspector in the *454310 Fuel Dealers* sector.²¹ This approach results in estimated costs of \$15.26–\$23.12 to requalify each residential and commercial cylinder, respectively. Total potentially avoided requalification costs for these cylinders are estimated to be approximately \$86 million dollars. See Exhibit 6–1.

EXHIBIT 6–1—ONE-TIME AVOIDED REQUALIFICATION TESTING COSTS DURING YEAR ONE

Cylinder type	Number of cylinders ²²	Hours to requalify ²³	Labor rate for fuel dealer inspectors ²⁴	Avoided requalification cost
Residential	3,750,000	0.33	\$46.23	\$57,209,625
Commercial	1,250,000	0.50	46.23	28,893,750
Total	\$86,103,375

PHMSA interprets this impact as a “one-time” cost savings that is assumed to occur over a one-year period during 2019. We do not distinguish these cost savings on a month-to-month basis because we do not have data relating

the specific manufacturing dates of the affected cylinders. Further, this may not be relevant if requalification dates are uniformly distributed across different months of the year.

There is also cost savings due to enduring, year-over-year effects in which the number of cylinders in need of requalification is expected to be fewer in the rulemaking scenario. With a longer requalification timeframe (12

¹⁵ <https://www.census.gov/cgi-bin/sssd/naics/naicsrch?code=332420&search=2012%20NAICS%20Search>.

¹⁶ U.S. Census Bureau. “2014 County Business Patterns.” American Fact Finder, April 21, 2016. <https://factfinder.census.gov/faces/nav/jsf/pages/searchresults.xhtml?refresh=t>.

¹⁷ See P–1696, pg. 7: <https://www.regulations.gov/docket?D=PHMSA-2017-0019>.

¹⁸ U.S. Census Bureau. “2014 County Business Patterns.” American Fact Finder, April 21, 2016. <https://factfinder.census.gov/faces/nav/jsf/pages/searchresults.xhtml?refresh=t>.

¹⁹ See NPGA Supplement, Appendix A, for estimates of labor-hours to requalify residential and commercial cylinders: <https://www.regulations.gov/document?D=PHMSA-2017-0083-0003>.

²⁰ May 2015 National Industry-Specific Occupational Employment and Wage Estimates NAICS 454300—Direct Selling Establishments; available at: https://www.bls.gov/oes/current/naics4_454300.htm.

²¹ There may be additional costs, aside from labor, particularly to the extent that the temporary increased volume of testing increases wear-and-tear of hydrostatic test equipment and associated maintenance costs.

²² See Exhibit 4: Affected Cylinders.

²³ See NPGA Supplement: <https://www.regulations.gov/document?D=PHMSA-2017-0083-0003>.

²⁴ U.S. BLS wage rate is based on 2015 Occupational and Employment Statistics Survey (OES) for NAICS 454310 (https://www.bls.gov/oes/current/naics4_454300.htm). Total labor rate also includes other costs of employee compensation (i.e., benefits) based on BLS’ Employer Costs for Employee Compensation Summary, which indicates that private industry labor rates are, overall, comprised of wages/salaries (68.6%) and benefits (30.2%), <https://www.bls.gov/news.release/ecec.nr0.htm>.

years vs. 10 years), there are fewer cylinders in need of requalification in a given year. In a previous section regarding the affected number of cylinders, PHMSA estimated that 20% fewer cylinders would be in need of requalification in the rulemaking scenario. Combining this 20% estimate with the cost findings related to year one impacts, we can estimate enduring, year-over-year cost savings. This assumes that input values (e.g., labor rates, time to requalify, breakdown of cylinder types) remain constant over the

time period of analysis. For example, labor rates are assumed to be constant; if they were adjusted to reflect inflation, our cost savings estimate would be higher.

Thus, Exhibit 6–1 above provides that the accelerated requalification of 2 cylinder vintages would result in approximately \$86 million. We divide that figure in half to represent annual requalification costs and then take 20% of the resulting figure to estimate enduring, year-over-year cost savings.²⁵ This gives approximately \$8.6 million

in undiscounted, yearly cost savings. Equivalently, if 500,000 extra cylinders need requalification on an on-going basis in the baseline, this amounts to 1/10th of the “glut” created by the accelerated requalification in year one and hence 10% of the estimated costs.²⁶ Exhibit 6–2 below presents these cost savings in years 2–10, as well as the year-one cost savings based on avoidance of accelerated requalification. We present undiscounted (0%) and 3% and 7% discount rates.

EXHIBIT 6–2—COST SAVINGS DUE TO AVOIDANCE OF ACCELERATED REQUALIFICATION IN YEAR 1 AND REDUCTION IN NUMBER OF NEEDED REQUALIFICATIONS IN YEARS 2–10; NET PRESENT VALUE AND ANNUALIZED AT 0%, 3%, AND 7% DISCOUNT RATES

Year	Undiscounted (0%)	3%	7%
1	\$86,103,375	\$86,103,375	\$86,103,375
2	8,610,338	8,359,551	8,047,044
3	8,610,338	8,116,069	7,520,602
4	8,610,338	7,879,679	7,028,600
5	8,610,338	7,650,173	6,568,785
6	8,610,338	7,427,353	6,139,052
7	8,610,338	7,211,022	5,737,431
8	8,610,338	7,000,992	5,362,085
9	8,610,338	6,797,080	5,011,295
10	8,610,338	6,599,107	4,683,453
Net Present Value (Total)		153,144,405	142,201,727
Annualized		17,953,196	20,246,327

Therefore, if this proposed rule is adopted, cylinder marketers in the 454310 Fuel Dealers NAICS sector would be relieved of requalifying approximately 5 million cylinders in year one, which would save them approximately \$86 million dollars in costs (undiscounted). Conversely, \$86 million in requalification costs would be imposed in year one if this rulemaking is not adopted, which this analysis assumes would sustain HM–233F’s requirement for a 10-year requalification timeframe. Moreover, if adopted, cylinder marketers would have 20% fewer cylinders to requalify in each year after year one. This results in cost savings of approximately \$8.6 million in years 2–10 (undiscounted).

Combining these two cost savings effects together, cylinder marketers are expected to save \$142.2 million over 10 years, discounted at 7%. On an annual basis, they are expected to save \$20.2 million annualized at 7%. We use these figures to calculate total net cost savings later in the document, but first we must account for training-related cost savings,

as well as some training-related costs, due to the rulemaking scenario.

Analysis of Training Costs and Cost Savings

This rulemaking may relieve approximately 18,000 cylinder manufacturing employees from needing training. In the baseline scenario, these cylinder manufacturing employees may need to change the way they voluntarily stamp newly-manufactured cylinders, necessitating training; conversely, in the rulemaking scenario, their stamping practices can remain unchanged, avoiding this training and associated costs. The net effect of these training-related impacts is quantified in the section, “Analysis of total net cost savings.”

However, this rulemaking is also likely to result in approximately 36,000 cylinder marketer employees to need training on the proposed changes to proof pressure requalification periods. Specifically, PHMSA is proposing to retain the 10-year requalification timeframe for cylinders that are initially requalified using proof pressure testing.

This may provide cylinder marketers regulatory relief by reducing the requalification frequency for proof pressure, but it is also likely to necessitate training because this proposal diverges from the standards in place before the HM–233F final rule. PHMSA seeks comment on this proposal.

Regarding the training of cylinder marketers, their employees need to understand that a 12-year timeframe applies to cylinders initially and subsequently requalified by volumetric expansion testing, and that a 10-year timeframe applies to cylinders requalified by proof pressure testing after an initial 12-year period. In P–1696, NPGA suggests that this training would take two hours per employee and that approximately half of employees would require training.²⁷ PHMSA believes only the training portion related to proof pressure testing is a relevant change, so we assume this training takes just one hour per employee, and, as stated by NPGA, that half of employees would require training. Thus, we take the number of

²⁵ \$86,103,375/2 = \$43,051,688. \$43,051,688 * 0.2 = \$8,610,337.60.

²⁶ \$86,103,375 * 0.10 = \$8,610,337.5

²⁷ See P–1696: <https://www.regulations.gov/docket?D=PHMSA-2017-0019>.

employees for the 454310 *Fuel Dealers* sector from Exhibit 5 (73,555) and divide it by 2 to get the number of these employees requiring training (73,555/2 = 36,778, with rounding). We use the hourly labor rate for these 454310 *Fuel Dealers* employees, as exhibited in Exhibit 6–1 (\$46.23), and multiply by 1 training hour to estimate the cost to train each employee (\$46.23 * 1 = \$46.23). We then multiply \$46.23 by the number of 454310 *Fuel Dealers* employees requiring training to estimate the training cost for these employees (\$46.23 * 36,778 = \$1,700,247, with rounding).

As NPGA explains in P–1696, millions of cylinders currently in service show a stamp placed during manufacture, indicating that the cylinder must be requalified 12 years after the manufacture date. Under the baseline scenario, cylinder

manufacturers would need to adjust this stamp to indicate a 10-year period. From this vantage, this proposed rulemaking results in training *cost savings* for cylinder manufacturers, not training costs; in other words, the regulations proposed here ensure that cylinder manufacturers can continue the industry practice of stamping to reflect the 12-year timeframe for initial requalification.

To estimate training cost savings for cylinder manufacturers, PHMSA references NPGA's estimate that training would take two hours per employee and that approximately half of employees would require training.²⁸ Thus, we take the number of employees for the 332420 *Metal Tank Manufacturing* NAICS sector from Exhibit 5 (36,869) and divide it by 2 to get the number of these employees requiring training (36,869/2 = 18,435, with rounding). We use \$52.48

as the hourly labor rate for 332420 *Metal Tank Manufacturing* employees and multiply by 2 training hours to estimate the cost to train each employee (\$52.48 * 2 = \$104.96).²⁹ We then multiply \$104.96 by the number of 332420 *Metal Tank Manufacturing* employees requiring training to estimate the training cost savings for these employees (\$104.96 * 18,435 = \$1,934,938, with rounding).

Based on these assumptions, input values, and methods, PHMSA estimates net cost savings related to training, totaling approximately \$0.2 million dollars (undiscounted). See Exhibit 7. These training costs and cost savings would occur in year one of implementation of the rulemaking and are not discounted. They are not modeled to repeat in subsequent years.

EXHIBIT 7—TRAINING COSTS/(COST SAVINGS)

[Year one; undiscounted]

NAICS Sector	Number of employees ³⁰	Percent trained	Number of employees trained	Training hour(s)	Labor rate ³¹	Total training cost
Fuel Dealers (454310)	73,555	50	36,778	1	\$46.23	\$1,700,247
Manufacturers (332420)	36,869	50	18,435	2	52.48	(1,934,938)
Total						(234,691)

Analysis of Total Net Cost Savings

PHMSA outlined our assumptions, input values, and methods for

estimating the expected costs and cost savings of this rulemaking. We now present the total net cost savings as the sum of net cost savings to both 454310

Fuel Dealers and 332420 *Manufacturers*. See Exhibit 8–1. As such, we estimate total net cost savings at approximately \$163.8 million dollars, undiscounted.

EXHIBIT 8–1—TOTAL NET COST SAVINGS

[Undiscounted]

Sector	Cost savings ("avoided accelerated requalification" in year 1)	Cost savings ("enduring" reduction in annual number of needed requalifications)	Training cost savings ³²	Net cost savings
Fuel Dealers (454310)	\$86,103,375	\$77,493,038	(\$1,700,247)	\$161,896,166
Manufacturers (332420)	0	0	1,934,938	1,934,938
Total	86,103,375	77,493,038	234,691	163,831,104

We also discount these savings over the time period of analysis. See Exhibit 8–2. To year one, we add the net cost savings related to training (\$234,691) to cost savings related to the avoidance of accelerated requalification (\$86,103,375), yielding \$86,338,066 in

cost savings in year one. The year-one impacts related to both effects are not discounted; they are assumed to occur at present value. However, the "enduring" cost savings are discounted according to the discount rate and the appropriate year in which the savings

occurs. As such, we estimate total net cost savings of \$142.4 million over 10 years, discounted at 7%, and \$20.3 million annualized at 7%. These total figures do not differ much from the results presented in Exhibit 6–2 because

²⁸ *Ibid.*

²⁹ U.S. BLS wage rate is based on 2015 Occupational and Employment Statistics Survey (OES) for NAICS 332420. Total labor rate also includes other costs of employee compensation (*i.e.*, benefits) based on BLS' Employer Costs for

Employee Compensation Summary; available at: <https://www.bls.gov/news.release/ecec.nr0.htm>.

³⁰ CB1400A11: Geography Area Series: County Business Patterns 2014 Business Patterns.

³¹ U.S. BLS wage rate is based on 2015 Occupational and Employment Statistics Survey (OES) for NAICS 454310 and 332420. Total labor

rate also includes other costs of employee compensation (*i.e.*, benefits) based on BLS' Employer Costs for Employee Compensation Summary, available at: <https://www.bls.gov/news.release/ecec.nr0.htm>.

³² A value in parenthesis indicates a cost, or a "negative cost savings."

training impacts are very small relative to requalification impacts.

EXHIBIT 8–2—TOTAL NET COST SAVINGS OVER 10 YEARS; NET PRESENT VALUE AND ANNUALIZED AT 3% AND 7% DISCOUNT RATES

Year	Undiscounted	3%	7%
1	\$86,338,066	\$86,338,066	\$86,338,066
2	8,610,338	8,359,551	8,047,044
3	8,610,338	8,116,069	7,520,602
4	8,610,338	7,879,679	7,028,600
5	8,610,338	7,650,173	6,568,785
6	8,610,338	7,427,353	6,139,052
7	8,610,338	7,211,022	5,737,431
8	8,610,338	7,000,992	5,362,085
9	8,610,338	6,797,080	5,011,295
10	8,610,338	6,599,107	4,683,453
Net Present Value (Total)		\$153,379,096	\$142,436,418
Annualized		\$17,980,709	\$20,279,741

Evaluation of Non-Quantified and Non-Monetized Impacts

PHMSA has not estimated quantitatively all the possible cost and cost-savings impacts of this rulemaking. This is due to data availability and uncertainty surrounding the actual impacts of the rulemaking if it is made effective. Ultimately, the actual impacts of the rulemaking may vary from the representation in this analysis; this analysis merely represents our expectations based on the available data and our professional judgment. For these reasons, PHMSA solicits comment on this rulemaking and its analysis as expressed in this NPRM.

To address some of these uncertainties and data limitations, we have identified various non-quantified costs and cost savings that might result from adopting this rulemaking. Our discussion here of non-quantified and non-monetized impacts is not exhaustive. For example, PHMSA can identify the following potential impacts, which are not quantified or monetized in this analysis:

1. Changes in the number of cylinders taken out of service due to accelerated requalification requirements;
2. Changes in the demand for or supply of DOT 4-series cylinders and requalification services; and
3. Changes in the prices faced by propane consumers.

If this rulemaking is not adopted, PHMSA expects there may be changes in the number of cylinders that are taken out of service in the first year of the rule's effect due to failure of a requalification test. The HM-233F final rule accelerated initial requalification requirements, resulting in industry performing triple the number of requalification tests during year one.

The increase in the number of requalification tests performed in year one means there could also be an increase in the number of cylinders that are taken out of service as a result of the requalification testing. To the degree that accelerated testing would result in cylinders being removed from service sooner, cylinder marketers would incur costs to acquire more replacement cylinders. PHMSA has not quantified the number of cylinders that might be “prematurely” taken from service and has not monetized the costs of replacing them. This represents a new category of potential costs under the baseline scenario and a new category of potential cost savings for cylinder marketers under the petition scenario. As such, the cost savings of adopting this rulemaking may be understated. Therefore, PHMSA seeks comments and any supporting data on this analysis, including comments and data regarding the potential effect of accelerated requalification on the number of cylinders removed from service and associated costs.

In addition, if this rulemaking is not adopted, PHMSA can anticipate changes in the supply of and demand for DOT 4-series specification cylinders, as well as cylinder requalification services. For instance, accelerated requalification requirements may be expected to result in higher costs for cylinder marketers, disincentivizing cylinder supply in the overall market. Similarly, a temporary increase in the demand for cylinder requalification services could affect the price of these services faced by cylinder marketers. As another example, accelerated requalification requirements may result in increased demand for newly manufactured cylinders to the extent that they are a substitute for

requalified cylinders. A temporary increase in the demand for newly manufactured cylinders might result in a temporary increase in economic activity for that sector and could affect the prices for these cylinders and the revenues of cylinder manufacturing companies. PHMSA has not quantified these market dynamics because of their complexity and highly uncertain nature.

Lastly, there is uncertainty about the potential impact on consumers (e.g., propane end-users), so PHMSA has not quantified downstream price impacts. This is also a question of market dynamics. Specifically, the baseline scenario may result in price increases for propane-related goods and services for end-use consumers to the degree that the cylinder manufacturers and marketers are able to pass additional costs onto consumers.

Characterization of Additional Uncertainty in Impacts, Including Estimated Costs, Cost Savings, and Net Cost Savings

The discussion in the previous section characterizes non-quantified and non-monetized impacts of this rulemaking. Other impacts were quantified and/or monetized in this analysis, but PHMSA's estimates remain uncertain. As such, this section characterizes additional uncertainty in the quantitative impacts estimated in this analysis. Note that this discussion is not exhaustive. PHMSA solicits comments on our analysis, including commentary on where our estimates could be improved and findings made more accurate. We note uncertainty in these quantitative areas:

1. Estimate of the number of affected entities and employees;

2. Estimate of the training hours necessitated by the rulemaking;
3. Estimate of the labor hours needed to requalify affected cylinders;
4. Estimate of the number of affected cylinders;
5. Proportion of cylinders initially requalified by proof pressure testing (estimated only in the supplemental analysis); and
6. Number of cylinders initially requalified by proof pressure testing (estimated only in the supplemental analysis).

As outlined, there is uncertainty regarding the estimate of the number of affected entities and, thus, the number of affected employees, per Exhibit 5. This uncertainty arises from the fact that only some establishments in NAICS 454310 *Fuel Dealers* may sell fuels in DOT 4-series specification cylinders affected by § 180.209(e). There may also be propane marketing entities in other NAICS sectors, but current data do not support estimates of the portion of affected establishments in additional sectors. These uncertainties may result in training costs or cost savings being over or underestimated. Since the number of affected entities is not actually used as an input variable to determine training costs or cost savings, we do not explore this variable in a supplemental analysis.

As another example of uncertainty in this analysis, PHMSA is not able to corroborate the NPGA estimate regarding the amount of time required for training. NPGA estimated that each employee would need two hours to be appropriately trained on the revised requalification periods. Since training costs are proportionately small compared to estimated requalification cost savings, we do not explore this uncertainty in a supplemental analysis. To illustrate this point, consider a simple example. Doubling the amount of time for training cylinder marketing employees would double estimated training costs, from approximately \$1.7 million to \$3.4 million, yet training costs would remain a relatively small proportion of the estimated, year-one requalification cost savings (\$3.4 million/\$86.1 million = 3.9%). It is unlikely that variance in this input value would alter PHMSA's assessment that this rulemaking provides total net cost savings.

We are also unable to corroborate NPGA's estimate regarding the amount of time required to requalify affected cylinders. To the extent that it takes longer to requalify affected cylinders, requalification costs are understated in the baseline scenario and cost savings are understated in the rulemaking

scenario. If less time is required to requalify affected cylinders, the reverse is true: Requalification costs are overstated in the baseline scenario and requalification cost savings are overstated in the rulemaking scenario. However, we believe that NPGA is uniquely positioned to estimate this variable due to the nature of its member representation. For this reason, we do not explore this variable with a supplemental analysis.

Furthermore, PHMSA is not able to corroborate the NPGA estimate for the number of affected cylinders. In this analysis, we rely on NPGA's estimate of approximately 5 million cylinders affected due to accelerated requalification. The number of cylinders affected is a critical input value for the estimation of cylinder requalification costs and cost savings in the baseline and rulemaking scenarios, respectively. Moreover, this specific variable presents uncertainty in that the NPGA estimate may be overestimated. This is because the HMR allow a cylinder, filled before the requalification becomes due, to remain in service until it is emptied.³³ As such, filled cylinders may remain in service, and cylinder marketers would not need to remove compliant cylinders from service to meet the 10-year requalification timeframe codified in the HM-233F final rule and presented in this analysis as the baseline scenario. To the extent that fewer cylinders need to be requalified to meet the 10-year timeframe in the baseline scenario, the requalification costs estimated in the baseline scenario and the requalification cost savings in the rulemaking scenario are both overstated. To explore this uncertainty further, we provide a supplemental analysis regarding the number of affected cylinders in the following section.

Lastly, PHMSA notes uncertainty regarding the proportion and number of affected cylinders that would be requalified using proof pressure testing versus other methods. Proof pressure testing is an alternative to volumetric expansion testing. Despite proposing to retain the 10-year timeframe for a cylinder initially requalified by proof pressure testing, PHMSA did not include proof pressure-related requalification cost savings in our primary estimates because of the uncertainty surrounding the extent to which proof pressure testing is used to requalify the affected cylinders. If it is costlier to requalify using proof pressure testing than volumetric expansion testing and requalifiers continue to use proof pressure methods, then costs may

be understated in the baseline scenario and cost savings may be understated in the rulemaking scenario. To the extent that requalifiers use proof pressure testing and it is less costly to requalify by proof pressure testing, then costs may be overstated in the baseline scenario and cost savings may be overstated in the rulemaking scenario. There also may be little or no difference between the costs of requalifying by volumetric expansion and proof pressure testing. PHMSA solicits comment on the extent of proof pressure testing versus other requalification methods.

Furthermore, our requalification cost savings analysis characterizes the timing of initial requalification in relation to cylinder manufacture. Refer to Exhibit 3. For volumetric expansion testing, the distinction between initial and subsequent requalification tests is not relevant since they would both occur at 12-year intervals; however, for proof pressure testing, the question of whether the cylinder is being initially or subsequently requalified is relevant and would determine the regulatory timeframe that applies (12 or 10 years). Noting this distinction, it may be reasonable to conceive of the cost-savings impacts on proof pressure-tested cylinders as altogether separate and possibly affecting a different, older pool of cylinders. We do not know whether the estimate of affected cylinders that NPGA provided accommodates this distinction. Put another way, uncertainty surrounds the proportion and number of cylinders that would be initially requalified by proof pressure testing versus volumetric expansion testing, as well as the overall number of cylinders that are requalified using proof pressure testing during subsequent requalification tests. These uncertainties are substantial to the point that we refrain from including cost savings related to proof pressure-tested cylinders in our primary estimates.

Nevertheless, we provide a supplemental analysis for the possible cost savings effects on proof pressure-tested cylinders, specifically how this proposed rulemaking would affect different vintages of cylinders that would initially be requalified by proof pressure (at the 12-year mark) and subsequently requalified at the 10-year mark as opposed to the 7-year mark, amounting to a 3-year deferral of these requalification tests and associated costs. This supplemental analysis is found in the section, "Supplemental analysis regarding possible effects on proof pressure-tested cylinders."

See Exhibit 9 for a distillation of the uncertainties discussed in this analysis.

³³ See § 180.205(c).

EXHIBIT 9—UNCERTAINTIES ASSOCIATED WITH THE REGULATORY COST ANALYSIS
[Quantified and non-quantified]

Variable	Estimate(s)	Source	Description of uncertainty
Number of affected entities	<i>Fuel Dealers:</i> 8,677	U.S. Census	<ul style="list-style-type: none"> • Additional NAICS sectors may be affected. • Affected entities may be a subset of represented NAICS sectors. • Number of affected entities may vary from estimates, which is likely to affect the number of employees in need of training.
	<i>Manufacturers:</i> 739		
	Total: 9,416		
Number of affected employees	<i>Fuel Dealers:</i> 36,778	U.S. Census	<ul style="list-style-type: none"> • Additional employees in other NAICS sectors may require training. • The number of employees in represented NAICS sectors may vary. • Training costs are positively related to the number of employees.
	<i>Manufacturers:</i> 18,435		
	Total: 55,213		
Training hours per employee ..	1–2	NPGA	<ul style="list-style-type: none"> • Training hours per employee may vary. • Training costs are positively related to the training hours per employee.
Percent of affected employees in need of training.	50%	NPGA	
Labor hours to requalify residential and commercial cylinders.	<i>Residential:</i> 0.33 hours	NPGA	
	<i>Commercial:</i> 0.5 hours		<ul style="list-style-type: none"> • Labor hours to requalify affected cylinders is positively related to requalification costs and cost savings. • Labor rates for cylinder marketers and cylinder manufacturers may vary. • Labor rates for cylinder marketers are positively related to cylinder requalification costs and cost savings, as well as training costs.
Labor rates	<i>Fuel Dealers:</i> \$46.23	U.S. BLS	
	<i>Manufacturers:</i> \$52.48		
Number of affected cylinders ..	5,000,000	NPGA	<ul style="list-style-type: none"> • Labor rates for cylinder manufacturers are positively related to training cost savings. • Number of affected cylinders may vary. • HMR allows compliant in-service cylinders to remain in service past required requalification dates.
Number of cylinders removed from service early.	Non-quantified	N/A	
Cost to requalify (market dynamics).	Non-quantified	N/A	
Cost of newly manufactured cylinders (market dynamics).	Non-quantified	N/A	<ul style="list-style-type: none"> • Number of affected cylinders positively relates to requalification costs and cost savings. • Accelerated requalification may increase or expedite the number of cylinders removed from service. • Cylinder marketers may face increased replacement costs.
End-user cylinder prices (market dynamics).	Non-quantified	N/A	
Proportion of proof pressure-tested cylinders.	Non-quantified in primary analysis.	N/A	
Number of affected proof pressure-tested cylinders.	Non-quantified in primary analysis.	N/A	<ul style="list-style-type: none"> • Accelerated requalification may affect requalification capacity or throughput. • Accelerated requalification may increase requalification costs/pricing. • Increased requalification costs may reduce supply of available requalified cylinders. • Newly manufactured cylinders may be a substitute for a requalified cylinder. • Demand for newly manufactured cylinders may increase. • Price of newly manufactured cylinders may in turn increase. • End-user market prices may be positively related to requalification and training costs. • Cylinder marketers and manufacturers may pass on compliance costs to end-users (e.g., propane consumers). • See supplemental analysis. • High proportion of proof pressure-tested cylinders could result in material cost savings due to deferred subsequent requalification. • Low proportion of these cylinders minimizes forgone cost savings if 7-year requirement were adopted (not proposed). • See supplemental analysis. • Large number of proof pressure-tested cylinders could result in material cost savings due to deferred subsequent requalification. • Small number of these cylinders minimizes forgone cost savings if 7-year requirement were adopted (not proposed).

Supplemental Analysis Regarding the Number of Affected Cylinders

As previously discussed, PHMSA believes the number of affected cylinders may differ from NPGA's estimate of 5 million affected cylinders. For example, affected cylinders may be fewer than 5 million due to existing allowances in the HMR. Specifically, a cylinder that is filled prior to its requalification date may remain in service until it is emptied. For this reason, the number of cylinders that would need to undergo accelerated requalification in the baseline scenario could be fewer than estimated, and associated costs would be less than estimated. Similarly, the cost savings in the rulemaking scenario would be less than estimated. For example, imagine a cylinder manufactured in 2009; in the baseline scenario, this cylinder would

need to be initially requalified in 2019 (10 years later), even though cylinder marketers conventionally expected this cylinder to be requalified in 2021 (12 years later). If that cylinder were filled prior to 2019, but remained in service to the end-user until 2021, this cylinder would not need to be requalified until 2021 despite the regulatory change made in the HM-233F final rule.

Thus, for this cylinder, the baseline and rulemaking scenario are no different. No new cost is imposed in the baseline; no cost savings are achieved by adopting this rulemaking.

Nevertheless, PHMSA does not have data to estimate the number of cylinders that would remain in service under HMR allowances despite the acceleration of their requalification date, and NPGA may have considered this factor when developing its estimate. Even if data were available, this task of

differentiating cylinders in this manner would undoubtedly be complicated given differences in service periods. Since we are unable at this time to corroborate NPGA's estimate, PHMSA also considers a scenario where the number of affected cylinders may be greater than estimated in this analysis. This could be the case if NPGA based its estimate on information from its members and there are marketers that are not members of NPGA who requalify cylinders.

In the absence of additional data, PHMSA uses a simple, assumption-based method to present the cost saving variances that would be expected if the number of affected cylinders were 25 percent fewer or 25 percent greater. This gives us a range of requalification cost-savings estimates occurring in year one, and over the 10-year time period of analysis. See Exhibit 10.

EXHIBIT 10—HIGH-, MID-, AND LOW-RANGE COST SAVINGS ESTIMATES BASED ON THE NUMBER OF AFFECTED CYLINDERS

Scenario label(s)	Number of affected cylinders	Proportion of primary estimate	Estimated requalification cost savings (year one)	Total estimated requalification cost savings (years 1–10)
High	6,250,000	1.25	\$107,629,219	\$204,495,516
Primary/Middle/NPGA	5,000,000	1.0	86,103,375	163,596,413
Low	3,750,000	0.75	64,577,531	122,697,309

This simple, straightforward exercise shows that cost savings would be lower if fewer cylinders are affected by the proposed rule due to, for example, the current HMR allowance to keep a cylinder in service past its requalification date. Similarly, if the number of affected cylinders is greater than estimated, cost savings would also be greater. PHMSA solicits comments on this analysis, including the supplemental analysis and our estimate of the number of affected cylinders (5 million) in year one, which is the same as NPGA's. Despite the allowance for in-service cylinders in the HMR and other uncertainties, we continue to use NPGA's estimate because it is the best data available.

Supplemental Analysis Regarding Possible Effects on Proof Pressure-Tested Cylinders

PHMSA focused its cost savings analysis on revising the requalification timeframe for cylinders that are requalified by volumetric expansion. This reflects NPGA's emphasis in its petition for rulemaking (P-1696) and the uncertainty surrounding the extent of impacts on proof pressure-tested

cylinders. As discussed in this analysis, PHMSA does not know the proportion or total number of affected cylinders that would be requalified using proof pressure testing, or whether these variables would have any material influence on our cost and cost savings estimates. Similarly, we do not know whether proof pressure-tested cylinders constitute an additional (and possibly older) pool of affected cylinders beyond NPGA's estimate of 5 million cylinders affected in year one. If so, then cost and cost savings estimates may be understated in this analysis.

Nevertheless, PHMSA explores the possible effects on proof pressure-tested cylinders in this supplemental analysis. Specifically, we explore the difference between a 7-year timeframe and a 10-year timeframe for cylinder requalification occurring after initial requalification (*i.e.*, "subsequent" or second requalification). By way of the HM-233F final rule, the HMR currently reflect a 10-year timeframe for both initial and subsequent requalification of proof pressure-tested cylinders, whereas the pre-HM-233F standard held that proof pressure-tested cylinders would

be initially requalified at the 12-year mark and subsequently requalified on a 7-year timeframe.

In its petition, NPGA appears to recommend that the proof pressure standard for subsequent requalification be reverted to the 7-year timeframe in the HMR prior to HM-233F's publication.³⁴ In contrast, this NPRM proposes to retain the 10-year requalification timeframe since it may add relief. PHMSA solicits comment on this proposal.



PHMSA believes this proposal would offer additional relief because it would enable cylinder marketers to defer by up to 3 years the subsequent requalification of cylinders that would otherwise be subject to the 7-year requirement. This deferral changes the timing of cash flow obligations for cylinder marketers and presents a potential cost savings.

Exhibit 11 illustrates the difference between the 7- and 10-year proof pressure requalification timeframes. Please note, this supplemental analysis relays these abstract scenarios for analysis purposes only; one must refer to the regulatory text of the proposed

³⁴ See P-1696: <https://www.regulations.gov/docket?D=PHMSA-2017-0019>.

rule to understand actual regulatory changes and effects.

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Exhibit 11: Effect of Extending the Subsequent Requalification Period to 10 Years from 7 Years for Proof Pressure-Tested Cylinders										
		Year in which the second cylinder requalification is performed, for cylinders initially requalified using the proof pressure testing								
Year of cylinder manufacture	Year of initial requalification	2018	2019	2020	2021	2022	2023	2024	2025	2026
1999	2011									
2000	2012									
2001	2013									
2002	2014									
2003	2015									
2004	2016									
 secondary requalification requirement, when initially requalified using proof-pressure test petition and conditions before HM-233F)										
 to 10-year subsequent requalification, per HM-233F (baseline) and HM-219B proposal										
Note: By 2022, although the timeframe has shifted, industry is back to the steady-state condition where subsequent requalification needs to be performed for a particular vintage of cylinders. No secondary requalification is required during 2019 – 2021 under the 10-year timeframe scenario (for cylinders initially requalified using the proof-pressure test).										

BILLING CODE 4910-60-C

Exhibit 11 illustrates the effects of the proposal to allow a 3-year deferral of subsequent requalification by proof pressure test. In 2019, under the 7-year requirement, industry would requalify cylinders manufactured in 2000 and initially requalified using proof pressure in 2012; that same set of cylinders would need to be subsequently requalified 7 years later in 2019. In contrast, under the 10-year requirement, industry could defer requalifying those same cylinders until 2022. By 2022, although the timeframe has shifted, industry is back to a more normal condition where subsequent requalification needs to be performed annually.

The potential value of these cost savings is less certain than the cost savings estimates in the primary analysis, because it is not clear what proportion of requalification tests are performed using proof pressure testing (and therefore what number of cylinders

would be affected).³⁵ Due to this uncertainty, we do not incorporate proof pressure-related cost savings into our primary analysis and its estimation of requalification cost savings. However, by adopting some assumptions similar to those used in our primary analysis, it is possible to provide an approximate measure of these cost savings.

Based on NPGA's estimate, the primary analysis assumed that 5 million cylinders would be affected by the changes to the volumetric expansion timeframes. These 5 million affected cylinders came from two different vintages of cylinders. Assuming there are 2.5 million affected cylinders per vintage, there would be 7.5 million cylinders *potentially* affected by the 3-year deferral of subsequent proof pressure requalification requirements. Absent information on the frequency with which proof pressure testing is used, we assume a range of 5 percent to 15 percent of these cylinders were

initially requalified using proof pressure testing. This suggests an estimate of approximately 0.38–1.13 million potentially affected cylinders during 2019 to 2021 ($7,500,000 * 0.05 = 375,000$; $7,500,000 * 0.15 = 1,125,000$). We adopt the same prior assumptions regarding the allocation of cylinders between residential and commercial customers (75 percent residential and 25 percent commercial), the labor rate for employees performing the requalification tests (\$46.23), and the time required to perform a requalification (0.33 hours for each residential cylinder and 0.5 hours for each commercial cylinder). Please note, the amount of time required to complete a requalification may vary between volumetric expansion and proof pressure testing.

This approach results in total potentially avoided requalification costs of \$6.46–\$19.38 million dollars, as presented in Exhibit 12.

³⁵ It is also somewhat further complicated by the fact that the provision applies not just to a *second*

requalification, but any requalification that follows

a prior requalification performed using the proof-pressure test (third, fourth, etc.).

EXHIBIT 12—ESTIMATE OF POTENTIALLY AVOIDED REQUALIFICATION COSTS ASSOCIATED WITH THE HM-233F PROOF PRESSURE TEST PROVISION

Cylinder type	Number of affected cylinders ³⁶ (million)	Hours to requalify ³⁷	Labor rate for fuel dealer inspectors ³⁸	Avoided requalification cost (million)
Residential	0.281–0.844	0.33	\$46.23	\$4.29–\$12.88
Commercial	0.094–0.281	0.50	\$46.23	\$2.17–\$6.50
Total				\$6.46–\$19.38

³⁶ Exhibit 4: Affected Cylinders.

³⁷ This is based on the NPGA's estimate.

³⁸ U.S. BLS wage rate is based on 2015 Occupational and Employment Statistics Survey (OES) for NAICS 454310 (https://www.bls.gov/oes/current/naics4_454300.htm). Total labor rate also includes other costs of employee compensation (i.e., benefits) based on BLS' Employer Costs for Employee Compensation Summary, which indicates that private industry labor rates are, overall, comprised of wages/salaries (68.6%) and benefits (30.2%), <https://www.bls.gov/news.release/cec.nr0.htm>.

In its petition, NPGA appears to recommend maintaining the status quo (pre-HM-233F conditions), that is, a 7-year requirement for proof pressure testing after initial requalification, while foregoing the possible cost savings suggested by this supplemental analysis and proposed rule. This supplemental analysis gives some indication that the combined net effect of both provisions would remain beneficial to the petitioner; specifically, the incremental costs that are avoided by NPGA's petition are expected to be larger than the cost savings foregone by its petition. By this logic, the gains of avoiding the acceleration of volumetric expansion requalification testing should outweigh the gains of deferring subsequent proof pressure requalification testing. Quantitatively, within this framework, the value of foregone cost savings begins to exceed the value of avoided costs if one assumes that approximately 67 percent or more of cylinders are requalified using the proof pressure test. This is simply an abstract comparison between the primary analysis' estimation of cost savings at initial requalification (assuming use of volumetric expansion) and the supplemental analysis' estimation of cost savings at subsequent qualifications (assuming use of proof pressure). Many other factors could affect whether NPGA's recommendations in P-1696 will yield net cost savings, such as there being a different cost to perform the different tests.

In summation, based on this supplemental analysis, PHMSA's proposal in this NPRM might lead to overall cost savings that exceed the estimates specified in the primary analysis. The primary analysis yielded net cost savings of \$163.83 million (undiscounted), whereas this supplemental analysis estimated an additional \$6.46–\$19.38 million in cost savings. Thus, if the two effects affect separate cylinder cohorts and are

combined, adoption of this rulemaking might result in approximately \$170.29–\$183.21 million in total net cost savings (undiscounted). Again, we have not incorporated the findings of this supplemental analysis into our primary analysis' findings because of the substantial uncertainty that surrounds the extent of proof pressure cylinder requalification testing. Please refer to the above section, "Summary of preliminary findings," for the net cost savings estimates of our primary analysis.

C. Executive Order 13771

This proposed rulemaking is expected to be an Executive Order 13771 deregulatory action. Details on the estimated cost savings of this proposed rule can be found above in "Section III.B. Executive Order 12866 and DOT Regulatory Policies and Procedures."

D. Executive Order 13132

This rulemaking was analyzed in accordance with the principles and criteria contained in Executive Order 13132 ("Federalism") and the President's memorandum ("Preemption") that was published in the **Federal Register** on May 22, 2009 [74 FR 24693]. Executive Order 13132 requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may have "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." This rulemaking will preempt State, local, and Tribal requirements but does not propose any regulation that has substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. Therefore, the

consultation and funding requirements of Executive Order 13132 do not apply.

The Federal hazmat law, 49 U.S.C. 5101–5128, contains an express preemption provision [49 U.S.C. 5125 (b)] that preempts State, local, and Indian tribal requirements on the following subjects:

(1) The designation, description, and classification of hazardous materials;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous materials;

(3) The preparation, execution, and use of shipping documents related to hazardous materials and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) The design, manufacture, fabrication, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material.

This proposed rule addresses covered subject item (5) above and preempts State, local, and Indian tribe requirements not meeting the "substantively the same" standard. This proposed rule is necessary to provide cost savings and regulatory flexibility to the propane industry. If the proposed changes are not adopted, propane industry members likely will incur substantial costs related to the accelerated requalification schedule when using the volumetric expansion test. PHMSA invites those with an interest in the issues presented in this NPRM to comment on the effect the adoption of specific proposals may have on State or local governments.

E. Executive Order 13175

This rulemaking was analyzed in accordance with the principles and criteria contained in Executive Order

13175 (“Consultation and Coordination with Indian Tribal Governments”). Executive Order 13175 requires agencies to assure meaningful and timely input from Indian tribal government representatives in the development of rules that significantly or uniquely affect Tribal communities by imposing “substantial direct compliance costs” or “substantial direct effects” on such communities or the relationship and distribution of power between the Federal Government and Indian tribes. This rulemaking does not have tribal implications. Therefore, the funding and consultation requirements of Executive Order 13175 do not apply.

However, we invite Indian tribal governments to provide comments on the costs and effects that this or a future rulemaking could potentially have on Tribal communities.

F. Regulatory Flexibility Act, Executive Order 13272, and DOT Policies and Procedures

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires agencies to review regulations to assess their impact on a substantial number of small entities unless the agency determines that a rulemaking is not expected to have significant impact on a substantial number of small entities. This proposed rule provides cost savings and regulatory flexibility to the propane industry, as previously discussed. The proposed changes are generally intended to provide relief to members of the propane industry, including small entities, by easing requirements with no anticipated reduction in safety.

Consideration of alternative proposals for small businesses. The Regulatory Flexibility Act directs agencies to establish exceptions and differing compliance standards for small businesses, where it is possible to do so and still meet the objectives of applicable regulatory statutes.

The impact of this proposed rule is not expected to be significant. The proposed changes are generally intended to provide regulatory flexibility and cost savings to industry members.

This proposed rule has been developed in accordance with Executive Order 13272 (“Proper Consideration of Small Entities in Agency Rulemaking”) and DOT’s procedures and policies to promote compliance with the Regulatory Flexibility Act to ensure that potential impacts of draft rules on small entities are properly considered.

G. Paperwork Reduction Act

While this NPRM proposes to address the requalification of certain DOT 4-

series specification cylinders, we do not anticipate that it will affect the burden for this or any other information collection. Under the Paperwork Reduction Act of 1995, no person is required to respond to any information collection unless it has been approved by OMB and displays a valid OMB control number. Section 1320.8(d) of 5 CFR requires that PHMSA provide interested members of the public and affected agencies an opportunity to comment on information and recordkeeping requests. PHMSA specifically solicits comment on the information collection and recordkeeping burdens associated with developing, implementing, and maintaining these proposed requirements. Address written comments to the Dockets Unit as identified in the **ADDRESSES** section of this rulemaking. We must receive comments regarding information collection burdens prior to the close of the comment period as identified in the **DATES** section of this rulemaking. In addition, you may submit comments specifically related to the information collection burden to the PHMSA Desk Officer, Office of Management and Budget, at fax number 202–395–6974. Requests for a copy of this information collection should be directed to Steven Andrews or Shelby Geller, Standards and Rulemaking Division (PHH–10), Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

H. Regulation Identifier Number (RIN)

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

I. Unfunded Mandates Reform Act

This rulemaking does not impose unfunded mandates under the Unfunded Mandates Reform Act of 1995. It does not result in costs of \$155 million or more to either State, local, or Tribal governments, in the aggregate, or to the private sector and is the least burdensome alternative that achieves the objective of the rulemaking. Further, in compliance with the Unfunded Mandates Reform Act of 1995, PHMSA will evaluate any regulatory action that might be proposed in subsequent stages of the proceeding to assess the effects on

State, local, and Tribal governments and the private sector.

J. Environmental Assessment

The National Environmental Policy Act of 1969 (NEPA) requires Federal agencies to consider the consequences of major Federal actions and prepare a detailed statement on actions significantly affecting the quality of the human environment. The Council on Environmental Quality (CEQ) implementing regulations (40 CFR part 1500) require Federal agencies to conduct an environmental review considering (1) the need for the action, (2) alternatives to the action, (3) probable environmental impacts of the action and alternatives, and (4) the agencies and persons consulted during the consideration process (*see* 40 CFR 1508.9(b)).

1. Need for the Action

The purpose of this NPRM is to amend the HMR through revisions to the requalification period for certain DOT 4-series specification cylinders in non-corrosive gas service. This proposed action is intended to provide regulatory relief. If the changes in this proposed rule are not adopted in the HMR, PHMSA would forgo the opportunity to provide regulatory relief.

2. Alternatives Considered

Transportation of hazardous materials in commerce is subject to requirements in the HMR, issued under authority of Federal hazmat law, codified at 49 U.S.C. 5101 *et seq.* To facilitate the safe and efficient transportation of hazardous materials in international commerce, the HMR provide that both domestic and international shipment of hazardous materials may be offered for transportation and transported under provisions of the international regulations.

In proposing this rulemaking, PHMSA is considering the following alternatives:

Alternative 1: No Action Alternative

The No Action Alternative does not incorporate the regulatory changes proposed in this NPRM. If PHMSA were to select this alternative, it would not proceed with any rulemaking on this subject and the current regulatory standards would remain in effect. If the current regulatory standards remain in effect, § 108.209(e) would not be amended, and the requalification period for volumetric expansion and proof pressure testing would remain at a 10-year period. This alternative would not address NPGA’s petition for rulemaking. The requalification period for the

volumetric expansion test would not be extended to a 12-year period and the requalification period for the proof pressure test would not be extended to an initial 12-year period followed by a 10-year period.

Alternative 2: Preferred Alternative

The Preferred Alternative is the current proposal as it appears in the NPRM, applying to transportation of hazardous materials by various modes (highway, rail, vessel, and aircraft). The proposed amendments encompassed in this alternative are more fully addressed in the preamble and regulatory text sections. However, the general amendment in this NPRM is to revise the requalification period in § 180.209(e) for DOT 4-series specification cylinders to allow for a 12-year period for volumetric expansion testing and an initial 12-year period followed by a 10-year requalification period for proof pressure testing.

3. Environmental impacts

Alternative 1: No Action Alternative

If PHMSA were to select the No Action Alternative, current regulations would remain in place and no new provisions would be added. This alternative would not address NPGA's petition for rulemaking. The current regulatory requirements, with shorter requalification intervals for volumetric expansion testing, are more conservative and, assuming 100% compliance, there would be more opportunities to identify cylinders with defects so that they could be repaired or removed from service. The failure of a DOT 4B, 4BA, 4BW, or 4E specification cylinder results in a large release of energy, which can result in destruction to property, injury, and death. Nonetheless, PHMSA believes that prior cylinder requalification intervals, both under HM-233F standards and the standards prior to that change, were unnecessarily burdensome.

Alternative 2: Preferred Alternative

PHMSA proposes that amending the requalification period for DOT 4-series specification cylinders in non-corrosive gas service will result in decreased regulatory and economic burden. PHMSA does not anticipate that increased cylinder failures will occur because PHMSA believes that prior standards were unnecessarily conservative. The proposed change clarifies and broadens regulatory requalification periods, ensuring consistency with training programs developed within the industry. There are no anticipated significant impacts in the release of environmental pollutants

under either alternative. However, fewer trips transporting cylinders for retest may result in minor reductions to air pollutants, including greenhouse gases.

4. Agencies Consulted

PHMSA has coordinated with the Federal Aviation Administration, the Federal Motor Carrier Safety Administration, the Federal Railroad Administration, and the U.S. Coast Guard in the development of this proposed rule. PHMSA will consider the views expressed in comments to the NPRM submitted by members of the public, State and local governments, and industry.

5. Conclusion

PHMSA proposes to find that no significant environmental impact will result from this proposed rule. PHMSA welcomes any views, data, or information related to safety or environmental impacts that may result if the proposed requirements are adopted, as well as possible alternatives and their environmental impacts.

K. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

L. Executive Order 13609 and International Trade Analysis

Under Executive Order 13609, "Promoting International Regulatory Cooperation," agencies must consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally. See 77 FR 26413 (May 4, 2012). In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements. This rulemaking does not impact international trade.

M. National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) directs Federal agencies to use voluntary consensus standards in their regulatory activities unless doing so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specification of materials, test methods, or performance requirements) that are developed or adopted by voluntary consensus standards bodies. This rulemaking makes revisions to the requalification periods for DOT 4-series specification cylinder consistent with current Federal statute and guidance and PHMSA policies and procedures; it does not involve use of voluntary consensus standards.

N. 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 a Statement of Energy Effects for any "significant energy action." Under the executive order, a "significant energy action" is defined as any action by an agency (normally published in the **Federal Register**) that promulgates, or is expected to lead to the promulgation of, a final rule or regulation (including a notice of inquiry, ANPRM, and NPRM) that (1)(i) is a significant regulatory action under Executive Order 12866 or any successor order and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. PHMSA welcomes any data or information related to energy impacts that may result from this NPRM, as well as possible alternatives and their energy impacts. Please describe the impacts and the basis for the comment.

List of Subjects in 49 CFR Part 180

Hazardous materials transportation, Motor carriers, Motor vehicle safety, Packaging and containers, Railroad safety, Reporting and recordkeeping requirements.

In consideration of the foregoing, PHMSA proposes to amend 49 CFR chapter I as follows:

**PART 180—CONTINUING
QUALIFICATION AND MAINTENANCE
OF PACKAGINGS**

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 49 CFR 1.81 and 1.97.

■ 2. In § 180.209:

■ a. Revise Table 1—Requalification of Cylinders in paragraph (a); and

■ b. Revise paragraph (e).
The revisions read as follows.

§ 180.209 Requirements for requalification of specification cylinders.

(a) * * *

TABLE 1—REQUALIFICATION OF CYLINDERS ¹

Specification under which cylinder was made	Minimum test pressure (psig) ²	Requalification period (years)
3	3,000 psig	5.
3A, 3AA	5/3 times service pressure, except non-corrosive service (see § 180.209(g)).	5, 10, or 12 (see § 180.209(b), (f), (h), and (j)).
3AL	5/3 times service pressure	5 or 12 (see § 180.209(j) and (m) ³).
3AX, 3AAX	5/3 times service pressure	5.
3B, 3BN	2 times service pressure (see § 180.209(g)) ...	5 or 10 (see § 180.209(f)).
3E	Test not required.	
3HT	5/3 times service pressure	3 (see §§ 180.209(k) and 180.213(c)).
3T	5/3 times service pressure	5.
4AA480	2 times service pressure (see § 180.209(g)) ...	5 or 10 (see § 180.209(h)).
4B, 4BA, 4BW, 4B–240ET	2 times service pressure, except non-corrosive service (see § 180.209(g)).	5, 7, 10, or 12 (see § 180.209(e), (f), and (j)).
4D, 4DA, 4DS	2 times service pressure	5.
4E	2 times service pressure, except non-corrosive service (see § 180.209(g)).	5, 10, or 12 (See § 180.209(e)).
4L	Test not required.	
8, 8AL		10 or 20 (see § 180.209(i)).
Exemption or special permit cylinder	See current exemption or special permit	See current exemption or special permit.
Foreign cylinder (see § 173.301(j) of this subchapter for restrictions on use).	As marked on cylinder, but not less than 5/3 of any service or working pressure marking.	5 (see §§ 180.209(l) and 180.213(d)(2)).

¹ Any cylinder not exceeding 2 inches outside diameter and less than 2 feet in length is excepted from volumetric expansion test.

² For cylinders not marked with a service pressure, see § 173.301a(b) of this subchapter.

³ This provision does not apply to cylinders used for carbon dioxide, fire extinguisher or other industrial gas service.

* * * * *

(e) *Cylinders in non-corrosive gas service.* A cylinder made in conformance with DOT Specifications 4B, 4BA, 4BW, or 4E protected externally by a suitable corrosion-resistant coating and used exclusively for non-corrosive gas that is commercially free from corroding components may be requalified by volumetric expansion testing every 12 years instead of every 5 years. As an alternative, the cylinder may be subjected to a proof pressure test at least two times the marked service pressure, but this latter type of test must be repeated every 10 years after expiration of the initial 12-year period. When subjected to a proof pressure test, the cylinder must be carefully examined under test pressure and removed from service if a leak or defect is found.

* * * * *

Issued in Washington, DC, on July 31, 2019, under authority delegated in 49 CFR 1.97.

William S. Schoonover,

Associate Administrator of Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2019–16677 Filed 8–5–19; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

RIN 0648–BI84

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; State Management Program; Amendments 50A–F

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

ACTION: Notice of availability; request for comments.

SUMMARY: The Gulf of Mexico (Gulf) Fishery Management Council (Council) has submitted Amendments 50A, 50B, 50C, 50D, 50E, and 50F to the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP), for review, approval, and implementation by NMFS (Amendments 50A–F). Amendments 50A–F would delegate authority to Louisiana, Mississippi, Alabama, Florida, and Texas (Gulf states), to establish specific management measures for the harvest of red snapper in Federal

waters in the Gulf by the private angling component of the recreational sector. The purposes of Amendments 50A–F are to increase fishing opportunities and economic benefits by allowing each Gulf state to establish specific management measures for the recreational harvest of red snapper in Federal waters by private anglers landing in that state.

DATES: Written comments must be received on or before October 7, 2019.

ADDRESSES: You may submit comments on Amendments 50A–F identified by “NOAA–NMFS–2017–0122” by either of the following methods:

• *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to www.regulations.gov/#/docketDetail;D=NOAA-NMFS-2017-0122, click the “Comment Now!” icon, complete the required fields, and enter or attach your comments.

• *Mail:* Submit written comments to Lauren Waters, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public

viewing on www.regulations.gov without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous).

Electronic copies of Amendments 50A–F, which include an environmental impact statement, a fishery impact statement, a Regulatory Flexibility Act (RFA) analysis, and a regulatory impact review, may be obtained from the website: http://sero.nmfs.noaa.gov/sustainable_fisheries/gulf_fisheries/reef_fish/2017/am46_gray_trigger/documents/pdfs/gulf_reef_am46_gray_trigg_final.pdf.

FOR FURTHER INFORMATION CONTACT: Lauren Waters, Southeast Regional Office, NMFS, telephone: 727–824–5305; email: Lauren.Waters@noaa.gov.

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) requires each regional fishery management council to submit any FMP or amendment to NMFS for review and approval, partial approval, or disapproval. The Magnuson-Stevens Act also requires that NMFS, upon receiving an FMP or amendment, publish an announcement in the **Federal Register** notifying the public that the FMP or amendment is available for review and comment.

The FMP being revised by Amendments 50A–F was prepared by the Council and implemented by NMFS through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Act.

Background

The red snapper stock annual catch limit (ACL) is divided into commercial (51 percent) and recreational (49 percent) sector allocations. In 2015, through Amendment 40 to the FMP, the recreational sector was separated into a private angling component and a Federal charter vessel and headboat (for-hire) component until the end of 2022 (80 FR 22422, April 22, 2015). Within the recreational sector, the recreational ACL is allocated 57.7 percent to the private angling component and 42.3 percent to the for-hire component. Recreational harvest of red snapper in Gulf Federal waters is managed through a two-fish bag limit, a 16-inch (40.6 cm) total length (TL) minimum size limit, and fishing seasons for each component that begin on June 1 and close when the annual catch target (ACT) of the

respective recreational component is projected to be reached. However for the 2018 and 2019 fishing years, NMFS issued exempted fishing permits to each of the five Gulf states to allow each state to set the fishing season for private anglers landing in that state. The for-hire component fishing season continues to be set by NMFS. The Gulf red snapper stock is not undergoing overfishing, and is not overfished but continues to be managed under a rebuilding plan that ends in 2032.

From 1996 through 2014, the recreational fishing season for red snapper in Gulf Federal waters became progressively shorter, and increased catch rates and inconsistent (longer) Gulf state water recreational fishing seasons contributed to recreational harvest overages. Recreational fishermen throughout the Gulf have requested more flexibility from the Council and NMFS in recreational red snapper management to provide greater socio-economic benefits to their local areas.

In 2017, the Council began developing Amendments 50A–50F to establish state management programs for the harvest of red snapper in the Gulf by the recreational sector. State management refers to allowing a state to set some regulations applicable to anglers landing red snapper in that state (e.g., recreational bag limits and season length), or in some circumstances applicable to anglers fishing for red snapper in Federal waters off that state (e.g., closed areas). Amendment 50A includes actions affecting all Gulf states and the overall Federal management of recreational red snapper, regardless of whether all Gulf states participate in a state management program. Amendments 50B–F are individual amendments for each Gulf state (Louisiana, Mississippi, Alabama, Florida, and Texas, respectively) and contain the Council's selection of preferred alternatives for each individual state management plan.

Management measures under a state's approved state management program would have to achieve the same conservation goals as the current Federal management measures (e.g., constrain harvest to the state's allocated portion of the recreational ACL). Although under state management for measures controlling certain harvesting activities, red snapper would remain a federally managed species. The Council's Scientific and Statistical Committee would continue to recommend the acceptable biological catch for red snapper, while the Council would determine the total recreational sector, component, and state ACLs.

Unless area closures off a state are established in Federal waters, enforcement would primarily be conducted in state waters and dockside.

Actions Contained in Amendments 50A–F

Amendments 50A–F include measures: Identifying the recreational component to include in state management programs; establishing the state-specific allocation of the annual catch limit (ACL); delegating the authority to the states to establish the recreational fishing season, recreational bag limit, and size limits; establishing the post-season ACL adjustments; and establishing the procedure for states to request an area closure in Federal waters off their state.

Recreational Components Included in State Management Programs

Currently, the Council and NMFS establish all management measures for both the Federal private angling and for-hire components in Gulf Federal waters. Amendments 50A–F would delegate to each state the authority to establish specific management measures applicable to the private angling component only. The Council and NMFS would continue to specify all management measures applicable to the Federal for-hire component. The sunset provision ending sector separation after the 2022 fishing year would be removed, and separate component ACLs would continue to be set for each component indefinitely. The Council decided not to pursue state management of the for-hire component at this time in order to reduce the administrative burden and potential complication of enforcement in developing a program for that component. The Council wanted to have Amendments 50A–F implemented for the 2020 fishing year, and including the for-hire component may have affected this timeline.

Delegation

Currently, each Gulf state decides when to open and close their respective state waters to fishing for reef fish. These state water recreational reef fish seasons may not be consistent with the fishing seasons in Federal waters. In state waters, the states establish other management measures, such as recreational bag limits and size limits, while the Council has the responsibility for reef fish management measures applicable in Federal waters. Amendments 50A–F would delegate some management authority to a Gulf state to regulate recreational harvest of red snapper in Federal waters by private anglers landing in that state. Each state

would be required to establish the private angling season structure for harvest of its assigned portion of the ACL, monitor landings, and prohibit further landings of red snapper when the state-specific component ACL is reached or projected to be reached. Each state would also be required to specify a bag limit and a minimum size limit within the range of 14 to 18 inches (35.6 cm to 45.7 cm), TL. In combination, these measures must be expected to maintain harvest levels within the state's ACL. A state could also establish a maximum size limit.

If NMFS determines that a state's red snapper private angling regulations are inconsistent with the FMP and the state fails to correct the inconsistency after notice and an opportunity to do so, or a state does not specify the required management measures, then NMFS would suspend that state's delegation and publish a document in the **Federal Register** stating that the default management measures for the red snapper private angling component apply in Federal waters off that state. The default management measures are the current season (June 1 until the projected closure date), bag limit (2 fish per person per day), and minimum size limit (16 inches (40.6 cm), TL).

The areas of Federal waters off Florida and off Texas are currently defined in the regulations. Amendment 50A would specify the area of Federal waters off Alabama, Mississippi, and Louisiana so that each Gulf state would have a defined Federal water boundary off that state.

Allocation

Currently, the red snapper private angling component ACL is managed as a single unit for all of the Gulf states. Amendment 50A would apportion the private angling component ACL to each state. The allocation would be based on the allocations requested by each state in its EFP application, which totaled 96.22 percent of the overall component ACL. The remaining 3.78 percent would be apportioned between Florida and Alabama, proportionally, based on their EFP allocation request. This results in the apportionment of the private angling ACL to each Gulf state as follows: Alabama 26.298 percent (1,122,662 lb (509,231 kg)), round weight, Florida 44.822 percent (1,913,451 lb (867,927 kg)), round weight, Louisiana 19.120 percent (816,233 lb (370,237 kg)), round weight, Mississippi 3.550 percent (151,550 lb (68,742 kg)), round weight, and Texas 6.210 percent (265,105 lb (120,250 kg)), round weight.

If NMFS suspends one or more state's delegation, NMFS would project the

private angling season in Federal waters off the applicable states based on the remaining aggregate portion of the ACL reduced by the established 20 percent buffer that is used to determine the Federal annual catch target. Anglers who fish in Federal waters off a state without an active delegation of authority would fish under the default Federal regulations described previously.

Post-Season ACL Adjustments

Amendments 50B–F would establish post-season quota adjustments. An overage adjustment, or payback provision, is an accountability measure (AM) that reduces the following year's ACL by some specified amount, usually the amount the ACL was exceeded. The current recreational red snapper post-season AM applies when the stock is classified as overfished and an overage of the total recreational sector's ACL occurs. The AM requires NMFS to reduce the recreational sector ACL and ACT, and applicable component ACL and ACT, in the year following an overage of the total recreational ACL by the full amount of the overage, unless the best scientific information available determines that a greater, lesser, or no overage adjustment is necessary. Amendments 50B–F would establish post-season ACL overage adjustments for states with an active delegation, regardless of stock status. If the landings of a state exceed that state's ACL, then in the following fishing year that state's ACL would be reduced by the amount of the ACL overage in the prior fishing year, unless the best scientific information available determines that a greater, lesser, or no overage adjustment is necessary. The total recreational ACL and the private angling component ACL would also be reduced.

In Amendments 50B–F, the Council expressed its intent to allow for carryover of a state's unused portion of its ACL to the following fishing year if permitted under a separate amendment to the FMP that the Council was developing to add a carryover provision to the Acceptable Biological Catch Control Rule. In June 2019, the Council postponed work on that amendment. Therefore, NMFS is not proposing to implement this provision at this time.

Area Closures

Amendment 50A would allow a Gulf state, consistent with the terms of an active delegation, to request that NMFS close all, or an area of, Federal waters off that state to the harvest and possession of red snapper by private anglers. The state would request the closure by letter to NMFS, providing

dates and geographic coordinates for the closure. If the request is within the scope of the analysis in Amendment 50A, NMFS would publish a document in the **Federal Register** implementing the closure in Federal waters off that state for the fishing year.

Based on the analysis in Amendment 50A, Texas would be able to request a closure of all Federal waters off the state to allow a year-round fishing season in state waters and a limited season in Federal waters. Florida would be able to request a closure of Federal waters off the state seaward of the 20-fathom (36.6-m) depth contour, or seaward of the 35-fathom (64.0-m) depth contour, for the duration of Florida's open private angling component season. Alabama would be able to request a closure of Federal waters off the state seaward of the 20-fathom (36.6-m) depth contour, or seaward of the 35-fathom (64.0-m) depth contour, for the duration of Alabama's open private angling component season. Florida and Alabama want the ability to close deeper waters to potentially extend their seasons by decreasing the average size of fish landed. These areas were chosen because an approximation for the 20-fathom depth contour is currently defined in 50 CFR 622.34(d) for the seasonal shallow-water grouper closure, and an approximation of the 35-fathom depth contour is partially defined in 50 CFR 622.35(b) for the seasonal eastern Gulf longline closure. The coordinates for any closure off Texas, Florida, or Alabama are provided in Appendix H of Amendment 50A and would be included in the **Federal Register** document implementing the closure. Neither Louisiana nor Mississippi provided any potential closures to analyze in Amendment 50A and these states would not be able to request Federal waters closures through this process without further action by the Council.

Proposed Rule for Amendments 50A–F

A proposed rule that would implement Amendments 50A–F has been drafted. In accordance with the Magnuson-Stevens Act, NMFS is evaluating the proposed rule to determine whether it is consistent with the FMP, the Magnuson-Stevens Act, and other applicable law. If that determination is affirmative, NMFS will publish the proposed rule in the **Federal Register** for public review and comment.

Consideration of Public Comments

The Council has submitted Amendments 50A–F for Secretarial review, approval, and implementation.

Comments on Amendments 50A–F must be received by October 7, 2019.

Comments received during the respective comment periods, whether specifically directed to Amendments 50A–F or the proposed rule, will be considered by NMFS in its decision to

approve, partially approve, or disapprove Amendments 50A–F and will be addressed in the final rule.

All comments received by NMFS on Amendments 50A–F or the proposed rule during their respective comment periods will be addressed in the final rule.

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

Dated: July 31, 2019.

Alan D. Risenhoover,

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

[FR Doc. 2019–16657 Filed 8–5–19; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 84, No. 151

Tuesday, August 6, 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

Submission for OMB Review; Comment Request

August 1, 2019.

The Department of Agriculture has submitted the following information collection requirement(s) to Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding: 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; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by September 5, 2019 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW, Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: OIRA_Submission@OMB.EOP.GOV or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information

displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Utilities Service

Title: Broadband Grant Program.

OMB Control Number: 0572–0127.

Summary of Collection: Congress has recognized the need to facilitate the deployment of broadband service to unserved rural areas. The provision to broadband transmission service is vital to the economic development, education, health, and safety of rural Americans.

The Consolidated Appropriations Act, 2004 (Title III, Pub. L. 108–199, Stat. 3), 7 CFR 1739 Subpart A, as amended, authorizes the Rural Development, Rural Utilities Service (RUS) to administer the Community Connect Grant Program for the provision of broadband transmission service in rural America. Grant authority is utilized to deploy broadband infrastructure to extremely rural, lower income communities on a “community-oriented connectivity” basis.

Need and Use of the Information: RUS gives priority to rural areas that it believes have the greatest need for broadband transmission services. This broadband access is intended to promote economic development and provide enhanced educational and health care opportunities. RUS will provide financial assistance to eligible entities that are proposing to deploy broadband transmission service in rural communities where such service does not currently exist and who will connect the critical community facilities including the local schools, libraries, hospitals, police, fire and rescue services and who will operate a community center that provides free and open access to residents.

Description of Respondents: Business or other for-profit.

Number of Respondents: 82.

Frequency of Responses: Reporting; On occasion.

Total Burden Hours: 13,380.

Kimble Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2019–16756 Filed 8–5–19; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2019–0045]

National Wildlife Services Advisory Committee; Meeting

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of meeting.

SUMMARY: We are giving notice of a meeting of the National Wildlife Services Advisory Committee.

DATES: The meeting will be held on September 18 and 19, 2019 from 8 a.m. to 5 p.m. each day.

ADDRESSES: The meeting will be held at the Jamie L. Whitten Building, 1400 Independence Avenue SW, Washington, DC 20250, in Room 104–A.

FOR FURTHER INFORMATION CONTACT: Ms. Carrie Joyce, Designated Federal Officer, Wildlife Services, APHIS, 4700 River Road Unit 87, Riverdale, MD 20737; (301) 851–3999.

SUPPLEMENTARY INFORMATION: The National Wildlife Services Advisory Committee (the Committee) advises the Secretary of Agriculture concerning policies, program issues, and research needed to conduct the Wildlife Services (WS) program. The Committee also serves as a public forum enabling those affected by the WS program to have a voice in the program's policies.

The meeting will focus on operational and research activities conducted by the Wildlife Services Program. The committee will discuss pertinent WS operational and research activities and programs and how to increase their effectiveness, as well as ensuring WS remains an active participant in the goal of agricultural protection.

The meeting will be open to the public. Attendees should arrive between 8 and 8:30 a.m. Picture identification is required to gain access to the Whitten Building.

Due to time constraints, the public will not be allowed to participate in the

discussions during the meeting. Written statements on meeting topics may be filed with the Committee before or after the meeting by sending them to the person listed under **FOR FURTHER INFORMATION CONTACT**. Written statements may also be filed at the meeting. Please refer to Docket No. APHIS–2019–0045 when submitting your statements.

This notice of meeting is given pursuant to section 10 of the Federal Advisory Committee Act.

Done in Washington, DC, this 30th day of July 2019.

Cikena Reid,

Committee Management Officer, USDA.

[FR Doc. 2019–16758 Filed 8–5–19; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2018–0044]

Changes to the *Campylobacter* Verification Testing Program: Revised Performance Standards for *Campylobacter* in Not-Ready-To-Eat Comminuted Chicken and Turkey and Related Agency Procedures

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing and requesting comments on revised pathogen reduction performance standards for *Campylobacter* in not-ready-to-eat (NRTE) comminuted chicken and turkey products based on a microbiological method change from direct-plating to enrichment. The Agency is taking this step because the enrichment method more effectively recovers *Campylobacter* in contaminated poultry samples as compared to the direct-plating method.

FSIS will consider comments received on this notice before announcing the final standards in the **Federal Register** and assessing whether establishments are meeting the standards.

After collecting sufficient data, FSIS plans to propose and request comments on revised pathogen reduction performance standards for *Campylobacter* in young chicken and turkey carcasses and in raw chicken parts, also based on the enrichment method.

DATES: Submit comments on or before October 7, 2019.

ADDRESSES: FSIS invites interested persons to submit comments on this notice. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides commenters the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- *Mail, including CD-ROMs, etc.:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250–3700.

- *Hand- or Courier-Delivered Submittals:* Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2018–0044. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or comments received, call (202) 720–5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: Roberta Wagner, Assistant Administrator, Office of Policy and Program Development by telephone at (202) 205–0495.

SUPPLEMENTARY INFORMATION: FSIS is responsible for verifying that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and properly labeled and packaged.

Campylobacter is the most common bacterial cause of foodborne illness in the United States. The Centers for Disease Control and Prevention (CDC) estimate *Campylobacter* infections affect 1.3 million people every year in the United States.¹ During 2018, CDC's Foodborne Diseases Active Surveillance Network, or FoodNet,² reported that the incidence of foodborne infection was highest for *Campylobacter* (19.5 per 100,000 population).³ Most non-dairy, outbreak-associated *Campylobacter* illnesses are attributed to the

consumption of poultry.⁴ *Campylobacter* outbreaks are not commonly identified considering how often people get sick from this bacteria, but the frequency of outbreaks has been increasing.⁵

Poultry Carcasses and Raw Chicken Parts

FSIS finalized and announced *Campylobacter* performance standards for establishments that produce young chicken carcasses and turkey carcasses on May 14, 2010 (75 FR 27288). FSIS initially proposed to use the results from both the 1-mL direct-plating analytical method and the 30-mL enrichment analytical method to assess whether establishments were meeting the *Campylobacter* performance standards for young chicken and turkey carcasses.⁶ However, on March 21, 2011, after further analysis and in response to public comments, FSIS announced that it would: Only use the direct-plating method results to assess whether young chicken and turkey slaughter establishments were meeting the performance standards; also concurrently analyze young chicken and turkey carcass rinsates using the enrichment method; and conduct an internal analysis of all of these results—direct-plating and enrichment method generated results—to develop additional policy options (76 FR 15282). In July 2011, FSIS began compiling sample sets⁷ to generate data to assess whether young chicken and turkey slaughter establishments were meeting the *Campylobacter* standards. Poultry slaughter establishments subject to the *Campylobacter* performance standards were assessed against the standards based solely on the results generated using the direct-plating method. However, samples collected as part of these sample sets were analyzed concurrently using the enrichment method.

After FSIS completed two sample sets for nearly 90 percent of the young chicken and turkey slaughter establishments, the results generated using both the 1-mL direct-plating and

⁴ <https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2016-report-TriAgency-508.pdf>.

⁵ <https://www.cdc.gov/Campylobacter/outbreaks/outbreaks.html>.

⁶ FSIS's direct-plating and enrichment analytical methods are described in the Microbiology Laboratory Guidebook, Chapter 41; at <https://www.fsis.usda.gov/wps/wcm/connect/0273bc3d-2363-45b3-befb-1190c25f3c8b/MLG-41.pdf?MOD=AJPERES>.

⁷ At the time, FSIS inspection program personnel were collecting poultry carcass samples over a defined number of sequential days of production to complete a sample set. In May 2015, FSIS began testing poultry carcasses using a continuous sampling program and discontinued the previous set-based verification projects.

¹ <https://www.cdc.gov/Campylobacter/faq.html>.

² <https://www.cdc.gov/foodnet/index.html>.

³ <https://www.cdc.gov/mmwr/volumes/68/wr/mm6816a2.htm>.

30-mL enrichment methods were evaluated. FSIS announced in the *Constituent Update* on May 31, 2013 that it had evaluated the available *Campylobacter* sample set data⁸ and the analysis at that time showed that the direct-plating method was sufficiently sensitive to identify poultry carcass establishments with substandard process control. Thus, on June 3, 2013, FSIS suspended the use of the 30-mL enrichment method for *Campylobacter* for young chicken and turkey carcasses.⁹

However, in July 2016, when FSIS modified its sampling procedure for young chicken and turkey carcasses and raw chicken parts by replacing buffered peptone water (BPW) with neutralizing BPW (nBPW), the Agency began to observe a marked and significant reduction in *Campylobacter* recovery from turkey carcasses and chicken parts using the 1-mL direct-plating method, suggesting nBPW affected *Campylobacter* recovery in these products. In May 2018, FSIS further investigated this effect by performing a side-by-side analysis of poultry carcasses and raw chicken parts samples with the direct-plating and enrichment methods and found significantly higher percentages of *Campylobacter* positive samples, indicating more effective recovery of *Campylobacter*, using the enrichment method as compared to the direct-plating method for young chicken carcasses (18 percent compared to 1 percent), turkey carcasses (1 percent compared to 0 percent) and chicken parts (16 percent compared to 2 percent). In the near future, FSIS also intends to propose and request comments on revised *Campylobacter* performance standards for these commodities based on the enrichment method.

Comminuted Poultry

On January 26, 2015, FSIS proposed new *Campylobacter* performance standards for NRTE comminuted chicken and turkey products and raw chicken parts, including a cost-benefit analysis (80 FR 3940), and released a risk assessment estimating the effect of these new performance standards on reducing *Campylobacter* illnesses attributed to these products (2015 Risk Assessment).¹⁰ FSIS finalized the

performance standards on February 11, 2016 (81 FR 7285).

These *Campylobacter* performance standards were based on the 1-mL direct-plating method and, for both NRTE comminuted chicken and turkey products, specified one (1) allowable positive sample in 52 samples. In 2014, before these performance standards were announced, FSIS tested NRTE comminuted chicken, but not NRTE comminuted turkey products using the 30-mL enrichment method and found the enrichment method to have greater *Campylobacter* recovery and thus generate more positive results. In the February 2015 *Federal Register* notice, FSIS announced its intention to continue to perform the 30-mL enrichment method concurrently with the 1-mL direct-plating method for both NRTE comminuted chicken and turkey products, and to analyze data generated from both analytical approaches (81 FR at 7292). As part of this effort, all NRTE comminuted chicken and turkey product samples collected between June 2015 and May 2017 were analyzed for the presence of *Campylobacter* using both the 1-mL direct-plating method and the 30-mL enrichment method. In May 2017, FSIS suspended use of the enrichment method while it analyzed the data. The Agency resumed using the enrichment method concurrent with the direct-plating method on August 27, 2018.¹¹ These results were not affected by the July 2016 switch from BPW to nBPW because nBPW is not used to collect or test NRTE comminuted poultry product samples.¹²

Enrichment Method

As stated above, FSIS originally developed *Campylobacter* performance standards for NRTE comminuted chicken and turkey products using the 1-mL direct-plating method while simultaneously analyzing the same samples using the 30-mL enrichment method. The enrichment method enhances the probability of recovering *Campylobacter* from raw poultry samples. For both methods, the test portion consists of 325 grams of NRTE comminuted poultry suspended in 1625 mL of BPW. Because the direct-plating method requires at least 1,950 colony forming units (CFU) in the suspended

mixture to be reasonably likely to detect a positive *Campylobacter* sample, its theoretical limit of detection (LOD) is 6 CFU/gram. The enrichment method requires at least 65 CFU in the suspended mixture for *Campylobacter* to be detected, giving it a theoretical LOD of 0.2 CFU/gram.

The enrichment method includes a two-day enrichment step, which may allow for the repair of bacteria injured by exposure to extremes of pH, temperature, pressure, antimicrobial compounds, or other injurious conditions and growth of any viable bacteria present. Therefore, the enrichment step increases the potential for the growth and recovery of *Campylobacter* cells injured during comminuted poultry processing steps as compared with the direct-plating method. The enrichment method for *Campylobacter* is comparable to the enrichment method currently used to assess the pathogen reduction performance standards for *Salmonella* in raw poultry.

The enhanced recovery of the enrichment method compared to the direct-plating method will improve FSIS's ability to distinguish establishments that are meeting or not meeting the *Campylobacter* performance standards. The *Campylobacter* performance standards proposed in this notice were revised to account for a microbiological method change and would retain the same potential benefits and costs as the original, 1-mL direct-plating-based performance standards. A peer-reviewed manuscript was published which explains the technical details used to determine the mathematical equivalence between the 1-mL direct-plating and 30-mL enrichment methods. The article uses the NRTE comminuted chicken performance standard as an example.¹³ Brief explanations of FSIS's process for developing the current *Campylobacter* performance standards for NRTE comminuted chicken and turkey based on the 1-mL direct-plating method and the revised performance standards for NRTE comminuted chicken and turkey based on the 30-mL enrichment method are provided below.

How FSIS Develops *Campylobacter* Performance Standards

The current FSIS *Campylobacter* and *Salmonella* performance standards are based on a 2-class attributes sampling plan, which specifies a maximum

⁸ http://www.fsis.usda.gov/wps/wcm/connect/9a3a7078-0ff4-4ebc-8de6-ad889382fd7f/Const_Update_053113.pdf?MOD=AJPERES.

⁹ FSIS announced full discontinuation of this analysis for poultry carcasses on February 21, 2014 (79 FR 9875).

¹⁰ The 2015 Risk Assessment is available at <https://www.fsis.usda.gov/wps/wcm/connect/afe9a946-03c6-4f0d-b024-12aba4c01aef/Effects->

<Performance-Standards-Chicken-Parts-Comminuted.pdf?MOD=AJPERES>.

¹¹ <https://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/newsletters/constituent-updates/archive/2018/ConstUpdate082718>.

¹² The sampling procedures for NRTE comminuted chicken and turkey products can be seen at <https://www.fsis.usda.gov/wps/wcm/connect/801ffca3-a226-45c4-ac68-10670e3ac32b/NRTE-Comminuted-Poultry-Sampling-Program.pdf?MOD=AJPERES>.

¹³ Williams, M.S., Ebel, E.D., Golden, N.J., 2018. Revising a Constrained 2-Class Attributes Sampling Plan When Laboratory Methods are Changed. *Microbial Risk Analysis*; <https://doi.org/10.1016/j.mran.2018.12.002>.

number of positive samples out of a fixed number of total samples. This can also be expressed as a maximum allowable percent positive. Positive samples are those in which the pathogen is detectable using a microbiological assay. Since 2011, FSIS has taken a common approach to determine performance standards for each pathogen-product pair, and this approach is described most recently in the January 26, 2015 **Federal Register** (80 FR at 3942). Briefly, FSIS measures the public health effect of a performance standard as the number of illnesses avoided each year.¹⁴ This effect is calculated from the volume-weighted prevalence of a contaminated poultry product before and after successfully implementing the performance standard. Volume-weighted prevalence means that establishments with higher production volumes have a greater influence on the overall prevalence estimates. Because the volume-weighted prevalence after implementing a performance standard cannot be known when the standard is proposed, FSIS models the impact of the performance standard by assuming that a certain percentage of establishments (and their production volume) would initially not meet the standard but eventually do meet it. This is referred to as the “compliance fraction.”

Using the sampling and production volume data collected from each eligible establishment, FSIS can estimate the impact of all possible performance standards. Establishments are classified as meeting or not meeting each possible performance standard. The compliance fraction is then used to estimate the number of avoided or reduced illnesses. FSIS’s current performance standards for *Campylobacter* in poultry were intended to achieve at least a 33-percent reduction in illnesses, a target based on Healthy People 2020 goals.^{15 16} The

proportion of establishments and their production volume initially not meeting the performance standard also allows FSIS to estimate the costs associated with implementing the performance standard (*i.e.*, the costs to industry).

How FSIS Developed the Current *Campylobacter* Performance Standards for NRTE Comminuted Chicken and Turkey Using the 1-mL Direct-Plating Method

To estimate the illnesses reduced by the current NRTE comminuted chicken and turkey *Campylobacter* performance standards, FSIS sampled establishments producing NRTE comminuted chicken and/or turkey products between June 2013 and May 2014. Each sample was tested for *Campylobacter* using the 1-mL direct-plating method. Three important factors varied across the establishments: Production volume, prevalence of contaminated samples, and the number of samples collected. Underlying all of the results is a statistical distribution of volume-weighted establishment prevalence accounting for these factors.¹⁷ This distribution is demonstrated as the smooth line in Figure 1 (a).

The risk assessment model uses estimates from the statistical distribution of volume-weighted prevalence and assumes a 50-percent compliance fraction to predict the illness reduction. Figure 1 (b) shows the predicted illnesses reduced by *Campylobacter* performance standards based on 1-mL direct-plating data collected between 2013 and 2014. Using

through food <http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=14>. Once the Healthy People 2030 objectives have been finalized, FSIS intends to assess whether changes to its performance standards are warranted.

¹⁶ Although the Healthy People 2020 goal of 33-percent reduction in *Campylobacter* illnesses was achieved with other poultry products, the most restrictive and achievable performance standard for NRTE comminuted turkey is 1 positive in 52 samples, which would achieve a 19-percent reduction in *Campylobacter* illnesses.

¹⁷ Williams, M.S., Ebel, E.D., Cao, Y., 2013. Fitting distributions to microbial contamination data collected with an unequal probability sampling design. *Journal of Applied Microbiology* 114, 152–160.

this curve, and FSIS’s stated intent of at least a 33-percent illness reduction for *Campylobacter* from NRTE comminuted chicken, FSIS selected a performance standard of one (1) allowable positive out of 52 samples, or a maximum allowable percent positive of 1.9. FSIS actually predicted a 37-percent reduction in the illness rate for *Campylobacter* after implementing the NRTE comminuted chicken performance standard, corresponding to an annual reduction of approximately 1,300 illnesses.

The statistical distribution is also used to determine the proportion of NRTE comminuted chicken product that would meet a *Campylobacter* performance standard of one (1) positive out of 52 samples. Figure 1 (c) shows the proportion of product that would meet the performance standard based on the 1-mL direct-plating data collected from 2013–2014. With a performance standard of one (1) positive out of 52 samples, 56 percent of all NRTE comminuted chicken product (corresponding to 24 percent of eligible establishments) would initially not meet the standard. FSIS used this information to estimate the associated costs.

The same procedures were used to determine the *Campylobacter* performance standard for NRTE comminuted turkey product. FSIS determined that the direct-plating method-based performance standard of one (1) allowable positive in 52 samples in NRTE comminuted turkey product would provide a 19-percent illness reduction, and 20 percent of production volume (which accounts for 9 percent of eligible establishments) would initially not meet the standard.¹⁸

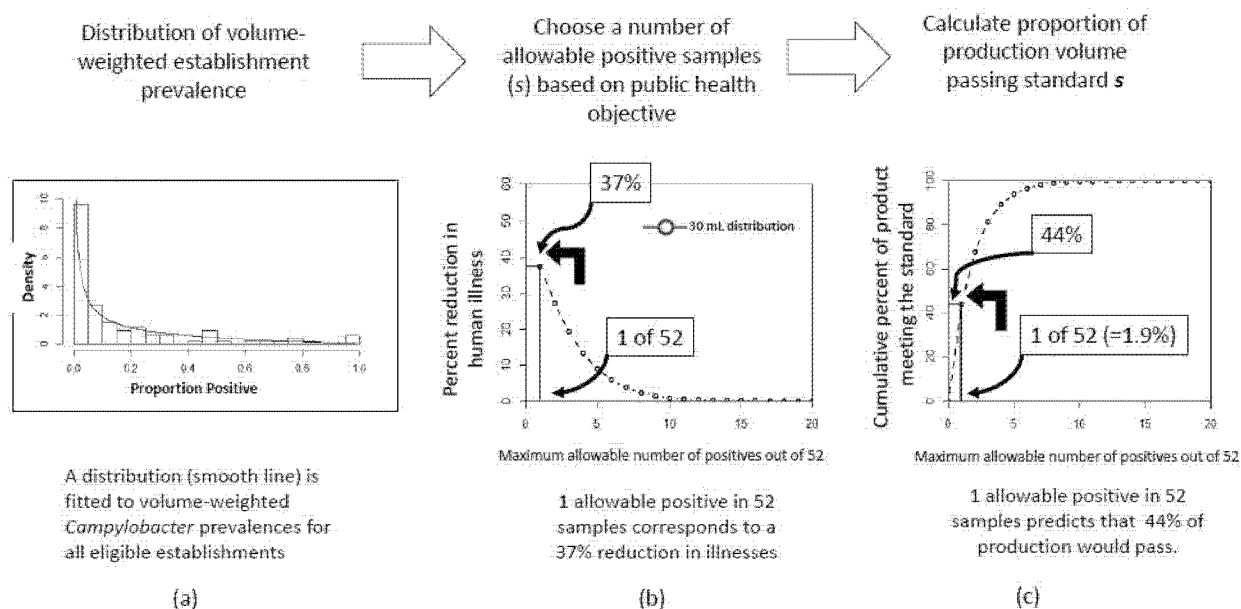
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¹⁸ FSIS initially intended for *Campylobacter* performance standards to reduce illness by approximately 33 percent. However, because FSIS found the prevalence for *Campylobacter* in comminuted turkey to be especially low, the highest practical illness reduction for this product was estimated to be 19 percent. The revised standard based on the 30-mL enrichment method was therefore designed to achieve the same predicted illness reduction of 19 percent.

¹⁴ Ebel, Williams et al. 2012. Simplified framework for predicting changes in public health from performance standards applied in slaughter establishments. *Food Control* 28:250–257.

¹⁵ HHS. (2010). “Healthy People Topics & Objectives: Food Safety.” Reduce infections caused by *Campylobacter* species transmitted commonly

Figure 1. Example demonstrating how FSIS calculated the illness reduction and costs associated with the current NRTE comminuted chicken *Campylobacter* performance standard. Panel (a) demonstrates the statistical distribution of volume-weighted sampling results. Panel (b) demonstrates how illness reduction estimates were used to choose a performance standard. A 37-percent illness reduction would be achieved by a performance standard of one (1) positive in 52 samples. Panel (c) demonstrates how different performance standards would affect the proportion of product that would initially meet each potential standard, which FSIS used to calculate the associated costs to industry. A performance standard of one (1) positive in 52 samples would predict that 44 percent of production volume would initially meet the standard. This corresponds to 56 percent of production volume (24 percent of establishments) that would initially not meet the standard. The “direction” of the arrows reflects the process FSIS used to determine the performance standard, illness reduction, and industry costs. FSIS uses the performance standard to predict illness reduction in panel (b) and industry costs in panel (c).



How FSIS Revised the *Campylobacter* Performance Standards for NRTE Comminuted Chicken and Turkey Using Data Generated Using the 30-mL Enrichment Method

As is discussed above, from June 2015 through May 2017, FSIS tested all NRTE comminuted chicken samples using both the 1-mL direct-plating and 30-mL enrichment methods. There were approximately five times as many samples that tested positive for *Campylobacter* using the 30-mL enrichment method as compared to the 1-mL direct-plating method (*i.e.*, 267

versus 53). FSIS believes this increase was facilitated by a larger test portion size (30-mL compared to 1-mL) and the potential for growth and recovery of injured *Campylobacter* cells allowed by the enrichment process.

FSIS developed a revised *Campylobacter* performance standard by fitting a statistical distribution of the volume-weighted prevalence and then finding the point that reaches the same illness reduction goal determined for the current, 1-mL direct-plating-based performance standard, which was a 37-percent reduction in illnesses. Figure 2 (a) shows the predicted illnesses

reduced by potential *Campylobacter* performance standards based on the 30-mL enrichment data collected between 2015 and 2017. A 37-percent reduction in illnesses could be achieved with a 30-mL enrichment method-based standard of five (5) positives in 52 samples. That is, the point on the 30-mL curve that reaches a 37-percent reduction in illnesses corresponds to a performance standard of five (5) positives in 52 samples.

Similarly, the 1-mL direct-plating and 30-mL enrichment-based curves were used to determine the proportion of NRTE comminuted chicken product that

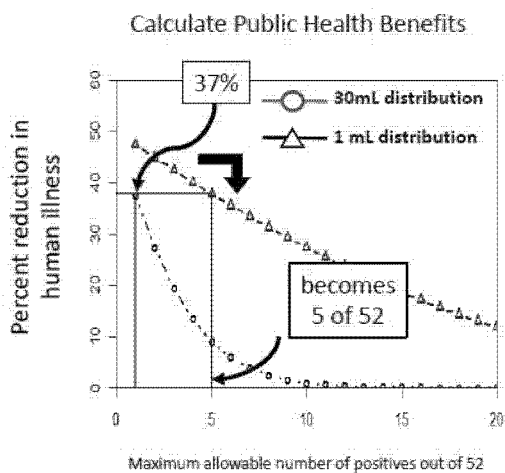
would initially be classified as meeting/not meeting the standard. Figure 2 (c) shows that a performance standard of five (5) allowable positives in 52 samples would result in 44 percent of production volume meeting the standard. That is, the point on the 30-mL curve corresponding to five (5) positives in 52 samples results in 44 percent of the production volume

meeting the performance standard, and 56 percent not meeting it. A more detailed description of the methodology, and the treatment of statistical uncertainty is presented in the peer-reviewed technical manuscript (Williams et al, 2018; citation 12).

The same procedures were used to revise the *Campylobacter* performance standard for NRTE comminuted turkey

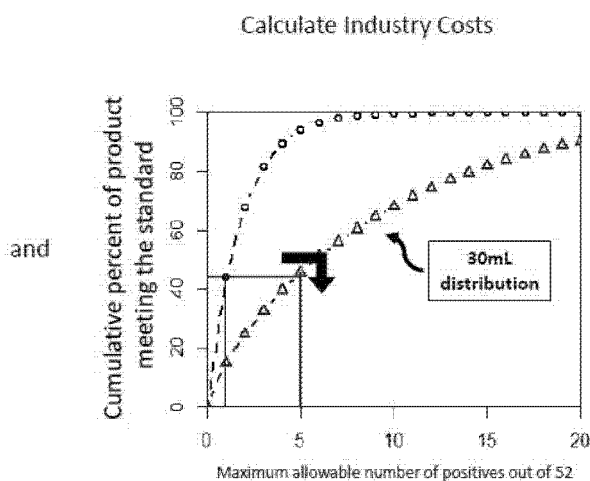
product. FSIS determined that an enrichment method-based performance standard of five (5) allowable positives in 52 samples would provide a 19-percent illness reduction, and 20 percent of production volume (which accounts for 9 percent of eligible establishments) would initially not meet the revised performance standard.

Figure 2. Example of how the predicted illness reduction based on 1-mL direct-plating method generated data was used to revise the *Campylobacter* performance standard established using 30-mL enrichment method generated data. Panel (a) demonstrates how illness reduction estimates were used to choose a performance standard. A 37-percent reduction in illnesses is predicted by a performance standard of one (1) positive in 52 samples for the 1-mL direct-plating data from 2013-2014, or five (5) positives in 52 samples for the 30-mL enrichment data from 2015-2017. Panel (c) demonstrates how different performance standards would affect the proportion of NRTE comminuted chicken product that would initially meet each potential standard, which FSIS used to calculate the associated costs to industry. A *Campylobacter* performance standard of either one (1) positive in 52 samples (1-mL direct-plating) or five (5) positives in 52 samples (30-mL enrichment) would predict that 44 percent of production volume would meet the standard, and 56 percent would not meet it. These data are used to determine the associated costs. Note the "direction" of the arrows is reversed from Figures 2 (a) and 2 (b). FSIS first determines the predicted illness reduction and then uses the corresponding performance standard to determine the associated costs.



~37% reduction in illnesses corresponds to an enrichment standard of $s=5$ positive of 52 samples

(a)



~44% of product would also meet an enrichment standard of $s=5$ positive of 52 samples

(b)

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Revised Pathogen Reduction Performance Standards

FSIS is proposing revised performance standards to improve the Agency's ability to identify *Campylobacter* contamination in NRTE comminuted chicken and turkey

products using the enrichment method. A summary of the revised *Campylobacter* performance standards for NRTE comminuted poultry products is provided in Table 1. Should FSIS finalize these proposed performance standards, FSIS will announce the final standards in the **Federal Register** before assessing whether establishments meet

the standards. Any changes to the performance standards for *Campylobacter* in young chicken and turkey carcasses, and in raw chicken parts, will be proposed in a separate **Federal Register** notice.

As described above, FSIS has revised the pathogen reduction performance standards for *Campylobacter* in NRTE

comminuted chicken and turkey products based on the 30-mL enrichment method, such that the same public health objectives announced in 2015 for the 1-mL direct-plating method-based standards are achieved.

Minimum Number of Samples To Assess Performance

FSIS uses the following formula to estimate the minimum number of samples (n) needed to assess establishment performance: $n = (1/$

percent positive allowed) $\times 100$ (80 FR at 3947). Revising the *Campylobacter* performance standard from one allowable positive per 52 samples (1.9 percent) to five allowable positive samples per 52 samples (9.6 percent) changes the minimum number of samples needed to assess establishments from $(\frac{1}{1.9\%}) \times 100$, or 52 samples, to $(\frac{1}{9.6\%}) \times 100$, or 10.4 samples. Because samples are necessarily whole numbers, a fractional number is rounded up to the next highest whole number. Therefore,

11 samples would be the minimum number of samples needed to assess performance for *Campylobacter* in both NRTE comminuted chicken and comminuted turkey producing establishments under the revised standards. Significantly, since the proposed revised performance standards reduce the minimum number of samples needed to assess establishment performance, FSIS would be able to assess performance for a greater number of otherwise eligible establishments.

TABLE 1—REVISED PERFORMANCE STANDARDS FOR *Campylobacter* IN NRTE COMMINUTED CHICKEN AND TURKEY PRODUCTS

Product	Revised performance standard for <i>Campylobacter</i>	Revised maximum allowable percent positive *	Revised minimum number of samples to assess
NRTE Comminuted Chicken (325 g sample)	5 of 52	9.6	11
NRTE Comminuted Turkey (325 g sample)	5 of 52	9.6	11

* Consistent with existing FSIS procedures, if the total number of samples in a 52-week moving window ranges from 11 to 51, FSIS will subtract 1 from the number of positive samples to calculate the percent positive, which is compared to the revised maximum acceptable percent positive determined by dividing 5 by 52 to determine the Category. If the total number of samples in a moving window exceeds 51, FSIS will calculate a percent positive without subtracting 1 from the number of positives.

Changes to Related Agency Procedures

Once FSIS begins assessing whether establishments meet the revised *Campylobacter* performance standards, FSIS would use the categorization methodology, as well as the web posting procedures announced in the **Federal Register** on November 9, 2018 (83 FR 56046; Nov. 9, 2018). As explained in the November 2018 **Federal Register** notice, the Category status reported on the public website would be based on FSIS sample results during the 52-week window ending the last Saturday of the previous month, and would not include follow-up sampling results, if any were collected and analyzed, as part of the window.

In addition, establishments would not be categorized as *meeting* or *not meeting* as previously announced in the February 2016 **Federal Register** notice. Instead, FSIS would categorize eligible establishments using the same 3-category system it uses for poultry establishments currently subject to a *Salmonella* pathogen reduction performance standard. The criteria for each category are as follows:

- Category 1: Establishments that have achieved 50 percent or less of the maximum allowable percent positive during the most recently completed 52-week moving window.
- Category 2: Establishments that meet the maximum allowable percent positive but have results greater than 50 percent of the maximum allowable percent positive during the most

recently completed 52-week moving window.

- Category 3: Establishments that have exceeded the maximum allowable percent positive during the most recently completed 52-week moving window.

All other FSIS verification procedures outlined in the February 2016 **Federal Register** notice are unchanged.

Additional Information

Should these *Campylobacter* standards for comminuted poultry products be finalized, FSIS will post aggregate *Campylobacter* sampling results relative to categories and prevalence estimates for NRTE comminuted chicken and turkey products, consistent with how FSIS handles *Salmonella* postings.¹⁹ FSIS would also announce when it expects to begin posting individual establishment category information in the **Federal Register** notice that announces final *Campylobacter* standards for comminuted poultry products.

Cost-Benefit Analysis

The February 2016 **Federal Register** notice announcing pathogen reduction performance standards for *Salmonella* and *Campylobacter* in NRTE comminuted chicken and turkey products and raw chicken parts

included a supplementary cost-benefit analysis (2016 CBA).²⁰ The 2016 CBA estimated the economic effects of the new pathogen reduction performance standards for *Salmonella* and *Campylobacter* in both NRTE comminuted poultry and raw chicken parts. The 2016 CBA used estimates on whether establishments would meet the standards and illness reduction estimates from the 2015 Risk Assessment, which relied on results obtained using the direct-plating method.

As explained above, FSIS is proposing to revise the pathogen reduction performance standards for *Campylobacter* in NRTE comminuted chicken and turkey products based on an enrichment method. To ensure the revised performance standards would be statistically equivalent to the previously announced *Campylobacter* standards for these products, FSIS analyzed 2015–2017 sample results generated using both the enrichment and direct-plating methods. Based on this analysis, FSIS concluded the revised pathogen reduction performance standards are consistent with the previously announced standards in terms of the estimated reduction in illnesses and the

¹⁹ The information is posted at <https://www.fsis.usda.gov/wps/portal/food/topics/data-collection-and-reports/microbiology/salmonella-verification-testing-program/aggregate-data>.

²⁰ U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS). (2016). Final Cost-Benefit Analysis Chicken Parts and Not Ready-To-Eat Comminuted Poultry Performance Standards; available at: <https://www.fsis.usda.gov/wps/wcm/connect/2f98f0a2-6a89-4316-aa95-86e5b103610f/CBA-Salmonella-Campy-2014-0023F-022016.pdf?MOD=AJPERES>.

percent of the industry expected to initially not meet the performance standards (Williams et al, 2018; citation 12). Therefore, the associated costs and public health benefits of the revised performance standards remain unchanged from those estimated in the 2016 CBA.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication online through the FSIS web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS also will announce and provide a link to it through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

USDA Non-Discrimination Statement

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Done at Washington, DC:

Carmen M. Rottenberg,
Administrator.

[FR Doc. 2019-16765 Filed 8-5-19; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Forest Service

Ochoco, Umatilla and Wallowa-Whitman National Forest; Oregon; Blue Mountain Forest Resiliency Project

AGENCY: Forest Service, USDA.

ACTION: Withdrawal of notice of intent to prepare an Environmental Impact Statement.

SUMMARY: The Ochoco, Umatilla and Wallowa-Whitman National Forests are withdrawing their Notice of Intent (NOI) to prepare an Environmental Impact Statement (EIS) for the Blue Mountain Forest Resiliency Project. The original NOI was published in the **Federal Register** on February 5, 2016.

FOR FURTHER INFORMATION CONTACT:

Questions concerning this notice should be directed to David Hatfield via mail at Umatilla National Forest Supervisors Office, 72510 Coyote Rd Pendleton, OR 97801; via telephone at 541-278-3855; or via email at david.hatfield@usda.gov.

SUPPLEMENTARY INFORMATION: The forest supervisors of the Ochoco, Umatilla and Wallowa-Whitman National Forests have modified the Forest Resiliency Project planning approach from one dedicated interdisciplinary team working across portions of the three national forests to each national forest addressing individual restoration needs through their regular program of work.

The forest supervisors decided the most efficient way to ensure successful completion and implementation of this important restoration work would be to transfer all existing data and completed analysis to individual interdisciplinary teams on each forest to more efficiently start and complete local restoration efforts. This decision will also allow each forest to work closely with local communities during project development to ensure the right work is

completed in the right locations to increase forest health and productivity, while also contributing to local economies and protecting natural resources. A new NOI will be published for any projects being considered for analysis under an EIS.

Dated: July 16, 2019.

Frank R. Beum,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2019-16712 Filed 8-5-19; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF AGRICULTURE

Forest Service

Southern Region Recreation Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Southern Region Recreation Resource Advisory Committee (Recreation RAC) will meet in Decatur, Georgia. The committee is authorized under the Federal Lands Recreation Enhancement Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to provide recommendations to the Secretaries on recreation fees on lands and waters managed by the Forest Service and the Department of the Interior's Bureau of Land Management in the regions covered by each Committee. Additional Recreation RAC information, including the meeting agenda and the meeting summary/minutes can be found at the following website: <http://www.fs.usda.gov/main/r8/recreation/racs>.

DATES: The meetings will be held on the following dates:

- Tuesday, August 27, 2019, from 8:30 a.m. to 4:30 p.m., and
- Wednesday, August 28, 2019, from 8:30 a.m. to 4:30 p.m., Eastern Standard Time.

All Recreation RAC meetings are subject to cancellation. For status of the meeting prior to attendance, please contact Tiffany Williams, by telephone at 404-347-2769 or by email at tiffany.p.williams@usda.gov.

ADDRESSES: The meeting will be held at the Courtyard Marriott, 130 Clairemont Avenue, Decatur, Georgia.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses, when provided, are placed in the record and available for public inspection and copying. The public may inspect comments received

at the USDA Forest Service, 1720 Peachtree Road Northwest, Atlanta, Georgia. Please call ahead at 404-347-2769 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT:

Tiffany Williams, Committee Coordinator, USDA Forest Service, 1720 Peachtree Road Northwest, Atlanta, Georgia 30309, by telephone at 404-347-2769 or by email at tiffany.p.williams@usda.gov.

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.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

(1) Receive recommendations concerning recreation fee proposals on areas managed by the Forest Service in Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and the territory of Puerto Rico; and

(2) Discuss other items of interest related to the Act.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by August 20, 2019, to be scheduled on the agenda. Committee discussion is limited to Forest Service staff and committee members. However, persons who wish to bring recreation fee matters to the attention of the committee may file written statements with the committee staff before the meeting. Written comments and time requests for oral comments must be sent to Tiffany Williams, Committee Coordinator, USDA Forest Service, 1720 Peachtree Road Northwest, Atlanta, Georgia 30309; by email tiffany.p.williams@usda.gov or by facsimile to 404-347-6217. A summary of the meeting will be posted on the website listed above within 21 days of the meeting.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make your request in advance for sign language interpreting, assistive listening devices or other reasonable accommodation. For access to the facility or proceedings, please contact Tiffany Williams, by telephone at 404-347-6217 or by email at tiffany.p.williams@usda.gov. All reasonable accommodation requests are managed on a case by case basis.

Dated: July 17, 2019.

Richard A. Cooksey,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2019-16713 Filed 8-5-19; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B-22-2019]

Foreign-Trade Zone (FTZ) 136—Brevard County, Florida; Authorization of Production Activity; Airbus OneWeb Satellites, LLC (Satellites and Satellite Systems), Merritt Island, Florida

On April 2, 2019, the Canaveral Port Authority, grantee of FTZ 136, submitted a notification of proposed production activity to the FTZ Board on behalf of Airbus OneWeb Satellites, LLC, within FTZ 136, in Merritt Island, Florida.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (84 FR 14086—14087, April 9, 2019). On July 31, 2019, the applicant was notified of the FTZ Board's decision that no further review of the proposed activity is warranted at this time. The FTZ Board authorized the production activity described in the notification, subject to the FTZ Act and the Board's regulations, including Section 400.14. Given the applicant's commitment in its notification, lithium batteries must be admitted to the zone in privileged foreign status (19 CFR 146.41).

Dated: July 31, 2019.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2019-16751 Filed 8-5-19; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-983]

Drawn Stainless Sinks From the People's Republic of China: Final Results of the Antidumping Duty Administrative Review; 2017-2018

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

SUMMARY: The Department of Commerce (Commerce) finds that certain companies covered by this administrative review sold drawn

stainless steel sinks from the People's Republic of China (China) at less than normal value during the period of review (POR) April 1, 2017 through March 31, 2018.

DATES: Applicable August 6, 2019.

FOR FURTHER INFORMATION CONTACT:

Rebecca M. Janz or Joshua Tucker, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-2972 or (202) 482-2044, respectively.

Background

Commerce published the *Preliminary Results* on December 28, 2018.¹ For events subsequent to the *Preliminary Results*, see the Issues and Decision Memorandum.² Commerce conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Commerce exercised its discretion to toll all deadlines affected by the partial federal government closure from December 22, 2018 through the resumption of operations on January 29, 2019.³ In May 2019, Commerce extended the final results of this review by 60 days.⁴ Accordingly, the revised deadline for the final results is now July 30, 2019.

Scope of the Order

The products covered by the order include drawn stainless steel sinks. Imports of subject merchandise are currently classified under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7324.10.0000 and 7324.10.0010.

¹ See *Drawn Stainless Steel Sinks from the People's Republic of China: Antidumping Duty Administrative Review and Preliminary Determination of No Shipments: 2017-2018*, 83 FR 67226 (December 28, 2018) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

² See Memorandum, "Issues and Decision Memorandum for the Antidumping Duty Administrative Review: Drawn Stainless Steel Sinks from the People's Republic of China; 2017-2018," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

³ See Memorandum to the Record from Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, "Deadlines Affected by the Partial Shutdown of the Federal Government," dated January 28, 2019. Because the *Preliminary Results* published on December 28, 2018, six days into the partial government closure, the deadline for these final results has been extended by 34 days.

⁴ See Memorandum, "Drawn Stainless Steel Sinks from the People's Republic of China: Extension of Deadline for Final Results of 2017-2018 Antidumping Duty Administrative Review," dated May 29, 2018.

Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.⁵

Analysis of Comments Received

All issues raised in the case brief are addressed in the Issues and Decision Memorandum. A list of the issues raised and to which we respond in the Issues and Decision Memorandum is attached to this notice as an Appendix. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>, and it is available to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <http://enforcement.trade.gov/frn/index.html>. The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on our analysis of the comments received, we made no changes to the *Preliminary Results*.

Final Determination of No Shipments

In the *Preliminary Determination*, we determined that Zhuhai KOHLER Kitchen & Bathroom Products Co., Ltd. (Zhuhai KOHLER) and Yuyao Afa Kitchenware Co., Ltd. (Yuyao Afa) had no shipments of subject merchandise during the POR.⁶ We received no comments since the issuance of the *Preliminary Results* on this issue. Therefore, for these final results, we continue to determine that Zhuhai KOHLER and Yuyao Afa had no shipments of subject merchandise during the POR, and we intend to issue appropriate instructions to U.S. Customs and Border Protection (CBP) that are consistent with our "automatic assessment" clarification for these final results of review.⁷

Separate Rate Respondents

In the *Preliminary Results*, we determined that KaiPing Dawn

Plumbing Products, Inc. (KaiPing Dawn); Guangdong New Shichu Import & Export Company Limited (New Shichu); Elkay (China) Kitchen Solutions Co., Ltd (Elkay); and B&R Industries Limited (B&R) demonstrated their eligibility for separate rates.⁸ With respect to three of these companies, we received no comments since the issuance of the *Preliminary Results* on this issue; thus, we continue to find that these three companies are eligible for a separate rate.

With respect to one exporter, we received comments from the petitioner with regards to that exporter's separate rate claim. However, we continue to find that this exporter demonstrated the absence of *de jure* and *de facto* government control; thus, we continue to grant this company a separate rate for these final results.⁹

With respect to Feidong Import and Export Co., Ltd. (Feidong); Xinhe Stainless Steel Products Co., Ltd. (Xinhe); Jiangmen New Star Hi-Tech Enterprise Ltd. (New Star); Ningbo Afa Kitchen and Bath Co., Ltd. (Ningbo Afa); Guangdong G-Top Import & Export Co., Ltd. (Guangdong G-Top); Jiangmen Pioneer Import & Export Co., Ltd. (Jiangmen Pioneer); and Zhongshan Superte Kitchenware Co., Ltd. (Superte), we preliminarily determined that these companies failed to establish their entitlement to a separate rate, and, thus, we found them to be part of the China-wide entity. We received no comments since the issuance of the *Preliminary Results* on this issue with respect to these companies. Therefore, we continue to find that these companies are not eligible for a separate rate and are part of the China-wide entity.

Rate for Non-Examined Separate-Rate Respondents

In the *Preliminary Results*,¹⁰ consistent with our recent practice, we preliminarily assigned the non-selected separate rate companies a weighted-average dumping margin of 1.78 percent (*i.e.*, the most recently assigned separate rate in this proceeding)¹¹ because we did not calculate any individual rates or assign a rate based on facts available during this review.¹² No parties

commented on the methodology for calculating this separate rate. Therefore, in these final results of the review, we continue to assign a rate of 1.78 percent for those companies that were not individually examined and are eligible for a separate rate. These companies, KaiPing, New Shichu, Elkay, and B&R, are also listed below in the section entitled "Final Results of the Review."

Final Results of the Administrative Review

Because Feidong, Xinhe, New Star, Ningbo Afa, Guangdong G-Top, Jiangmen Pioneer, and Superte did not demonstrate that they are entitled to a separate rate, Commerce finds these seven companies to be part of the China-wide entity. Because no party requested a review of the China-wide entity, and Commerce no longer considers the China-wide entity as an exporter conditionally subject to administrative reviews,¹³ we did not conduct a review of the China-wide entity. The rate previously established for the China-wide entity is 76.45 percent and is not subject to change as a result of this review.

For companies subject to this review that established their eligibility for a separate rate, we continue to determine that the following weighted-average dumping margins exist for the period April 1, 2017 through March 31, 2018:

Exporter	Weighted-average dumping margin (percent)
KaiPing Dawn Plumbing Products, Inc	1.78
Guangdong New Shichu Import & Export Company Limited	1.78
Elkay (China) Kitchen Solutions Co., Ltd	1.78
B&R Industries Limited	1.78

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b), Commerce has determined, and CBP shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. Commerce intends to issue appropriate assessment instructions directly to CBP 15 days after publication

(November 9, 2016), and accompanying PDM at 10–11, unchanged in *Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Final Results of Antidumping Duty Administrative Review; 2015–2016*, 82 FR 11431, 11432–33 (February 23, 2017).

¹³ See *Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity (NME) in NME Antidumping Duty Proceedings*, 78 FR 65963, 65970 (November 4, 2013).

⁸ See *Preliminary Results*, 83 FR at 67227.

⁹ For further discussion, see the Issues and Decision Memorandum at Comments 1 and 2.

¹⁰ See *Preliminary Results*, 83 FR at 67227.

¹¹ See *Drawn Stainless Steel Sinks from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2015–2016*, 82 FR 28639, 28640 (June 23, 2017).

¹² See, e.g., *Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Preliminary Results of Antidumping Duty Administrative Review; 2015–2016*, 81 FR 78789, 78790–91

⁵ For a complete description of the scope of the order, see *Preliminary Results*, and accompanying PDM at 4.

⁶ See *Preliminary Results*, 83 FR at 67226.

⁷ See *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties*, 76 FR 65694, 65694–95 (October 24, 2011); see also "Assessment Rates" section of this notice.

of the final results of this administrative review.

For the respondents that were not selected for individual examination in this administrative review and qualified for a separate rate, we will instruct CBP to assess dumping duties at the rate of 1.78 percent.

For Feidong, Xinhe, New Star, Ningbo Afa, Guangdong G-Top, Jiangmen Pioneer, and Superte, because Commerce determined that these companies did not qualify for a separate rate, we will instruct CBP to assess dumping duties on the companies' entries of subject merchandise at the rate of 76.45 percent, which is the rate applicable to the China-wide entity.

For Zhuhai KOHLER and Yuyao Afa, because Commerce determined that these companies had no shipments of the subject merchandise during the POR, any suspended entries of subject merchandise from these companies will be liquidated at China-wide rate.¹⁴

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For the exporters listed above, the cash deposit rate will be equal to the weighted-average dumping margin established in the final results of this review; (2) for previously investigated or reviewed China and non-China exporters not listed above that currently have a separate rate, the cash deposit rate will continue to be the exporter-specific rate published for the most recently completed segment of this proceeding where the exporter received that separate rate; (3) for all China exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the rate for the China-wide entity, 76.45 percent; and (4) for all non-China exporters of subject merchandise which have not received their own separate rate, the cash deposit rate will be the rate applicable to the China exporter that supplied that non-China exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

¹⁴ For a full discussion of this practice, see *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties*, 76 FR 65694 (October 24, 2011).

Notification to Importers

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

Administrative Protective Order

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

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary

II. Background

III. Discussion of the Issues

Comment 1. Liquidation Rate for Exporter A's Shipments of Xinhe-Produced Subject Merchandise

Comment 2. Exporter A's Separate Rate Status

IV. Recommendation

[FR Doc. 2019-16752 Filed 8-5-19; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-570-936]

Circular Welded Carbon Quality Steel Line Pipe From the People's Republic of China: Final Results of the Expedited Second Sunset Review of the Countervailing Duty Order

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

SUMMARY: The Department of Commerce (Commerce) finds that revocation of the countervailing duty (CVD) order on circular welded carbon quality steel line pipe (welded line pipe) from the People's Republic of China (China) would be likely to lead to continuation or recurrence of a countervailable subsidy at the levels indicated in the "Final Results of Sunset Review" section of this notice, *infra*.

DATES: Applicable August 6, 2019.

FOR FURTHER INFORMATION CONTACT: Kristen Johnson, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-4793.

SUPPLEMENTARY INFORMATION:

Background

On January 23, 2009, Commerce published in the **Federal Register** the CVD order on welded line pipe from China.¹ On June 9, 2016, Commerce implemented its revised countervailable subsidy rates pursuant to the findings in the section 129 proceeding of the Uruguay Round Agreements Act.² On April 1, 2019, Commerce published the notice of initiation of this sunset review of the *Order*, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).³ On April 17, 2019, Commerce received a notice of intent to participate from California Steel Industries, Inc., TMK IPSCO, Welspun Tubular LLC, and Zekelman Industries (collectively, the domestic interested

¹ See *Circular Welded Carbon Quality Steel Line Pipe from the People's Republic of China: Notice of Amended Final Affirmative Countervailing Duty Determination and Notice of Countervailing Duty Order*, 74 FR 4136 (January 23, 2009) (*Order*).

² See *Implementation of Determinations Pursuant to Section 129 of the Uruguay Round Agreements Act*, 81 FR 37180 (June 9, 2016); see also Memorandum, "Section 129 Proceeding: United States—Countervailing Duty Measures on Certain Products from the People's Republic of China (WTO/DS 437): Final Determination for Pressure Pipe, Line Pipe, OCTG, Wire Strand, and Solar Panels," dated May 19, 2016.

³ See *Initiation of Five-Year (Sunset) Reviews*, 84 FR 12227 (April 1, 2019).

parties).⁴ The domestic interested parties claimed interested party status under section 771(9)(C) of the Act as manufacturers in the United States of the domestic like product.⁵

On April 30, 2019, pursuant to 19 CFR 351.218(d)(3)(i), the domestic interested parties filed a timely and adequate substantive response.⁶ Commerce did not receive a substantive response from the Government of China or a respondent interested party to this proceeding. On May 23, 2019, Commerce notified the U.S. International Trade Commission (ITC) that it did not receive an adequate substantive response from respondent interested parties.⁷ As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted an expedited (120-day) sunset review of the *Order*.

Scope of the Order

The merchandise covered by this order is circular welded carbon quality steel pipe of a kind used for oil and gas pipelines (welded line pipe) not more than 406.4 mm (16 inches) in outside diameter, regardless of wall thickness, length, surface finish, end finish or stenciling.

The welded line pipe products that are the subject of this order are currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 7306.19.10.10, 7306.19.10.50, 7306.19.51.10, and 7306.19.51.50. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.⁸

⁴ See Domestic Interested Parties' Letter, "Notice of Intent to Participate in Second Five-Year Review of the Antidumping and Countervailing Duty Orders on Circular Welded Carbon Quality Steel Line Pipe from the People's Republic of China—Request for Extension of Deadline and Acceptance of Submission," dated April 17, 2019 (Notice to Participate); see also Commerce's Letter, "Acceptance of Notice of Intent to Participate," dated April 18, 2019.

⁵ See Notice to Participate at 2.

⁶ See Domestic Interested Parties' Letter, "Second Five-Year Review of the Countervailing Duty Order on Circular Welded Carbon Quality Steel Line Pipe from the People's Republic of China: Substantive Response to Notice of Initiation," dated April 30, 2019.

⁷ See Commerce's Letter, "Sunset Review Initiated on April 1, 2019," dated May 23, 2019.

⁸ For a complete description of the scope of the *Order*, see Memorandum, "Issues and Decision Memorandum for the Final Results of the Expedited Second Sunset Review of Circular Welded Carbon Quality Steel Line Pipe from the People's Republic of China," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review, including the likelihood of continuation or recurrence of a countervailable subsidy and the net countervailable subsidy rates likely to prevail if the *Order* were to be revoked, is provided in the accompanying Issues and Decision Memorandum. A list of the topics discussed in the Issues and Decision Memorandum is attached as an Appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov> and in the Central Records Unit, room B8024 of the main Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed at <http://enforcement.trade.gov/frn/>. The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Final Results of Sunset Review

Pursuant to sections 751(c)(1) and 752(b) of the Act, Commerce determines that revocation of the *Order* would be likely to lead to continuation or recurrence of a net countervailable subsidy at the following rates:⁹

Producers/exporters	Net countervailable subsidy ad valorem rate (percent)
Huludao Seven-Star Steel Pipe Group Co., Ltd., Huludao Steel Pipe Industrial Co., Ltd., and Huludao Bohai Oil Pipe Industrial Co., Ltd. (collectively, the Huludao Companies)	32.65
Liaoning Northern Steel Pipe Co., Ltd	40.05
All Others	36.35

Administrative Protective Order

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

⁹ *Id.*

Notification to Interested Parties

We are issuing and publishing the results and notice in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act and 19 CFR 351.218 and 19 CFR 351.221(c)(5)(ii).

Dated: July 30, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. History of the Order
- V. Legal Framework
- VI. Discussion of the Issues
 - A. Likelihood of Continuation or Recurrence of a Countervailable Subsidy
 - B. Net Countervailable Subsidy Rates Likely to Prevail
 - C. Nature of the Subsidy
- VII. Final Results of Sunset Review
- VIII. Recommendation

[FR Doc. 2019–16754 Filed 8–5–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Meeting of the United States Travel and Tourism Advisory Board

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of an open meeting.

SUMMARY: The United States Travel and Tourism Advisory Board (Board or TTAB) will hold a meeting on Thursday, August 22, 2019. The Board advises the Secretary of Commerce on matters relating to the U.S. travel and tourism industry. The purpose of the meeting is for Board members to consider recommendations on how the U.S. Government may, through potential membership in the United Nations World Tourism Organization, advance U.S. travel and tourism interests. The final agenda will be posted on the Department of Commerce website for the Board at <http://trade.gov/ttab> at least one week in advance of the meeting.

DATES: Thursday, August 22, 2019, 2:00 p.m.–3:00 p.m. EDT. The deadline for members of the public to register, including requests to make comments during the meeting, or to submit written comments for dissemination prior to the meeting, is 5:00 p.m. EDT on Thursday, August 15, 2019.

ADDRESSES: The meeting will be held via conference call. The call-in number

and passcode will be provided by email to registrants.

Requests to register (including to speak) and any written comments should be submitted to: National Travel and Tourism Office, U.S. Department of Commerce, 1401 Constitution Ave. NW, Room 10003, Washington, DC 20230 or by email to TTAB@trade.gov. Members of the public are encouraged to submit registration requests and written comments via email to ensure timely receipt.

FOR FURTHER INFORMATION CONTACT:

Brian Beall, the United States Travel and Tourism Advisory Board, National Travel and Tourism Office, U.S. Department of Commerce, 1401 Constitution Ave. NW, Room 10003, Washington, DC 20230; telephone: 202-482-0140; email: TTAB@trade.gov.

SUPPLEMENTARY INFORMATION:

Background: The Board advises the Secretary of Commerce on matters relating to the U.S. travel and tourism industry.

Public Participation: The meeting will be open to the public. Any member of the public requesting to join the meeting is asked to register in advance by the deadline identified under the **DATES** caption. Last minute requests will be accepted but may not be possible to fill. There will be fifteen (15) minutes allotted for oral comments from members of the public joining the meeting. To accommodate as many speakers as possible, the time for public comments may be limited to three (3) minutes per person. Members of the public wishing to reserve speaking time during the meeting must submit a request at the time of registration, as well as the name and address of the proposed speaker. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the International Trade Administration may conduct a lottery to determine the speakers. Speakers are requested to submit a written copy of their prepared remarks by 5:00 p.m. EDT on Thursday, August 15, 2019 for inclusion in the meeting records and for circulation to the members of the Board.

In addition, any member of the public may submit pertinent written comments concerning the Board's affairs at any time before or after the meeting. Comments may be submitted to Brian Beall at the contact information indicated above. To be considered during the meeting, comments must be received no later than 5:00 p.m. EDT on Thursday, August 15, 2019 to ensure transmission to the Board prior to the meeting. Comments received after that

date and time will be distributed to the members but may not be considered during the meeting. Copies of Board meeting minutes will be available within 90 days of the meeting.

Brian Beall,

Deputy Director for Policy and Planning, National Travel and Tourism Office, Industry & Analysis, International Trade Administration, U.S. Department of Commerce.

[FR Doc. 2019-16715 Filed 8-5-19; 8:45 am]

BILLING CODE 3510-DR-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-935]

Circular Welded Carbon Quality Steel Line Pipe From the People's Republic of China: Final Results of the Expedited Second Sunset Review of the Antidumping Duty Order

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

SUMMARY: The Department of Commerce (Commerce) finds that revocation of the antidumping duty order on circular welded carbon quality steel line pipe (welded line pipe) from the People's Republic of China (China) would be likely to lead to continuation or recurrence of dumping, at the level indicated in the "Final Results of Sunset Review" section of this notice, *infra*.

DATES: Applicable August 6, 2019.

FOR FURTHER INFORMATION CONTACT: Thomas Hanna, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-0835.

SUPPLEMENTARY INFORMATION:

Background

On May 13, 2009 Commerce published in the **Federal Register** the antidumping duty order on welded line pipe from China.¹ On April 1, 2019, Commerce published the notice of initiation of this sunset review of the *Order*, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).² On April 16, 2019, Commerce received a timely and complete notice of intent to participate in the sunset review from California Steel Industries, TMK

IPSCO, Welspun Tubular, and Zekelman Industries (collectively, domestic interested parties), within the deadline specified in 19 CFR 351.218(d)(1)(i).³ The domestic interested parties claimed interested party status under section 771(9)(C) of the Act as manufacturers in the United States of the domestic like product.⁴ On April 30, 2019, pursuant to 19 CFR 351.218(d)(3)(i), the domestic interested parties filed a timely and adequate substantive response.⁵ Commerce did not receive a substantive response from any respondent interested party. As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted an expedited (120-day) sunset review of the *Order*.

Scope of the Order

The merchandise covered by this order is circular welded carbon quality steel pipe of a kind used for oil and gas pipelines (welded line pipe) not more than 406.4 mm (16 inches) in outside diameter, regardless of wall thickness, length, surface finish, end finish or stenciling.

The welded line pipe products that are the subject of the order are currently classifiable in the HTSUS under subheadings 7306.19.10.10, 7306.19.10.50, 7306.19.51.10, and 7306.19.51.50. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.⁶

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review, including the likelihood of continuation or recurrence of dumping in the event of revocation of the *Order* and the magnitude of the margins likely to prevail if the *Order* were to be revoked, is provided in the accompanying Issues and Decision Memorandum, which is

³ See Domestic Interested Parties' Letter, "Notice of Intent to Participate in Second Five-Year Review of the Antidumping Duty Order on Circular Welded Carbon Quality Steel Line Pipe from the People's Republic of China," dated April 16, 2019.

⁴ *Id.* at 2.

⁵ See Domestic Interested Parties' Letter, "Second Five-Year Review of the Antidumping Duty Order on Circular Welded Carbon Quality Steel Line Pipe from the People's Republic of China: Substantive Response to Notice of Initiation," dated April 30, 2019.

⁶ For a complete description of the scope of the *Order*, see Memorandum, "Issues and Decision Memorandum for the Expedited Second Sunset Review of the Antidumping Duty Order on Circular Welded Carbon Quality Steel Line Pipe from the People's Republic of China," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

¹ See *Certain Circular Welded Carbon Quality Steel Line Pipe from the People's Republic of China: Antidumping Duty Order*, 74 FR 22515 (May 13, 2009) (*Order*).

² See *Initiation of Five-Year (Sunset) Reviews*, 84 FR 12227 (April 1, 2019).

hereby adopted by this notice.⁷ A list of the topics discussed in the Issues and Decision Memorandum is attached as an Appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <http://access.trade.gov> and to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed on the internet at <http://enforcement.trade.gov/frn/>. The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Final Results of Sunset Review

Pursuant to sections 751(c)(1), 752(c)(1) and (3) of the Act, Commerce determines that revocation of the *Order* would be likely to lead to continuation or recurrence of dumping, and that the magnitude of the dumping margins likely to prevail would be weighted-average dumping margins up to 101.10 percent.

Administrative Protective Orders

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

Notification to Interested Parties

We are issuing and publishing these results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act, and 19 CFR 351.218 and 19 CFR 351.221(c)(5)(ii).

Dated: July 30, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order

IV. History of the Order

V. Legal Framework

VI. Discussion of the Issues

1. Likelihood of Continuation or Recurrence of Dumping
2. Magnitude of the Margin of Dumping Likely to Prevail

VII. Final Results of Sunset Review

VIII. Recommendation

[FR Doc. 2019-16755 Filed 8-5-19; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C-122-868, C-560-834, C-552-826]

Utility Scale Wind Towers From Canada, Indonesia, and the Socialist Republic of Vietnam: Initiation of Countervailing Duty Investigations

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

DATES: Applicable July 29, 2019.

FOR FURTHER INFORMATION CONTACT:

Tyler Weinhold at (202) 482-1121 (Canada); Alex Wood at (202) 482-1959 (Indonesia); Julie Geiger at (202) 482-2057 (Socialist Republic of Vietnam (Vietnam)), AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

The Petitions

On July 9, 2019, the U.S. Department of Commerce (Commerce) received countervailing duty (CVD) petitions concerning imports of utility scale wind towers (wind towers) from Canada, Indonesia, and Vietnam, filed in proper form on behalf of the Wind Tower Trade Coalition (the petitioner).¹ The Petitions were accompanied by antidumping duty (AD) petitions concerning imports of wind towers from Canada, Indonesia, the Republic of Korea, and Vietnam.

During the period July 12 through 18, 2019, Commerce requested supplemental information pertaining to certain aspects of the Petitions in separate supplemental questionnaires.²

¹ See Petitioner's Letter, "Petitions for the Imposition of Antidumping and Countervailing Duties on Utility Scale Wind Towers from Canada, Indonesia, The Republic of Korea, and the Socialist Republic of Vietnam," dated July 9, 2019 (the Petitions).

² See Commerce's Letters, "Petitions for the Imposition of Antidumping Duties on Imports of Utility Scale Wind Towers from Canada, Indonesia, the Republic of Korea, and the Socialist Republic of Vietnam and Countervailing Duties on Imports of Utility Scale Wind Towers from Canada, Indonesia,

The petitioner filed responses to the supplemental questionnaires between July 16 and 19, 2019.³

In accordance with section 702(b)(1) of the Tariff Act of 1930, as amended (the Act), the petitioner alleges that the Governments of Canada, Indonesia, and Vietnam (GOC, GOI, and GOV, respectively) are providing countervailable subsidies, within the meaning of sections 701 and 771(5) of the Act, to producers of wind towers in Canada, Indonesia and Vietnam, and that imports of such products are materially injuring, or threatening material injury to, the domestic wind tower industry in the United States. Consistent with section 702(b)(1) of the Act and 19 CFR 351.202(b), for those alleged programs on which we are initiating CVD investigations, the Petitions are accompanied by information reasonably available to the petitioner supporting its allegations.

Commerce finds that the petitioner filed the Petitions on behalf of the domestic industry, because the petitioner is an interested party, as defined in section 771(9)(E) of the Act. Commerce also finds that the petitioner demonstrated sufficient industry support necessary for the initiation of the requested CVD investigations.⁴

and the Socialist Republic of Vietnam: Supplemental Questions" (General Issues Supplemental Questionnaire), "Petition for the Imposition of Countervailing Duties on Imports of Utility Scale Wind Towers from Canada: Supplemental Questions," "Petition for the Imposition of Countervailing Duties on Imports of Utility Scale Wind Towers from Indonesia: Supplemental Questions," and "Petition for the Imposition of Countervailing Duties on Imports of Utility Scale Wind Towers from the Socialist Republic of Vietnam: Supplemental Questions," dated July 12, 2019; *see also* Memorandum, "Phone Call with Counsel to the Petitioner," dated July 18, 2019 (July 18, 2019 Memorandum).

³ See Petitioner's Letters, "Utility Scale Wind Towers from Canada, Indonesia, the Republic of Korea, and the Socialist Republic of Vietnam: Responses to First Supplemental Questions on Common Issues and Injury Volume I of the Petition," dated July 16, 2019 (General Issues Supplemental); "Utility Scale Wind Towers from Canada: Response to First Supplemental Questions on Canada CVD Volume III {sic} of the Petition," (Canada CVD Supplement Response), "Utility Scale Wind Towers from {Indonesia}: Response to First Supplemental Questions on Indonesia CVD Volume VII of the Petition," (Indonesia CVD Supplement Response), and "Utility Scale Wind Towers from the Socialist Republic of Vietnam: Response to First Supplemental Questions on Vietnam CVD Volume VIII of the Petition" (Vietnam CVD Supplement Response), each dated July 17, 2019; and, "Utility Scale Wind Towers from Canada, Indonesia, the Republic of Korea, and the Socialist Republic of Vietnam: Responses to Second Supplemental Questions on Common Issues and Injury Volume I of the Petition," dated July 19, 2019 (Scope Supplement).

⁴ See the "Determination of Industry Support for the Petition" section, *infra*.

⁷ *Id.*

Period of Investigations

Because the Petitions were filed on July 9, 2019, the period of investigation is January 1, 2018 through December 31, 2018.

Scope of the Investigations

The product covered by these investigations is wind towers from Canada, Indonesia, and Vietnam. For a full description of the scope of these investigations, *see* the Appendix to this notice.

Scope Comments

During our review of the Petitions, we contacted the petitioner regarding the proposed scope to ensure that the scope language in the Petitions is an accurate reflection of the products for which the domestic industry is seeking relief.⁵ As a result, the scope of the Petitions was modified to clarify the description of merchandise covered by the Petitions. The description of the merchandise covered by these investigations, as described in the Appendix to this notice, reflects these clarifications.

As discussed in the *Preamble* to Commerce's regulations, we are setting aside a period for interested parties to raise issues regarding product coverage (*i.e.*, scope).⁶ Commerce will consider all comments received from interested parties and, if necessary, will consult with interested parties prior to the issuance of the preliminary determination. If scope comments include factual information,⁷ all such factual information should be limited to public information. To facilitate preparation of its questionnaires, Commerce requests that all interested parties submit such comments by 5:00 p.m. Eastern Time (ET) on August 19, 2019, which is 20 calendar days from the signature date of this notice.⁸ Any rebuttal comments, which may include factual information, must be filed by 5:00 p.m. ET on August 29, 2019 which is 10 calendar days from the initial comment deadline.⁹

Commerce requests that any factual information parties consider relevant to the scope of the investigations be submitted during this period. However, if a party subsequently finds that additional factual information

pertaining to the scope of the investigations may be relevant, the party may contact Commerce and request permission to submit the additional information. All such submissions must be filed on the records of the concurrent AD and CVD investigations.

Filing Requirements

All submissions to Commerce must be filed electronically via Enforcement and Compliance's Antidumping Duty and Countervailing Duty Centralized Electronic Service System (ACCESS).¹⁰ An electronically filed document must be received successfully in its entirety by the time and date it is due. Documents exempted from the electronic submission requirements must be filed manually (*i.e.*, in paper form) with Enforcement and Compliance's APO/Dockets Unit, Room 18022, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, and stamped with the date and time of receipt by the applicable deadlines.

Consultations

Pursuant to sections 702(b)(4)(A)(i) and (ii) of the Act, Commerce notified representatives of the GOC, GOI, and GOV of the receipt of the Petitions and provided them the opportunity for consultations with respect to the Petitions.¹¹ Consultations were held with the GOC and GOV on July 19, 2019,¹² and with the GOI on July 22, 2019.¹³

¹⁰ See *Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures*, 76 FR 39263 (July 6, 2011); *see also Enforcement and Compliance: Change of Electronic Filing System Name*, 79 FR 69046 (November 20, 2014) for details of Commerce's electronic filing requirements, which went into effect on August 5, 2011. Information on help using ACCESS can be found at <https://access.trade.gov/help.aspx>, and a handbook can be found at <https://access.trade.gov/help/Handbook%20on%20Electronic%20Filing%20Procedures.pdf>.

¹¹ See Commerce's Letters, "Utility Scale Wind Towers from Indonesia: Invitation for Consultations to Discuss the Countervailing Duty Petition," and "Utility Scale Wind Towers from the Socialist Republic of Vietnam: Invitation for Consultations to Discuss the Countervailing Duty Petition," each dated July 10, 2019; and "Utility Scale Wind Towers from Canada: Invitation for Consultations to Discuss the Countervailing Duty Petition," dated July 12, 2019.

¹² See Memoranda, "Consultations with Government Officials from the Government of Canada on the Countervailing Duty Petition Regarding Utility Scale Wind Towers from Canada," dated July 24, 2019, and "Consultations with Government Officials from the Government of the Socialist Republic of Vietnam on the Countervailing Duty Petition Regarding Utility Scale Wind Towers from the Socialist Republic of Vietnam," dated July 22, 2019.

¹³ See Memorandum, "Utility Scale Wind Towers from Canada, Indonesia, and the Socialist Republic

Determination of Industry Support for the Petitions

Section 702(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 702(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 702(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, Commerce shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the "industry."

Section 771(4)(A) of the Act defines the "industry" as the producers, as a whole, of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs Commerce to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether "the domestic industry" has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both Commerce and the ITC must apply the same statutory definition regarding the domestic like product,¹⁴ they do so for different purposes and pursuant to a separate and distinct authority. In addition, Commerce's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.¹⁵

Section 771(10) of the Act defines the domestic like product as "a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title." Thus, the reference point from which the domestic like product analysis begins is

of Vietnam: Government of Indonesia Consultations," dated July 22, 2019.

¹⁴ See section 771(10) of the Act.

¹⁵ See *USEC, Inc. v. United States*, 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd. v. United States*, 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Federal Circuit 1989)).

⁵ See General Issues Supplement; and July 18, 2019 Memorandum.

⁶ See *Antidumping Duties; Countervailing Duties, Final Rule*, 62 FR 27296, 27323 (May 19, 1997) (*Preamble*).

⁷ See 19 CFR 351.102(b) (21) (defining "factual information").

⁸ Because the deadline falls on a Sunday (*i.e.*, August 18, 2019), the deadline becomes the next business day (*i.e.*, August 19, 2019).

⁹ See 19 CFR 351.303(b).

“the article subject to an investigation” (*i.e.*, the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, the petitioner does not offer a definition of the domestic like product distinct from the scope of the Petitions.¹⁶ Based on our analysis of the information submitted on the record, we have determined that wind towers, as defined in the scope, constitute a single domestic like product, and we have analyzed industry support in terms of that domestic like product.¹⁷

On July 26, 2019, we received industry support challenges from Marmen Energy Co. (Marmen) and Vestas Towers America, Inc. (Vestas), U.S. producers of wind towers.¹⁸ On July 29, 2019, the petitioner responded to the standing challenges from Marmen and Vestas.¹⁹ Based on information provided in the Petitions and in the letters from Marmen and Vestas, the share of total U.S. production of the domestic like product in calendar year 2018 represented by the supporters of the Petitions did not account for more than 50 percent of the total production of the domestic like product. Therefore, in accordance with section 702(c)(4)(D) of the Act, we relied on other

information to determine industry support.²⁰

In determining whether the petitioner has standing under sections 702(c)(4)(A) and 702(c)(4)(D) of the Act, we considered the industry support data contained in the Petitions and other information on the record with reference to the domestic like product as defined in the “Scope of the Investigations,” in the Appendix to this notice. To establish industry support, the petitioner provided its own 2018 production of the domestic like product as well as the 2018 production by the supporters of the Petitions. Other information on the record establishes the total 2018 production of other U.S. producers of the domestic like product.

Section 702(c)(4)(B) of the Act states that (i) Commerce “shall disregard the position of domestic producers who oppose the petition if such producers are related to foreign producers, as defined in section 771(4)(B)(ii), unless such domestic producers demonstrate that their interests as domestic producers would be adversely affected by the imposition of an antidumping duty order;” and (ii) Commerce “may disregard the position of domestic producers of a domestic like product who are importers of the subject merchandise.” In addition, 19 CFR 351.203(e)(4) states that the position of a domestic producer that opposes the petition (i) will be disregarded if such producer is related to a foreign producer or to a foreign exporter under section 771(4)(B)(ii) of the Act, unless such domestic producer demonstrates to the Secretary’s satisfaction that its interests as a domestic producer would be adversely affected by the imposition of an antidumping order; and (ii) may be disregarded if the producer is an importer of the subject merchandise or is related to such an importer under section 771(4)(B)(ii) of the Act. Certain producers of the domestic like product that opposed the Petitions are related to foreign producers and/or imported subject merchandise from the subject countries. We have analyzed the information provided by the petitioner and information provided in the submissions from Marmen and Vestas. Based on our analysis, we have determined that it is appropriate to disregard the opposition to the Petitions from certain producer(s) pursuant to section 702(c)(4)(B) of the Act. When the opposition to the Petitions is disregarded, the industry support

requirements of section 702(c)(4)(A) of the Act are satisfied.²¹

Based on our analysis and review of the information on the record, we have determined that the petitioner has established industry support for the Petitions.²² The information on the record demonstrates that the domestic producers of wind towers who support the Petitions account for at least 25 percent of the total production of the domestic like product and, once certain opposition is disregarded, account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petitions.²³ Accordingly, Commerce determines that the Petitions were filed on behalf of the domestic industry within the meaning of section 702(b)(1) of the Act.

Injury Test

Because Canada, Indonesia, and Vietnam are “Subsidies Agreement Countries” within the meaning of section 701(b) of the Act, section 701(a)(2) of the Act applies to these investigations. Accordingly, the ITC must determine whether imports of the subject merchandise from Canada, Indonesia, and/or Vietnam materially injure, or threaten material injury to, a U.S. industry.

Allegations and Evidence of Material Injury and Causation

The petitioner alleges that imports of the subject merchandise are benefitting from countervailable subsidies and that such imports are causing, or threaten to cause, material injury to the U.S. industry producing the domestic like product. In addition, the petitioner alleges that subject imports from Canada, Indonesia, and Vietnam exceed the negligibility threshold provided for under section 771(24)(A) of the Act.²⁴ In CVD petitions, section 771(24)(B) of the Act provides that imports of subject merchandise from developing and least developed countries must exceed the negligibility threshold of four percent. The petitioner also demonstrates that

¹⁶ See Volume I of the Petitions, at 17–18 and Exhibits I–9 and I–14.

¹⁷ For a discussion of the domestic like product analysis as applied to this case and information regarding industry support, see Countervailing Duty Investigation Initiation Checklist: Utility Scale Wind Towers from Canada (Canada CVD Initiation Checklist), at Attachment II, Analysis of Industry Support for the Antidumping and Countervailing Duty Petitions Covering Utility Scale Wind Towers from Canada, Indonesia, the Republic of Korea, and the Socialist Republic of Vietnam (Attachment II); see also Countervailing Duty Investigation Initiation Checklist: Utility Scale Wind Towers from Indonesia (Indonesia CVD Initiation Checklist), at Attachment II; and Countervailing Duty Investigation Initiation Checklist: Utility Scale Wind Towers from the Socialist Republic of Vietnam (Vietnam CVD Initiation Checklist), at Attachment II. These checklists are dated concurrently with this notice and on file electronically via ACCESS. Access to documents filed via ACCESS is also available in the Central Records Unit, Room B8024 of the main Department of Commerce building.

¹⁸ See letter from Marmen, “Utility Scale Wind Towers from Canada, Indonesia, the Republic of Korea, and the Socialist Republic of Vietnam: Standing Challenge,” dated July 26, 2019 (Marmen Letter); see also letter from Vestas, “Utility Scale Wind Towers from Canada, Indonesia, South Korea, and Vietnam: Vestas Towers America, Inc.’s Comments on Industry Support,” dated July 26, 2019 (Vestas Letter).

¹⁹ See letter from the petitioner, “Utility Scale Wind Towers from Canada, Indonesia, the Republic of Korea, and the Socialist Republic of Vietnam: Response to Standing Challenge and Comments on Industry Support,” dated July 29, 2019 (Petitioner Letter).

²⁰ For further discussion, see Canada AD Initiation Checklist, at Attachment II; see also Indonesia AD Initiation Checklist, at Attachment II; Korea AD Initiation Checklist, at Attachment II; and Vietnam AD Initiation Checklist, at Attachment II.

²¹ See Canada AD Initiation Checklist, at Attachment II; see also Indonesia AD Initiation Checklist, at Attachment II; Korea AD Initiation Checklist, at Attachment II; and Vietnam AD Initiation Checklist, at Attachment II.

²² See Canada CVD Initiation Checklist, at Attachment II; see also Indonesia CVD Initiation Checklist, at Attachment II; and Vietnam CVD Initiation Checklist, at Attachment II.

²³ See Canada AD Initiation Checklist, at Attachment II; see also Indonesia AD Initiation Checklist, at Attachment II; Korea AD Initiation Checklist, at Attachment II; and Vietnam AD Initiation Checklist, at Attachment II.

²⁴ See Volume I of the Petitions, at 31–32 and Exhibit I–17.

subject imports from Indonesia, which has been designated as a least developed country under section 771(36)(B) of the Act, exceed the negligibility threshold of four percent.²⁵

The petitioner contends that the industry's injured condition is illustrated by a significant and increasing volume of subject imports; reduced market share; lost sales and lost revenues; underselling and price depression or suppression; negative impact on the domestic industry's production, shipments, capacity utilization, and employment; and declining financial performance.²⁶ We have assessed the allegations and supporting evidence regarding material injury, threat of material injury, causation, cumulation, as well as negligibility, and we have determined that these allegations are properly supported by adequate evidence, and meet the statutory requirements for initiation.²⁷

Initiation of CVD Investigations

Based upon the examination of the Petitions and supplemental responses, we find that they meet the requirements of section 702 of the Act. Therefore, we are initiating CVD investigations to determine whether imports of wind towers from Canada, Indonesia, and Vietnam benefit from countervailable subsidies conferred by the GOC, GOI, and GOV, respectively. In accordance with section 703(b)(1) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determination no later than 65 days after the date of this initiation.

Canada

Based on our review of the petition, we find that there is sufficient information to initiate a CVD investigation on 23 of the 30 alleged programs. For a full discussion of the basis for our decision whether to initiate on each program, *see* Canada CVD Initiation Checklist. A public version of the initiation checklist for this investigation is available on ACCESS.

Indonesia

Based on our review of the petition, we find that there is sufficient information to initiate a CVD investigation on seven of the eight alleged programs. For a full discussion of the basis for our decision whether to initiate on each program, *see* Indonesia CVD Initiation Checklist. A public version of the initiation checklist for this investigation is available on ACCESS.

Vietnam

Based on our review of the petition, we find that there is sufficient information to initiate a CVD investigation, in whole or part, on each of the alleged programs. For a full discussion of the basis for our decision to initiate on each program, *see* Vietnam CVD Initiation Checklist. A public version of the initiation checklist for this investigation is available on ACCESS.

Respondent Selection

The petitioner named four companies in Canada, two companies in Indonesia, and three companies in Vietnam as producers/exporters of wind towers.²⁸ Commerce intends to follow its standard practice in CVD investigations and calculate company-specific subsidy rates in these investigations. In the event Commerce determines that the number of companies is large and it cannot individually examine each company based upon Commerce's resources, where appropriate, Commerce intends to select mandatory respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports of wind towers from Canada, Indonesia, and Vietnam during the POI under the appropriate Harmonized Tariff Schedule of the United States numbers listed in the "Scope of the Investigation," in the Appendix.

On July 22, 2019, Commerce released CBP data on imports of wind towers under Administrative Protective Order (APO) to all parties with access to information protected by APO.²⁹ Interested parties wishing to comment

regarding the CBP data and respondent selection must do so within three business days of the publication date of the notice of initiation of these CVD investigations. Commerce will not accept rebuttal comments regarding the CBP data or respondent selection.

On July 22, 2019, Commerce also released CBP data on imports of wind towers from Indonesia under APO to all parties with access to information protected by APO.³⁰ Although the petitioner claims that there are two known producers/exporters from Indonesia, record evidence indicates that there is one known producer/exporter, PT Kenertec Power System (Kenertec). Based on this evidence, Commerce intends to examine Kenertec. Parties wishing to comment on Commerce's decision to individually examine Kenertec must do so within three days of the publication of this notice. Any such comments must be submitted no later than 5:00 p.m. ET on the due date and must be filed electronically via ACCESS.

The CBP data identified two companies as producers/exporters of wind towers in Vietnam: CS Wind Tower Co Ltd (CS Wind Tower) and Metacor Vietnam Co., Ltd (Metacor Vietnam).³¹ Accordingly, Commerce intends to examine the two producers/exporters identified in the CBP data. Parties wishing to comment on the selection of CS Wind Tower and Metacor Vietnam as mandatory respondents must do so within three days of the publication of this notice. Any such comments must be submitted no later than 5:00 p.m. ET on the due date and must be filed electronically via ACCESS.

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305(b). Instructions for filing such applications may be found on the Commerce's website at <http://enforcement.trade.gov/apo>.

Comments must be filed electronically using ACCESS. An electronically filed document must be received successfully, in its entirety, by ACCESS no later than 5:00 p.m. ET on the date noted above. We intend to finalize our decisions regarding respondent selection within 20 days of publication of this notice.

Distribution of Copies of the Petitions

In accordance with section 702(b)(4)(A)(i) of the Act and 19 CFR 351.202(f), copies of the public version of the Petitions have been provided to

²⁵ *Id.*

²⁶ *Id.* at 15–16, 20–48 and Exhibits I–4, I–6, I–8, I–9, I–14, I–17 and I–19 through I–28.

²⁷ *See* Canada CVD Initiation Checklist, at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Utility Scale Wind Towers from Canada, Indonesia, the Republic of Korea, and the Socialist Republic of Vietnam (Attachment III); *see also* Indonesia CVD Initiation Checklist, at Attachment III; and Vietnam CVD Initiation Checklist, at Attachment III.

²⁸ *See* Volume I of the Petitions at Exhibit I–16.

²⁹ *See* Commerce's Letters, "Utility Scale Wind Towers from Canada Countervailing Duty Petition: Release of Customs Data from U.S. Customs and Border Protection" dated July 22, 2019 (Canada CBP Data Release Letter); "Utility Scale Wind Towers from Indonesia Countervailing Duty Petition: Release of Customs Data from U.S. Customs and Border Protection" dated July 22, 2019 (Indonesia CBP Data Release Letter); and "Utility Scale Wind Towers from the Socialist Republic of Vietnam Countervailing Duty Petition: Release of Customs Data from U.S. Customs and Border Protection" dated July 22, 2019 (Vietnam CBP Data Release Letter).

³⁰ *See* Indonesia CBP Data Release Letter.

³¹ *See* Vietnam CBP Data Release Letter.

the GOC, GOI, and GOV *via* ACCESS. To the extent practicable, we will attempt to provide a copy of the public version of the Petitions to each exporter named in the Petitions, as provided under 19 CFR 351.203(c)(2).

ITC Notification

We will notify the ITC of our initiation, as required by section 702(d) of the Act.

Preliminary Determinations by the ITC

The ITC will preliminarily determine, within 45 days after the date on which the Petitions were filed, whether there is a reasonable indication that imports of wind towers from Canada, Indonesia, and Vietnam are materially injuring, or threatening material injury to, a U.S. industry.³² A negative ITC determination in any country will result in the investigations being terminated with respect to that country.³³ Otherwise, these investigations will proceed according to statutory and regulatory time limits.

Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). 19 CFR 351.301(b) requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted³⁴ and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct.³⁵ Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Interested parties should review the regulations prior to submitting factual information in these investigations.

Extensions of Time Limits

Parties may request an extension of time limits before the expiration of a

time limit established under 19 CFR 351.301, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under 19 CFR 351.301. For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. ET on the due date. Under certain circumstances, we may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, we will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, stand-alone submission; under limited circumstances we will grant untimely-filed requests for the extension of time limits. Parties should review *Extension of Time Limits; Final Rule*, 78 FR 57790 (September 20, 2013), available at <http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm>, prior to submitting factual information in these investigations.

Certification Requirements

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.³⁶ Parties must use the certification formats provided in 19 CFR 351.303(g).³⁷ Commerce intends to reject factual submissions if the submitting party does not comply with the applicable certification requirements.

Notification to Interested Parties

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. On January 22, 2008, Commerce published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures*, 73 FR 3634 (January 22, 2008). Parties wishing to participate in these investigations should ensure that they meet the requirements of these procedures (e.g., the filing of letters of appearance as discussed at 19 CFR 351.103(d)).

³⁶ See section 782(b) of the Act.

³⁷ See *Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings*, 78 FR 42678 (July 17, 2013) (“*Final Rule*”); see also frequently asked questions regarding the *Final Rule*, available at http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.

This notice is issued and published pursuant to sections 702 and 777(i) of the Act and 19 CFR 351.203(c).

Dated: July 29, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Investigations

The merchandise covered by these investigations consists of certain wind towers, whether or not tapered, and sections thereof. Certain wind towers support the nacelle and rotor blades in a wind turbine with a minimum rated electrical power generation capacity in excess of 100 kilowatts and with a minimum height of 50 meters measured from the base of the tower to the bottom of the nacelle (*i.e.*, where the top of the tower and nacelle are joined) when fully assembled.

A wind tower section consists of, at a minimum, multiple steel plates rolled into cylindrical or conical shapes and welded together (or otherwise attached) to form a steel shell, regardless of coating, end-finish, painting, treatment, or method of manufacture, and with or without flanges, doors, or internal or external components (e.g., flooring/decking, ladders, lifts, electrical buss boxes, electrical cabling, conduit, cable harness for nacelle generator, interior lighting, tool and storage lockers) attached to the wind tower section. Several wind tower sections are normally required to form a completed wind tower.

Wind towers and sections thereof are included within the scope whether or not they are joined with nonsubject merchandise, such as nacelles or rotor blades, and whether or not they have internal or external components attached to the subject merchandise.

Specifically excluded from the scope are nacelles and rotor blades, regardless of whether they are attached to the wind tower. Also excluded are any internal or external components which are not attached to the wind towers or sections thereof, unless those components are shipped with the tower sections.

Further, excluded from the scope of the antidumping duty investigations are any products covered by the existing antidumping duty order on utility scale wind towers from the Socialist Republic of Vietnam. See *Utility Scale Wind Towers from the Socialist Republic of Vietnam: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order*, 78 FR 11150 (February 15, 2013).

Merchandise covered by these investigations is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheading 7308.20.0020 or 8502.31.0000. Wind towers of iron or steel are classified under HTSUS 7308.20.0020 when imported separately as a tower or tower section(s). Wind towers may be classified under HTSUS 8502.31.0000 when imported as combination goods with a wind turbine (*i.e.*, accompanying nacelles and/or rotor blades). While the HTSUS

³² See section 703(a)(2) of the Act.

³³ See section 703(a)(1) of the Act.

³⁴ See 19 CFR 351.301(b).

³⁵ See 19 CFR 351.301(b)(2).

subheadings are provided for convenience and customs purposes, the written description of the scope of the investigations is dispositive.

[FR Doc. 2019-16887 Filed 8-5-19; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-570-971]

Multilayered Wood Flooring From the People's Republic of China: Final Results and Partial Rescission of Countervailing Duty Administrative Review; 2016

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

SUMMARY: The Department of Commerce (Commerce) determines that Jiangsu Senmao Bamboo Wood Industry Co., Ltd. (Jiangsu Senmao) and Riverside Plywood Corp. and its cross-owned affiliates (Riverside Plywood), producers and/or exporters of multilayered wood flooring (wood flooring) from the People's Republic of China (China), received countervailable subsidies during the period of review (POR) January 1, 2016 through December 31, 2016.

DATES: Applicable August 6, 2019.

FOR FURTHER INFORMATION CONTACT: Dennis McClure or Suzanne Lam, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-5973 or (202) 482-0783, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the *Preliminary Results* of the administrative review in the *Federal Register* on December 28, 2018.¹ For the events that occurred since Commerce published the *Preliminary Results*, see the Issues and Decision Memorandum.² We invited

interested parties to comment on the *Preliminary Results*. On April 23, 2019, we received comments from Jiaxing Brilliant Import & Export Co. (Jiaxing Brilliant) in lieu of a case brief.³ On April 23, 2019, we received case briefs from American Manufacturers of Multilayered Wood Flooring (Petitioner), the GOC, Jiangsu Senmao, and Riverside Plywood.⁴ On May 1, 2019, we received rebuttal case briefs from the Petitioner, the Government of the People's Republic of China (GOC), Jiangsu Senmao, and Riverside Plywood.⁵

Commerce exercised its discretion to toll all deadlines affected by the partial federal government closure from December 22, 2018 through the resumption of operations on January 29, 2019.⁶ The revised deadline for the final results was May 30, 2019. On May 29, 2019, we extended this deadline to July 30, 2019.⁷

Scope of the Order⁸

The product covered by the *Order* is wood flooring from the China. A full

2016" (Issues and Decision Memorandum), dated concurrently with, and hereby adopted by, this notice.

³ See Letter from Jiaxing Brilliant, "Multilayered Wood Flooring from the People's Republic of China—Letter In Lieu of Case Brief," dated April 23, 2019.

⁴ See Letters from Petitioner, "Multilayered Wood Flooring from the People's Republic of China: Case Brief," dated April 23, 2019; the Government of China (GOC), "Government of China's Affirmative Case Brief Multilayered Wood Flooring from the People's Republic of China," dated April 23, 2019; Jiangsu Senmao, "Multilayered Wood Flooring from the People's Republic of China: Case Brief," dated April 23, 2019; and Riverside Plywood, "Riverside Plywood Co., Ltd.—Administrative Case Brief: 2016 Administrative Review of the Countervailing Duty Order on Multilayered Wood Flooring from China (C-570-971)," dated April 23, 2019.

⁵ See Letters from the Petitioner, "Multilayered Wood Flooring from the People's Republic of China: Rebuttal Brief," dated May 1, 2019; the GOC, "Government of China's Rebuttal Case Brief Multilayered Wood Flooring from the People's Republic of China," dated May 1, 2019; Jiangsu Senmao, "Multilayered Wood Flooring from the People's Republic of China: Rebuttal Brief," dated May 1, 2019; and Riverside Plywood, "Riverside Plywood—Rebuttal Brief: 2016 Administrative Review of the Countervailing Duty Order on Multilayered Wood Flooring from China (C-570-971)," dated May 1, 2019.

⁶ See Memorandum to the Record from Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, "Deadlines Affected by the Partial Shutdown of the Federal Government," dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

⁷ See Memorandum, "Multilayered Wood Flooring from the People's Republic of China: Extension of the Deadline for the Final Results of Countervailing Duty Administrative Review," dated May 29, 2019.

⁸ See *Order*; see also *Multilayered Wood Flooring from the People's Republic of China: Final*

description of the scope of the order is contained in the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in the parties' briefs are addressed in the Issues and Decision Memorandum. A list of the issues addressed is attached to this notice.⁹ The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <http://access.trade.gov> and in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <http://enforcement.trade.gov/frn/>. The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Changes From the Preliminary Results

Based on our analysis of the comments received, Commerce made certain revisions to the rates assigned to Jiangsu Senmao and Riverside Plywood. The Issues and Decision Memorandum contains descriptions of these revisions.

Methodology

Commerce conducted this review in accordance with section 751(a)(1)(A) of the Act. For each of the subsidy programs found countervailable, we find that there is a subsidy, *i.e.*, a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific.¹⁰ The Issues and Decision Memorandum contains a full description of the methodology underlying Commerce's conclusions, including any determination that relied upon the use of adverse facts available pursuant to sections 776(a) and (b) of the Act.

Partial Rescission of Administrative Review

As noted in the *Preliminary Results*, Commerce timely received no-shipment certifications from Anhui Boya Bamboo & Wood Products Co., Ltd., Chinafloors Timber (China) Co., Ltd., Hunchun

Clarification of the Scope of the Antidumping and Countervailing Duty Orders, 82 FR 27799 (June 19, 2017).

⁹ See Appendix I.

¹⁰ See sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

¹ See *Multilayered Wood Flooring from the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review, Rescission of Review, in Part, and Intent to Rescind the Review in Part*; 2016, 83 FR 67229 (December 28, 2018) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

² See Memorandum to Christian Marsh, Deputy Assistant Secretary for Enforcement and Compliance, from James Maeder, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, "Decision Memorandum for Final Results and Partial Rescission of Countervailing Duty Administrative Review: Multilayered Wood Flooring from the People's Republic of China;

Forest Wolf Wooden Industry Co., Ltd. (Hunchun Forest), Jiangsu Keri Wood Co., Ltd., Jiashan On-Line Lumber Co., Ltd., Kingman Floors Co., Ltd., Linyi Bonn Flooring Manufacturing Co., Ltd., and Zhejiang Shiyu Timber Co., Ltd. We inquired with U.S. Customs and Border Protection (CBP) whether these companies had shipped merchandise to the United States during the POR. CBP provided no evidence to contradict the claims of no shipments made by these companies, except for Hunchun Forest. Accordingly, we stated our intention to rescind the review with respect to these companies in the *Preliminary Results*. As the facts have remained the same since the *Preliminary Results*, we are rescinding the administrative review of these companies, pursuant to 19 CFR 351.213(d)(3).

On October 29, 2018, Huzhou Muyun Wood Co., Ltd. (Muyun Wood) filed a no-shipment certification. On November

13, 2018, we rejected Muyun Wood's request for no-shipment status because the request was untimely filed.

Therefore, we are including Muyun Wood in this administrative review for purposes of the final results.

Hunchun Forest also timely filed a no-shipment certification. However, Hunchun Forest subsequently withdrew its no-shipment submission. Therefore, we are including Hunchun Forest in this administrative review for purposes of the final results.

Rate for Non-Selected Companies Under Review

In this review, in addition to the two selected mandatory respondents, there are 132 companies for which a review was requested and not rescinded, but which were not selected for individual examination (non-selected companies). For these companies, we applied the average of the rates calculated for the mandatory respondents, Jiangsu Senmao

and Riverside Plywood, which are above *de minimis*. For further information on the calculation of the non-selected rate, refer to the section in the Issues and Decision Memorandum entitled, "*Ad Valorem* Rate for Non-Selected Companies Under Review." Concerning Jiaying Brilliant's April 23, 2019, comments, we note that we inadvertently included the company in our review. Jiaying Brilliant was excluded from the order as a result of the final determination in the investigation segment of this case.¹¹ Therefore, Jiaying Brilliant is not subject to this review and is excluded from the list of non-selected companies receiving a rate below.

Final Results

In accordance with 19 CFR 351.221(b)(4)(i), we determine the following net subsidy rates for the 2016 administrative review:

Producer/exporter	Subsidy rate (percent)
Jiangsu Senmao Bamboo Wood Industry Co., Ltd	2.96
Riverside Plywood Corp. and its Cross-Owned Affiliates ¹²	3.20

Review-Specific Average Rate Applicable to the Following Non-Selected Companies:

Producer/exporter	Subsidy rate (percent)
A&W (Shanghai) Woods Co., Ltd	3.10
Anhui Longhua Bamboo Product Co., Ltd	3.10
Anhui Suzhou Dongda Wood Co., Ltd	3.10
Armstrong Wood Products (Kunshan) Co., Ltd	3.10
Baishan Huafeng Wooden Product Co., Ltd	3.10
Baiying Furniture Manufacturer Co., Ltd	3.10
Benxi Flooring Factory (General Partnership)	3.10
Benxi Wood Company	3.10
Changbai Mountain Development and Protection Zone Hongtu Wood Industrial Co., Ltd	3.10
Changzhou Hawd Flooring Co., Ltd	3.10
Cheng Hang Wood Co., Ltd	3.10
Dalian Dajen Wood Co., Ltd	3.10
Dalian Huade Wood Product Co., Ltd	3.10
Dalian Huilong Wooden Products Co., Ltd	3.10
Dalian Jaenmaken Wood Industry Co., Ltd	3.10
Dalian Jiahong Wood Industry Co., Ltd	3.10
Dalian Jiuyuan Wood Industry Co., Ltd	3.10
Dalian Kemian Wood Industry Co., Ltd	3.10
Dalian Qianqiu Wooden Product Co., Ltd	3.10
Dalian T-Boom Wood Products Co., Ltd	3.10
Dalian Xinjinghua Wood Co., Ltd	3.10
Dongtai Fuan Universal Dynamics, LLC	3.10
Dongtai Zhangshi Wood Industry Co. Ltd	3.10
Dun Hua Sen Tai Wood Co., Ltd	3.10
Dunhua City Dexin Wood Industry Co., Ltd	3.10
Dunhua City Hongyuan Wood Industry Co., Ltd	3.10
Dunhua City Wanrong Wood Industry Co., Ltd	3.10
Dunhua Shengda Wood Industry Co., Ltd	3.10
Fine Furniture (Shanghai) Limited	3.10

¹¹ See *Multilayered Wood Flooring From the People's Republic of China: Countervailing Duty Order*, 76 FR 76693, 76694 (December 8, 2011).

¹² Cross-owned affiliates are Baroque Timber Zhongshan Co. Ltd. and Suzhou Times Flooring Co., Ltd.

Producer/exporter	Subsidy rate (percent)
Fu Lik Timber (HK) Co., Ltd	3.10
Fujian Wuyishan Werner Green Industry Co., Ltd	3.10
Fusong Jinlong Wooden Group Co., Ltd	3.10
Fusong Qianqiu Wooden Product Co., Ltd	3.10
GTP International Ltd	3.10
Guangdong Fu Lin Timber Technology Limited	3.10
Guangdong Yihua Timber Industry Co., Ltd	3.10
Guangzhou Homebon Timber Manufacturing Co., Ltd	3.10
Guangzhou Panyu Kangda Board Co., Ltd	3.10
Guangzhou Panyu Southern Star Co., Ltd	3.10
HaiLin LinJing Wooden Products, Ltd	3.10
HaiLin XinCheng Wooden Products, Ltd	3.10
Hangzhou Dazhuang Floor Co., Ltd (dba Dasso Industrial Group Co., Ltd)	3.10
Hangzhou Hanje Tec Company Limited	3.10
Hangzhou Huahi Wood Industry Co., Ltd	3.10
Hangzhou Zhengtian Industrial Co., Ltd	3.10
Henan Xingwangjia Technology Co., Ltd	3.10
Hong Kong Easoon Wood Technology Co., Ltd	3.10
Huaxin Jiasheng Wood Co., Ltd	3.10
Huber Engineering Wood Corp	3.10
Hunchun Forest Wolf Wooden Industry Co., Ltd	3.10
Hunchun Xingjia Wooden Flooring Inc	3.10
Huzhou Chenghang Wood Co., Ltd	3.10
Huzhou City Nanxun Guangda Wood Co., Ltd	3.10
Huzhou Fulinmen Imp. & Exp. Co., Ltd	3.10
Huzhou Fuma Wood Co., Ltd	3.10
Huzhou Muyun Wood Co., Ltd	3.10
Huzhou Sunergy World Trade Co., Ltd	3.10
Innomaster Home (Zhongshan) Co., Ltd	3.10
Jiafeng Wood (Suzhou) Co., Ltd	3.10
Jiangsu Guyu International Trading Co., Ltd	3.10
Jiangsu Kentier Wood Co., Ltd	3.10
Jiangsu Simba Flooring Co., Ltd	3.10
Jiangsu Yuhui International Trade Co., Ltd	3.10
Jiashan Fengyun Timber Co., Ltd	3.10
Jiashan HuiJiaLe Decoration Material Co., Ltd	3.10
Jiaxing Hengtong Wood Co., Ltd	3.10
Jilin Forest Industry Jinqiao Flooring Group Co., Ltd	3.10
Jilin Xinyuan Wooden Industry Co., Ltd	3.10
Jingsu Mingle Flooring Co., Ltd	3.10
Karly Wood Product Limited	3.10
Kember Flooring, Inc	3.10
Kemian Wood Industry (Kunshan) Co., Ltd	3.10
Kornbest Enterprises Limited	3.10
Kunming Alston (AST) Wood Products Co., Ltd	3.10
Les Planchers Mercier, Inc	3.10
Linyi Anying Wood Co., Ltd	3.10
Linyi Youyou Wood Co., Ltd	3.10
Metropolitan Hardwood Floors, Inc	3.10
Mudanjiang Bosen Wood Industry Co., Ltd	3.10
Nakahiro Jyou Sei Furniture (Dalian) Co., Ltd	3.10
Nanjing Minglin Wooden Industry Co., Ltd	3.10
Ningbo Tianyi Bamboo and Wood Products Co., Ltd	3.10
Pinge Timber Manufacturing (Zhejiang) Co., Ltd	3.10
Power Dekor Group Co. Ltd	3.10
Qingdao Barry Flooring Co., Ltd	3.10
Samling Elegant Living Trading (Labuan) Ltd	3.10
Samling Global USA, Inc	3.10
Samling Riverside Co., Ltd	3.10
Scholar Home (Shanghai) New Material Co. Ltd	3.10
Shandong Kaiyuan Wood Industry Co., Ltd	3.10
Shandong Longteng Wood Co., Ltd	3.10
Shandong Puli Trading Co., Ltd	3.10
Shanghai Anxin (Weiguang) Timber Co., Ltd	3.10
Shanghai Demeija Timber Co., Ltd	3.10
Shanghai Eswell Timber Co., Ltd	3.10
Shanghai Lairunde Wood Co., Ltd	3.10
Shanghai Lizhong Wood Products Co., Ltd (aka The Lizhong Wood Industry Limited Company of Shanghai)	3.10
Shanghai New Sihe Wood Co., Ltd	3.10
Shanghai Shenlin Corporation	3.10
Shenyang Haobainian Wooden Co., Ltd	3.10
Shenyang Sende Wood Co., Ltd	3.10
Shenzhen Huanwei Woods Co., Ltd	3.10

Producer/exporter	Subsidy rate (percent)
Sino-Maple (Jiangsu) Co., Ltd	3.10
Suzhou Anxin Weiguang Timber Co., Ltd	3.10
Suzhou Dongda Wood Co., Ltd	3.10
Tak Wah Building Material (Suzhou) Co	3.10
Tech Wood International Ltd	3.10
Tongxiang Jisheng Import and Export Co., Ltd	3.10
Vicwood Industry (Suzhou) Co. Ltd	3.10
Xiamen Yung De Ornament Co., Ltd	3.10
Xuzhou Antop International Trade Co., Ltd	3.10
Xuzhou Shenghe Wood Co., Ltd	3.10
Yekalon Industry, Inc	3.10
Yihua Lifestyle Technology Co., Ltd	3.10
Yingyi-Nature (Kunshan) Wood Industry Co., Ltd	3.10
Yixing Lion-King Timber Industry	3.10
Zhejiang Anji Xinfeng Bamboo and Wood Industry Co., Ltd	3.10
Zhejiang Biyork Wood Co., Ltd	3.10
Zhejiang Dadongwu Green Home Wood Co., Ltd	3.10
Zhejiang Desheng Wood Industry Co., Ltd	3.10
Zhejiang Fudeli Timber Industry Co., Ltd	3.10
Zhejiang Fuerjia Wooden Co., Ltd	3.10
Zhejiang Fuma Warm Technology Co., Ltd	3.10
Zhejiang Haoyun Wooden Co., Ltd	3.10
Zhejiang Jesonwood Co., Ltd	3.10
Zhejiang Jiechen Wood Industry Co., Ltd	3.10
Zhejiang Longsen Lumbering Co., Ltd	3.10
Zhejiang Shuimojiangnan New Material Technology Co., Ltd	3.10
Zhejiang Simite Wooden Co., Ltd	3.10
Zhejiang Tianzhen Bamboo & Wood Development Co., Ltd	3.10
Zhejiang Yongyu Bamboo Joint-Stock Co., Ltd	3.10

Assessment Rates

Pursuant to 19 CFR 351.212(b)(2), Commerce will determine, and CBP shall assess, countervailing duties on all appropriate entries of subject merchandise in accordance with the final results of this review, for the above-listed companies at the applicable *ad valorem* assessment rates listed. We intend to issue assessment instructions to CBP 15 days after the date of publication of these final results of review.

For the companies for which this review is rescinded, Commerce will instruct CBP to assess countervailing duties on all appropriate entries at a rate equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, during the POR in accordance with 19 CFR 351.212(c)(1)(i).

Cash Deposit Requirements

Commerce also intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for each of the respective companies listed above on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits of

estimated countervailing duties at the most recent company-specific or all others rate applicable to the company, as appropriate. These cash deposit requirements, effective upon publication of these final results, shall remain in effect until further notice.

Administrative Protective Orders

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

We are issuing and publishing these final results in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: July 30, 2019.

Christian Marsh,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Final Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Partial Rescission of Administrative

Review

V. Period of Review

VI. Subsidies Valuation Information

VII. Changes From the Preliminary Results

VIII. Use of Facts Otherwise Available

IX. Analysis of Programs

X. Analysis of Comments

Comment 1: Application of Total Adverse Facts Available (AFA) to the GOC and Riverside Plywood

Comment 2: Application of Partial AFA with Respect to Riverside's Plywood's Purchases of Veneers for Less than Adequate Remuneration (LTAR)

Comment 3: Application of AFA with Respect to the Jiangsu Senmao's Receipt of Policy Loans for LTAR

Comment 4: Application of AFA with Respect to the Export Buyer's Credit Program

Comment 5: Selection of the AFA Rate for the Export Buyer's Credit Program

Comment 6: Countervailability of Other Subsidies

Comment 7: Whether to Adjust Benchmark Prices to Account for Prevailing Market Conditions

Comment 8: Applicable Value Added Tax (VAT) Rate for Benchmark Prices

Comment 9: Applicable Import Duty for Benchmark Prices

Comment 10: Requirements Necessary to Determine Countervailability of Land Use

Comment 11: Amount to Use as Benefit for Grants

Comment 12: Exclusion of Certain Export Data Used to Calculate the Veneers Benchmark

XI. Recommendation

[FR Doc. 2019-16753 Filed 8-5-19; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XR008

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to U.S. Navy Training and Testing Activities in the Northwest Training and Testing Study Area

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

ACTION: Notice; receipt of application for a Letter of Authorization; request for comments and information.

SUMMARY: NMFS has received a request from the U.S. Navy (Navy) for authorization to take marine mammals incidental to training and testing activities conducted in the Northwest Training and Testing (NWT) Study Area for a period of seven years, from November, 2020 through November, 2027. Pursuant to regulations implementing the Marine Mammal Protection Act (MMPA), NMFS is announcing receipt of the Navy's request for the development and implementation of regulations governing the incidental taking of marine mammals. NMFS invites the public to provide information, suggestions, and comments on the Navy's application and request.

DATES: Comments and information must be received no later than September 5, 2019.

ADDRESSES: Comments on the application should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service. Physical comments should be sent to 1315 East-West Highway, Silver Spring, MD 20910 and electronic comments should be sent to ITP.Piniak@noaa.gov.

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments received electronically, including all attachments, must not exceed a 25-megabyte file size. Attachments to electronic comments will be accepted in Microsoft Word or Excel or Adobe PDF file formats only. All comments received are a part of the public record

and will generally be posted to the internet at www.nmfs.noaa.gov/pr/permits/incidental/military.htm without change. All personal identifying information (e.g., name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT:

Wendy Piniak, Office of Protected Resources, NMFS, (301) 427-8401. An electronic copy of the Navy's application may be obtained online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities>. In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (Secretary) to allow, upon request, the incidental, but not intentional taking of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographic region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, 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).

The National Defense Authorization Act (NDAA) for Fiscal Year 2004 (Public Law (Pub. L.) 108-136) removed the "small numbers" and "specified geographical region" limitations indicated above and amended the definition of "harassment" as it applies to a "military readiness activity" to read as follows (Section 3(18)(B) of the MMPA): (i) Any act that injures or has the significant potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) Any act that disturbs or is likely to disturb a marine mammal or marine mammal stock in the wild by causing disruption of natural behavioral patterns, including, but not limited to, migration, surfacing, nursing, breeding, feeding, or sheltering, to a point where such behavioral patterns are abandoned or significantly altered (Level B harassment). On August 13, 2018, the 2019 NDAA (Pub. L. 115-232) amended the MMPA to allow incidental take regulations for military readiness activities to be issued for up to seven years.

Summary of Request

On March 11, 2019, NMFS received an adequate and complete application from the Navy requesting authorization for the take of marine mammals, by Level A harassment and B harassment, incidental to training, testing, and routine military operations (all categorized as military readiness activities) from the use of sonar and other transducers and in-water detonations. In addition, the Navy is requesting authorization of three takes of large whales by serious injury or mortality resulting from vessel strikes. NMFS received a revised application on June 24, 2019. The requested regulations would be valid for seven years, from 2020 through 2027.

This will be the third time NMFS has promulgated incidental take regulations pursuant to the MMPA relating to similar military readiness activities in the NWT Study Area, following those effective from November 9, 2010 through November 8, 2015 (75 FR 69275; November 10, 2010) and from November 9, 2015 through November 8, 2010 (80 FR 73555; November 24, 2015).

Description of the Specified Activity

The NWT Study Area is composed of established maritime operating and warning areas in the eastern North

Pacific Ocean region, including areas of the Strait of Juan de Fuca, Puget Sound, and Western Behm Canal in southeastern Alaska (see Figure 2–1 of the Navy's application). The Study Area includes four existing range complexes and facilities: The Northwest Training Range Complex, the Keyport Range Complex, Carr Inlet Operations Area, and the Southeast Alaska Acoustic Measurement Facility (Western Behm Canal, Alaska). In addition to these range complexes, the Study Area also includes Navy pierside locations where sonar maintenance and testing occurs as part of overhaul, modernization, maintenance, and repair activities at Naval Base Kitsap, Bremerton; Naval Base Kitsap, Bangor; and Naval Station Everett.

The following types of training and testing activities, which are classified as military readiness activities pursuant to section 315(f) of Pub. L. 101–314 (16 U.S.C. 703), are included in the specified activity described in the Navy's application: Anti-submarine warfare (sonar and other transducers, underwater detonations), mine warfare (sonar and other transducers, underwater detonations), surface warfare (underwater detonations), and other (sonar and other transducers).

The Navy's application includes proposed mitigation measures for marine mammals that would be implemented during training and testing activities in the NWT Study Area (see Section 11 of the Navy's application). Proposed procedural mitigation measures and geographic mitigation areas generally include: (1) The use of Lookouts to observe for biological resources and communicate the need for mitigation implementation; (2) powerdowns, shutdowns, and delay of starts to avoid exposure of marine mammals to high levels of sound or explosive blasts more likely to result in injury or more serious behavioral disruption; and (3) limiting the use of active sonar or explosives in certain biologically important areas to reduce the probability or severity of impacts when they are more likely to contribute to fitness impacts (see Figure 11–1 of the Navy's application).

The Navy also proposes to undertake monitoring and reporting efforts to track compliance with incidental take authorizations and to help investigate the effectiveness of implemented mitigation measures in the NWT Study Area. This includes Adaptive Management, the Integrated Comprehensive Monitoring Program, the Strategic Planning Process, and Annual Monitoring and Activity Reports. As an example, under the

Integrated Comprehensive Monitoring Program, the monitoring relating to the effects of Navy training and testing activities on protected marine species are designed to increase the understanding of the likely occurrence of marine mammals in the vicinity of the action (*i.e.*, presence, abundance, distribution, and density of species) and to increase the understanding of the nature, scope, or context of the likely exposure of marine mammals to any of the potential stressors associated with the action.

Information Solicited

Interested persons may submit information, suggestions, and comments concerning the Navy's request (see **ADDRESSES**). NMFS will consider all information, suggestions, and comments related to the request during the development of proposed regulations governing the incidental taking of marine mammals by the Navy, if appropriate.

Dated: August 1, 2019.

Donna S. Wieting,

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

[FR Doc. 2019–16759 Filed 8–5–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

U.S. Integrated Ocean Observing System (IOOS®) Advisory Committee

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

ACTION: Notice of open meeting.

SUMMARY: Notice is hereby given of a virtual meeting of the U.S. Integrated Ocean Observing System (IOOS®) Advisory Committee (Committee).

DATES: The meeting will be held on Wednesday, August 21, 2019, from 11:00 a.m. to 3:00 p.m. EST. These times and the agenda topics described below are subject to change. Refer to the web page listed below for the most up-to-date agenda and dial-in information.

ADDRESSES: The meeting will be held virtually. Refer to the web page listed below for the most up-to-date information.

FOR FURTHER INFORMATION CONTACT: Krisa Arzayus, Designated Federal Official, U.S. IOOS Advisory Committee, U.S. IOOS Program, 1315 East-West Highway, Silver Spring, MD

20910; Phone 240–533–9455; Fax 301–713–3281; Email krisa.arzayus@noaa.gov or visit the U.S. IOOS Advisory Committee website at <http://ioos.noaa.gov/community/u-s-ioos-advisory-committee/>.

SUPPLEMENTARY INFORMATION: The Committee was established by the NOAA Administrator as directed by Section 12304 of the Integrated Coastal and Ocean Observation System Act, part of the Omnibus Public Land Management Act of 2009 (Pub. L. 111–11). The Committee advises the NOAA Administrator and the Interagency Ocean Observation Committee (IOOC) on matters related to the responsibilities and authorities set forth in section 12302 of the Integrated Coastal and Ocean Observation System Act of 2009 and other appropriate matters as the Under Secretary refers to the Committee for review and advice.

The Committee will provide advice on:

(a) Administration, operation, management, and maintenance of the System;

(b) Expansion and periodic modernization and upgrade of technology components of the System;

(c) Identification of end-user communities, their needs for information provided by the System, and the System's effectiveness in dissemination information to end-user communities and to the general public; and

(d) Any other purpose identified by the Under Secretary of Commerce for Oceans and Atmosphere or the Interagency Ocean Observation Committee.

The meeting will be open to public participation with a 15-minute public comment period on August 21, 2019, from 2:45 p.m. to 3:00 p.m. (check agenda on website to confirm time.) The Committee expects that public statements presented at its meetings will not be repetitive of previously submitted verbal or written statements. In general, each individual or group making a verbal presentation will be limited to a total time of three (3) minutes. Written comments should be received by the Designated Federal Official by August 16, 2019 to provide sufficient time for Committee review. Written comments received after August 16, 2019 will be distributed to the Committee, but may not be reviewed prior to the meeting date. Please send your name as it appears on driver's license and the organization/company affiliation you represent to Krisa Arzayus. This information must be received by August 9, 2019.

Matters To Be Considered: The meeting will focus on ongoing committee priorities, and developing the next set of recommendations. The latest version of the agenda will be posted at <http://ioos.noaa.gov/community/u-s-ioos-advisory-committee/>.

Special Accommodations: These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Krisa Arzayus, Designated Federal Official at 240-533-9455 by August 16, 2019.

Dated: July 10, 2019.

Carl C. Gouldman,

Director, U.S. IOOS Program, National Ocean Service.

[FR Doc. 2019-16773 Filed 8-5-19; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XG910

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Sand Island Pile Dike System Test Piles Project Near the Mouth of the Columbia River

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

ACTION: Notice; proposed incidental harassment authorization; request for comments on proposed authorization and possible Renewal.

SUMMARY: NMFS has received a request from U.S. Army Corps of Engineers, Portland District (Corps) for authorization to take marine mammals incidental to the Sand Island Pile Dike System Test Piles project near the Mouth of the Columbia River. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an incidental harassment authorization (IHA) to incidentally take marine mammals during the specified activities. NMFS is also requesting comments on a possible one-year Renewal that could be issued under certain circumstances and if all requirements are met, as described in *Request for Public Comments* at the end of this notice. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorizations and agency responses will be summarized in the final notice of our decision.

DATES: Comments and information must be received no later than September 5, 2019.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service. Physical comments should be sent to 1315 East-West Highway, Silver Spring, MD 20910 and electronic comments should be sent to ITP.Pauline@noaa.gov.

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments received electronically, including all attachments, must not exceed a 25-megabyte file size. Attachments to electronic comments will be accepted in Microsoft Word or Excel or Adobe PDF file formats only. All comments received are a part of the public record and will generally be posted online at <https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act> without change. All personal identifying information (e.g., name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

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

SUPPLEMENTARY INFORMATION:

Background

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

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

The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

National Environmental Policy Act

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

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

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

Summary of Request

On March 6, 2019, NMFS received a request from the Corps for an IHA to take marine mammals incidental to pile driving activities in the Columbia River Estuary. The application was deemed adequate and complete on June 20, 2019. The Corps’ request is for take of a small number of harbor porpoises

(*Phocoena phocoena*), Steller sea lions (*Eumetopias jubatus*), California sea lions (*Zalophus californianus*), and harbor seals (*Phoca vitulina richardii*) by Level B harassment and Level A harassment. Neither the Corps nor NMFS expect serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Description of Proposed Activity

Overview

The Corps is proposing to drive test piles in order to investigate the feasibility of different construction methods at two of the four Sand Island pile dikes at the Mouth of the Columbia River (MCR) (Figure 1 in application). The Sand Island pile dikes are comprised of four pile dikes, which are named according to river mile (RM) location, at RMs 4.01, 4.47, 5.15, and 6.37 (the pile dike at RM 6.37 is also referred to as the Chinook pile dike). Three of the pile dikes are connected to West Sand Island and East Sand Island, and the fourth pile dike in open water runs parallel to the Chinook Channel on the upstream side (Figure 2 in application). The Sand Island pile dikes are part of the Columbia River pile dike system and were installed in the 1930's. The Corps intends to restore full functionality of pile dikes in the future but needs to drive test piles in order to inform possible design. The existing pile dikes have deteriorated greatly due to lack of maintenance. Impact and vibratory pile installation and vibratory pile removal would introduce underwater sounds at levels that may result in take, by Level A and Level B harassment, of marine mammals in the Columbia River Estuary. Construction activities are expected to last between 6 and 41 days.

Dates and Duration

The work is anticipated to take between 6 and 41 days with work occurring during standard daylight working hours, 8 to 10 hours per day, beginning on September 15, 2019. Work is planned to take place in September, October, or November.

Specific Geographic Region

The proposed work would occur at the Sand Island pile dikes in Clatsop County, Oregon. The Sand Island pile dikes are located near the MCR. The pile dike at RM 4.01 is located within Oregon, while the pile dike at RM 6.37 is in both Oregon and Washington. The MCR is the downstream terminus of the Columbia River tidal estuary which is dominated by freshwater inputs from the Columbia and Willamette rivers. This estuary stretches from the mouth upstream to Bonneville Dam at RM 146.

Detailed Description of Specific Activity

Records from previous timber pile dike repairs concluded that trying to drive new timber piles through the existing scour protection rock apron at the base of the pile dike was challenging and would likely not meet sufficient embedment depths or alignment tolerances needed for structural and functional requirements. Since timber piles had insufficient structural capacity to support necessary environmental loading, steel piles were selected for all potential design options.

Preliminary pile dike repair design revealed three options, hereafter described as the offset alignment, existing alignment, and sleeve existing piles. The Corps needs to drive test piles in order to evaluate which of these three designs could achieve the most favorable hydraulic and sediment transport functions, while also considering costs associated with construction and long-term maintenance.

The Sand Island Pile Dikey System Test Piles project entails testing the three aforementioned designs at two pile dikes, each with 9 piles. The Corps has designed a specific testing sequence in which up to 3 tests could occur at each of those 18 piles, yielding a total of 41 pile driving events over a maximum of 41 days. The test sequence at any given location includes an attempt with a vibratory hammer or impact hammer with various shoes including ring, cone, or rock tip (See Table 1).

The maximum 41 days of work includes the following estimates for various pile driving activities:

- Up to 20 days of impact driving only (steel piles);
- Up to 18 days of impact driving AND vibratory installation/removal of steel piles; and
- Up to 3 days for vibratory removal of timber piles only.

Piles are generally installed by a rig which supports the pile leads, raises the pile, and operates a hammer. The rigs will use either impact hammers or vibratory drivers. Up to ten existing timber piles may be removed by vibratory methods, pulling, cutting or snapping at the approximate level of the enrockment. Removal with a vibratory hammer is expected to take approximately 5 minutes. After timber pile removal, one of the test methods would be attempted. When refusal criteria is reached, the attempt would cease and the next test method would be attempted as prescribed in the work summary.

The contractor may use barge-mounted cranes equipped with survey grade positioning software to ensure the piles are installed with precision. Driving shoes may also be used. Should unusually difficult driving conditions be encountered, the contractor will be allowed to temporarily excavate the minimum amount of existing scour protection rock needed in order to drive new piles. The contractor will then reinstall the rock to provide scour protection for new piles. Barges will transport all equipment and material to and from the site and serve as staging platforms for construction. Barges may be spudded or anchored into position. Test piles will be removed upon completion of the tests.

Pile driving for test piles may be done with either vibratory or impact hammer, but due to existing enrockment surrounding existing piles, it is anticipated that impact hammer will primarily be used. It is not possible to use bubble curtains or other noise-attenuating devices due to heavy tidal action.

TABLE 1—PILE DRIVING SUMMARY

Pile location and alignment	1st test	2nd test	3rd test	Number of timber piles for vibratory removal (maximum)	Number of steel pile driving events with vibratory hammer	Number of steel pile driving events with impact hammer	Number of steel piles for vibratory removal after testing (maximum)
4-1C Center	Pile Only ¹	Ring ³	Cone ⁴	1	2	1
4-1F Offset	Pile Only	Ring	Cone	1	2	1
4-2C Center	Ring	Cone	2	1
4-2F Offset	Cone	Rock Tip ⁵	2	1
4-3C Center	Ring	Cone	2	1
4-3F Offset	Ring	Cone	2	1

TABLE 1—PILE DRIVING SUMMARY—Continued

Pile location and alignment	1st test	2nd test	3rd test	Number of timber piles for vibratory removal (maximum)	Number of steel pile driving events with vibratory hammer	Number of steel pile driving events with impact hammer	Number of steel piles for vibratory removal after testing (maximum)
4–4C Center	Cone	Rock Tip	2	1
4–4F Offset	Ring	Cone	2	1
4–S Center	Pile	Ring	1	1	1
	Only+Sleeve ² .						
6–1C Center	Cone	Rock Tip	2	1
6–1F Offset	Pile Only	Ring	Cone	1	2	1
6–2C Center	Ring	Cone	2	1
6–2F Offset	Ring	Cone	2	1
6–3C Center	Cone	Rock Tip	2	1
6–3F Offset	Ring	Cone	2	1
6–4C Center	Pile Only	Ring	Cone	1	2	1
6–4F Offset	Pile Only	Ring	Cone	1	2	1
6–S Center	Pile Only+Sleeve	Ring	1	1	1
Totals	10	7	34	18

¹ Pile only consists of only the open steel pile without an end treatment.

² Pile only+sleeve consists of an attempt to drive the new test pile as a sleeve over the existing timber piles.

³ Ring consists of the steel pile fitted with an open-ended cutting shoe.

⁴ Cone consists of the steel pile fitted with a conical shoe.

⁵ Rock tip consists of the steel pile fitted with a conical rock-breaking tip.

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

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history, of the potentially affected species. Additional information regarding population trends and threats may be found in NMFS's Stock Assessment Reports (SARs; <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments>) and more general information about these species (e.g., physical and behavioral

descriptions) may be found on NMFS's website (<https://www.fisheries.noaa.gov/find-species>).

Table 2 lists all species with expected potential for occurrence near the test piles project area and summarizes information related to the population or stock, including regulatory status under the MMPA and ESA and potential biological removal (PBR), where known. For taxonomy, we follow Committee on Taxonomy (2016). PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS's SARs). While no mortality is anticipated or authorized here, PBR and annual serious injury and mortality from anthropogenic sources

are included here as gross indicators of the status of the species and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS's stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS's U.S. Pacific Marine Mammal SARs (Carretta *et al.*, 2019). All values presented in Table 2 are the most recent available at the time of publication and are available in the 2018 SARs (Carretta *et al.*, 2019).

TABLE 2—MARINE MAMMAL SPECIES LIKELY TO BE FOUND NEAR THE TEST PILES PROJECT AREA

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) ¹	Stock abundance (CV, N _{min} , most recent abundance survey) ²	PBR	Annual M/SI ³
Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)						
Family Eschrichtiidae: Gray whale	<i>Eschrichtius robustus</i>	Eastern North Pacific	-, -, N	26,960 (0.05, 25849, 2016)	801	139
Family Balaenopteridae (rorquals): Humpback whale	<i>Megaptera novaeangliae</i>	California/Oregon/Washington	-, -, Y	2,900 (0.05, 2,784, 2014)	16.7	40.2
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
Family Delphinidae: Killer whale	<i>Orcinus orca</i>	West Coast Transient	-, -, N	243 (N/A, 243, 2009)	2.4	0
Family Phocoenidae (porpoises): Harbor porpoise	<i>Phocoena phocoena</i>	Northern Oregon/Washington Coast.	-, -, N	21,487 (044, 15,123, 2011)	151	3.0

TABLE 2—MARINE MAMMAL SPECIES LIKELY TO BE FOUND NEAR THE TEST PILES PROJECT AREA—Continued

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) ¹	Stock abundance (CV, N _{min} , most recent abundance survey) ²	PBR	Annual M/SI ³
Order Carnivora—Superfamily Pinnipedia						
Family Otariidae (eared seals and sea lions):						
California sea lion	<i>Zalophus californianus</i>	U.S. Stock	- , - , N	257,606 (N/A, 233,515, 2014)	14,011	>320
Steller sea lion	<i>Eumetopias jubatus</i>	Eastern U.S.	- , - , N	41,638 (See SAR, 41,638, 2015).	2,498	108
Family Phocidae (earless seals):						
Harbor seal	<i>Phoca vitulina richardii</i>	Oregon and Washington Coast	- , - , N	UNK (UNK, UNK, 1999)	UND	10.6

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

² NMFS marine mammal stock assessment reports online at: www.nmfs.noaa.gov/pr/sars/. CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance. In some cases, CV is not applicable.

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

All species that could potentially occur in the proposed project area are included in Table 2. However, the temporal and/or spatial occurrence of gray, humpback, and killer whales is such that take is not expected to occur, and they are not discussed further beyond the explanation provided here.

Gray whales have not been documented near the proposed project area although anecdotal evidence indicates they have been seen at the MCR. However, they are not a common visitor as they mostly remain in the vicinity of the offshore shelf-break (Griffith 2015). They migrate along the Oregon coast in three discernible phases from early December through May (Herzing and Mate 1984). Therefore, they are unlikely to occur near the project area in September, October, or November. Additionally, NMFS issued an IHA to the Corps for incidental take of marine mammals associated with vibratory driving activities occurring at Jetty A which is located approximately 2.5 km east of RM 4.01 (80 FR 53777, September 8, 2015). The Level B harassment zone established for that project overlaps with the proposed Level B harassment zone for this proposed test piles project. A marine mammal monitoring report submitted to NMFS on August 1, 2016 included 5 days of observation in June and July of 2016. During that time there were no gray whale sightings. A subsequent marine mammal monitoring report was submitted by the Corps on December 7, 2017 as part of the reporting requirements for a Letter of Authorization (LOA) issued for the rehabilitation of the entire Columbia River Jetty System (82 FR 15046; March 23, 2017). Monitoring by two PSOs

during work on Jetty A for two days in July 2017 resulted in no gray whale sightings. Given the size of these whales they could be readily identifiable at a considerable distance. If a gray whale were to approach the established Level B harassment isopleths, shutdown would be initiated to avoid take. The Corps plan to employ at least one vessel-based PSO who would be able to adequately monitor these zones. Therefore, NMFS does expect take to occur.

Humpback whales have been observed in the vicinity of the project area in recent years. They have been arriving in the lower Columbia estuary as early as mid-June and have been observed as late as mid-November with a peak of abundance coinciding with the peak abundance of forage fish in mid-summer. While it is possible that humpback whales could pass through the project area during the construction period, there is a decreased chance of their presence in September, October, and November. The 2016 Jetty A monitoring report recorded nine sightings of humpback whale during the five-day in-water construction period but only a single sighting occurred within the Level B harassment zone. Furthermore, these sightings occurred at the peak of forage fish abundance in June and July. The 2017 LOA monitoring report did not record any sightings. The Corps would initiate shutdown if a humpback was observed approaching the Level B harassment zones. Humpbacks are readily identifiable from a distance, and the Corps will be placing Protected Species Monitors (PSOs) on at least one boat to ensure complete coverage of harassment

zones. Therefore, take of humpback whales is not anticipated.

Killer whales from the Southern Resident and West Coast transient stocks could occur near the MCR. Historically, killer whales were regular visitors in the vicinity of the estuary. However, they are much less common presently and are rarely seen in the interior of the Columbia River Jetty system (Wilson 2015). While not regularly seen in the project area, West Coast Transient killer whales have been observed near the MCR during the peak spring Chinook salmon migration in March and April but members of this stock are not likely to occur in the vicinity of the project area during the proposed construction period. Both the 2016 Corps monitoring report and 2017 monitoring report did not record any killer whale sightings. Due to the absence of killer whales observations in the project vicinity, the limited timeframe of proposed pile driving activities, it is highly unlikely that killer whales would be near the Sand Island pile dike system. Should any killer whales be observed approaching the Level B harassment zone, shutdown procedures would be implemented. Therefore, take of killer whales is not expected.

Harbor Porpoise

In the eastern North Pacific Ocean, harbor porpoise are found in coastal and inland waters from Point Barrow, along the Alaskan coast, and down the west coast of North America to Point Conception, California. Harbor porpoise are known to occur year-round in the inland trans-boundary waters of Washington and British Columbia, Canada and along the Oregon/

Washington coast. The Northern Oregon/Washington Coast stock of harbor porpoises ranges from Lincoln City, OR, to Cape Flattery, WA (Carretta *et al.* 2019).

Harbor porpoises are usually found in shallow water, most often nearshore, although they occasionally travel over deeper offshore waters (NOAA 2013a). West Coast populations have more restricted movements and do not migrate as much as East Coast populations (Halpin, OBIS–SEAMAP 2019). Most harbor porpoise groups are small, generally consisting of less than five or six individuals, though for feeding or migration they may aggregate into large, loose groups of 50 to several hundred animals (Halpin, OBIS–SEAMAP 2019). Behavior tends to be inconspicuous, compared to most dolphins, and they feed by seizing prey which consists of wide variety of fish and cephalopods ranging from benthic or demersal (Halpern, OBIS–SEAMAP 2019). Harbor porpoises are sighted year round in the MCR (Griffith 2015). Their abundance peaks with the abundance of anchovy presence in the river and nearshore.

California Sea Lion

California sea lions are found along the west coast from the southern tip of Baja California to southeast Alaska. They breed mainly on offshore islands from Southern California's Channel Islands south to Mexico. Non-breeding males often roam north in spring foraging for food. Since the mid-1980s, increasing numbers of California sea lions have been documented feeding on fish along the Washington coast and—more recently—in the Columbia River as far upstream as Bonneville Dam, 145 mi (233 km) from the river mouth. Large numbers of California sea lions use the nearby South Jetty for hauling out (Jeffries 2000). According to Oregon Department of Fish and Wildlife (ODFW 2014) counts most California sea lions are concentrated near the tip of the South Jetty. ODFW survey information (2007 and 2014) indicates that California sea lions are relatively less prevalent in the Pacific Northwest during June and July, though in the months just before and after their absence there can be several hundred using the South Jetty. More frequent Washington Department of Fish and

Wildlife (WDFW 2014) surveys indicate greater numbers in the summer, and use remains concentrated to fall and winter months. Nearly all California sea lions in the Pacific Northwest are sub-adult and adult males (females and young generally stay in California).

Steller Sea Lion

The range of the Steller sea lion includes the North Pacific Ocean rim from California to northern Japan. Steller sea lions forage in nearshore and pelagic waters where they are opportunistic predators. Steller sea lion populations that primarily occur east of 144° W (Cape Suckling, Alaska) comprise the Eastern Distinct Population Segment (DPS) (Carretta *et al.* 2019).

Large numbers of Steller sea lions use the nearby South Jetty for hauling out (Jeffries 2000) and are present, in varying abundances, all year. Use occurs chiefly at the concrete block structure at the terminus, or head of the jetty. According to ODFW (2014), during the summer months it is not uncommon to observe between 500–1,000 Steller sea lions present per day. Steller sea lions are most abundant in the vicinity during the winter months and tend to disperse elsewhere to rookeries during breeding season between May and July (Corps 2007). All population age classes, and both males and females, use the South Jetty to haul out.

While California sea lions also use this area and can intermingle with Steller sea lions, it appears that Steller out-compete California sea lions for the preferred haul out area. Previous monthly averages between 1995 and 2004 for Steller sea lions hauled out at the South Jetty head ranged from about 168 to 1,106 animals. ODFW data from 2000–2014 reflects a lower frequency of surveys, and numbers ranged from zero animals to 606 Steller sea lions (ODFW 2014). More frequent surveys by WDFW for the same time frame (2000–2014) put the monthly range at 177 to 1,663 animals throughout the year.

Harbor Seal

Harbor seals range from Baja California, north along the western coasts of the United States, British Columbia and southeast Alaska, west through the Gulf of Alaska, Prince William Sound, and the Aleutian Islands, and north in the Bering Sea to

Cape Newenham and the Pribilof Islands. They are one of the most abundant pinnipeds in Oregon and can typically be found in coastal marine and estuarine waters of the Oregon coast throughout the year. On land, they can be found on offshore rocks and islands, along shore, and on exposed flats in the estuary (Harvey 1987). They haul out on rocks, reefs, beaches, and drifting glacial ice and feed in marine, estuarine, and occasionally fresh waters. Harbor seals generally are non-migratory, with local movements associated with tides, weather, season, food availability, and reproduction. Harbor seals do not make extensive pelagic migrations. (Carretta *et al.* 2019)

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Current data indicate that not all marine mammal species have equal hearing capabilities (*e.g.*, Richardson *et al.*, 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007) recommended that marine mammals be divided into functional hearing groups based on directly measured or estimated hearing ranges on the basis of available behavioral response data, audiograms derived using auditory evoked potential techniques, anatomical modeling, and other data. Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.*, low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in Table 3.

TABLE 3—MARINE MAMMAL HEARING GROUPS
[NMFS, 2018]

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

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

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

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information. Seven marine mammal species (three cetacean and three pinniped (two otariid and one phocid) species) have the reasonable potential to co-occur at the time of the proposed survey activities. Please refer to Table 2. Of the cetacean species that may be present, two are classified as low-frequency cetaceans (*i.e.*, all mysticete species), one is classified as a mid-frequency cetacean (*i.e.*, all delphinid and ziphiid species and the sperm whale), and one is classified as a high-frequency cetacean (*i.e.*, harbor porpoise and *Kogia* spp.).

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section includes a summary and discussion of the ways that components of the specified activity may impact marine mammals and their habitat. The *Estimated Take by Incidental Harassment* section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The *Negligible Impact Analysis and Determination* section considers the content of this section, the *Estimated Take by Incidental Harassment* section, and the *Proposed Mitigation* section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and how those impacts on individuals are likely to impact marine mammal species or stocks.

Acoustic effects on marine mammals during the specified activity can occur

from vibratory and impact pile driving as well vibratory pile removal. The effects of underwater noise from the Corps' proposed activities have the potential to result in Level A and Level B harassment of marine mammals in the vicinity of the project area.

Description of Sound Sources

This section contains a brief technical background on sound, on the characteristics of certain sound types, and on metrics used in this proposal inasmuch as the information is relevant to the specified activity and to a discussion of the potential effects of the specified activity on marine mammals found later in this document. For general information on sound and its interaction with the marine environment, please see, *e.g.*, Au and Hastings (2008); Richardson *et al.* (1995); Urick (1983).

Sound travels in waves, the basic components of which are frequency, wavelength, velocity, and amplitude. Frequency is the number of pressure waves that pass by a reference point per unit of time and is measured in hertz (Hz) or cycles per second. Wavelength is the distance between two peaks or corresponding points of a sound wave (length of one cycle). Higher frequency sounds have shorter wavelengths than lower frequency sounds, and typically attenuate (decrease) more rapidly, except in certain cases in shallower water. Amplitude is the height of the sound pressure wave or the "loudness" of a sound and is typically described using the relative unit of the decibel (dB). A sound pressure level (SPL) in dB is described as the ratio between a measured pressure and a reference pressure (for underwater sound, this is 1 microPascal (μPa)), and is a logarithmic unit that accounts for large variations in amplitude; therefore, a relatively small change in dB corresponds to large changes in sound pressure. The source level (SL) represents the SPL referenced at a

distance of 1 m from the source (referenced to 1 μPa), while the received level is the SPL at the listener's position (referenced to 1 μPa).

Root mean square (rms) is the quadratic mean sound pressure over the duration of an impulse. Root mean square is calculated by squaring all of the sound amplitudes, averaging the squares, and then taking the square root of the average (Urick, 1983). Root mean square accounts for both positive and negative values; squaring the pressures makes all values positive so that they may be accounted for in the summation of pressure levels (Hastings and Popper, 2005). This measurement is often used in the context of discussing behavioral effects, in part because behavioral effects, which often result from auditory cues, may be better expressed through averaged units than by peak pressures.

Sound exposure level (SEL; represented as dB re 1 $\mu\text{Pa}^2\text{-s}$) represents the total energy in a stated frequency band over a stated time interval or event, and considers both intensity and duration of exposure. The per-pulse SEL is calculated over the time window containing the entire pulse (*i.e.*, 100 percent of the acoustic energy). SEL is a cumulative metric; it can be accumulated over a single pulse, or calculated over periods containing multiple pulses. Cumulative SEL represents the total energy accumulated by a receiver over a defined time window or during an event. Peak sound pressure (also referred to as zero-to-peak sound pressure or 0-pk) is the maximum instantaneous sound pressure measurable in the water at a specified distance from the source, and is represented in the same units as the rms sound pressure.

When underwater objects vibrate or activity occurs, sound-pressure waves are created. These waves alternately compress and decompress the water as the sound wave travels. Underwater sound waves radiate in a manner similar to ripples on the surface of a pond and

may be either directed in a beam or beams or may radiate in all directions (omnidirectional sources), as is the case for sound produced by the pile driving activity considered here. The compressions and decompressions associated with sound waves are detected as changes in pressure by aquatic life and man-made sound receptors such as hydrophones.

Even in the absence of sound from the specified activity, the underwater environment is typically loud due to ambient sound, which is defined as environmental background sound levels lacking a single source or point (Richardson *et al.*, 1995). The sound level of a region is defined by the total acoustical energy being generated by known and unknown sources. These sources may include physical (e.g., wind and waves, earthquakes, ice, atmospheric sound), biological (e.g., sounds produced by marine mammals, fish, and invertebrates), and anthropogenic (e.g., vessels, dredging, construction) sound. A number of sources contribute to ambient sound, including wind and waves, which are a main source of naturally occurring ambient sound for frequencies between 200 Hz and 50 kilohertz (kHz) (Mitson, 1995). In general, ambient sound levels tend to increase with increasing wind speed and wave height. Precipitation can become an important component of total sound at frequencies above 500 Hz, and possibly down to 100 Hz during quiet times. Marine mammals can contribute significantly to ambient sound levels, as can some fish and snapping shrimp. The frequency band for biological contributions is from approximately 12 Hz to over 100 kHz. Sources of ambient sound related to human activity include transportation (surface vessels), dredging and construction, oil and gas drilling and production, geophysical surveys, sonar, and explosions. Vessel noise typically dominates the total ambient sound for frequencies between 20 and 300 Hz. In general, the frequencies of anthropogenic sounds are below 1 kHz and, if higher frequency sound levels are created, they attenuate rapidly.

The sum of the various natural and anthropogenic sound sources that comprise ambient sound at any given location and time depends not only on the source levels (as determined by current weather conditions and levels of biological and human activity) but also on the ability of sound to propagate through the environment. In turn, sound propagation is dependent on the spatially and temporally varying properties of the water column and sea floor, and is frequency-dependent. As a

result of the dependence on a large number of varying factors, ambient sound levels can be expected to vary widely over both coarse and fine spatial and temporal scales. Sound levels at a given frequency and location can vary by 10–20 dB from day to day (Richardson *et al.*, 1995). The result is that, depending on the source type and its intensity, sound from the specified activity may be a negligible addition to the local environment or could form a distinctive signal that may affect marine mammals.

Sounds are often considered to fall into one of two general types: pulsed and non-pulsed (defined in the following). The distinction between these two sound types is important because they have differing potential to cause physical effects, particularly with regard to hearing (e.g., Ward, 1997 in Southall *et al.*, 2007). Please see Southall *et al.* (2007) for an in-depth discussion of these concepts. The distinction between these two sound types is not always obvious, as certain signals share properties of both pulsed and non-pulsed sounds. A signal near a source could be categorized as a pulse, but due to propagation effects as it moves farther from the source, the signal duration becomes longer (e.g., Greene and Richardson, 1988).

Pulsed sound sources (e.g., airguns, explosions, gunshots, sonic booms, impact pile driving) produce signals that are brief (typically considered to be less than one second), broadband, atonal transients (ANSI, 1986, 2005; Harris, 1998; NIOSH, 1998; ISO, 2003) and occur either as isolated events or repeated in some succession. Pulsed sounds are all characterized by a relatively rapid rise from ambient pressure to a maximal pressure value followed by a rapid decay period that may include a period of diminishing, oscillating maximal and minimal pressures, and generally have an increased capacity to induce physical injury as compared with sounds that lack these features.

Non-pulsed sounds can be tonal, narrowband, or broadband, brief or prolonged, and may be either continuous or intermittent (ANSI, 1995; NIOSH, 1998). Some of these non-pulsed sounds can be transient signals of short duration but without the essential properties of pulses (e.g., rapid rise time). Examples of non-pulsed sounds include those produced by vessels, aircraft, machinery operations such as drilling or dredging, vibratory pile driving, and active sonar systems. The duration of such sounds, as received at a distance, can be greatly

extended in a highly reverberant environment.

The impulsive sound generated by impact hammers is characterized by rapid rise times and high peak levels. Vibratory hammers produce non-impulsive, continuous noise at levels significantly lower than those produced by impact hammers. Rise time is slower, reducing the probability and severity of injury, and sound energy is distributed over a greater amount of time (e.g., Nedwell and Edwards, 2002; Carlson *et al.*, 2005).

Acoustic Effects on Marine Mammals

We previously provided general background information on marine mammal hearing (see “Description of Marine Mammals in the Area of the Specified Activity”). Here, we discuss the potential effects of sound on marine mammals.

Note that, in the following discussion, we refer in many cases to a review article concerning studies of noise-induced hearing loss conducted from 1996–2015 (i.e., Finneran, 2015). For study-specific citations, please see that work. Anthropogenic sounds cover a broad range of frequencies and sound levels and can have a range of highly variable impacts on marine life, from none or minor to potentially severe responses, depending on received levels, duration of exposure, behavioral context, and various other factors. The potential effects of underwater sound from active acoustic sources can potentially result in one or more of the following: temporary or permanent hearing impairment, non-auditory physical or physiological effects, behavioral disturbance, stress, and masking (Richardson *et al.*, 1995; Gordon *et al.*, 2004; Nowacek *et al.*, 2007; Southall *et al.*, 2007; Götz *et al.*, 2009). The degree of effect is intrinsically related to the signal characteristics, received level, distance from the source, and duration of the sound exposure. In general, sudden, high level sounds can cause hearing loss, as can longer exposures to lower level sounds. Temporary or permanent loss of hearing will occur almost exclusively for noise within an animal's hearing range. We first describe specific manifestations of acoustic effects before providing discussion specific to pile driving and removal activities.

Richardson *et al.* (1995) described zones of increasing intensity of effect that might be expected to occur, in relation to distance from a source and assuming that the signal is within an animal's hearing range. First is the area within which the acoustic signal would be audible (potentially perceived) to the

animal but not strong enough to elicit any overt behavioral or physiological response. The next zone corresponds with the area where the signal is audible to the animal and of sufficient intensity to elicit behavioral or physiological responsiveness. Third is a zone within which, for signals of high intensity, the received level is sufficient to potentially cause discomfort or tissue damage to auditory or other systems. Overlaying these zones to a certain extent is the area within which masking (*i.e.*, when a sound interferes with or masks the ability of an animal to detect a signal of interest that is above the absolute hearing threshold) may occur; the masking zone may be highly variable in size.

We describe the more severe effects (*i.e.*, certain non-auditory physical or physiological effects) only briefly as we do not expect that there is a reasonable likelihood that pile driving may result in such effects (see below for further discussion). Potential effects from explosive impulsive sound sources can range in severity from effects such as behavioral disturbance or tactile perception to physical discomfort, slight injury of the internal organs and the auditory system, or mortality (Yelverton *et al.*, 1973). Non-auditory physiological effects or injuries that theoretically might occur in marine mammals exposed to high level underwater sound or as a secondary effect of extreme behavioral reactions (*e.g.*, change in dive profile as a result of an avoidance reaction) caused by exposure to sound include neurological effects, bubble formation, resonance effects, and other types of organ or tissue damage (Cox *et al.*, 2006; Southall *et al.*, 2007; Zimmer and Tyack, 2007). The construction activities considered here do not involve the use of devices such as explosives or mid-frequency tactical sonar that are associated with these types of effects.

Threshold Shift—Marine mammals exposed to high-intensity sound, or to lower-intensity sound for prolonged periods, can experience hearing threshold shift (TS), which is the loss of hearing sensitivity at certain frequency ranges (Finneran, 2015). TS can be permanent (PTS), in which case the loss of hearing sensitivity is not fully recoverable, or temporary (TTS), in which case the animal's hearing threshold would recover over time (Southall *et al.*, 2007). Repeated sound exposure that leads to TTS could cause PTS. In severe cases of PTS, there can be total or partial deafness, while in most cases the animal has an impaired ability to hear sounds in specific frequency ranges (Kryter, 1985).

When PTS occurs, there is physical damage to the sound receptors in the ear (*i.e.*, tissue damage), whereas TTS represents primarily tissue fatigue and is reversible (Southall *et al.*, 2007). In addition, other investigators have suggested that TTS is within the normal bounds of physiological variability and tolerance and does not represent physical injury (*e.g.*, Ward, 1997). Therefore, NMFS does not consider TTS to constitute auditory injury.

Relationships between TTS and PTS thresholds have not been studied in marine mammals, and there is no PTS data for cetaceans, but such relationships are assumed to be similar to those in humans and other terrestrial mammals. PTS typically occurs at exposure levels at least several decibels above (a 40-dB threshold shift approximates PTS onset; *e.g.*, Kryter *et al.*, 1966; Miller, 1974) that inducing mild TTS (a 6-dB threshold shift approximates TTS onset; *e.g.*, Southall *et al.*, 2007). Based on data from terrestrial mammals, a precautionary assumption is that the PTS thresholds for impulse sounds (such as impact pile driving pulses as received close to the source) are at least 6 dB higher than the TTS threshold on a peak-pressure basis and PTS cumulative sound exposure level thresholds are 15 to 20 dB higher than TTS cumulative sound exposure level thresholds (Southall *et al.*, 2007). Given the higher level of sound or longer exposure duration necessary to cause PTS as compared with TTS, it is considerably less likely that PTS could occur.

TTS is the mildest form of hearing impairment that can occur during exposure to sound (Kryter, 1985). While experiencing TTS, the hearing threshold rises, and a sound must be at a higher level in order to be heard. In terrestrial and marine mammals, TTS can last from minutes or hours to days (in cases of strong TTS). In many cases, hearing sensitivity recovers rapidly after exposure to the sound ends. Few data on sound levels and durations necessary to elicit mild TTS have been obtained for marine mammals.

Marine mammal hearing plays a critical role in communication with conspecifics, and interpretation of environmental cues for purposes such as predator avoidance and prey capture. Depending on the degree (elevation of threshold in dB), duration (*i.e.*, recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious. For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS

in a non-critical frequency range that occurs during a time where ambient noise is lower and there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during time when communication is critical for successful mother/calf interactions could have more serious impacts.

Currently, TTS data only exist for four species of cetaceans (bottlenose dolphin (*Tursiops truncatus*), beluga whale (*Delphinapterus leucas*), harbor porpoise, and Yangtze finless porpoise (*Neophocoena asiaticaorientalis*)) and three species of pinnipeds (northern elephant seal, harbor seal, and California sea lion) exposed to a limited number of sound sources (*i.e.*, mostly tones and octave-band noise) in laboratory settings (Finneran, 2015). TTS was not observed in trained spotted (*Phoca largha*) and ringed (*Pusa hispida*) seals exposed to impulsive noise at levels matching previous predictions of TTS onset (Reichmuth *et al.*, 2016). In general, harbor seals and harbor porpoises have a lower TTS onset than other measured pinniped or cetacean species (Finneran, 2015). Additionally, the existing marine mammal TTS data come from a limited number of individuals within these species. There are no data available on noise-induced hearing loss for mysticetes. For summaries of data on TTS in marine mammals or for further discussion of TTS onset thresholds, please see Southall *et al.* (2007), Finneran and Jenkins (2012), Finneran (2015), and NMFS (2018).

Behavioral Effects—Behavioral disturbance may include a variety of effects, including subtle changes in behavior (*e.g.*, minor or brief avoidance of an area or changes in vocalizations), more conspicuous changes in similar behavioral activities, and more sustained and/or potentially severe reactions, such as displacement from or abandonment of high-quality habitat. Behavioral responses to sound are highly variable and context-specific and any reactions depend on numerous intrinsic and extrinsic factors (*e.g.*, species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day), as well as the interplay between factors (*e.g.*, Richardson *et al.*, 1995; Wartzok *et al.*, 2003; Southall *et al.*, 2007; Weilgart, 2007; Archer *et al.*, 2010). Behavioral reactions can vary not only among individuals but also within an individual, depending on previous experience with a sound source, context, and numerous other factors (Ellison *et al.*, 2012), and can vary depending on characteristics associated

with the sound source (e.g., whether it is moving or stationary, number of sources, distance from the source). Please see Appendices B–C of Southall *et al.* (2007) for a review of studies involving marine mammal behavioral responses to sound.

Habituation can occur when an animal's response to a stimulus wanes with repeated exposure, usually in the absence of unpleasant associated events (Wartzok *et al.*, 2003). Animals are most likely to habituate to sounds that are predictable and unvarying. It is important to note that habituation is appropriately considered as a "progressive reduction in response to stimuli that are perceived as neither aversive nor beneficial," rather than as, more generally, moderation in response to human disturbance (Bejder *et al.*, 2009). The opposite process is sensitization, when an unpleasant experience leads to subsequent responses, often in the form of avoidance, at a lower level of exposure. As noted, behavioral state may affect the type of response. For example, animals that are resting may show greater behavioral change in response to disturbing sound levels than animals that are highly motivated to remain in an area for feeding (Richardson *et al.*, 1995; NRC, 2003; Wartzok *et al.*, 2003). Controlled experiments with captive marine mammals have showed pronounced behavioral reactions, including avoidance of loud sound sources (Ridgway *et al.*, 1997; Finneran *et al.*, 2003). Observed responses of wild marine mammals to loud pulsed sound sources (typically airguns or acoustic harassment devices) have been varied but often consist of avoidance behavior or other behavioral changes suggesting discomfort (Morton and Symonds, 2002; see also Richardson *et al.*, 1995; Nowacek *et al.*, 2007). However, many delphinids approach low-frequency airgun source vessels with no apparent discomfort or obvious behavioral change (e.g., Barkaszi *et al.*, 2012), indicating the importance of frequency output in relation to the species' hearing sensitivity.

Available studies show wide variation in response to underwater sound; therefore, it is difficult to predict specifically how any given sound in a particular instance might affect marine mammals perceiving the signal. If a marine mammal does react briefly to an underwater sound by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, *let alone* the stock or population. However, if a sound source displaces marine mammals from an important feeding or

breeding area for a prolonged period, impacts on individuals and populations could be significant (e.g., Lusseau and Bejder, 2007; Weilgart, 2007; NRC, 2005). However, there are broad categories of potential response, which we describe in greater detail here, that include alteration of dive behavior, alteration of foraging behavior, effects to breathing, interference with or alteration of vocalization, avoidance, and flight.

Changes in dive behavior can vary widely and may consist of increased or decreased dive times and surface intervals as well as changes in the rates of ascent and descent during a dive (e.g., Frankel and Clark, 2000; Costa *et al.*, 2003; Ng and Leung, 2003; Nowacek *et al.*, 2004; Goldbogen *et al.*, 2013a, 2013b). Variations in dive behavior may reflect interruptions in biologically significant activities (e.g., foraging) or they may be of little biological significance. The impact of an alteration to dive behavior resulting from an acoustic exposure depends on what the animal is doing at the time of the exposure and the type and magnitude of the response.

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

Variations in respiration naturally vary with different behaviors and alterations to breathing rate as a function of acoustic exposure can be expected to co-occur with other behavioral reactions, such as a flight response or an alteration in diving. However, respiration rates in and of themselves may be representative of annoyance or an acute stress response. Various studies have shown that respiration rates may either be unaffected or could increase, depending on the species and signal characteristics, again highlighting the importance in

understanding species differences in the tolerance of underwater noise when determining the potential for impacts resulting from anthropogenic sound exposure (e.g., Kastelein *et al.*, 2001, 2005, 2006; Gailey *et al.*, 2007).

Marine mammals vocalize for different purposes and across multiple modes, such as whistling, echolocation click production, calling, and singing. Changes in vocalization behavior in response to anthropogenic noise can occur for any of these modes and may result from a need to compete with an increase in background noise or may reflect increased vigilance or a startle response. For example, in the presence of potentially masking signals, humpback whales and killer whales have been observed to increase the length of their songs (Miller *et al.*, 2000; Fristrup *et al.*, 2003; Foote *et al.*, 2004), while right whales have been observed to shift the frequency content of their calls upward while reducing the rate of calling in areas of increased anthropogenic noise (Parks *et al.*, 2007). In some cases, animals may cease sound production during production of aversive signals (Bowles *et al.*, 1994).

Avoidance is the displacement of an individual from an area or migration path as a result of the presence of a sound or other stressors, and is one of the most obvious manifestations of disturbance in marine mammals (Richardson *et al.*, 1995). For example, gray whales are known to change direction—deflecting from customary migratory paths—in order to avoid noise from airgun surveys (Malme *et al.*, 1984). Avoidance may be short-term, with animals returning to the area once the noise has ceased (e.g., Bowles *et al.*, 1994; Goold, 1996; Stone *et al.*, 2000; Morton and Symonds, 2002; Gailey *et al.*, 2007). Longer-term displacement is possible, however, which may lead to changes in abundance or distribution patterns of the affected species in the affected region if habituation to the presence of the sound does not occur (e.g., Blackwell *et al.*, 2004; Bejder *et al.*, 2006; Teilmann *et al.*, 2006).

A flight response is a dramatic change in normal movement to a directed and rapid movement away from the perceived location of a sound source. The flight response differs from other avoidance responses in the intensity of the response (e.g., directed movement, rate of travel). Relatively little information on flight responses of marine mammals to anthropogenic signals exist, although observations of flight responses to the presence of predators have occurred (Connor and Heithaus, 1996). The result of a flight response could range from brief,

temporary exertion and displacement from the area where the signal provokes flight to, in extreme cases, marine mammal strandings (Evans and England, 2001). However, it should be noted that response to a perceived predator does not necessarily invoke flight (Ford and Reeves, 2008), and whether individuals are solitary or in groups may influence the response.

Behavioral disturbance can also impact marine mammals in more subtle ways. Increased vigilance may result in costs related to diversion of focus and attention (*i.e.*, when a response consists of increased vigilance, it may come at the cost of decreased attention to other critical behaviors such as foraging or resting). These effects have generally not been demonstrated for marine mammals, but studies involving fish and terrestrial animals have shown that increased vigilance may substantially reduce feeding rates (*e.g.*, Beauchamp and Livoreil, 1997; Fritz *et al.*, 2002; Purser and Radford, 2011). In addition, chronic disturbance can cause population declines through reduction of fitness (*e.g.*, decline in body condition) and subsequent reduction in reproductive success, survival, or both (*e.g.*, Harrington and Veitch, 1992; Daan *et al.*, 1996). However, Ridgway *et al.* (2006) reported that increased vigilance in bottlenose dolphins exposed to sound over a five-day period did not cause any sleep deprivation or stress effects.

Many animals perform vital functions, such as feeding, resting, traveling, and socializing, on a diel cycle (24-hour cycle). Disruption of such functions resulting from reactions to stressors such as sound exposure are more likely to be significant if they last more than one diel cycle or recur on subsequent days (Southall *et al.*, 2007). Consequently, a behavioral response lasting less than one day and not recurring on subsequent days is not considered particularly severe unless it could directly affect reproduction or survival (Southall *et al.*, 2007). Note that there is a difference between multi-day substantive behavioral reactions and multi-day anthropogenic activities. For example, just because an activity lasts for multiple days does not necessarily mean that individual animals are either exposed to activity-related stressors for multiple days or, further, exposed in a manner resulting in sustained multi-day substantive behavioral responses.

Stress Responses—An animal's perception of a threat may be sufficient to trigger stress responses consisting of some combination of behavioral responses, autonomic nervous system responses, neuroendocrine responses, or immune responses (*e.g.*, Seyle, 1950;

Moberg, 2000). In many cases, an animal's first and sometimes most economical (in terms of energetic costs) response is behavioral avoidance of the potential stressor. Autonomic nervous system responses to stress typically involve changes in heart rate, blood pressure, and gastrointestinal activity. These responses have a relatively short duration and may or may not have a significant long-term effect on an animal's fitness.

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

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

Relationships between these physiological mechanisms, animal behavior, and the costs of stress responses are well-studied through controlled experiments and for both laboratory and free-ranging animals (*e.g.*, Holberton *et al.*, 1996; Hood *et al.*, 1998; Jessop *et al.*, 2003; Krausman *et al.*, 2004; Lankford *et al.*, 2005). Stress responses due to exposure to anthropogenic sounds or other stressors and their effects on marine mammals have also been reviewed (Fair and Becker, 2000; Romano *et al.*, 2002b) and, more rarely, studied in wild populations (*e.g.*, Romano *et al.*, 2002a). For example, Rolland *et al.* (2012) found that noise reduction from reduced ship traffic in the Bay of Fundy was associated with decreased stress in North Atlantic right whales. These and other studies lead to a reasonable expectation that some marine mammals

will experience physiological stress responses upon exposure to acoustic stressors and that it is possible that some of these would be classified as "distress." In addition, any animal experiencing TTS would likely also experience stress responses (NRC, 2003).

Auditory Masking—Sound can disrupt behavior through masking, or interfering with, an animal's ability to detect, recognize, or discriminate between acoustic signals of interest (*e.g.*, those used for intraspecific communication and social interactions, prey detection, predator avoidance, navigation) (Richardson *et al.*, 1995; Erbe *et al.*, 2016). Masking occurs when the receipt of a sound is interfered with by another coincident sound at similar frequencies and at similar or higher intensity, and may occur whether the sound is natural (*e.g.*, snapping shrimp, wind, waves, precipitation) or anthropogenic (*e.g.*, shipping, sonar, seismic exploration) in origin. The ability of a noise source to mask biologically important sounds depends on the characteristics of both the noise source and the signal of interest (*e.g.*, signal-to-noise ratio, temporal variability, direction), in relation to each other and to an animal's hearing abilities (*e.g.*, sensitivity, frequency range, critical ratios, frequency discrimination, directional discrimination, age or TTS hearing loss), and existing ambient noise and propagation conditions.

Under certain circumstances, marine mammals experiencing significant masking could also be impaired from maximizing their performance fitness in survival and reproduction. Therefore, when the coincident (masking) sound is man-made, it may be considered harassment when disrupting or altering critical behaviors. It is important to distinguish TTS and PTS, which persist after the sound exposure, from masking, which occurs during the sound exposure. Because masking (without resulting in TS) is not associated with abnormal physiological function, it is not considered a physiological effect, but rather a potential behavioral effect.

The frequency range of the potentially masking sound is important in determining any potential behavioral impacts. For example, low-frequency signals may have less effect on high-frequency echolocation sounds produced by odontocetes but are more likely to affect detection of mysticete communication calls and other potentially important natural sounds such as those produced by surf and some prey species. The masking of communication signals by

anthropogenic noise may be considered as a reduction in the communication space of animals (e.g., Clark *et al.*, 2009) and may result in energetic or other costs as animals change their vocalization behavior (e.g., Miller *et al.*, 2000; Foote *et al.*, 2004; Parks *et al.*, 2007; Di Iorio and Clark, 2009). Masking can be reduced in situations where the signal and noise come from different directions (Richardson *et al.*, 1995), through amplitude modulation of the signal, or through other compensatory behaviors (Houser and Moore, 2014). Masking can be tested directly in captive species (e.g., Erbe, 2008), but in wild populations it must be either modeled or inferred from evidence of masking compensation. There are few studies addressing real-world masking sounds likely to be experienced by marine mammals in the wild (e.g., Branstetter *et al.*, 2013).

Masking affects both senders and receivers of acoustic signals and can potentially have long-term chronic effects on marine mammals at the population level as well as at the individual level. Low-frequency ambient sound levels have increased by as much as 20 dB (more than three times in terms of SPL) in the world's ocean from pre-industrial periods, with most of the increase from distant commercial shipping (Hildebrand, 2009). All anthropogenic sound sources, but especially chronic and lower-frequency signals (e.g., from vessel traffic), contribute to elevated ambient sound levels, thus intensifying masking.

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

Airborne noise would primarily be an issue for pinnipeds that are swimming or hauled out near the project site within the range of noise levels elevated above the acoustic criteria. We recognize that pinnipeds in the water could be exposed to airborne sound that may result in behavioral harassment when looking with their heads above water. Most likely, airborne sound would cause behavioral responses similar to those discussed above in relation to underwater sound. For instance, anthropogenic sound could cause hauled out pinnipeds to exhibit changes in their normal behavior, such as reduction in vocalizations, or cause them to temporarily abandon the area

and move further from the source. However, these animals would previously have been 'taken' because of exposure to underwater sound above the behavioral harassment thresholds, which are in all cases larger than those associated with airborne sound. Thus, the behavioral harassment of these animals is already accounted for in these estimates of potential take. Therefore, we do not believe that authorization of incidental take resulting from airborne sound for pinnipeds is warranted, and airborne sound is not discussed further here.

Potential Effects of the Corps' Proposed Activity—As described previously (see "Description of Active Acoustic Sound Sources"), the Corps proposes to conduct impact and vibratory driving as well as vibratory removal. The effects of pile driving on marine mammals are dependent on several factors, including the size, type, and depth of the animal; the depth, intensity, and duration of the pile driving sound; the depth of the water column; the substrate of the habitat; the standoff distance between the pile and the animal; and the sound propagation properties of the environment. With both types, it is likely that the pile driving could result in temporary, short term changes in an animal's typical behavioral patterns and/or avoidance of the affected area. These behavioral changes may include (Richardson *et al.*, 1995): Changing durations of surfacing and dives, number of blows per surfacing, or moving direction and/or speed; reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); visible startle response or aggressive behavior (such as tail/fluke slapping or jaw clapping); avoidance of areas where sound sources are located; and/or flight responses.

The biological significance of many of these behavioral disturbances is difficult to predict, especially if the detected disturbances appear minor. However, the consequences of behavioral modification could be expected to be biologically significant if the change affects growth, survival, or reproduction. Significant behavioral modifications that could lead to effects on growth, survival, or reproduction, such as drastic changes in diving/surfacing patterns or significant habitat abandonment are extremely unlikely in this area (*i.e.*, relatively shallow waters in an area with considerable vessel traffic).

Whether impact or vibratory driving, sound sources would be active for relatively short durations, with relation to potential for masking. The

frequencies output by pile driving activity are lower than those used by most species expected to be regularly present for communication or foraging. We expect insignificant impacts from masking, and any masking event that could possibly rise to Level B harassment under the MMPA would occur concurrently within the zones of behavioral harassment already estimated for vibratory and impact pile driving, and which have already been taken into account in the exposure analysis.

Anticipated Effects on Marine Mammal Habitat

The proposed activities would not result in permanent impacts to habitats used directly by marine mammals except the actual footprint of the project. The footprint of the project covers a small section of the Sand Island Pile Dike system.

The proposed activities may have potential short-term impacts to food sources such as forage fish. The proposed activities could also affect acoustic habitat (see masking discussion above), but meaningful impacts are unlikely. There are no known foraging hotspots, or other ocean bottom structures of significant biological importance to marine mammals present in the marine waters in the vicinity of the project areas. Therefore, the main impact issue associated with the proposed activity would be temporarily elevated sound levels and the associated direct effects on marine mammals, as discussed previously. The most likely impact to marine mammal habitat occurs from pile driving effects on likely marine mammal prey (*i.e.*, fish) near where the piles are installed. Impacts to the immediate substrate during installation and removal of piles would be minor since piles would be driven through existing enrockment structures. This could result in limited, temporary suspension of sediments, which could impact water quality and visibility for a short amount of time, but which would not be expected to have any effects on individual marine mammals. Impacts to substrate are therefore not discussed further.

Effects to Prey—Sound may affect marine mammals through impacts on the abundance, behavior, or distribution of prey species (e.g., crustaceans, cephalopods, fish, zooplankton). Marine mammal prey varies by species, season, and location and, for some, is not well documented. Here, we describe studies regarding the effects of noise on known marine mammal prey.

Fish utilize the soundscape and components of sound in their

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

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

SPLs of sufficient strength have been known to cause injury to fish and fish mortality. However, in most fish species, hair cells in the ear continuously regenerate and loss of auditory function likely is restored when damaged cells are replaced with new cells. Halvorsen *et al.* (2012a) showed that a TTS of 4–6 dB was recoverable within 24 hours for one species. Impacts would be most severe when the individual fish is close to the source and when the duration of

exposure is long. Injury caused by barotrauma can range from slight to severe and can cause death, and is most likely for fish with swim bladders. Barotrauma injuries have been documented during controlled exposure to impact pile driving (Halvorsen *et al.*, 2012b; Casper *et al.*, 2013).

The most likely impact to fish from pile driving activities at the project areas would be temporary behavioral avoidance of the area. The duration of fish avoidance of an area after pile driving stops is unknown, but a rapid return to normal recruitment, distribution and behavior is anticipated. In general, impacts to marine mammal prey species are expected to be minor and temporary due to the expected short daily duration of individual pile driving events and the relatively small areas being affected.

In summary, given the short duration of sound (5–60 minutes) associated with individual pile driving and removal events and the small area being affected relative to available nearby habitat, pile driving and removal activities associated with the proposed action are not likely to have a permanent, adverse effect on any fish habitat, or populations of fish species or other prey. Thus, we conclude that impacts of the specified activity are not likely to have more than short-term adverse effects on any prey habitat or populations of prey species. Further, any impacts to marine mammal habitat are not expected to result in significant or long-term consequences for individual marine mammals, or to contribute to adverse impacts on their populations.

The area impacted by the project is relatively small compared to the available habitat in the MCR area. Any behavioral avoidance by fish of the disturbed area would still leave significantly large areas of fish and marine mammal foraging habitat in the nearby vicinity. As described in the preceding, the potential for the Corps' construction to affect the availability of prey to marine mammals or to meaningfully impact the quality of physical or acoustic habitat is considered to be insignificant. Effects to habitat will not be discussed further in this document.

Estimated Take

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

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities

not pertinent here, section 3(18) of the MMPA defines "harassment" as any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes would primarily be by Level B harassment, as impact and vibratory pile driving has the potential to result in disruption of behavioral patterns for individual marine mammals. There is also some potential for auditory injury (Level A harassment) to result, primarily for high frequency species and phocids because predicted auditory injury zones are larger than for low-frequency species, mid-frequency species and otariids. Auditory injury is unlikely to occur for low-frequency species, mid-frequency species and otariids. The proposed mitigation and monitoring measures are expected to minimize the severity of such taking to the extent practicable.

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

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

Acoustic Thresholds

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

Level B Harassment for non-explosive sources—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source (*e.g.*, frequency, predictability, duty cycle), the environment (*e.g.*, bathymetry), and the receiving animals (hearing, motivation, experience, demography, behavioral context) and can be difficult to predict (Southall *et al.*, 2007, Ellison *et al.*, 2012). Based on what the available science indicates and the practical need to use a threshold based on a factor that is both predictable and measurable for most activities, NMFS uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS predicts that marine

mammals are likely to be behaviorally harassed in a manner we consider Level B harassment when exposed to underwater anthropogenic noise above received levels of 120 dB re 1 μ Pa (rms) for continuous (*e.g.*, vibratory pile-driving, drilling) and above 160 dB re 1 μ Pa (rms) for non-explosive impulsive (*e.g.*, seismic airguns) or intermittent (*e.g.*, scientific sonar) sources.

The Corps' proposed activity includes the use of continuous (vibratory pile driving) and impulsive (impact pile driving) sources, and therefore the 120 and 160 dB re 1 μ Pa (rms) are applicable.

Level A harassment for non-explosive sources—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0)

(Technical Guidance, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). The Corp's proposed activity includes the use of impulsive (impact pile driving) and non-impulsive (vibratory pile driving) source.

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

TABLE 4—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT

Hearing group	PTS onset acoustic thresholds* (Received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	Cell 1: $L_{pk,flat}$: 219 dB; $L_E,LF,24h$: 183 dB	Cell 2: $L_E,LF,24h$: 199 dB.
Mid-Frequency (MF) Cetaceans	Cell 3: $L_{pk,flat}$: 230 dB; $L_E,MF,24h$: 185 dB	Cell 4: $L_E,MF,24h$: 198 dB.
High-Frequency (HF) Cetaceans	Cell 5: $L_{pk,flat}$: 202 dB; $L_E,HF,24h$: 155 dB	Cell 6: $L_E,HF,24h$: 173 dB.
Phocid Pinnipeds (PW) (Underwater)	Cell 7: $L_{pk,flat}$: 218 dB; $L_E,PW,24h$: 185 dB	Cell 8: $L_E,PW,24h$: 201 dB.
Otariid Pinnipeds (OW) (Underwater)	Cell 9: $L_{pk,flat}$: 232 dB; $L_E,OW,24h$: 203 dB	Cell 10: $L_E,OW,24h$: 219 dB.

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

Note: Peak sound pressure (L_{pk}) has a reference value of 1 μ Pa, and cumulative sound exposure level (L_E) has a reference value of 1 μ Pa²s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript "flat" is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.*, varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that will feed into identifying the area ensonified above the acoustic thresholds, which include source levels and transmission loss coefficient.

Sound Propagation

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

$$TL = B * \log_{10} (R_1/R_2),$$

where:

B = transmission loss coefficient (assumed to be 15)

R_1 = the distance of the modeled SPL from the driven pile, and
 R_2 = the distance from the driven pile of the initial measurement.

This formula neglects loss due to scattering and absorption, which is assumed to be zero here. The degree to which underwater sound propagates away from a sound source is dependent on a variety of factors, most notably the water bathymetry and presence or absence of reflective or absorptive conditions including in-water structures and sediments. Spherical spreading occurs in a perfectly unobstructed (free-field) environment not limited by depth or water surface, resulting in a 6 dB reduction in sound level for each doubling of distance from the source ($20 * \log(\text{range})$). Cylindrical spreading occurs in an environment in which sound propagation is bounded by the water surface and sea bottom, resulting in a reduction of 3 dB in sound level for

each doubling of distance from the source ($10 * \log(\text{range})$). As is common practice in coastal waters, here we assume practical spreading loss (4.5 dB reduction in sound level for each doubling of distance). Practical spreading is a compromise that is often used under conditions where water depth increases as the receiver moves away from the shoreline, resulting in an expected propagation environment that would lie between spherical and cylindrical spreading loss conditions.

Sound Source Levels

The intensity of pile driving sounds is greatly influenced by factors such as the type of piles, hammers, and the physical environment in which the activity takes place. There are no source level measurements available for the piles proposed for installation at part of the test piles project. Sound pressure levels for impact driving of 24-in steel piles

were taken from Caltrans 2015. Vibratory driving source levels for 24-in steel piles came from the United States Navy (2015). There was no data available pertaining to vibratory removal of 24-in timber piles. NMFS recommended that the Corps use data derived from Washington Department of Transportation Seattle Pier 62 project collected by the Greenbusch Group

(2018) for vibratory removal of 14-in timber piles. NMFS reviewed the Greenbusch Group (2018) report and determined that the findings were incorrectly derived by pooling together all steel pile and timber pile measurements at various distances. Furthermore, the data was not normalized to the standard 10 m distance. NMFS analyzed source

measurements at different distances for all 63 individual timber piles that were removed and normalized the values to 10 m. The results showed that the median is 152 dB SPLrms. This value was used as the proxy source level for vibratory removal of 24-in timber piles as shown in Table 5.

TABLE 5—ESTIMATED UNATTENUATED UNDERWATER SOUND PRESSURE LEVELS ASSOCIATED WITH PILE INSTALLATION AND REMOVAL

Pile type & activity	Sound source level at 10 m		
24-Inch Steel Pile Impact Installation ¹	203 dB _{PK}	190 dB _{RMS}	177 dB _{SEL}
24-Inch Steel Piles Vibratory Installation/Removal ²	Not Available	161 dB _{RMS}	Not Available.
24-Inch Timber Pile Vibratory Removal ³	Not Available	152 dB _{RMS}	Not Available.

¹ From CalTrans 2015 Table I.2–1. Summary of Near-Source (10-Meter) Unattenuated Sound Pressure Levels for In-Water Pile Driving Using an Impact Hammer: 0.61-meter (24-inch) steel pipe pile in water ~5 meters deep.

² From United States Navy. 2015. Prepared by Michael Slater, Naval Surface Warfare Center, Carderock Division, and Sharon Rainsberry, Naval Facilities Engineering Command Northwest. Revised January 2015. Table 2–2.

³ Due to the lack of information for vibratory removal of 24" diameter timber piles, an estimate based on removal of 14-inch timber piles is used as a proxy (Greenbusch Group, 2018)

Level A Harassment

When the NMFS Technical Guidance (2016) was published, in recognition of the fact that ensonified area/volume could be more technically challenging to predict because of the duration component in the new thresholds, we developed a User Spreadsheet that includes tools to help predict a simple isopleth that can be used in conjunction with marine mammal density or

occurrence to help predict takes. We note that because of some of the assumptions included in the methods used for these tools, we anticipate that isopleths produced are typically going to be overestimates of some degree, which may result in some degree of overestimate of Level A harassment take. However, these tools offer the best way to predict appropriate isopleths when more sophisticated 3D modeling methods are not available, and NMFS

continues to develop ways to quantitatively refine these tools, and will qualitatively address the output where appropriate. For stationary sources such as pile driving, NMFS User Spreadsheet predicts the closest distance at which, if a marine mammal remained at that distance the whole duration of the activity, it would not incur PTS. Inputs used in the User Spreadsheet, and the resulting isopleths are reported below in Table 6.

TABLE 6—NMFS TECHNICAL GUIDANCE (2018) USER SPREADSHEET INPUT TO CALCULATE PTS ISOPLETHS

Inputs	24-in steel impact installation	24-in steel vibratory installation/removal	24-in timber pile removal
Spreadsheet Tab Used	E. (1) Impact Pile Driving ..	A. (1) Vibratory Pile Driving	A. (1) Vibratory Pile Driving.
Source Level (Single Strike/shot SEL)	177 dB SEL/203 dB Peak	161 dB RMS	152 dB RMS
Weighting Factor Adjustment (kHz)	2	2.5	2.5
Number of strikes per pile	550	6	6
Number of piles per day	60	30/5	5
Duration to install/removal single pile (minutes)	15	15	15
Propagation (xLogR)	10	10	10
Distance of source level measurement (meters)			

TABLE 7—LEVEL A HARASSMENT (PTS) ISOPLETHS

Activity	PTS Isopleth distance (meters)				
	LF cetacean	MF cetacean	HF cetacean	Phocid pinniped	Otariid pinniped
24" Steel Pipe Pile Impact Installation	881.2	31.3	1,049.7	* 471.6	34.3
24" Steel Pipe Vibratory Installation	14.2	1.3	21.0	8.6	0.6
24" Steel Pipe Vibratory Removal	5.6	0.5	8.3	3.4	0.2
24" Timber Pile Removal Vibratory	1.4	0.1	2.1	0.9	0.1

Level B Harassment

Utilizing the practical spreading loss model, the Corps determined

underwater noise will fall below the behavioral effects threshold of 160 dB and 120 dB rms for marine mammals at

the distances shown in Table 8 with corresponding ensonified areas.

TABLE 8—LEVEL B HARASSMENT ISOPLETHS

Activity	Isopleth distance (m)	Isopleth area (km ²) *
24" Steel Pipe Pile Impact Installation	1,000	3–4
24" Steel Pipe Vibratory Installation	5,412	64–73
24" Steel Pipe Vibratory Removal	5,412	64–73
24" Timber Pile Removal Vibratory	1,359	0.6–0.7

* The lower limit represents the isopleth area for the pile dike at RM 4.01, which has a slightly smaller area due to land impedances. The upper limit of the range is the calculated isopleth area for the pile dike at RM 6.37.

Marine Mammal Occurrence and Take Calculation and Estimation

In this section we provide the information about the presence, density, or group dynamics of marine mammals that will inform the take calculations. Potential exposures to impact pile driving, vibratory pile driving and vibratory pile removal were estimated using group size estimates and local observational data. As previously stated, take by Level B harassment as well as small numbers of take by Level A harassment will be considered for this action. Take by Level B and Level A harassment are calculated differently for some species based on monthly or daily sightings data and average group sizes within the action area using the best available data. Take by Level A harassment is being proposed for two species where the Level A harassment isopleths are very large during impact pile driving (harbor porpoise and harbor seal). Distances to Level A harassment thresholds for other project activities (vibratory pile driving/removal) are considerably smaller compared to impact pile driving, and mitigation is expected to avoid Level A harassment from these other activities.

*Cetaceans**Harbor Porpoise*

Harbor porpoises are regularly observed in the oceanward waters near the MCR and are known to occur there year-round. Porpoise abundance peaks when anchovy (*Engraulis mordax*) abundance in the river and nearshore are highest, which is usually between April and August (Litz *et al.* 2008). The 2016 monitoring report indicated that there were sightings of a total of 6 porpoises during 5 sighting events (Grette Associates, 2016) while none were recorded as part of the 2017 LOA

monitoring report. All of the porpoises described in the 2016 report were solitary except for one pod of two animals. While porpoises generally occur in groups of 2–3 or larger, most sightings contained in the report were of solitary animals. Therefore, for the purposes of this proposed IHA, NMFS will conservatively assume a sighting rate of one animal per day.

There are 3 days of vibratory removal of timber piles so we will assume all sightings are equivalent to takes by Level B harassment. Both impact and vibratory driving will occur on 18 days. We will assume all of these are by Level B harassment due to the larger Level B monitoring zone during vibratory driving activities. Due to their cryptic behavior, it is plausible that during the 20 days of impact only driving porpoises could enter into the shutdown zone without being detected by PSOs and remain long enough to experience PTS. NMFS will assume that a smaller subset of the 20 expected animals (one per day) will enter into the PTS zone for a period of time that would result in PTS. We will conservatively assume that every other day an animal would enter into the PTS zone. Therefore, NMFS proposes to authorize 10 takes of harbor porpoise by Level A harassment and 21 takes by Level B harassment.

Pinnipeds

Take calculations for Steller sea lions, California sea lions, and harbor seals are estimated using abundance estimates from the South Jetty recorded by the Washington Department of Fish and Wildlife (WDFW) between 2000 and 2014. The South Jetty is approximately four kilometers to the south of Sand Island. The Level B harassment area includes the entirety of the South Jetty where pinnipeds haul out. In order to estimate take, the average number of

animals seen for the months of September, October, and November was used as a basis for overall pinniped abundance as shown in Table 9. Since there was no data available for harbor seals during those three months, the December average was used to represent the average during the previous three months. We assumed animals counted at the South Jetty comprised the majority of pinnipeds present in the Lower Columbia River west of Interstate 101 between September and November. This total area, including the jetties, was approximately 275 km². We calculated the density of each pinniped species per km², then multiplied by the area of the harassment zone and number of workdays anticipated at each pile dike (Table 10). These estimates likely represent take of the same individuals over multiple days throughout the construction period. Therefore, the take estimate serves as a good estimate of instances of take, but is likely an overestimate of individuals taken.

NMFS proposes to establish a 100-m shutdown zone and 475-m Level A harassment zone for harbor seals during impact pile driving activities. If a 475-m shutdown zone is adopted for harbor seals to avoid take by Level A harassment it was felt that there may be a high shutdown rate since harbor seals have been known to approach active construction sites. This would negatively impact the construction schedule and prolong the duration of heightened underwater noise levels. While the likelihood of this type of behavior by seals is unknown in the vicinity of the project area, authorizing limited take by Level A harassment should reduce the chances of unscheduled shutdown due to incursion of harbor seals into the delineated PTS zone.

TABLE 9—AVERAGE NUMBER OF PINNIPEDS PER MONTH ON SOUTH JETTY, 2000–2014

Month	Avg. number of Steller sea lions/month	Avg. number of California sea lions/month	Avg. number of harbor seals/month
September	209	249
October	384	508
November	1,663	1,214
December	57
Construction Period Average	752	657	57

Source: Data from Washington Department of Fish and Wildlife 2014.

TABLE 10—ESTIMATED LEVEL B AND LEVEL A TAKE CALCULATIONS FOR PINNIPEDS

Species	Density (animals/km²)	Activity type	Level B Isopleth area RM 4.01	Level B Isopleth area RM 6.37	Take/day RM 4.01	Take/day RM 6.37	Total take RM 4.01	Total take RM 6.37	Estimated total takes (Level B)
Stellar Sea lion	2.73	Impact Installation ¹	3	4	8.19	10.92	82	109	3,563
		Vibratory Installation/Re- moval ²	64	73	174.72	199.29	1572	1794	
		Timber Vibratory Removal ³ ...	0.6	0.7	1.64	1.91	2	3	
							1657	1906	
California Sea lion	2.39	Impact Installation	3	4	7.17	9.56	72	96	3,119
		Vibratory Installation/Removal	64	73	152.96	174.47	1377	1570	
		Timber Vibratory Removal	0.6	0.7	1.43	1.67	2	3	
							1450	1668	
Harbor Seal (Level B)	0.21	Impact Installation	3	4	0.61	0.5	6	5	270
		Vibratory Installation/Removal	64	73	13.44	15.33	121	138	
		Timber Vibratory Removal	0.6	0.7	0.13	0.15	0	0	
							127	143	
Harbor Seal (Level A)			Level A Isopleth area RM 4.01	Level A Isopleth area RM 6.37	Take/day RM 4.01	Take/day RM 6.37	Total Take RM 4.01	Total Take RM 6.37 3 (Level A)
		Impact Installation	0.8	0.9	0.15	0.11	2	1	

¹ Assumes 10 days each at RM 4.01 and RM 6.37 for all pinniped species.

² Assumes 9 days each at RM 4.01 and RM 6.37 for all pinniped species.

³ Assumes 1.5 days each at RM 4.01 and RM 6.37 for all pinniped species.

Table 11 illustrates the stocks NMFS numbers proposed for authorization, proposed to authorize for take, the and the percentage of the stock taken.

TABLE 11—LEVEL A AND LEVEL B HARASSMENT TAKE ESTIMATES FOR THE SAND ISLAND PILE DIKES TEST PILES

Species	Level A take	Level B take	Stock abundance	Percentage of stock taken
Harbor porpoise	10	21	21,487	0.1
California Sea Lion	3,119	296,750	1.1
Stellar Sea Lion	3,563	61,746	5.8
Harbor Seal	3	270	24,732	1.1

Proposed Mitigation

In order to issue an IHA under Section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for

certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting such activity or other means of effecting the least practicable adverse impact upon the affected species or stocks and their habitat (50 CFR 216.104(a)(11)).

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

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers

the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned), and;

(2) the practicability of the measures for applicant implementation, which may consider such things as cost, impact on operations, and, in the case of a military readiness activity, personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

In addition to the measures described later in this section, the Corps must employ the following standard mitigation measures:

- Conduct briefings between construction supervisors and crews and the marine mammal monitoring team prior to the start of all pile driving activity, and when new personnel join the work, to explain responsibilities, communication procedures, marine

mammal monitoring protocol, and operational procedures;

- For in-water heavy machinery work other than pile driving/removal (e.g., standard barges, tug boats), if a marine mammal comes within 25 m, operations shall cease and vessels shall reduce speed to the minimum level required to maintain steerage and safe working conditions. This type of work could include the following activities: (1) Movement of the barge to the pile location; or (2) positioning of the pile on the substrate via a crane (i.e., stabbing the pile);

- Work may only occur during daylight hours, when visual monitoring of marine mammals can be conducted;

- For any marine mammal species for which take by Level B harassment has not been requested or authorized, in-water pile installation/removal will shut down immediately when the animals are sighted;

- If take by Level B harassment reaches the authorized limit for an authorized species, pile installation will be stopped as these species approach the Level B harassment zone to avoid additional take of them.

Establishment of Shutdown Zones and Level A Harassment Zones—For all pile driving/removal and activities, the Corps establish a shutdown zone. The purpose of a shutdown zone is generally to define an area within which shutdown of activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area). Shutdown zones will vary based on the type of driving/removal activity type and by marine mammal hearing group, (See Table 10). Here, shutdown zones are larger than the calculated Level A harassment isopleth shown in Table 7, except for harbor seals during impact driving when a 100-m shutdown zone and a 475-m Level A harassment zone will be visually monitored. The largest shutdown zones are generally for low frequency and high frequency cetaceans. The placement of (PSOs) during all pile driving/removal activities (described in detail in the Proposed Monitoring and Reporting Section) will ensure that the entirety of all shutdown zones are visible during pile installation.

TABLE 12—SHUTDOWN ZONES DURING PROJECT ACTIVITIES

Activity	Distance (meters)				
	LF cetacean	MF cetacean	HF cetacean	Phocid pinniped	Otariid pinniped
24" Steel Pipe Pile Impact Installation	890	35	1,050	100	35
24" Steel Pipe Vibratory Installation	25	25	25	25	25
24" Steel Pipe Vibratory Removal	25	25	25	25	25
24" Timber Pile Removal Vibratory	25	25	25	25	25

Establishment of Monitoring Zones for Level B Harassment—The Corps will establish monitoring zones, based on the Level B harassment zones which are areas where SPLs are equal to or exceed the 160 dB rms threshold for impact driving and the 120 dB rms threshold

during vibratory driving/removal. Monitoring zones provide utility for observing by establishing monitoring protocols for areas adjacent to the shutdown zones. Monitoring zones enable observers to be aware of and communicate the presence of marine

mammals in the project area outside the shutdown zone and thus prepare for a potential cease of activity should the animal enter the shutdown zone. Distances to the Level B harassment zones are depicted in Table 13.

TABLE 13—DISTANCES TO LEVEL B HARASSMENT ZONES DURING PROJECT ACTIVITIES

Activity	Distance (m)
24" Steel Pipe Pile Impact Installation	1,000
24" Steel Pipe Vibratory Installation	5,420
24" Steel Pipe Vibratory Removal	5,420
24" Timber Pile Removal Vibratory	1,360

Soft Start—The use of a soft-start procedure are believed to provide additional protection to marine mammals by providing warning and/or giving marine mammals a chance to leave the area prior to the hammer operating at full capacity. For impact

pile driving, contractors will be required to provide an initial set of strikes from the hammer at reduced percent energy, each strike followed by no less than a 30-second waiting period. This procedure will be conducted a total of three times before impact pile driving

begins. Soft Start is not required during vibratory pile driving and removal activities. A soft start must be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of thirty minutes or

longer. If a marine mammal is present within the Level A harassment zone, soft start will be delayed until the animal leaves the Level A harassment zone. Soft start will begin only after the PSO has determined, through sighting, that the animal has moved outside the Level A harassment zone. If a marine mammal is present in the Level B harassment zone, soft start may begin and a Level B take will be recorded. Soft start up may occur when these species are in the Level B harassment zone, whether they enter the Level B zone from the Level A zone or from outside the monitoring area.

Pre-Activity Monitoring—Prior to the start of daily in-water construction activity, or whenever a break in pile driving of 30 minutes or longer occurs, PSOs will observe the shutdown and monitoring zones for a period of 30 minutes. The shutdown zone will be cleared when a marine mammal has not been observed within the zone for that 30-minute period. If a marine mammal is observed within the shutdown zone, a soft-start cannot proceed until the animal has left the zone or has not been observed for 15 minutes. If the Level B harassment zone has been observed for 30 minutes and marine mammals are not present within the zone, soft start procedures can commence and work can continue even if visibility becomes impaired within the Level B harassment zone. When a marine mammal permitted for take by Level B harassment is present in the Level B harassment zone, piling activities may begin and take by Level B will be recorded. As stated above, if the entire Level B harassment zone is not visible at the start of construction, pile driving/removal activities can begin. If work ceases for more than 30 minutes, the pre-activity monitoring of both the Level B harassment and shutdown zone will commence.

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

Proposed Monitoring and Reporting

In order to issue an IHA for an activity, Section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that

requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

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

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

Visual Monitoring

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

There will be at least two PSOs employed during all pile driving/removal activities. PSO will not perform duties for more than 12 hours in a 24-hour period. One PSO would be positioned close to pile driving/removal activities at the best practical vantage point. A second PSO would be vessel-based to provide best coverage of the appropriate Level A and Level B harassment zones. If waters exceed a sea-state which restricts the observers' ability to make boat-based observations for the full Level A shutdown zone (e.g., excessive wind, wave action, or fog), impact pile installation will cease until conditions allow monitoring to resume. Contractors should ensure compliance with NOAA advisories for safe boat operations based on the size of vessel to be used by the marine mammal observer.

As part of monitoring, PSOs would scan the waters using binoculars, and/or spotting scopes, and would use a handheld GPS or range-finder device to verify the distance to each sighting from the project site. All PSOs would be trained in marine mammal identification and behaviors and are required to have no other project-related tasks while conducting monitoring. In addition, monitoring will be conducted by qualified observers, who will be placed at the best vantage point(s) practicable to monitor for marine mammals and implement shutdown/delay procedures when applicable by calling for the shutdown to the hammer operator. Qualified observers are trained and/or experienced professionals, with the following minimum qualifications:

- Visual acuity in both eyes (correction is permissible) sufficient for discernment of moving targets at the water's surface with ability to estimate target size and distance; use of binoculars may be necessary to correctly identify the target;
- Independent observers (i.e., not construction personnel);
- Observers must have their CVs/resumes submitted to and approved by NMFS;
- Advanced education in biological science or related field (i.e., undergraduate degree or higher). Observers may substitute education or training for experience;
- Experience and ability to conduct field observations and collect data according to assigned protocols (this may include academic experience);
- At least one observer must have prior experience working as an observer;
- Experience or training in the field identification of marine mammals, including the identification of behaviors;

- Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;
- Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates and times when in-water construction activities were suspended to avoid potential incidental injury from construction sound of marine mammals observed within a defined shutdown zone; and marine mammal behavior; and
- Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

Reporting

A draft marine mammal monitoring report must be submitted to NMFS within 90 days after the completion of pile driving/removal activities. This reports will include an overall description of work completed, a narrative regarding marine mammal sightings, and associated PSO data sheets. Specifically, the reports must include:

- Date and time that monitored activity begins or ends;
- Construction activities occurring during each observation period;
- Weather parameters (*e.g.*, percent cover, visibility);
- Water conditions (*e.g.*, sea state, tide state);
- Species, numbers, and, if possible, sex and age class of marine mammals;
- Description of any observable marine mammal behavior patterns, including bearing and direction of travel and distance from pile driving activity;
- Distance from pile driving activities to marine mammals and distance from the marine mammals to the observation point;
- Locations of all marine mammal observations;
- An estimate of total take based on proportion of the monitoring zone that was observed; and
- Other human activity in the area.

If no comments are received from NMFS within 30 days, that phase's draft final report will constitute the final report. If comments are received, a final report for the given phase addressing NMFS comments must be submitted within 30 days after receipt of comments. In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by the IHAs (if

issued), such as an injury, serious injury or mortality, the Corps would immediately cease the specified activities and report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the West Coast Regional Stranding Coordinator. The report would include the following information:

- Description of the incident;
- Environmental conditions (*e.g.*, Beaufort sea state, visibility);
- Description of all marine mammal observations in the 24 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

Activities would not resume until NMFS is able to review the circumstances of the prohibited take. NMFS would work with the Corps to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. The Corps would not be able to resume their activities until notified by NMFS via letter, email, or telephone.

In the event that the Corps discovers an injured or dead marine mammal, and the lead PSO determines that the cause of the injury or death is unknown and the death is relatively recent (*e.g.*, in less than a moderate state of decomposition as described in the next paragraph), the Corps would immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the West Coast Regional Stranding Coordinator. The report would include the same information identified in the paragraph above. Activities would be able to continue while NMFS reviews the circumstances of the incident. NMFS would work with the Corps to determine whether modifications in the activities are appropriate.

In the event that the Corps discovers an injured or dead marine mammal and the lead PSO determines that the injury or death is not associated with or related to the activities authorized in these IHAs (*e.g.*, previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), the Corps would report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the West Coast Regional Stranding Coordinator, within 24 hours of the discovery. The Corps would provide photographs, video footage (if available),

or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network.

Negligible Impact Analysis and Determination

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

To avoid repetition, our analysis applies to all species listed in Table 11, given that NMFS expects the anticipated effects of the proposed pile driving/removal to be similar in nature. Where there are meaningful differences between species or stocks, or groups of species, in anticipated individual responses to activities, impact of expected take on the population due to differences in population status, or impacts on habitat, NMFS has identified species-specific factors to inform the analysis.

NMFS does not anticipate that serious injury or mortality would occur as a result of the Corps' proposed activity. As stated in the proposed mitigation section, shutdown zones that equal or exceed Level A harassment isopleths shown in Table 12 will be implemented. Take by Level A harassment is proposed for authorization for some species

(harbor seals, harbor porpoises) to account for the slight possibility that these species escape observation by the PSOs within the Level A harassment zone. Further, any take by Level A harassment is expected to arise from, at most, a small degree of PTS because animals would need to be exposed to higher levels and/or longer duration than are expected to occur here in order to incur any more than a small degree of PTS. Additionally, as noted previously, some subset of the individuals that are behaviorally harassed could also simultaneously incur some small degree of TTS for a short duration of time. Because of the small degree anticipated, though, any PTS or TTS potentially incurred here would not be expected to adversely impact individual fitness.

Behavioral responses of marine mammals to pile driving and removal at the proposed test piles project sites are expected to be mild, short term, and temporary. Marine mammals within the Level B harassment zone may not show any visual cues they are disturbed by activities or they could become alert, avoid the area, leave the area, or display other mild responses that are not observable such as changes in vocalization patterns. Given the short duration of noise-generating activities (between 6–41 days over 3-month period), any harassment would be likely be intermittent and temporary. Additionally, many of the species occurring near the MCR or in the Columbia River estuary would only be present temporarily based on seasonal patterns or during transit between other habitats. These temporarily present species would be exposed to even smaller periods of noise-generating activity, further decreasing the impacts.

In addition, for all species there are no known biologically important areas (BIAs) within the MCR or Columbia River estuary and there is no ESA-designated marine mammal critical habitat. The estuary represents a very small portion of the total available habitat to marine mammal species.

More generally, there are no known calving or rookery grounds within the project area, but anecdotal evidence from local experts shows that marine mammals are more prevalent during spring and summer associated with feeding on aggregations of fish. Because the Corps' activities would occur in the fall months, the project area represents a small portion of available foraging habitat, and the duration of noise-producing activities relatively is short, meaning impacts on marine mammal feeding for all species should be minimal.

Any impacts on marine mammal prey that would occur during the Corps' proposed activity would have at most short-terms effects on foraging of individual marine mammals, and likely no effect on the populations of marine mammals as a whole. Therefore, indirect effects on marine mammal prey during the construction are not expected to be substantial, and these insubstantial effects would therefore be unlikely to cause substantial effects on marine mammals.

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

- No mortality is anticipated or authorized;
- The Corps would implement mitigation measures including soft-starts for impact pile driving and shutdown zones that exceed Level A harassment zones for authorized species, except for harbor seals which will help to ensure that take by Level A harassment is at most a small degree of PTS;
- Anticipated incidents of Level B harassment consist of, at worst, temporary modifications in behavior;
- There are no BIAs within the MCR and Columbia River estuary or other known areas of particular biological importance to any of the affected stocks are impacted by the activity;
- The project area represents a very small portion of the available foraging area for all marine mammal species and anticipated habitat impacts are minimal; and
- The required mitigation measures (e.g., shutdown zones, soft-start) are expected to be effective in reducing the effects of the specified activity.

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

Small Numbers

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

the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

Table 11 in the *Marine Mammal Occurrence and Take Calculation and Estimation* section, present the number of animals that could be exposed to received noise levels that may result in take by Level A harassment or Level B harassment from the Corps' proposed activities. Our analysis shows that 6 percent or less of the best population estimates of each affected stock could be taken. Additionally, the proposed test piles project is located near the pinniped haulout at the South Jetty. Therefore, it is likely that many of these takes will be repeated takes of the same animals over multiple days. As such, the take estimate serves as a good estimate of instances of take, but is likely an overestimate of individuals taken, so actual percentage of stocks taken would be even lower.

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

Unmitigable Adverse Impact Analysis and Determination

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

Endangered Species Act (ESA)

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

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to the Corps for conducting test pile installation and removal, near the MCR, from one year from the date of issuance, provided the previously mentioned mitigation, monitoring, and

reporting requirements are incorporated. A draft of the proposed IHA can be found at <https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act>.

Request for Public Comments

We request comment on our analyses, the proposed authorization, and any other aspect of this Notice of Proposed IHA for the proposed Sand Island Pile Dike System Test Piles Project. We also request at this time comment on the potential renewal of this proposed IHA as described in the paragraph below. Please include with your comments any supporting data or literature citations to help inform decisions on the request for this IHA or a subsequent Renewal.

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

- A request for renewal is received no later than 60 days prior to expiration of the current IHA;

- The request for renewal must include the following:

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

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

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

and the findings in the initial IHA remain valid.

Dated: July 31, 2019.

Donna S. Wieting,

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

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BILLING CODE 3510-22-P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB-2019-0043]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Consumer Financial Protection (Bureau) is proposing to renew with change the Office of Management and Budget (OMB) approval for an existing information collection titled, “Policy On No-Action Letters and Compliance Assistance Sandbox Policy.”

DATES: Written comments are encouraged and must be received on or before September 5, 2019 to be assured of consideration.

ADDRESSES: Comments in response to this notice are to be directed towards OMB and to the attention of the OMB Desk Officer for the Bureau of Consumer Financial Protection. You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Electronic:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Email:* OIRA_submission@omb.eop.gov.

- *Fax:* (202) 395-5806.

- *Mail:* Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT:

Documentation prepared in support of this information collection request is available at www.reginfo.gov (this link becomes active on the day following publication of this notice). Select

“Information Collection Review,” under “Currently under review, use the dropdown menu “Select Agency” and select “Consumer Financial Protection Bureau” (recent submissions to OMB will be at the top of the list). The same documentation is also available at <http://www.regulations.gov>. Requests for additional information should be directed to Darrin King, PRA Officer, at (202) 435-9575, or email: CFPB_PRA@cfpb.gov. If you require this document in an alternative electronic format, please contact CFPB_Accessibility@cfpb.gov. Please do not submit comments to these email boxes.

SUPPLEMENTARY INFORMATION:

Title of Collection: Policy on No-Action Letters and Compliance Assistance Sandbox Policy.

OMB Control Number: 3170-0059.

Type of Review: Revision of a currently approved collection.

Affected Public: Private Sector.

Estimated Number of Respondents: 9.

Estimated Total Annual Burden

Hours: 1,200.

Abstract: The Bureau is revising its initial 2016 Policy on No-Action Letters (Policy). The revised Policy will govern the process for persons to apply for Bureau no-action letters for proposed conduct, subject to specified conditions and limitations. Issuance of no-action letters under the Policy will be discretionary on the part of the Bureau. The information will be collected from persons, primarily businesses or other for-profit entities, who apply for no-action letters from the Bureau. The information will be used by the Bureau to determine whether issuance of a no-action letter is warranted.

The Bureau is also finalizing its Compliance Assistance Sandbox Policy (CASP). The CASP will govern the process for persons to apply for Bureau approvals, subject to specified conditions and limitations. Issuance of approvals will be discretionary on the part of the Bureau. The information will be collected from persons, primarily businesses or other for-profit entities, who apply for approvals from the Bureau. The information will be used by the Bureau to determine whether issuance of an approval is warranted.

Request for Comments: The Bureau issued a 60-day **Federal Register** notice on December 13, 2018, 83 FR 64036, Docket Number: CFPB-2018-0042. Comments were solicited and continue to be invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the

Bureau's estimate of the burden of the collection of information, including the validity of the methods and the 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 information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be reviewed by OMB as part of its review of this request. All comments will become a matter of public record.

Dated: August 2, 2019.

Mary McLeod,

General Counsel, Bureau of Consumer Financial Protection.

[FR Doc. 2019-16919 Filed 8-2-19; 4:15 pm]

BILLING CODE 4810-AM-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER19-2460-000]

DWW Solar II, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced DWW Solar II, 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 20, 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: July 31, 2019.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2019-16728 Filed 8-5-19; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER19-2479-000]

Aera Energy LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced Aera 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 20, 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: July 31, 2019.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2019-16725 Filed 8-5-19; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

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

Docket Numbers: EG19-158-000.

Applicants: Wright Solar Park LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Wright Solar Park LLC.

Filed Date: 7/31/19.

Accession Number: 20190731-5102.

Comments Due: 5 p.m. ET 8/21/19.

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

Docket Numbers: ER18-1906-001; ER16-221-002; ER18-1907-001; ER17-

1757-002; ER10-1767-004; ER10-1532-004; ER10-1541-005; ER10-1642-006; ER13-2349-003; ER13-2350-003.

Applicants: Entergy Arkansas, LLC, Entergy Louisiana, LLC, Entergy Mississippi, LLC, Entergy New Orleans, LLC, Entergy Texas, Inc., Entergy Nuclear Palisades, LLC, Entergy Power, LLC, EWO Marketing, LLC, EAM Nelson Holding, LLC, RS Cogen, LLC.

Description: Supplement to June 24, 2019 Notification of Change in Status [Attachment B—Excel format] of the Entergy Central MBR Utilities.

Filed Date: 7/26/19.

Accession Number: 20190726-5175.

Comments Due: 5 p.m. ET 8/5/19.

Docket Numbers: ER18-1918-003.

Applicants: Kestrel Acquisition, LLC.

Description: Report Filing: Refund Report 2019 to 5 to be effective N/A.

Filed Date: 7/31/19.

Accession Number: 20190731-5141.

Comments Due: 5 p.m. ET 8/21/19.

Docket Numbers: ER19-1936-001.

Applicants: Idaho Power Company.

Description: Compliance filing: Response to Deficiency Letter Regarding Order Nos. 845 and 845-A Filing to be effective 5/22/2019.

Filed Date: 7/30/19.

Accession Number: 20190730-5101.

Comments Due: 5 p.m. ET 8/20/19.

Docket Numbers: ER19-2496-000.

Applicants: Pacific Gas and Electric Company.

Description: § 205(d) Rate Filing: Amendment to Agreement of Cotenancy (RS 139) to be effective 7/31/2019.

Filed Date: 7/30/19.

Accession Number: 20190730-5099.

Comments Due: 5 p.m. ET 8/20/19.

Docket Numbers: ER19-2497-000.

Applicants: California Independent System Operator Corporation.

Description: § 205(d) Rate Filing: 2019-07-30 Real-Time Neutrality Settlement Amendment to be effective 8/1/2019.

Filed Date: 7/30/19.

Accession Number: 20190730-5100.

Comments Due: 5 p.m. ET 8/20/19.

Docket Numbers: ER19-2498-000.

Applicants: Midcontinent

Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2019-07-31 SA 3152 Polaris Wind Energy-METC 1st Rev GIA (J533) to be effective 7/17/2019.

Filed Date: 7/31/19.

Accession Number: 20190731-5022.

Comments Due: 5 p.m. ET 8/21/19.

Docket Numbers: ER19-2499-000.

Applicants: Tuscola Wind II, LLC.

Description: Baseline eTariff Filing: Reactive Power Compensation Filing to be effective 9/29/2019.

Filed Date: 7/31/19.

Accession Number: 20190731-5047.

Comments Due: 5 p.m. ET 8/21/19.

Docket Numbers: ER19-2500-000.

Applicants: Pheasant Run Wind, LLC.
Description: Baseline eTariff Filing: Reactive Power Compensation Filing to be effective 9/29/2019.

Filed Date: 7/31/19.

Accession Number: 20190731-5048.

Comments Due: 5 p.m. ET 8/21/19.

Docket Numbers: ER19-2501-000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 3126R4 WAPA NITSA and NOA to be effective 7/1/2019.

Filed Date: 7/31/19.

Accession Number: 20190731-5056.

Comments Due: 5 p.m. ET 8/21/19.

Docket Numbers: ER19-2502-000.

Applicants: Alabama Power Company.

Description: § 205(d) Rate Filing: Wiregrass LGIA Filing to be effective 7/17/2019.

Filed Date: 7/31/19.

Accession Number: 20190731-5077.

Comments Due: 5 p.m. ET 8/21/19.

Docket Numbers: ER19-2503-000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: SCE Revised TO Tariff Appendix X to be effective 7/26/2019.

Filed Date: 7/31/19.

Accession Number: 20190731-5084.

Comments Due: 5 p.m. ET 8/21/19.

Docket Numbers: ER19-2504-000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: SCE Revised WDAT Attachment J to be effective 7/26/2019.

Filed Date: 7/31/19.

Accession Number: 20190731-5085.

Comments Due: 5 p.m. ET 8/21/19.

Docket Numbers: ER19-2505-000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: WDAT Energy Storage to be effective 9/30/2019.

Filed Date: 7/31/19.

Accession Number: 20190731-5101.

Comments Due: 5 p.m. ET 8/21/19.

Docket Numbers: ER19-2506-000.

Applicants: Pacific Gas and Electric Company.

Description: § 205(d) Rate Filing: Q2 2019 Quarterly Filing of City and County of San Francisco's WDT SA (SA 275) to be effective 6/30/2019.

Filed Date: 7/31/19.

Accession Number: 20190731-5115.

Comments Due: 5 p.m. ET 8/21/19.

Docket Numbers: ER19-2507-000.

Applicants: Convergent Energy and Power LP.

Description: § 205(d) Rate Filing: Normal filing 2019 to be effective 8/1/2019.

Filed Date: 7/31/19.

Accession Number: 20190731-5116.

Comments Due: 5 p.m. ET 8/21/19.

Docket Numbers: ER19-2508-000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 3215R6 People's Electric Cooperative NITSA NOA to be effective 7/1/2019.

Filed Date: 7/31/19.

Accession Number: 20190731-5121.

Comments Due: 5 p.m. ET 8/21/19.

Docket Numbers: ER19-2509-000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 3563 ETEC, MISO and Entergy Services Attachment AO to be effective 7/1/2019.

Filed Date: 7/31/19.

Accession Number: 20190731-5130.

Comments Due: 5 p.m. ET 8/21/19.

Docket Numbers: ER19-2510-000.

Applicants: Public Service Company of Colorado.

Description: § 205(d) Rate Filing: PSCo-Multi-CFA-350-Exh I & L 0.1.0-Exh N 0.0.0 to be effective 9/30/2019.

Filed Date: 7/31/19.

Accession Number: 20190731-5143.

Comments Due: 5 p.m. ET 8/21/19.

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

Docket Numbers: ES19-47-000.

Applicants: Consumers Energy Company.

Description: Application under Section 204 of the Federal Power Act for Authorization to Issue Securities of Consumers Energy Company.

Filed Date: 7/30/19.

Accession Number: 20190730-5124.

Comments Due: 5 p.m. ET 8/20/19.

Take notice that the Commission received the following qualifying facility filings:

Docket Numbers: QF19-1431-000.

Applicants: Milton Regional Sewer Authority.

Description: Form 556 of Milton Regional Sewer Authority.

Filed Date: 7/31/19.

Accession Number: 20190731-5032.

Comments Due: Non-Applicable.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's

Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: July 31, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019-16726 Filed 8-5-19; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. Er19-2461-000]

Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization; Crowned Ridge Wind, LLC

This is a supplemental notice in the above-referenced Crowned Ridge Wind, 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 20, 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: July 31, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019-16724 Filed 8-5-19; 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 Numbers: RP19-1406-000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Rate Schedule S-2 Tracker Filing eff 8-1-2019 to be effective 8/1/2019.

Filed Date: 7/30/19.

Accession Number: 20190730-5020.

Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19-1407-000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rates—Keyspan release to Vitrol eff 8-1-19 to be effective 8/1/2019.

Filed Date: 7/30/19.

Accession Number: 20190730-5027.

Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19-1408-000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing: Negotiated Rate—MC Global to Morgan 8958691 eff 8-1-19 to be effective 8/1/2019.

Filed Date: 7/30/19.

Accession Number: 20190730-5031.

Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19-1409-000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rates—BUG release to Emera eff 8-1-19 to be effective 8/1/2019.

Filed Date: 7/30/19.

Accession Number: 20190730-5039.

Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19-1410-000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Negotiated Rates—Cherokee AGL—Replacement Shippers—Aug 2019 to be effective 8/1/2019.

Filed Date: 7/30/19.

Accession Number: 20190730-5045.

Comments Due: 5 p.m. ET 8/12/19.

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: July 31, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019-16727 Filed 8-5-19; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2017-0751; FRL-9997-26]

Interim Registration Review Decisions and Case Closures for Several Pesticides; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's interim registration review decision for the following chemicals: abamectin, ametryn,

bicarbonates, butralin, citronellol, corn glutens, diphenylamine, IAA [Indole acetic acid], LPE [Lysophosphatidylethanolamines, egg yolk], methiocarb, oil of black pepper, oryzalin, predator urines, prohexadione-calcium, pyriithiobac-sodium, Quillaja extract [Quillaja saponins], quinoa saponins [saponins of *Chenopodium*], sodium cyanide, sodium fluoroacetate, tebuthiuron, *Verticillium dahlia* Isolate WCS 850, yeast extract hydrolysate, and zinc borate. In addition, it announces the closure of the registration review cases for diallyl sulfides because the last U.S. registrations for these pesticides have been canceled.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2017-0751, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

For pesticide specific information, contact: The Chemical Review Manager for the pesticide of interest identified in the Table in Unit IV., Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental

Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001.

For general questions on the registration review program, contact: Melanie Biscoe, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (703) 305-7106; email address: biscoe.melanie@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the Chemical Review Manager for the pesticide of interest identified in the Table in Unit IV., or the general contact listed under **FOR FURTHER INFORMATION CONTACT**.

II. Background

Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. As part of the registration review process, the

Agency has completed interim decisions for all pesticides listed in the Table in Unit IV. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

III. Authority

EPA is conducting its registration review of the chemicals listed in the Table in Unit IV pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

IV. What action is the Agency taking?

Pursuant to 40 CFR 155.58, this notice announces the availability of EPA's interim registration review decisions for the pesticides shown in the following table. The interim registration review decisions are supported by rationales included in the docket established for each chemical.

TABLE—REGISTRATION REVIEW INTERIM DECISIONS BEING ISSUED

Registration review case name and No.	Docket ID No.	Chemical review manager and contact information
Abamectin, Case Number 7430	EPA-HQ-OPP-2013-0360	Eric Fox Fox.eric@epa.gov , 703-347-0104.
Ametryn, Case Number 2010	EPA-HQ-OPP-2013-0249	Christian Bongard, Bongard.Christian@epa.gov , 703-347-0337.
Bicarbonates, Case Number 4048	EPA-HQ-OPP-2012-0407	Donna Kamarei, Kamarei.donna@epa.gov , 703-347-0443.
Butralin, Case Number 2075	EPA-HQ-OPP-2011-0720	Lauren Bailey, Bailey.lauren@epa.gov , 703-347-0374.
Citronellol, Case Number 6086	EPA-HQ-OPP-2017-0250	Donna Kamarei, Kamarei.donna@epa.gov , 703-347-0443.
Corn Glutens, Case Number 6040	EPA-HQ-OPP-2016-0253	Joseph Mabon, Mabon.joseph@epa.gov , 703-347-0177.
Diphenylamine (DPA), Case Number 2210	EPA-HQ-OPP-2015-0749	Samantha Thomas, Thomas.samantha@epa.gov , 703-347-0514.
IAA [Indole acetic acid], Case Number 6205 ...	EPA-HQ-OPP-2016-0665	Joseph Mabon, Mabon.joseph@epa.gov , 703-347-0177.
LPE [Lysophosphatidylethanolamines, egg yolk], Case Number 6043.	EPA-HQ-OPP-2017-0059	Daniel Schoeff, Schoeff.daniel@epa.gov , 703-347-0143.
Methiocarb, Case Number 0577	EPA-HQ-OPP-2010-0278	Veronica Dutch, Dutch.Veronica@epa.gov , 703-308-8585.
Oil of Black Pepper, Case Number 6004	EPA-HQ-OPP-2017-0262	Cody Kendrick, Kendrick.cody@epa.gov , 703-347-0468.
Oryzalin, Case Number 0186	EPA-HQ-OPP-2010-0940	Christina Scheltema, Scheltema.christina@epa.gov , 703-308-2201.
Predator Urines: Coyote Urine and Fox Urine, Case Number 6202.	EPA-HQ-OPP-2016-0086	Alexandra Boukedes, Boukedes.alexandra@epa.gov , 703-347-0305.
Prohexadione calcium	EPA-HQ-OPP-2012-0870	Andrew Muench, Muench.Andrew@epa.gov , 703-347-8263.
Case Number 7030		
Pyriithiobac-sodium, Case Number 7239	EPA-HQ-OPP-2011-0661	Nathan Sell, Sell.Nathan@epa.gov , 703-347-8020.
Quillaja extract [Quillaja Saponins], Case Number 6512.	EPA-HQ-OPP-2017-0230	Susanne Cerrelli, Cerrelli.susanne@epa.gov , 703-308-8077.

TABLE—REGISTRATION REVIEW INTERIM DECISIONS BEING ISSUED—Continued

Registration review case name and No.	Docket ID No.	Chemical review manager and contact information
Quinoa Saponins [Saponins of Chenopodium], Case Number 6200.	EPA-HQ-OPP-2017-0274	Daniel Schoeff, Schoeff.daniel@epa.gov , 703-347-0143.
Sodium cyanide, Case number 8002	EPA-HQ-OPP-2010-0752	Nicole Zinn, Zinn.nicole@epa.gov , 703-308-7076.
Sodium fluoroacetate, Case number 3073	EPA-HQ-OPP-2010-0753	Nicole Zinn, Zinn.nicole@epa.gov , 703-308-7076.
Tebuthiuron, Case number 0054	EPA-HQ-OPP-2009-0327	Michelle Nolan, Nolan.michelle@epa.gov , (703) 347-0258.
<i>Verticillium dahlia</i> Isolate WCS 850, Case Number 6508.	EPA-HQ-OPP-2016-0306	Susanne Cerrelli, Cerrelli.susanne@epa.gov , 703-308-8077.
Yeast extract hydrolysate, Case Number 6081	EPA-HQ-OPP-2017-0282	Daniel Schoeff, Schoeff.daniel@epa.gov , 703-347-0143.
Zinc Borate, Case Number 5025	EPA-HQ-OPP-2007-0675	Stephen Savage, Savage.stephen@epa.gov , 703-347-0345.

The proposed interim registration review decisions for the chemicals in the table above were posted to the docket and the public was invited to submit any comments or new information. EPA addressed the comments or information received during the 60-day comment period for the proposed interim decisions in the discussion for each pesticide listed in the table. Comments from the 60-day comment period that were received may or may not have affected the Agency's interim decision. Pursuant to 40 CFR 155.58(c), the registration review case docket for the chemicals listed in the Table will remain open until all actions required in the interim decision have been completed.

This document also announces the closure of the registration review case for Diallyl sulfides (DADs) (Case Number 6069, Docket ID Number EPA-HQ-OPP-2017-0325) because the last U.S. registrations for these pesticides have been canceled. Background on the registration review program is provided at: <http://www.epa.gov/pesticide-reevaluation>.

Authority: 7 U.S.C. 136 *et seq.*

Dated: July 23, 2019.

Mary Reaves,

Acting Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2019-16705 Filed 8-5-19; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9997-75-OA]

Notification of a Public Teleconference of the Science Advisory Board Computable General Equilibrium Model Review Panel

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Science Advisory Board

(SAB) Staff Office announces a public teleconference of the SAB Computable General Equilibrium (CGE) Model Review Panel to discuss its review of a CGE model from the EPA's National Center for Environmental Economics.

DATES: The public teleconference will be held on August 22, 2019, from 12:00 p.m. to 3:00 p.m. (Eastern Time).

ADDRESSES: The public teleconference will be held by telephone only.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further information regarding the public teleconference may contact Dr. Holly Stallworth, Designated Federal Officer (DFO), SAB Staff Office, by telephone at (202) 564-2073 or email at stallworth.holly@epa.gov. The SAB mailing address is U.S. EPA Science Advisory Board (1400R), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460. General information about the SAB, including information concerning the SAB teleconference announced in this notice, can be found at the SAB web page at <http://epa.gov/sab>.

SUPPLEMENTARY INFORMATION:

Background: The SAB was established pursuant to the Environmental Research, Development, and Demonstration Authorization Act (ERDAA) codified at 42 U.S.C. 4365, to provide independent scientific and technical peer review, advice, consultation, and recommendations to the EPA Administrator on the technical basis for Agency positions and regulations. The SAB is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2. The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Pursuant to FACA and EPA policy, notice is hereby given that the SAB CGE Model Review Panel will hold a public teleconference to discuss its review of a CGE model from EPA's National Center for Environmental Economics. The

Panel will provide advice to the Administrator through the chartered SAB. Background information on the SAB CGE Model Review Panel can be found at <https://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/18a2abac2e4b5ec9852583bc004ce70a!OpenDocument>.

The public teleconference on August 22, 2019, will be an orientation teleconference during which the National Center for Environmental Economics will brief the Panel on the context for the review, the CGE model itself and the charge questions. A face-to-face meeting date and location will be announced at a later time.

All draft reports developed by SAB panels, committees or workgroups are reviewed and approved by the Chartered SAB through a quality review process before being finalized and transmitted to the EPA Administrator.

Availability of the teleconference materials: An agenda will be posted on the SAB website prior to the August 22, 2019, orientation teleconference. Other materials to be posted prior to the public teleconference include PowerPoint slides for all EPA presentations and the charge questions. The CGE model source code and documentation as well as memos on model versioning and potential near-term model improvements will be posted shortly after the August 22, 2019, teleconference. While the source code and documentation will be available to the public, some of the data to run the model is proprietary and would have to be purchased from The IMPLAN Group LLC (implan.com). Instructions and source code to build the model's dataset from the IMPLAN data will be posted. To locate teleconference materials, go to epa.gov/sab and click on "Upcoming and Recent Meetings" to get to the SAB calendar. From the calendar, click on August 22, 2019. For questions concerning EPA's review materials on its CGE model, please contact Dr. Ann Wolverton, EPA National Center for Environmental Economics at

wolverton.ann@epa.gov or 202-566-2278.

Procedures for Providing Public Input: Public comment for consideration by EPA's federal advisory committees and panels has a different purpose from public comment provided to the EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office. Federal advisory committees and panels, including scientific advisory committees, provide independent advice to the EPA. Members of the public can submit relevant comments on the topic of this advisory activity, including the charge to the panel and the EPA review documents, and/or the group conducting the activity, for the SAB to consider during the advisory process. Input from the public to the SAB will have the most impact if it consists of comments that provide specific scientific or technical information or analysis for the SAB panel to consider or if it relates to the clarity or accuracy of the technical information.

Oral Statements: In general, individuals or groups requesting an oral presentation at the will be limited to five minutes per speaker. Interested parties should contact Dr. Holly Stallworth, DFO, in writing (preferably via email), at the contact information noted above by August 15, 2019, to be placed on the list of public speakers for the orientation teleconference.

Written Statements: Written statements will be accepted throughout the advisory process; however, for timely consideration by Committee/Panel members, statements should be supplied to the DFO (preferably via email) at the contact information noted above by August 15, 2019, for consideration at the teleconference on August 22, 2019.

It is the SAB Staff Office general policy to post written comments on the web page for the advisory meeting or teleconference. Submitters are requested to provide an unsigned version of each document because the SAB Staff Office does not publish documents with signatures on its website. Members of the public should be aware that their personal contact information, if included in any written comments, may be posted to the SAB website. Copyrighted material will not be posted without explicit permission of the copyright holder.

Accessibility: To request accommodation of a disability, please contact Dr. Stallworth at 202-564-2073 or stallworth.holly@epa.gov. To request accommodation of a disability please

contact Dr. Stallworth, preferably at least ten days prior to the teleconference, to give the EPA as much time as possible to process your request.

Dated: July 30, 2019.

Khanna Johnston,

Deputy Director, EPA Science Advisory Board Staff Office.

[FR Doc. 2019-16792 Filed 8-5-19; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2019-0039; FRL-9996-75]

Pesticide Product Registration; Receipt of Application for New Active Ingredient in June 2019

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received an application to register a pesticide product containing an active ingredient not included in any currently registered pesticide products. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on this application.

DATES: Comments must be received on or before September 5, 2019.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2019-0368, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001.

- **Hand Delivery:** To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets/about-epa-dockets>.

FOR FURTHER INFORMATION CONTACT:

Robert McNally, Biopesticides and Pollution Prevention Division (7511P),

Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: BPPDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. What should I consider as I prepare my comments for EPA?

1. **Submitting CBI.** Do not submit this information to EPA through [regulations.gov](https://www.regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. **Tips for preparing your comments.** When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

II. Registration Application

EPA has received an application to register a pesticide product containing an active ingredient not included in any currently registered pesticide products. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on this application. Notice of receipt of this application does not imply a decision by the Agency on this application.

New Active Ingredients

File symbol number: 87809–R. *Docket ID number:* EPA–HQ–OPP–2019–0368. *Applicant:* Acqua Concepts, Inc. (d/b/a Ag Water Chemical), 2665 S. Chestnut, Fresno, CA 93725. *Product name:* Protec-T. *Active ingredient:* Gopher repellent—Methyl mercaptan at 0.01%. *Proposed use:* Gopher repellent intended to protect irrigation/chemigation lines from damage caused by burrowing and chewing.

Authority: 7 U.S.C. 136 *et seq.*

Dated: July 15, 2019.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. 2019–16704 Filed 8–5–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2019–0045; FRL–9996–77]

Pesticide Product Registration; Receipt of Applications for New Uses in June 2019

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before September 5, 2019.

ADDRESSES: Submit your comments, identified by the docket identification (ID) number and the EPA File Symbol or EPA Registration Number of interest as shown in the body of this document, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.

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Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets/about-epa-dockets>.

FOR FURTHER INFORMATION CONTACT:

Robert McNally, Biopesticides and Pollution Prevention Division (BPPD) (7511P), main telephone number: (703) 305–7090, email address: BPPDFRNotices@epa.gov; or Michael Goodis, Registration Division (RD) (7505P), main telephone number: (703) 305–7090, email address: RDFFRNotices@epa.gov. The mailing address for each contact person is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code. The division to contact is listed at the end of each application summary.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through [regulations.gov](https://www.regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the

public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

II. Registration Applications

EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications.

New Uses

1. *EPA Registration Numbers:* 279–9586; 279–9596; 279–9597 and 279–9598. *Docket ID Number:* EPA–HQ–OPP–2019–0384. *Applicant:* E. I. du Pont de Nemours and Company, 974 Centre Road, Wilmington, Delaware 19805, requests to establish a tolerance for residues of the insecticide indoxacarb in or on corn, pop, grain at 0.02 parts per million (ppm) and corn, pop, stover at 15 ppm. The plant residue enforcement method detects and quantitates indoxacarb in various matrices including sweet corn, lettuce, tomato, broccoli, apple, grape, cottonseed, tomato, peanut and soybean commodity samples by HPLC UV. The limit of quantitation in the method allows monitoring of crops with KN128/KN127 residues at or above the levels proposed in these tolerances. *Contact:* RD.

2. *EPA Registration Numbers:* 352–890, 352–924. *Docket ID Number:* EPA–HQ–OPP–2019–0128. *Applicant:* DuPont Crop Protection, Chestnut Run Plaza—Bldg 735/4150–3, 974 Centre Road, Wilmington, DE 19805. *Active ingredient:* Oxathiapiprolin. *Product type:* Fungicide. *Proposed use:* Berry, low growing, subgroup 13–07G, except cranberry; Tropical and subtropical medium to large fruit, smooth, inedible peel, subgroup 24B; Hop, dried cones; Dwarf pea, edible podded; Edible podded pea; Green pea, edible podded; Snap pea, edible podded; Snow pea, edible podded; Sugar snap pea, edible podded; Grass-pea, edible podded; Lentil, edible podded; Pigeon pea, edible podded; Chickpea, edible podded; Chickpea, succulent shelled; English pea, succulent shelled; Garden pea, succulent shelled; Green pea, succulent shelled; Pigeon pea, succulent

shelled; Lentil, succulent shelled.

Contact: RD.

3. *EPA File Symbol Number:* 1021–EIEO; 1021–EIGN; 1021–EIGR; 1021–EIEI. *Docket ID Number:* EPA–HQ–OPP–2019–0280. *Applicant:* MGK, 8810 Tenth Avenue North, Minneapolis, MN 55427–4319. *Active Ingredient:* SI–183 (1R-Phenothrin 98%). *Product type:* Insecticide. *Proposed Use:* Non-food indoor, outdoor, and residential uses. *Contact:* RD.

4. *EPA File Symbol Number:* 1021–EIGE. *Docket ID Number:* EPA–HQ–OPP–2019–0364. *Applicant:* MGK, 8810 Tenth Avenue North, Minneapolis, MN 55427. *Active ingredient:* Metofluthrin. *Product type:* Insecticide. *Proposed Use:* Non-food outdoor residential broadcast spray. *Contact:* RD.

5. *EPA Registration Number:* 10308–30. *Docket ID Number:* EPA–HQ–OPP–2019–0364. *Applicant:* Sumitomo Chemical Co., Ltd.; 27–1 Shinkawa, 2-chome, Chuo-ku, Tokyo, Japan 104–8260 (c/o Technology Sciences Group; 1150 18th St. NW, Suite 1000, Washington, DC 20036). *Active ingredient:* Metofluthrin. *Product type:* Insecticide. *Proposed Use:* Non-food outdoor residential broadcast spray. *Contact:* RD.

6. *EPA File Symbol Number:* 10308–GT. *Docket ID Number:* EPA–HQ–OPP–2019–0280). *Applicant:* Sumitomo Chemical Company, Ltd., 27–1 Shinkawa, 2-Chome, Chuo-Ku, Tokyo, Japan 104–8260 (c/o Technology Sciences Group Inc., 1150 18th St. NW Suite 1000, Washington, DC 20036). *Active Ingredient:* SI–183 (1R-Phenothrin 98%). *Product type:* Insecticide. *Proposed use:* Non-food indoor, outdoor, and residential uses. *Contact:* RD.

7. *EPA Registration Numbers:* 59639–185 and 59639–186. *Docket ID Number:* EPA–HQ–OPP–2019–0230. *Applicant:* Valent U.S.A. LLC, P.O. Box 8025, Walnut Creek, CA 94596–8025. *Active ingredient:* ethaboxam. *Product type:* fungicide. *Proposed use:* seed treatment on sugar beet. *Contact:* RD.

8. *EPA File Symbol Number:* 62719–TGT. *Docket ID Number:* EPA–HQ–OPP–2018–0645. *Applicant:* Dow AgroSciences LLC, 9330 Zionsville Road Indianapolis, IN 46268. *Active ingredient:* Florpyrauxifen-benzyl. *Product type:* Herbicide. *Proposed uses:* Grass forage, fodder, hay, and clover. *Contact:* RD.

9. *EPA Registration Numbers:* 71512–7; 71512–9; 71512–10 and 71512–14. *Docket ID Number:* EPA–HQ–OPP–2019–0250. *Applicant:* ISK Biosciences Corporation, 7470 Auburn Road, Suite A, Concord, Ohio 44077, requests to establish a tolerance for residues of the

insecticide flonicamid in or on greenhouse lettuce, and an increase in the existing tolerance for leafy greens subgroup 4–16A. Adequate enforcement methodology (FMC Method No. P–3561M, a liquid chromatography with tandem mass spectrometry (LC/MS/MS) method) is available to enforce the tolerance expression for flonicamid and its metabolites in or on plant commodities. *Contact:* RD.

10. *EPA Registration Number:* 87301–1. *Docket ID Number:* EPA–HQ–OPP–2010–0247. *Applicant:* Biocontrol Technologies, S.L., Avgda. Madrid, 215–217, entresòl A, 08014 Barcelona, Spain (c/o Wagner Regulatory Associates, Inc., P.O. Box 640, Hockessin, DE 19707). *Active ingredient:* Trichoderma asperellum, strain T34. *Product type:* Fungicide and Bactericide. *Proposed use:* For use outdoors and on food in agricultural and residential settings to protect plants against diseases. *Contact:* BPPD.

Authority: 7 U.S.C. 136 *et seq.*

Dated: July 24, 2019.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. 2019–16732 Filed 8–5–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC–2019–0001; Docket Number NIOSH–323]

Final National Occupational Research Agenda for Hearing Loss Prevention

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: NIOSH announces the availability of the final *National Occupational Research Agenda for Hearing Loss Prevention*.

DATES: The final document was published on July 30, 2019 on the CDC website.

ADDRESSES: The document may be obtained at the following link: <https://www.cdc.gov/nora/councils/hlp/agenda.html>

FOR FURTHER INFORMATION CONTACT: Emily Novicki, M.A., M.P.H.,

(NORACoordinator@cdc.gov), National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Mailstop E–20, 1600 Clifton Road NE, Atlanta, GA 30329, phone (404) 498–2581 (not a toll free number).

SUPPLEMENTARY INFORMATION: On February 5, 2019, NIOSH published a request for public review in the **Federal Register** [84 FR 1736] of the draft version of the *National Occupational Research Agenda for Hearing Loss Prevention*. NIOSH received three comments, which were reviewed and addressed where appropriate. In the final document, an additional research need was added, to perform targeted surveillance of worker hearing, cardiovascular health, mental health, and related health outcomes within worker populations with limited available research, such as workers in small construction firms, landscaping companies, restaurants, bars, sports arenas and complexes, music venues, and within public service. A response to

Public Comment document can be found in the Supporting Documents section on www.regulations.gov for this docket.

John J. Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2019–16743 Filed 8–5–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Secretary's National Advisory Committee on Rural Health and Human Services (NACRHHS) has scheduled a public meeting. Information about NACRHHS and the agenda for this meeting can be found on the NACRHHS website at <https://www.hrsa.gov/advisory-committees/rural-health/index.html>.

DATES: September 9, 2019, 8:30 a.m.–5:15 p.m. Eastern Time (ET). September 10, 2019, 8:30 a.m.–5:15 p.m. ET. September 11, 2019, 8:30 a.m.–11:15 a.m. ET.

ADDRESSES: This meeting will be held in-person at the Hubert H. Humphrey Building, located at 200 Independence Avenue SW, Washington, DC 20201, on September 9, 2019. The meeting will be held in-person at the Residence Inn Washington, Capitol located at 333 E St. SW, Washington, DC 20024, on September 10, 2019, and September 11, 2019.

FOR FURTHER INFORMATION CONTACT: Steven Hirsch, Administrative Coordinator at the Federal Office of Rural Health Policy, HRSA, 5600 Fishers Lane, 17W59D, Rockville, Maryland 20857; 301-443-7322; or shirsch@hrsa.gov.

SUPPLEMENTARY INFORMATION: NACRHHS provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning both rural health and rural human services.

During the September 9, 2019, through September 11, 2019, meeting, NACRHHS will examine the current delivery of health care and human services in rural areas. Agenda items are subject to change as priorities dictate. Refer to the NACRHHS website for any updated information concerning the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to NACRHHS should be sent to Steven Hirsch, using the contact information above, at least three business days prior to the meeting. Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Steven Hirsch at the address and phone number listed above at least 10 business days prior to the meeting. Since the meeting on September 10, 2019, occurs in a federal government building, attendees must go through a security check to enter the building. Non-U.S. Citizen attendees must notify Steven Hirsch of their planned attendance at least 20 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Maria G. Button,

Director, Division of the Executive Secretariat.
[FR Doc. 2019-16770 Filed 8-5-19; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Interest Rate on Overdue Debts

Section 30.18 of the Department of Health and Human Services' claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest, which is determined and fixed by the Secretary of the Treasury after considering private consumer rates of interest on the date that the Department of Health and Human Services becomes entitled to recovery. The rate cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the "Schedule of Certified Interest Rates with Range of Maturities" unless the Secretary waives interest in whole or part, or a different rate is prescribed by statute, contract, or repayment agreement. The Secretary of the Treasury may revise this rate quarterly. The Department of Health and Human Services publishes this rate in the **Federal Register**.

The current rate of 10⁵/₈%, as fixed by the Secretary of the Treasury, is certified for the quarter ended June 30, 2019. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program (42 U.S.C. 254o(b)(1)(A))" and "National Research Service Award Program (42 U.S.C. 288(c)(4)(B))." This interest rate will be applied to overdue debt until the Department of Health and Human Services publishes a revision.

Dated: July 30, 2019.

David C. Horn,

Director, Office of Financial Policy and Reporting.

[FR Doc. 2019-16747 Filed 8-5-19; 8:45 am]

BILLING CODE 4150-04-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Division of Epidemiology and Disease Prevention; Epidemiology Program for American Indian/Alaska Native Tribes and Urban Indian Communities Ending the HIV Epidemic in Indian Country

Announcement Type: Competing Supplement

Funding Announcement Number: HHS-2019-IHS-EPI-0001

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.231

Key Dates

Application Deadline Date: September 5, 2019

Earliest Anticipated Start Date: September 30, 2019

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Public Health Support, Division of Epidemiology and Disease Prevention (DEDP), in partnership with the IHS Office of Clinical and Preventive Services (OCPS) National Human Immunodeficiency Virus (HIV) & Viral Hepatitis C (HCV) Program and the U.S. Department of Health and Human Services (HHS) Minority HIV/AIDS Fund (MHAF) is accepting applications for competitive supplemental funds to enhance activities in the Epidemiology Program for American Indian/Alaska Native (AI/AN) Tribes and Urban Indian communities. This program is funded by the Office of the Assistant Secretary for Health, HHS, is authorized under the statutory earmark for minority AIDS prevention and treatment activities, and is to be carried out pursuant to Title III of the Public Service Act. The funding is being made available through an intra-Departmental Delegation of Authority (IDDA) to award specific funding for fiscal year (FY) 2019. This program is described in the Assistance Listings located at <https://beta.sam.gov> (formerly known as Catalog of Federal Domestic Assistance) under 93.231.

Background

The Tribal Epidemiology Center (TEC) program was authorized by Congress in 1996 as a way to provide public health support to multiple Tribes and Urban Indian communities in each of the IHS Areas. Only current TEC grantees are eligible to apply for the competing supplemental funding under this announcement and must demonstrate that they have complied with previous terms and conditions of the TEC program.

The Office of Infectious Disease and HIV/AIDS Policy (OIDP) is located within the Office of the Assistant Secretary for Health HHS. The OIDP has directed the IHS to make awards to conduct projects and activities in support of the Ending the HIV Epidemic: A Plan for America initiative (EHE). The purpose of MHAF is to reduce new HIV infections, improve HIV-related health outcomes, and to reduce HIV-related health disparities for racial and ethnic minority communities by supporting innovation, collaboration, and the integration of best practices,

effective strategies, and promising emerging models in the response to HIV among minority communities.

Current data on the burden of HIV in the United States (U.S.) tells us where HIV transmission occurs more frequently than other jurisdictions. In 2016 and 2017, more than 50% of new HIV diagnoses occurred in 48 counties and the jurisdictions of Washington, District of Columbia (DC) and San Juan, Puerto Rico. In addition, seven states have a substantial rural burden reflecting more than 75 cases and 10% or more of their diagnoses in rural areas.

Our national investments in HIV for nearly four decades have shown remarkable results in preventing new infections, improving health outcomes, and reducing deaths in hundreds of thousands of Americans. Despite this, progress has plateaued and additional effort is needed to ensure that all affected groups derive benefit equally. Some groups, like American Indian/Alaska Native, African American and Latino gay and bisexual men, transgender individuals, or people living in the South, have a higher burden of HIV and experience health disparities at each stage of the HIV care continuum. Southern states today account for an estimated 44% of all people living with an HIV diagnosis in the U.S.,¹ despite having only about one-third (37%) of the overall U.S. population.² Diagnosis rates for people in the South are higher than for Americans overall. Eight of the 10 states and all 10 metropolitan statistical areas with the highest rates of new HIV diagnoses are in the South. In addition to the severe burden in the South, nationally there is a high incidence of HIV among transgender individuals, high-risk heterosexuals, and persons who inject drugs.³

As recognized by the President during the February 2019 State of the Union address, we have an unprecedented opportunity to end the HIV epidemic in America. We have access to the most powerful HIV prevention and treatment tools in history and new technology that allows us to pinpoint where infections

are spreading most rapidly. By effectively equipping all at-risk communities with these tools, we can end the HIV epidemic in America. The EHE acts boldly on this unprecedented opportunity by providing the hardest hit communities with the additional expertise, technology, and resources required to address the HIV epidemic in their communities. Phase One of the EHE focuses on the areas of the nation that comprised more than 50% of the new HIV diagnoses in 2016 and 2017, including 7 states with marked rural HIV burden, 48 individual counties among other states and the jurisdictions of Washington, DC, and San Juan, Puerto Rico. See <https://www.hiv.gov> and <https://files.hiv.gov/s3fs-public/Ending-the-HIV-Epidemic-Counties-and-Territories.pdf> for more information about the EHE and its Phase One focus jurisdictions. The utilization of the MHAFF for this funding announcement given its mission and goals, is a critical building block in this effort and reflects our decision to act now.

HHS recently developed a set of critical health priorities for the nation known as “Leading Health Indicators” (or LHIs) that are a call to action in critical public health areas. HHS will use the LHIs to assess the health of the U.S. population over the next decade, to facilitate collaboration among diverse groups, and to motivate individuals and communities to take action to improve their health. The following LHIs also will be used by policymakers and public health professionals to track progress in local communities as they work toward meeting these key national health goals:

(1) Diagnose 95 percent of persons aged 13 years and older living with HIV who are aware of their HIV infection by 2025, working from a baseline of 85.8 percent in 2016.

(2) Treat 95 percent of persons aged 13 years and older via linkage to appropriate care within one month of diagnosis by 2025, working from a baseline of 78.3 percent in 2017.

(3) Treat 95 percent of persons aged 13 years and older diagnosed with HIV via sufficient viral suppression (viral load, 200 copies/ml) by 2025, working from a baseline of 61.5 percent in 2016.

(4) Prevent new HIV infections by achieving 50–60 percent PrEP coverage among those for whom PrEP was indicated by 2025.

There are notable concerns in new HIV diagnoses in AI/AN populations compared to some other race/ethnicities: (1) New HIV diagnoses among AI/AN people increased by 70% from 2011 to 2016; (2) AI/AN patients have the lowest three-year survival rates of any race/ethnicity after an AIDS

diagnosis; and (3) both male and female AI/AN people had the highest percent of estimated diagnoses of HIV infection attributed to injection drug use.⁴ Mortality data also found that AI/AN individuals have significantly higher death rates from HIV/AIDS than whites, which could be attributable to later diagnosis, lack of linkage to care, difficulty accessing care, challenges to treatment adherence, or other factors or combination of factors.

Another common co-morbidity for bloodborne HIV infection is Hepatitis C Virus (HCV) infection. In 2009, approximately 21% of HIV-infected adults who were tested for past or present HCV infection tested positive, although co-infection prevalence varies substantially according to HIV-infected risk group (e.g., men who have sex with men (MSM), high-risk heterosexuals, and persons who inject drugs).^{5–7} As HCV is a bloodborne virus primarily transmitted through direct contact with the blood of an infected person, coinfection with HIV and HCV is common (62–80%) among HIV-infected injection-drug users.^{8–10} Although transmission via injection drug use remains the most common mode of HCV acquisition in the U.S.,⁹ sexual transmission is an important mode of acquisition among certain groups, including HIV-infected MSM with certain risk factors.¹¹ Data have shown

⁴ <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2016-vol-28.pdf>.

⁵ Garg S, Brooks J, Luo Q, Skarbinski J. Prevalence of and Factors Associated with Hepatitis C Virus (HCV) Testing and Infection Among HIV-infected Adults Receiving Medical Care in the United States. Infectious Disease Society of America (IDSA). Philadelphia, PA, 2014.

⁶ Yehia BR, Herati RS, Fleishman JA, Gallant JE, Agwu AL, Berry SA, et al. Hepatitis C virus testing in adults living with HIV: A need for improved screening efforts. PLoS ONE 2014;9(7):e102766. <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0102766>.

⁷ Spradling PR, Richardson JT, Buchacz K. Trends in hepatitis C virus infection among patients in the HIV Outpatient Study, 1996–2007. J Acquir Immune Defic Syndr 2010;53:388–396.

⁸ Yehia BR, Herati RS, Fleishman JA, Gallant JE, Agwu AL, Berry SA, et al. Hepatitis C virus testing in adults living with HIV: A need for improved screening efforts. PLoS ONE 2014;9(7):e102766. <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0102766>.

⁹ Spradling PR, Richardson JT, Buchacz K. Trends in hepatitis C virus infection among patients in the HIV Outpatient Study, 1996–2007. J Acquir Immune Defic Syndr 2010;53:388–396.

¹⁰ Centers for Disease Control and Prevention. <https://www.cdc.gov/hepatitis/statistics/2015/surveillance/commentary.htm>. Atlanta: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2017.

¹¹ Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents. Guidelines for the prevention and treatment of opportunistic

¹ Centers for Disease Control and Prevention (CDC). HIV Surveillance Report, 2014; vol. 26. Available at <http://www.cdc.gov/hiv/library/reports/surveillance/>. Published December 2015.

² U.S. Census Bureau. Annual Estimates of the Resident Population: April 1, 2010 to July 1, 2014. Available at http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=PEP_2014_PEPANNRES&src=pt. Accessed November 13, 2015.

³ Department of Health and Human Services, Centers for Disease Control and Prevention. HIV in the United States and dependent areas. <https://www.cdc.gov/hiv/statistics/overview/atlantance.html>. Updated January 29, 2019. Accessed February 5, 2019.

that HCV disproportionately affects AI/AN people, with HCV-related mortality more than double the national rate.¹² In a recent IHS survey, almost 50% of the AI/AN individuals diagnosed with HCV were born after 1965 and younger than the targeted birth cohort for HCV screening campaigns (1945–1965, ‘Baby Boomers’). Untreated HCV can lead to a myriad of extrahepatic manifestations and cirrhosis with complications such as portal hypertension, end stage liver disease, and hepatocellular carcinoma (HCC). Early diagnosis and treatment of HCV infection prevents the development of extrahepatic manifestations, and progressive liver disease including cirrhosis. Recently developed treatments for HCV are more accessible and highly effective at greatly reducing HCV- and HCC-related mortality. Treatment for HCV can be highly successful at the primary care level with appropriate planning and support.

Data also show that Sexually Transmitted Infection (STI) rates remain elevated in Indian Country. Recurrent STIs can increase the likelihood of HIV transmission. Gonorrhea and syphilis often present as co-morbid conditions with HIV diagnosis, particularly among MSM. The latest Indian Health Surveillance Report: Sexually Transmitted Diseases 2015¹³ showed that AI/AN people have 3.8 times the incidence rate of whites for chlamydia and 4.4 times the rate of whites for gonorrhea. Compared to other races/ethnicities, AI/AN people have the second highest rates for both chlamydia and gonorrhea. Gonorrhea rates have continued to increase drastically since 2011. Regional differences in STI incidence in Indian Country are also observed. There is a disparate and increased STI burden among AI/AN youth and AI/AN women, particularly women of reproductive age. In addition, recent outbreaks of syphilis have been observed among AI/AN communities. Some of these outbreaks are connected to the use of injection drugs and methamphetamines, all known risk factors for HIV transmission.

Finally, treatment for substance use disorders can be difficult to access in IHS catchment areas, as the

appropriated budget includes fewer dollars per patient compared to other federal direct-care networks. Untreated substance use disorders can exacerbate risk-taking behavior and reduce adherence to treatment.

Confronting these intersecting epidemics requires collaboration across sectors and disciplines and the use of existing public health and clinical infrastructures. Lasting changes to these trends for HIV and related comorbidities among AI/AN people will also require innovative new approaches, incorporating existing and new data sources, all driven by community input.

Purpose

The purpose of this IHS competitive supplement is to support communities in reducing new HIV infections and relevant co-morbidities, specifically STI and HCV infections, improve HIV-, STI- and HCV-related health outcomes, and to reduce HIV-, STI- and HCV-related health disparities among AI/AN people.

The MHAF is funding IHS grantees to meet the four strategies of EHE—diagnose, treat, protect, and respond. Our goal is ambitious and the pathway is clear—employ strategic practices in Indian Country to: (1) Diagnose all people with HIV as early as possible after infection; (2) treat the infection rapidly and effectively to achieve sustained viral suppression; (3) respond rapidly to detect and respond to growing HIV clusters and prevent new HIV infections and (4) establish local teams committed to the success of the initiative in each jurisdiction.

To reach the EHE goal of 75% reduction in new HIV infections in 5 years and at least 90% reduction in 10 years, the IHS, through an IDDA to obligate specific amounts from MHAF, is offering this funding opportunity to the TECs to support activities across Indian Country within the *Community Planning Domain*.

Developing the Foundation for Phase 1 of EHE: The Community Planning Domain

Each application must address the *Community Planning Domain* of the EHE. Aspects to include are listed below and are priority areas for this Notice of Funding Opportunity (NOFO). However, applications may include other aspects of the community planning domain not specifically mentioned below. Proposed activities should focus on HIV but should also include opportunities to address relevant STIs and HCV.

Limited Competition Justification

The IHS enters into cooperative agreements with TECs under the authority of Section 214(a)(1) of the Indian Health Care Improvement Act, Public Law 94–437, as amended by Public Law 102–573. The TECs carry out a variety of functions specified in statute. These functions include data collection and analysis; evaluation of existing delivery systems, data systems, and other systems that impact the improvement of Indian health; making recommendations for the targeting of services; and provision of requested technical assistance to Indian Tribes, Tribal Organizations, and Urban Indian Organizations [25 U.S.C. 1621m(b)]. Other organizations do not have the capacity to provide this support. With respect to access to information, TECs are treated as public health authorities for the purposes of the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191). Unlike their counterparts, they have no or little funding from their jurisdictional governments to perform these public functions.

This limited-eligibility NOFO will allow the TECs to directly support the communities they serve in their HIV/HCV/STI diagnosis, prevention, treatment, and response efforts. The TECs already possess technical expertise in program management, community-based interventions and educational tool development. The TECs must have demonstrated their ability to methodically and effectively reach Tribal members and efficiently work with AI/AN populations on their public health capacity building. Selected organizations that have previous experience working effectively with Tribal governments will help ensure that interventions and infrastructure are culturally appropriate and locally-minded.

II. Award Information

Funding Instrument

Cooperative Agreement.

Estimated Funds Available

The total funding identified for FY 2019 is approximately \$500,000. Individual award amounts will be up to \$100,000 total costs per year (direct costs plus indirect costs). 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.

infections in HIV-infected adults and adolescents: Recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Available at <https://www.ncbi.nlm.nih.gov/pubmed/19357635> July 6, 2018.

¹² <https://aspe.hhs.gov/system/files/pdf/260026/HepC.pdf>.

¹³ https://www.ihs.gov/epi/includes/themes/responsive2017/display_objects/documents/std/Indian_Health_Surveillance_Report_STD_2015.pdf.

The TEC sites serving areas that do not include the Phase One priority jurisdictions are eligible to apply for the 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 two years.

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 Involvement Description for Cooperative Agreement

(1) The IHS Office of Public Health Support (OPHS) Division of Epidemiology and Disease Prevention (DEDP) and the IHS Office of Clinical and Preventive Services (OCPS), Division of Clinical and Community Services (DCCS) will provide ongoing consultation and technical assistance to plan, implement, and evaluate each component as described under Recipient Activities.

(2) The IHS will conduct site visits to TECs and/or coordinate TEC visits to IHS and other federal, state, county, or AI/AN-serving agencies to assess work plans and ensure data security, confirm compliance with applicable laws and regulations, assess program activities, and to mutually resolve problems, as needed.

(3) The IHS OPHS/DEDP and OCPS/DCCS will provide a forum for outreach and education to advance the goals of this program through existing and new partnerships. The IHS will facilitate TECs' participation in the IHS National AI/AN STD Prevention workgroup, a forum that includes approximately 150 participants from clinical, public health, advocacy and education sectors working in HIV/STI control.

(4) The IHS OPHS/DEDP and OCPS/DCCS will coordinate reporting and technical assistance as required.

III. Eligibility Information

1. Eligibility

Only current TEC awardees are eligible to apply for the competing supplemental funding under this announcement and must demonstrate that they have complied with previous

terms and conditions of the TEC program.

TEC sites serving areas that do not include the Phase One priority jurisdictions are eligible to apply for the funding under this announcement.

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 are hosted on <http://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 goals, specific, measurable, achievable, realistic and time-bound) (SMART) objectives (see https://www.cdc.gov/tb/programs/Evaluation/Guide/PDF/b_write_objective.pdf, for more information),

scope of work, and activities (to be included in a one-page timeframe chart) 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.
- Glossary of terms and acronyms used in the application.
- Letters of Support from organization's Board of Directors (optional).
- 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.
- 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>,

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—3 pages)

Section 1: Needs. Describe the TEC's current health program activities, how long it has been operating, and what programs or services are currently being provided by the organization. Describe how the Tribal Organization has determined it has the administrative infrastructure to support the activities proposed.

Part 2: Program Planning and Evaluation (limit—3 pages)

Section 1: Program Plans. Describe fully and clearly the activities the TEC plans to conduct this work.

Section 2: Program Evaluation. Describe fully and clearly the improvements that will be made by the TEC to meet the public health needs of the community in the context of the funding requirements.

Part 3: Program Report (limit—4 pages)

Section 1: Describe your organization's significant program activities and accomplishments over the past five years associated with the goals of this announcement.

Please identify and describe significant program activities and achievements associated with the proposed activities. Provide a comparison of the actual accomplishments to the goals established for the project period, or if applicable, provide justification for the lack of progress.

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. For subsequent budget years, the narrative should highlight the changes from year one or clearly indicate that there are no substantive budget changes during the period of performance. 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 10 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 allowable up to 90 days before the start date of the award provided the costs are otherwise allowable if awarded. Pre-award costs are incurred at the risk of the applicant.
- The available funds are inclusive of direct and indirect costs.
- Only one supplement will be awarded per applicant.

6. Electronic Submission Requirements

All applications must be submitted via *Grants.gov*. Please use the <http://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 the 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 <http://www.Grants.gov> by entering the Assistance Listing (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 20 working days.
- Please follow the instructions on *Grants.gov* to include additional documentation that may be requested by this funding announcement.
- 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 nine-digit identification number provided by D&B that 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 <http://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 DGM Grants Management, Policy Topics website: <http://www.ihs.gov/dgm/policytopics/>.

V. Application Review Information

Weights assigned to each section are noted in parentheses. The 10-page project narrative should include only the first year of activities; information for multi-year projects should be included as an appendix. See "Multi-year Project Requirements" at the end of this section for more information. The narrative section 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 (10 Points)

Must include the applicant's background information, a description

of epidemiological service, epidemiologic capacity and history of support for such activities. Applicants need to include current public health activities, what program services are currently being provided, and interactions with other public health authorities in the region (state, local, or Tribal).

Please describe how the TEC will make improvements in capacity to address IHS, Tribal and Urban (I/T/U), local-level, and/or Area-level HIV/HCV/STI burden. In order to significantly reduce transmission of HIV/HCV/STI, I/T/U need baseline and annual measurements of HIV/HCV/STI diagnoses, linkage to care, and viral load measurements, as applicable. TECs will also help evaluate geographies with higher burden of HIV/HCV/STI and assist communities in targeting interventions.

B. Project Objective(s), Work Plan and Approach (25 Points)

a. Clearly identify the operational strategies to be addressed by the TEC. Activities in at least two of the EHE's key operational strategies should be planned for completion within the program period (indicate these two activities in bold).

b. Applicants will outline their approach for addressing the operational strategies in the work plan or logic model. Outline overarching activities, short-term and long term-outcomes. Make note of proposed timelines and partners who will be involved in each activity.

Activities

Applications must include the following activities:

1. Coordination Operational Strategy

i. Grantees will send at least one representative to the annual HIV Coordination meeting, scheduled in September of each year to coincide with the U.S. Conference on AIDS. Budget should include travel and associated costs for participation.

ii. Grantees will participate in the IHS National AI/AN STI Prevention workgroup.

2. Diagnosis Operational Strategy

The TECs will provide technical assistance and/or disease surveillance support to communities by developing analytical reports to examine the burden of HIV and other relevant comorbidities such as STIs and HCV in Tribal communities.

3. Treatment Operational Strategy

The TECs will provide support to communities in the development of enhanced activities and expanded capacity to better identify people who are not in care, including those who were never linked to care following an HIV, STI, or HCV diagnosis and those who have fallen out of care.

4. Respond Operational Strategy

Respond rapidly to detect and characterize growing HIV, STI, or HCV clusters and prevent new infections. TECs will provide technical assistance and/or direct support to communities on the following activities:

i. Develop or accelerate the development of community plans that are customized for AI/AN communities. Extensive community engagement in this process will help ensure that community-specific social norms and unique epidemic attributes are addressed. Initial community-specific plans will be requested by May 31, 2020. Planning should reflect the time-sensitive nature of this activity.

ii. Develop collaborative partnerships among Tribal, state, and local health departments, the clinical community, and community-based organizations to expand and routinize HIV diagnosis, treatment, prevention and response.

C. Program Evaluation (30 Points)

a. Clearly identify plans for program evaluation to ensure that objectives of the program are met at the conclusion of the funding period.

b. Include (SMART) evaluation criteria.

c. Evaluation should minimally include summaries of activities in each of the proposed key operational strategies.

D. Organizational Capabilities, Key Personnel and Qualifications (30 Points)

a. Include an organizational capacity statement which demonstrates the ability to execute program strategies within the program period.

b. Project management and staffing plan. Detail that the organization has the current staffing and expertise to address each of the program activities. If current capacity does not exist please describe the actions that the TEC will take to fulfill this gap within a specified timeline.

c. Demonstrate local partners' willingness to work with TEC on proposed efforts. Applicants are particularly encouraged to collaborate with other federally-funded organizations such as their local health departments and Ryan White HIV/AIDS Program awardees.

d. Demonstrate that the TEC has previous successful experience providing technical or programmatic support to Tribal communities.

E. Categorical Budget and Budget Justification (5 Points)

a. Provide a detailed budget and accompanying narrative to explain the activities being considered and how they are related to proposed program objectives.

Multi-Year Project Requirements

Applications must include a brief project narrative and budget (one additional page per year) addressing the developmental plans for each additional year of the project. This attachment will not count as part of the project narrative or the budget 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 Rate Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Glossary of terms and acronyms used in the application.
- 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 OPHS 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 agreement 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 <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.

Additional quarterly reports and quarterly calls discussing progress on a standardized form are required for this funding. Post-award, the standard form will be disseminated to all funded programs.

Special attention should be devoted to reporting on the development of community plans required under the Respond Operational Strategy.

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) 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. Data Collection and Reporting

The TEC must report annually (by their respective IHS Area or Tribal health board) the progress towards EHE goals via a standardized form.

The TEC will participate in quarterly calls with the program office.

D. 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 <http://www.ihs.gov/dgm/policytopics/>.

E. 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 the 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.

F. 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. 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: Mr. 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: Ms. Lisa C. Neel, Public Health Advisor, Office of Public Health Support, Division of Epidemiology & Disease Prevention, Indian Health Service, 5600 Fishers Lane, Mailstop: 09E17B, Rockville, MD 20857, Phone: (301) 443-4305, Email: Lisa.Neel@ihs.gov.

2. Questions on grants management and fiscal matters may be directed to: Mr. John Hoffman, Senior Grants Management Specialist, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-2116, Fax: (301) 594-0899, Email: John.Hoffman@ihs.gov.

3. Questions on systems matters may be directed to: Mr. 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, Email: 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.

Dated: July 31, 2019.

Michael D. Weahkee,

Assistant Surgeon General, U.S. Public Health Service, Principal Deputy Director, Indian Health Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Division of Epidemiology and Disease Prevention; Epidemiology Program for American Indian/Alaska Native Tribes and Urban Indian Communities Ending the HIV Epidemic in Indian Country

Announcement Type: Competing Supplement.

Funding Announcement Number: HHS-2019-IHS-EPI-0002.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.231.

Key Dates

Application Deadline Date: September 5, 2019.

Earliest Anticipated Start Date: September 30, 2019.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Public Health Support, Division of Epidemiology and Disease Prevention (DEDP), in partnership with the IHS Office of Clinical and Preventive Services (OCPS) National Human Immunodeficiency Virus (HIV) & Viral Hepatitis C (HCV) Program and the U.S. Department of Health and Human Services (HHS) Minority HIV/AIDS Fund (MHAF) is accepting applications for competitive supplemental funds to enhance

activities in the Epidemiology Program for American Indian/Alaska Native (AI/AN) Tribes and Urban Indian communities. This program is funded by the Office of the Assistant Secretary, HHS, is authorized under the statutory earmark for minority AIDS prevention and treatment activities, and is to be carried out pursuant to Title III of the Public Service Act. The funding is being made available through an intra-Departmental Delegation of Authority (IDDA) to award specific funding for fiscal year (FY) 2019. This program is described in the Assistance Listings located at <https://beta.sam.gov> (formerly known as Catalog of Federal Domestic Assistance) under 93.231.

Background

The Tribal Epidemiology Center (TEC) program was authorized by Congress in 1996 as a way to provide public health support to multiple Tribes and Urban Indian communities in each of the IHS Areas. Only current TEC grantees are eligible to apply for the competing supplemental funding under this announcement and must demonstrate that they have complied with previous terms and conditions of the TEC program.

The Office of Infectious Disease and HIV/AIDS Policy (OIDP) is located within the Office of the Assistant Secretary for Health HHS. The OIDP has directed the IHS to make awards to conduct projects and activities in support of the Ending the HIV Epidemic: A Plan for America initiative (EHE). The purpose of MHAF is to reduce new HIV infections, improve HIV-related health outcomes, and to reduce HIV-related health disparities for racial and ethnic minority communities by supporting innovation, collaboration, and the integration of best practices, effective strategies, and promising emerging models in the response to HIV among minority communities.

Current data on the burden of HIV in the United States (U.S.) tells us where HIV transmission occurs more frequently than other jurisdictions. In 2016 and 2017, more than 50% of new HIV diagnoses occurred in 48 counties and the jurisdictions of Washington, District of Columbia (DC) and San Juan, Puerto Rico. In addition, seven states have a substantial rural burden reflecting more than 75 cases and 10% or more of their diagnoses in rural areas.

Our national investments in HIV for nearly four decades have shown remarkable results in preventing new infections, improving health outcomes, and reducing deaths in hundreds of thousands of Americans. Despite this, progress has plateaued and additional

effort is needed to ensure that all affected groups derive benefit equally. Some groups, like American Indian/Alaska Native, African American and Latino gay and bisexual men, transgender individuals, or people living in the South, have a higher burden of HIV and experience health disparities at each stage of the HIV care continuum. Southern states today account for an estimated 44% of all people living with an HIV diagnosis in the U.S.,¹ despite having only about one-third (37%) of the overall U.S. population.² Diagnosis rates for people in the South are higher than for Americans overall. Eight of the 10 states and all 10 metropolitan statistical areas with the highest rates of new HIV diagnoses are in the South. In addition to the severe burden in the South, nationally there is a high incidence of HIV among transgender individuals, high-risk heterosexuals, and persons who inject drugs.³

As recognized by the President during the February 2019 State of the Union address, we have an unprecedented opportunity to end the HIV epidemic in America. We have access to the most powerful HIV prevention and treatment tools in history and new technology that allows us to pinpoint where infections are spreading most rapidly. By effectively equipping all at-risk communities with these tools, we can end the HIV epidemic in America. The EHE acts boldly on this unprecedented opportunity by providing the hardest hit communities with the additional expertise, technology, and resources required to address the HIV epidemic in their communities. Phase One of the EHE focuses on the areas of the nation that comprised more than 50% of the new HIV diagnoses in 2016 and 2017, including 7 states with marked rural HIV burden, 48 individual counties among other states and the jurisdictions of Washington, DC, and San Juan, Puerto Rico. See <https://www.hiv.gov> and <https://files.hiv.gov/s3fs-public/Ending-the-HIV-Epidemic-Counties-and-Territories.pdf> for more information about the EHE and its Phase One focus

jurisdictions. The utilization of the MHAFF for this funding announcement given its mission and goals, is a critical building block in this effort and reflects our decision to act now.

HHS recently developed a set of critical health priorities for the nation known as “Leading Health Indicators” (or LHIs) that are a call to action in critical public health areas. HHS will use the LHIs to assess the health of the U.S. population over the next decade, to facilitate collaboration among diverse groups, and to motivate individuals and communities to take action to improve their health. The following LHIs also will be used by policymakers and public health professionals to track progress in local communities as they work toward meeting these key national health goals:

(1) Diagnose 95 percent of persons aged 13 years and older living with HIV who are aware of their HIV infection by 2025, working from a baseline of 85.8 percent in 2016.

(2) Treat 95 percent of persons aged 13 years and older via linkage to appropriate care within one month of diagnosis by 2025, working from a baseline of 78.3 percent in 2017.

(3) Treat 95 percent of persons aged 13 years and older diagnosed with HIV via sufficient viral suppression (viral load, 200 copies/ml) by 2025, working from a baseline of 61.5 percent in 2016.

(4) Prevent new HIV infections by achieving 50–60 percent PrEP coverage among those for whom PrEP was indicated by 2025.

There are notable concerns in new HIV diagnoses in AI/AN populations compared to some other race/ethnicities: (1) New HIV diagnoses among AI/AN people increased by 70% from 2011 to 2016; (2) AI/AN patients have the lowest three-year survival rates of any race/ethnicity after an AIDS diagnosis; and (3) both male and female AI/AN people had the highest percent of estimated diagnoses of HIV infection attributed to injection drug use.⁴ Mortality data also found that AI/AN individuals have significantly higher death rates from HIV/AIDS than whites, which could be attributable to later diagnosis, lack of linkage to care, difficulty accessing care, challenges to treatment adherence, or other factors or combination of factors.

Another common co-morbidity for bloodborne HIV infection is Hepatitis C Virus (HCV) infection. In 2009, approximately 21% of HIV-infected adults who were tested for past or present HCV infection tested positive,

although co-infection prevalence varies substantially according to HIV-infected risk group (e.g., men who have sex with men (MSM), high-risk heterosexuals, and persons who inject drugs).^{5–7} As HCV is a bloodborne virus primarily transmitted through direct contact with the blood of an infected person, coinfection with HIV and HCV is common (62–80%) among HIV-infected injection-drug users.^{8–10} Although transmission via injection drug use remains the most common mode of HCV acquisition in the U.S.,⁹ sexual transmission is an important mode of acquisition among certain groups, including HIV-infected MSM with certain risk factors.¹¹ Data have shown that HCV disproportionately affects AI/AN people, with HCV-related mortality more than double the national rate.¹² In a recent IHS survey, almost 50% of the AI/AN individuals diagnosed with HCV were born after 1965 and younger than the targeted birth cohort for HCV screening campaigns (1945–1965, ‘Baby Boomers’). Untreated HCV can lead to a myriad of extrahepatic manifestations and cirrhosis with complications such as portal hypertension, end stage liver disease, and hepatocellular carcinoma (HCC). Early diagnosis and treatment of

⁵ Garg S, Brooks J, Luo Q, Skarbinski J. Prevalence of and Factors Associated with Hepatitis C Virus (HCV) Testing and Infection Among HIV-infected Adults Receiving Medical Care in the United States. Infectious Disease Society of America (IDSA). Philadelphia, PA, 2014.

⁶ Yehia BR, Herati RS, Fleishman JA, Gallant JE, Agwu AL, Berry SA, et al. Hepatitis C virus testing in adults living with HIV: A need for improved screening efforts. PLoS ONE 2014;9(7):e102766. <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0102766>.

⁷ Spradling PR, Richardson JT, Buchacz K. Trends in hepatitis C virus infection among patients in the HIV Outpatient Study, 1996–2007. J Acquir Immune Defic Syndr 2010;53:388–396.

⁸ Yehia BR, Herati RS, Fleishman JA, Gallant JE, Agwu AL, Berry SA, et al. Hepatitis C virus testing in adults living with HIV: a need for improved screening efforts. PLoS ONE 2014;9(7):e102766. <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0102766>.

⁹ Spradling PR, Richardson JT, Buchacz K. Trends in hepatitis C virus infection among patients in the HIV Outpatient Study, 1996–2007. J Acquir Immune Defic Syndr 2010;53:388–396.

¹⁰ Centers for Disease Control and Prevention. <https://www.cdc.gov/hepatitis/statistics/2015surveillance/commentary.htm>. Atlanta: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2017.

¹¹ Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents. Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Available at <https://www.ncbi.nlm.nih.gov/pubmed/19357635> July 6, 2018.

¹² <https://aspe.hhs.gov/system/files/pdf/260026/HepC.pdf>.

¹ Centers for Disease Control and Prevention (CDC). HIV Surveillance Report, 2014; vol. 26. Available at <https://www.cdc.gov/hiv/library/reports/surveillance/>. Published December 2015.

² U.S. Census Bureau. Annual Estimates of the Resident Population: April 1, 2010 to July 1, 2014. Available at http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=PEP_2014_PEPANNRES&src=pt. Accessed November 13, 2015.

³ Department of Health and Human Services, Centers for Disease Control and Prevention. HIV in the United States and dependent areas. <https://www.cdc.gov/hiv/statistics/overview/ata glance.html>. Updated January 29, 2019. Accessed February 5, 2019.

⁴ <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2016-vol-28.pdf>.

HCV infection prevents the development of extrahepatic manifestations, and progressive liver disease including cirrhosis. Recently developed treatments for HCV are more accessible and highly effective at greatly reducing HCV- and HCC-related mortality. Treatment for HCV can be highly successful at the primary care level with appropriate planning and support.

Data also show that Sexually Transmitted Infection (STI) rates remain elevated in Indian Country. Recurrent STIs can increase the likelihood of HIV transmission. Gonorrhea and syphilis often present as co-morbid conditions with HIV diagnosis, particularly among MSM. The latest Indian Health Surveillance Report: Sexually Transmitted Diseases 2015¹³ showed that AI/AN people have 3.8 times the incidence rate of whites for chlamydia and 4.4 times the rate of whites for gonorrhea. Compared to other races/ethnicities, AI/AN people have the second highest rates for both chlamydia and gonorrhea. Gonorrhea rates have continued to increase drastically since 2011. Regional differences in STI incidence in Indian Country are also observed. There is a disparate and increased STI burden among AI/AN youth and AI/AN women, particularly women of reproductive age. In addition, recent outbreaks of syphilis have been observed among AI/AN communities. Some of these outbreaks are connected to the use of injection drugs and methamphetamines, all known risk factors for HIV transmission.

Finally, treatment for substance use disorders can be difficult to access in IHS catchment areas, as the appropriated budget includes fewer dollars per patient compared to other federal direct-care networks. Untreated substance use disorders can exacerbate risk-taking behavior and reduce adherence to treatment.

Confronting these intersecting epidemics requires collaboration across sectors and disciplines and the use of existing public health and clinical infrastructures. Lasting changes to these trends for HIV and related comorbidities among AI/AN people will also require innovative new approaches, incorporating existing and new data sources, all driven by community input.

Purpose

The purpose of this IHS competitive supplement is to support communities in reducing new HIV infections and

relevant co-morbidities, specifically STI and HCV infections, improve HIV-, STI- and HCV-related health outcomes, and to reduce HIV-, STI- and HCV-related health disparities among AI/AN people.

The MHAF is funding IHS grantees to meet the four strategies of EHE—diagnose, treat, protect, and respond. Our goal is ambitious and the pathway is clear—employ strategic practices in Indian Country to: (1) Diagnose all people with HIV as early as possible after infection; (2) treat the infection rapidly and effectively to achieve sustained viral suppression; (3) respond rapidly to detect and respond to growing HIV clusters and prevent new HIV infections and (4) establish local teams committed to the success of the initiative in each jurisdiction.

To reach the EHE goal of 75% reduction in new HIV infections in 5 years and at least 90% reduction in 10 years, the IHS, through an IDDA to obligate specific amounts from MHAF, is offering this funding opportunity to the TECs to support activities across Indian Country within the *Community Planning Domain*.

Developing the Foundation for Phase 1 of EHE: the Community Planning Domain

Each application must address the *Community Planning Domain* of the EHE. Aspects to include are listed below and are priority areas for this Notice of Funding Opportunity (NOFO). However, applications may include other aspects of the community planning domain not specifically mentioned below. Proposed activities should focus on HIV but should also include opportunities to address relevant STIs and HCV.

Limited Competition Justification

The IHS enters into cooperative agreements with TECs under the authority of Section 214(a)(1) of the Indian Health Care Improvement Act, Public Law 94–437, as amended by Public Law 102–573. The TECs carry out a variety of functions specified in statute. These functions include data collection and analysis; evaluation of existing delivery systems, data systems, and other systems that impact the improvement of Indian health; making recommendations for the targeting of services; and provision of requested technical assistance to Indian Tribes, Tribal Organizations, and Urban Indian Organizations [25 U.S.C. 1621m(b)]. Other organizations do not have the capacity to provide this support. With respect to access to information, TECs are treated as public health authorities for the purposes of the Health Insurance

Portability and Accountability Act of 1996 (Pub. L. 104–191). Unlike their counterparts, they have no or little funding from their jurisdictional governments to perform these public functions.

This limited-eligibility NOFO will allow the TECs to directly support the communities they serve in their HIV/HCV/STI diagnosis, prevention, treatment, and response efforts. The TECs already possess technical expertise in program management, community-based interventions and educational tool development. The TECs must have demonstrated their ability to methodically and effectively reach Tribal members and efficiently work with AI/AN populations on their public health capacity building. Selected organizations that have previous experience working effectively with Tribal governments will help ensure that interventions and infrastructure are culturally appropriate and locally-minded.

II. Award Information

Funding Instrument Cooperative Agreement

Estimated Funds Available

The total funding identified for FY 2019 is approximately \$1,900,000. Individual award amounts for the first budget year are anticipated to be between \$250,000 and \$275,000. 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.

The TEC sites serving areas that include the Phase One priority jurisdictions are eligible to apply for the funding under this announcement.

Anticipated Number of Awards

Approximately seven awards will be issued under this program announcement.

Period of Performance

The period of performance is for two years.

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.

¹³ https://www.ihs.gov/epi/includes/themes/responsive2017/display_objects/documents/std/Indian_Health_Surveillance_Report_STD_2015.pdf.

Substantial Involvement Description for Cooperative Agreement

(1) The IHS Office of Public Health Support (OPHS) Division of Epidemiology and Disease Prevention (DEDP) and the IHS Office of Clinical and Preventive Services (OCPS), Division of Clinical and Community Services (DCCS) will provide ongoing consultation and technical assistance to plan, implement, and evaluate each component as described under Recipient Activities.

(2) The IHS will conduct site visits to TECs and/or coordinate TEC visits to IHS and other federal, state, county, or AI/AN-serving agencies to assess work plans and ensure data security, confirm compliance with applicable laws and regulations, assess program activities, and to mutually resolve problems, as needed.

(3) The IHS OPHS/DEDP and OCPS/DCCS will provide a forum for outreach and education to advance the goals of this program through existing and new partnerships. The IHS will facilitate TECs' participation in the IHS National AI/AN STD Prevention workgroup, a forum that includes approximately 150 participants from clinical, public health, advocacy and education sectors working in HIV/STI control.

(4) The IHS OPHS/DEDP and OCPS/DCCS will coordinate reporting and technical assistance as required.

III. Eligibility Information

1. Eligibility

Only current TEC awardees are eligible to apply for the competing supplemental funding under this announcement and must demonstrate that they have complied with previous terms and conditions of the TEC program.

TEC sites serving areas that include the Phase One priority jurisdictions are eligible to apply for the funding under this announcement.

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 are 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 goals, specific, measurable, achievable, realistic and time-bound) (SMART) objectives (see https://www.cdc.gov/tb/programs/Evaluation/Guide/PDF/b_write_objective.pdf, for more information), scope of work, and activities (to be included in a one-page timeframe chart) 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.
 - Glossary of terms and acronyms used in the application.
 - Letters of Support from organization's Board of Directors (optional).
 - 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.
- 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>

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—3 pages)

Section 1: Needs.

Describe the TEC's current health program activities, how long it has been operating, and what programs or services are currently being provided by the organization. Describe how the Tribal Organization has determined it has the administrative infrastructure to support the activities proposed.

Part 2: Program Planning and Evaluation (limit—3 pages)

Section 1: Program Plans.

Describe fully and clearly the activities the TEC plans to conduct this work.

Section 2: Program Evaluation.

Describe fully and clearly the improvements that will be made by the TEC to meet the public health needs of the community in the context of the funding requirements.

Part 3: Program Report (limit—4 pages)

Section 1: Describe your organization's significant program activities and accomplishments over the past five years associated with the goals of this announcement.

Please identify and describe significant program activities and achievements associated with the proposed activities. Provide a comparison of the actual accomplishments to the goals established for the project period, or if applicable, provide justification for the lack of progress.

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. For subsequent budget years, the narrative should highlight the changes from year one or clearly indicate that there are no substantive budget changes during the period of performance. 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 10 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 allowable up to 90 days before the start date of the award provided the costs are otherwise allowable if awarded. Pre-award costs are incurred at the risk of the applicant.
- The available funds are inclusive of direct and indirect costs.
- Only one supplement will be awarded per applicant.

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 the 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 Assistance Listing (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 20 working days.

- Please follow the instructions on *Grants.gov* to include additional documentation that may be requested by this funding announcement.

- 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 nine-digit identification number provided by D&B that 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 DGM Grants Management, Policy Topics website: <https://www.ihs.gov/dgm/policytopics/>.

V. Application Review Information

Weights assigned to each section are noted in parentheses. The 10-page project narrative should include only the first year of activities; information for multi-year projects should be included as an appendix. See “Multi-year Project Requirements” at the end of this section for more information. The narrative section 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 (10 Points)

Must include the applicant’s background information, a description of epidemiological service, epidemiologic capacity and history of support for such activities. Applicants need to include current public health activities, what program services are currently being provided, and interactions with other public health authorities in the region (state, local, or Tribal).

Please describe how the TEC will make improvements in capacity to address IHS, Tribal and Urban (I/T/U), local-level, and/or Area-level HIV/HCV/STI burden. In order to significantly reduce transmission of HIV/HCV/STI, I/T/U need baseline and annual measurements of HIV/HCV/STI diagnoses, linkage to care, and viral load measurements, as applicable. The TECs

will also help evaluate geographies with higher burden of HIV/HCV/STI and assist communities in targeting interventions.

B. Project Objective(s), Work Plan and Approach (25 Points)

a. Clearly identify the operational strategies to be addressed by the TEC. Activities in at least two of the EHE’s key operational strategies should be planned for completion within the program period (indicate these two activities in bold).

b. Applicants will outline their approach for addressing the operational strategies in the work plan or logic model. Outline overarching activities, short-term and long-term outcomes. Make note of proposed timelines and partners who will be involved in each activity.

Activities

Applications must include the following activities:

1. Coordination Operational Strategy

i. Grantees will send at least one representative to the annual HIV Coordination meeting, scheduled in September of each year to coincide with the U.S. Conference on AIDS. Budget should include travel and associated costs for participation.

ii. Grantees will participate in the IHS National AI/AN STI Prevention workgroup.

2. Diagnosis Operational Strategy

The TECs will provide technical assistance and/or disease surveillance support to communities by developing analytical reports to examine the burden of HIV and other relevant comorbidities such as STIs and HCV in Tribal communities.

3. Treatment Operational Strategy

The TECs will provide support to communities in the development of enhanced activities and expanded capacity to better identify people who are not in care, including those who were never linked to care following an HIV, STI, or HCV diagnosis and those who have fallen out of care.

4. Respond Operational Strategy

Respond rapidly to detect and characterize growing HIV, STI, or HCV clusters and prevent new infections. TECs will provide technical assistance and/or direct support to communities on the following activities:

i. Develop or accelerate the development of community plans that are customized for AI/AN communities. Extensive community engagement in

this process will help ensure that community-specific social norms and unique epidemic attributes are addressed. Initial community-specific plans will be requested by May 31, 2020. Planning should reflect the time-sensitive nature of this activity.

ii. Develop collaborative partnerships among Tribal, state, and local health departments, the clinical community, and community-based organizations to expand and routinize HIV diagnosis, treatment, prevention and response.

Further Activities

Applications are required to address the above activities, and must propose activities addressing at least two of the additional below operational strategies.

1. Diagnosis Operational Strategy

Diagnose all people with HIV, STIs, and HCV as early as possible after infection and connect them to immediate treatment. The TECs will provide technical assistance and/or direct support to AI/AN communities on the following activities:

i. Implementing HIV testing recommendations through the rapid replication of proven or innovative HIV screening models;

ii. Developing and implementing innovative testing and health care engagement strategies focused on meeting the needs of groups at higher risk, including MSM, transgender individuals, high-risk heterosexuals, and persons who inject drugs.

2. Protection Operational Strategy

Protect people at risk for HIV using potent and proven prevention interventions, including Pre-Exposure Prophylaxis (PrEP), a medication that can prevent new HIV infections. The TECs will provide technical assistance and/or direct support to communities on the following activities:

PrEP

i. Support efforts to increase the awareness of, access to, and utilization of PrEP among identified populations;

ii. Support efforts to incentivize providers and community-based healthcare organizations to integrate HIV testing, linkage, and referral to care, and linkage or referral to medical prevention (*i.e.*, PrEP) services into primary care services, particularly for their higher-risk patients;

TasP/U=U

i. Raise awareness about the prevention benefits of “Treatment as Prevention” (TasP) and “Undetectable = Untransmittable” (U=U) among providers, people living with and at risk for HIV, and the general population;

Opioids and Substance Misuse

i. As an entry point to recovery services and overdose and infection prevention, support the development, expansion, implementation, and evaluation of harm-reduction services for people who inject drugs.

a. Evaluate the local acceptability and opportunities for establishing or increasing syringe services programs (SSPs): including linkage to substance use disorder treatment; access to and disposal of sterile syringes and injection equipment; and vaccination, testing, and linkage to care and treatment for infectious diseases.

STIs other than HIV

i. Promote early identification of individuals with recurrent STI events with focus on Chlamydia, gonorrhea, and syphilis through analysis of clinical or other locally available data.

ii. Promote linkage to care including PrEP or other appropriate services to aid the prevention of HIV and other infectious disease transmission, especially for those diagnosed with STIs.

iii. Promote and support Expedited Partner Therapy (EPT) for individuals diagnosed with chlamydia and gonorrhea to control transmission.

iv. Promote enhanced STI screening among youth and MSM and engage providers in adopting best practices, such as obtaining a thorough sexual history and promoting an adolescent-friendly clinic environment.

3. Respond Operational Strategy

Respond rapidly to detect and characterize growing HIV, STI, or Viral hepatitis clusters and prevent new infections. The TECs will provide technical assistance and/or public health surveillance support to communities on the following activities:

i. Establish and support boots-on-the-ground public health workforce capacity that is culturally competent and committed to ensuring implementation of community-based HIV, STI, and/or Viral hepatitis control plans, including facilitating and troubleshooting collaborative community-wide disease control efforts;

ii. Develop or expand the capacity to detect and respond to all established or emerging HIV, STI, and/or Viral hepatitis clusters to reduce disease transmission.

C. Program Evaluation (30 Points)

a. Clearly identify plans for program evaluation to ensure that objectives of the program are met at the conclusion of the funding period.

b. Include (SMART) evaluation criteria.

c. Evaluation should minimally include summaries of activities in each of the proposed key operational strategies.

D. Organizational Capabilities, Key Personnel and Qualifications (30 Points)

a. Include an organizational capacity statement which demonstrates the ability to execute program strategies within the program period.

b. Project management and staffing plan. Detail that the organization has the current staffing and expertise to address each of the program activities. If current capacity does not exist please describe the actions that the TEC will take to fulfill this gap within a specified timeline.

c. Demonstrate local partners' willingness to work with TEC on proposed efforts. Applicants are particularly encouraged to collaborate with other federally-funded organizations such as their local health departments and Ryan White HIV/AIDS Program awardees.

d. Demonstrate that the TEC has previous successful experience providing technical or programmatic support to Tribal communities.

E. Categorical Budget and Budget Justification (5 Points)

a. Provide a detailed budget and accompanying narrative to explain the activities being considered and how they are related to proposed program objectives.

Multi-Year Project Requirements

Applications must include a brief project narrative and budget (one additional page per year) addressing the developmental plans for each additional year of the project. This attachment will not count as part of the project narrative or the budget 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 Rate Agreement.

- Organizational chart.
- Map of area identifying project location(s).
- Glossary of terms and acronyms used in the application.

- 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 OPHS 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 agreement 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 <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.

Additional quarterly reports and quarterly calls discussing progress on a standardized form are required for this funding. Post-award, the standard form will be disseminated to all funded programs.

Special attention should be devoted to reporting on the development of community plans required under the Respond Operational Strategy.

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) 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. Data Collection and Reporting

The TEC must report annually (by their respective IHS Area or Tribal health board) the progress towards EHE goals via a standardized form.

The TEC will participate in quarterly calls with the program office.

D. 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/>.

E. 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 the 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.

F. 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. 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: Mr. 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: Ms. Lisa C. Neel, Public Health Advisor, Office of Public Health Support, Division of Epidemiology & Disease Prevention, Indian Health Service, 5600 Fishers Lane, Mailstop: 09E17B, Rockville, MD 20857, Phone: (301) 443-4305, E-Mail: Lisa.Neel@ihs.gov.

2. Questions on grants management and fiscal matters may be directed to: Mr. John Hoffman, Senior Grants Management Specialist, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-2116, Fax: (301) 594-0899, Email: John.Hoffman@ihs.gov.

3. Questions on systems matters may be directed to: Mr. 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.

Dated: July 31, 2019.

Michael D. Weahkee,

Assistant Surgeon General, U.S. Public Health Service, Principal Deputy Director, Indian Health Service.

[FR Doc. 2019-16761 Filed 8-5-19; 8:45 am]

BILLING CODE 4165-16-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Amended Notice of Meeting

Notice is hereby given of a time and room change in the meeting of the National Advisory Council for Biomedical Imaging and Bioengineering, September 11, 2019, 08:30 a.m., to September 11, 2019, 03:00 p.m., The William F. Bolger Center, Franklin Building, #1, 9600 Newbridge Drive, Potomac, MD 20854 which was published in the **Federal Register** on March 29, 2019, 84 FR 11988.

The meeting notice is amended to change the start time of the meeting from September 11, 2019, 08:30 a.m. to September 11, 2019, 09:00 a.m. The meeting room is changed from the William F. Bolger Center, Franklin Building, Classroom 1, to the William F. Bolger Center, Franklin Building, Classrooms 15/16. The meeting is partially closed to the public.

Dated: July 31, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-16710 Filed 8-5-19; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in section 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, BRAIN Review.

Date: August 8-9, 2019.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Canopy by Hilton, 940 Rose Avenue, North Bethesda, MD 20852.

Contact Person: W. Ernest W. Lyons, Ph.D., Chief, Scientific Review Branch, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529 Bethesda, MD 20892-9529, 301-496-4056, lyonse@ninds.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.

Name of Committee: Neurological Sciences Training Initial Review Group NST-1 Subcommittee.

Date: September 23-24, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Warwick Denver, 1776 Grant St, Devner, CO 80203.

Contact Person: William C. Benzing, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS, NIH NSC, 6001 Executive Blvd., Suite 3204, MSC 9529, Bethesda, MD 20892-9529, (301) 496-0660, benzingw@mail.nih.gov.

(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: July 31, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-16709 Filed 8-5-19; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Treatment; Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given that the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) National Advisory Council (NAC) will meet on August 21, 2019, 9:00 a.m.-5:30 p.m. (EDT).

The meeting is open and will include consideration of minutes from the SAMHSA CSAT NAC meeting of March 28, 2019; updates from the Division Directors, discussions on Adult Drug Court, SAMHSA Leadership Discussion with CSAT Council Members, discussion on SAMHSA's data strategy, and discussion on trends and issues identified in the State Opioid Response Grants.

The meeting will be held at SAMHSA, 5600 Fishers Lane, 5A03, Rockville, MD 20857. Attendance by the public will be limited to space available. Interested persons may present data, information, or views, orally or in writing, on issues pending before the Council. Written submissions should be forwarded to the contact person on or before August 14, 2019. Oral presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making oral presentations must notify the contact person on or before August 14, 2019. Five minutes will be allotted for each presentation.

The meeting may be accessed via on site, telephone and or WebEx. To attend on site, obtain the call-in number and access code, submit written or brief oral comments, or request special accommodations for persons with disabilities, please register online at <http://snacregister.samhsa.gov/Registrations.aspx>, or communicate with the CSAT National Advisory Council Designated Federal Officer; Tracy Goss (see contact information below).

Meeting information and a roster of Council members may be obtained by accessing the SAMHSA Committee website at <http://www.samhsa.gov/about-us/advisory-councils/csat-national-advisory-council> or by contacting the CSAT National Advisory Council Designated Federal Officer; Tracy Goss (see contact information below).

Council Name: SAMHSA's Center for Substance Abuse Treatment National Advisory Council.

Date/Time/Type: August 21, 2019, 9:00 a.m.-5:30 p.m. EDT, OPEN.

Place: SAMHSA, 5600 Fishers Lane, Rockville, Maryland 20857.

Contact: Tracy Goss, Designated Federal Officer, CSAT National Advisory Council, 5600 Fishers Lane, Rockville, Maryland 20857 (mail), Telephone: (240) 276-0759, Fax: (240) 276-2252, Email: tracy.goss@samhsa.hhs.gov.

Dated: July 31, 2019.

Carlos Castillo,

Committee Management Officer, SAMHSA.

[FR Doc. 2019-16697 Filed 8-5-19; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA-4453-DR; Docket ID FEMA-2019-0001]

Oklahoma; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Oklahoma (FEMA-4453-DR), dated July 12, 2019, and related determinations.

DATES: The declaration was issued July 12, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646-2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated July 12, 2019, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"), as follows:

I have determined that the damage in certain areas of the State of Oklahoma resulting from severe storms, tornadoes, straight-line winds, and flooding during the period of April 30 to May 1, 2019, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"). Therefore, I declare that such a major disaster exists in the State of Oklahoma.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to section 428 of the Stafford Act.

Further, you are authorized to make changes to this declaration for the approved

assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Gerard M. Stolar, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Oklahoma have been designated as adversely affected by this major disaster:

Alfalfa, Atoka, Bryan, Coal, Craig, Kay, Lincoln, Love, Major, Noble, Nowata, Okmulgee, Osage, Ottawa, Pittsburg, Pushmataha, Stephens, and Tillman Counties for Public Assistance.

All areas within the State of Oklahoma are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019-16834 Filed 8-5-19; 8:45 am]

BILLING CODE 9111-23-P

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA-4446-DR; Docket ID FEMA-2019-0001]

Ponca Tribe of Nebraska; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the Ponca Tribe of Nebraska (FEMA-4446-DR), dated June 17, 2019, and related determinations.

DATES: The declaration was issued June 17, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and

Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646-2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated June 17, 2019, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"), as follows:

I have determined that the damage to the lands associated with the Ponca Tribe of Nebraska resulting from severe storms and flooding during the period of March 13 to April 1, 2019, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"). Therefore, I declare that such a major disaster exists for the Ponca Tribe of Nebraska.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance and Hazard Mitigation for the Ponca Tribe of Nebraska. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to section 428 of the Stafford Act.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Constance C. Johnson-Cage, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas have been designated as adversely affected by this major disaster:

The Ponca Tribe of Nebraska for Public Assistance.

The Ponca Tribe of Nebraska is eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA);

97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–16837 Filed 8–5–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3415–EM; Docket ID FEMA–2019–0001]

California; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of California (FEMA–3415–EM), dated July 8, 2019, and related determinations.

DATES: The declaration was issued July 8, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated July 8, 2019, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in certain areas of the State of California resulting from earthquakes beginning on July 4, 2019, and continuing, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (“the Stafford Act”). Therefore, I declare that such an emergency exists in the State of California.

You are authorized to provide appropriate assistance for required emergency measures, authorized under title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or

avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program.

Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, Robert J. Fenton, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following areas of the State of California have been designated as adversely affected by this declared emergency:

Kern and San Bernardino Counties for emergency protective measures (Category B), limited to direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–16802 Filed 8–5–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4451–DR; Docket ID FEMA–2019–0001]

Missouri; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Missouri (FEMA–4451–DR), dated July 9, 2019, and related determinations.

DATES: This amendment was issued July 15, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this disaster is closed effective July 5, 2019.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–16787 Filed 8–5–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4449–DR; Docket ID FEMA–2019–0001]

Kansas; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Kansas (FEMA-4449-DR), dated June 20, 2019, and related determinations.

DATES: This amendment was issued July 25, 2019.

FOR FURTHER INFORMATION CONTACT:

Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646-2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this disaster is closed effective July 12, 2019.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019-16790 Filed 8-5-19; 8:45 am]

BILLING CODE 9111-23-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4445-DR; Docket ID FEMA-2019-0001]

Vermont; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Vermont (FEMA-4445-DR), dated June 14, 2019, and related determinations.

DATES: The declaration was issued June 14, 2019.

FOR FURTHER INFORMATION CONTACT:

Dean Webster, Office of Response and Recovery, Federal Emergency

Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646-2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated June 14, 2019, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the “Stafford Act”), as follows:

I have determined that the damage in certain areas of the State of Vermont resulting from a severe storm and flooding on April 15, 2019, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the “Stafford Act”). Therefore, I declare that such a major disaster exists in the State of Vermont.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to section 428 of the Stafford Act.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, James N. Russo, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Vermont have been designated as adversely affected by this major disaster:

Bennington, Essex, Orange, Rutland, Washington, and Windsor Counties for Public Assistance.

All areas within the State of Vermont are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to

Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019-16836 Filed 8-5-19; 8:45 am]

BILLING CODE 9111-23-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4447-DR; Docket ID FEMA-2019-0001]

Ohio; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Ohio (FEMA-4447-DR), dated June 18, 2019, and related determinations.

DATES: The declaration was issued June 18, 2019.

FOR FURTHER INFORMATION CONTACT:

Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646-2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated June 18, 2019, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the “Stafford Act”), as follows:

I have determined that the damage in certain areas of the State of Ohio resulting from severe storms, straight-line winds, tornadoes, flooding, and landslides during the period of May 27 to May 29, 2019, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the “Stafford Act”). Therefore, I declare that such a major disaster exists in the State of Ohio.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance in the designated areas and

Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation and Other Needs Assistance under section 408 will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Steven W. Johnson, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Ohio have been designated as adversely affected by this major disaster:

Auglaize, Darke, Greene, Hocking, Mercer, Miami, Montgomery, Muskingum, Perry, and Pickaway Counties for Individual Assistance.

All areas within the State of Ohio are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–16824 Filed 8–5–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4452–DR; Docket ID FEMA–2019–0001]

Oregon; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Oregon (FEMA–4452–DR), dated July 9, 2019, and related determinations.

DATES: The declaration was issued July 9, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated July 9, 2019, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the “Stafford Act”), as follows:

I have determined that the damage in certain areas of the State of Oregon resulting from severe storms, flooding, landslides, and mudslides during the period of April 6 to April 21, 2019, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the “Stafford Act”). Therefore, I declare that such a major disaster exists in the State of Oregon.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation under section 408 will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to section 428 of the Stafford Act.

Further, you are authorized to make changes to this declaration for the approved

assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Rosalyn L. Cole, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Oregon have been designated as adversely affected by this major disaster:

Curry, Douglas, Grant, Linn, Umatilla, and Wheeler Counties for Public Assistance.

All areas within the State of Oregon are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–16833 Filed 8–5–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4429–DR; Docket ID FEMA–2019–0001]

Mississippi; Amendment No. 4 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Mississippi (FEMA–4429–DR), dated April 23, 2019, and related determinations.

DATES: This amendment was issued July 26, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency

Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Mississippi is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of April 23, 2019.

Humphreys County for Public Assistance. The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–16783 Filed 8–5–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3416–EM; Docket ID FEMA–2019–0001]

Louisiana; Amendment No. 1 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of Louisiana (FEMA–3416–EM), dated July 11, 2019, and related determinations.

DATES: This amendment was issued July 17, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of an emergency declaration for the State of Louisiana is hereby amended to include the following areas among those areas determined to have been adversely

affected by the event declared an emergency by the President in his declaration of July 11, 2019. Beauregard, Catahoula, Concordia, Evangeline, and Vernon Parishes for emergency protective measures (Category B), limited to direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–16778 Filed 8–5–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4451–DR; Docket ID FEMA–2019–0001]

Missouri; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Missouri (FEMA–4451–DR), dated July 9, 2019, and related determinations.

DATES: This amendment was issued July 29, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Missouri is hereby amended to include Public Assistance for the following areas among those areas determined to have been adversely affected by the event declared a major

disaster by the President in his declaration of July 9, 2019.

Andrew, Atchison, Buchanan, Carroll, Chariton, Cole, Holt, Jackson, Jasper, Livingston, Miller, and Pike Counties for Public Assistance (already designated for Individual Assistance).

Adair, Barry, Barton, Bates, Bollinger, Caldwell, Camden, Cape Girardeau, Cedar, Clark, Dade, Dallas, Daviess, Douglas, Gentry, Grundy, Harrison, Henry, Hickory, Howell, Knox, Laclede, Lewis, Linn, Macon, Maries, Marion, McDonald, Mercer, Mississippi, Monroe, Montgomery, New Madrid, Newton, Nodaway, Ozark, Pemiscot, Perry, Putnam, Ralls, Randolph, Ray, Saline, Schuyler, Scotland, Shannon, Shelby, Ste. Genevieve, Stoddard, Sullivan, Taney, Texas, Vernon, Wayne, Webster, and Wright Counties for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–16780 Filed 8–5–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4447–DR; Docket ID FEMA–2019–0001]

Ohio; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Ohio (FEMA–4447–DR), dated June 18, 2019, and related determinations.

DATES: This amendment was issued July 17, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency

Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Ohio is hereby amended to include Public Assistance for the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 18, 2019.

Columbiana County for Public Assistance. Greene, Mercer, and Montgomery Counties for Public Assistance (already designated for Individual Assistance).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–16796 Filed 8–5–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4448–DR; Docket ID FEMA–2019–0001]

Oglala Sioux Tribe; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the Oglala Sioux Tribe (FEMA–4448–DR), dated June 20, 2019, and related determinations.

DATES: The declaration was issued June 20, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated June

20, 2019, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the “Stafford Act”), as follows:

I have determined that the damage to the lands associated with the Oglala Sioux Tribe resulting from a severe winter storm, snowstorm, and flooding during the period of March 13 to March 26, 2019, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the “Stafford Act”). Therefore, I declare that such a major disaster exists for the Oglala Sioux Tribe.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance and Hazard Mitigation for the Oglala Sioux Tribe. You are further authorized to provide snow assistance under the Public Assistance program for a limited period of time during or proximate to the incident period. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to section 428 of the Stafford Act.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, James R. Stephenson, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas have been designated as adversely affected by this major disaster:

The Oglala Sioux Tribe of the Pine Ridge Reservation for Public Assistance.

The Oglala Sioux Tribe of the Pine Ridge Reservation for snow assistance under the Public Assistance program for any continuous 48-hour period during or proximate the incident period.

The Oglala Sioux Tribe of the Pine Ridge Reservation is eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora

Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–16829 Filed 8–5–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3412–EM; Docket ID FEMA–2019–0001]

Kansas; Amendment No. 3 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of Kansas (FEMA–3412–EM), dated May 28, 2019, and related determinations.

DATES: This amendment was issued July 25, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this emergency is closed effective July 12, 2019.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019-16779 Filed 8-5-19; 8:45 am]

BILLING CODE 9111-23-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-3416-EM; Docket ID FEMA-2019-0001]

Louisiana; Amendment No. 2 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of Louisiana (FEMA-3416-EM), dated July 11, 2019, and related determinations.

DATES: This amendment was issued July 18, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646-2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this emergency is closed effective July 15, 2019.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019-16776 Filed 8-5-19; 8:45 am]

BILLING CODE 9111-23-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4438-DR; Docket ID FEMA-2019-0001]

Oklahoma; Amendment No. 6 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Oklahoma (FEMA-4438-DR), dated June 1, 2019, and related determinations.

DATES: This amendment was issued July 16, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646-2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Oklahoma is hereby amended to include permanent work under the Public Assistance program for those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 1, 2019.

Muskogee, Tulsa, and Wagoner Counties for Public Assistance [Categories C-G] (already designated for Individual Assistance and assistance for debris removal and emergency protective measures [Categories A and B], including direct federal assistance, under the Public Assistance program).

Le Flore, Osage, Pawnee, and Sequoyah Counties for Public Assistance [Categories A and C-G] (already designated for Individual Assistance and assistance for emergency protective measures [Category B], limited to direct federal assistance, under the Public Assistance program).

Alfalfa, Canadian, Cherokee, Craig, Creek, Delaware, Garfield, Kingfisher, Logan, Mayes, Nowata, Payne, Pottawatomie, Rogers, Washington, and Woods Counties for Public Assistance, including direct federal assistance, under the Public Assistance program (already designated for Individual Assistance).

Adair, Beaver, Beckham, Blaine, Custer, Dewey, Ellis, Grady, Grant, Greer, Harper, Jackson, Lincoln, Okfuskee, Pittsburg, Pushmataha, Roger Mills, and Washita Counties for Public Assistance, including direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034,

Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019-16798 Filed 8-5-19; 8:45 am]

BILLING CODE 9111-23-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4450-DR; Docket ID FEMA-2019-0001]

Mississippi; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Mississippi (FEMA-4450-DR), dated June 20, 2019, and related determinations.

DATES: The declaration was issued June 20, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646-2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated June 20, 2019, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the “Stafford Act”), as follows:

I have determined that the damage in certain areas of the State of Mississippi resulting from severe storms, tornadoes, straight-line winds, and flooding during the period of April 13 to April 14, 2019, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the “Stafford Act”). Therefore, I declare that such a major disaster exists in the State of Mississippi.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as

you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to section 428 of the Stafford Act.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Jose M. Girot, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Mississippi have been designated as adversely affected by this major disaster:

Clarke, Clay, Itawamba, Kemper, Monroe, Oktibbeha, Warren, and Yazoo Counties for Public Assistance.

All areas within the State of Mississippi are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019-16830 Filed 8-5-19; 8:45 am]

BILLING CODE 9111-23-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4449-DR; Docket ID FEMA-2019-0001]

Kansas; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Kansas (FEMA-4449-DR), dated June 20, 2019, and related determinations.

DATES: This amendment was issued July 25, 2019.

FOR FURTHER INFORMATION CONTACT:

Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646-2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Kansas is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 20, 2019.

Bourbon, Comanche, Crawford, Dickinson, Douglas, Edwards, Ford, Gray, and Riley Counties for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019-16788 Filed 8-5-19; 8:45 am]

BILLING CODE 9111-23-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4421-DR; Docket ID FEMA-2019-0001]

Iowa; Amendment No. 14 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Iowa (FEMA-4421-DR), dated March 23, 2019, and related determinations.

DATES: This amendment was issued July 18, 2019.

FOR FURTHER INFORMATION CONTACT:

Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646-2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Iowa is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of March 23, 2019.

Appanoose, Davis, Henry, Lucas, Monroe, and Wayne Counties for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019-16799 Filed 8-5-19; 8:45 am]

BILLING CODE 9111-23-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[[Internal Agency Docket No. FEMA-4451-DR; Docket ID FEMA-2019-0001]]

Missouri; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Missouri (FEMA-4451-DR), dated July 9, 2019, and related determinations.

DATES: The declaration was issued July 9, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646-2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated July 9, 2019, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the “Stafford Act”), as follows:

I have determined that the damage in certain areas of the State of Missouri resulting from severe storms, tornadoes, and flooding beginning on April 29, 2019, and continuing, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the “Stafford Act”). Therefore, I declare that such a major disaster exists in the State of Missouri.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation and Other Needs Assistance under section 408 will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Seamus K. Leary, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Missouri have been designated as adversely affected by this major disaster:

Andrew, Atchison, Boone, Buchanan, Carroll, Chariton, Cole, Greene, Holt, Jackson, Jasper, Lafayette, Lincoln, Livingston, Miller, Osage, Pike, Platte, Pulaski, and St. Charles Counties for Individual Assistance.

All areas within the State of Missouri are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019-16832 Filed 8-5-19; 8:45 am]

BILLING CODE 9111-23-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[[Internal Agency Docket No. FEMA-3416-EM; Docket ID FEMA-2019-0001]]

Louisiana; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Louisiana (FEMA-3416-EM), dated July 11, 2019, and related determinations.

DATES: The declaration was issued July 11, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency

Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646-2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated July 11, 2019, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in certain areas of the State of Louisiana resulting from Tropical Storm Barry beginning on July 10, 2019, and continuing, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (“the Stafford Act”). Therefore, I declare that such an emergency exists in the State of Louisiana.

You are authorized to provide appropriate assistance for required emergency measures, authorized under title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program.

Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, John E. Long, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following areas of the State of Louisiana have been designated as adversely affected by this declared emergency:

Acadia, Ascension, Assumption, Avoyelles, Calcasieu, Cameron, East Baton Rouge, East Feliciana, Iberia, Iberville, Jefferson, Jefferson Davis, Lafayette, Lafourche, Livingston, Orleans, Ouachita, Plaquemines, Pointe Coupee, Rapides, St. Bernard, St. Charles, St. Helena, St. James, St. John the Baptist, St. Landry, St. Martin, St. Mary, St. Tammany, Tangipahoa, Terrebonne, Vermilion, Washington, West Baton Rouge, and West Feliciana Parishes for emergency protective measures (Category B), limited to direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–16801 Filed 8–5–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4450–DR; Docket ID FEMA–2019–0001]

Mississippi; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Mississippi (FEMA–4450–DR), dated June 20, 2019, and related determinations.

DATES: This amendment was issued July 26, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Mississippi is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 20, 2019.

Holmes County for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant;

97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–16782 Filed 8–5–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4449–DR; Docket ID FEMA–2019–0001]

Kansas; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Kansas (FEMA–4449–DR), dated June 20, 2019, and related determinations.

DATES: The declaration was issued June 20, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street, SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated June 20, 2019, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the “Stafford Act”), as follows:

I have determined that the damage in certain areas of the State of Kansas resulting from severe storms, straight-line winds, tornadoes, flooding, landslides, and mudslides beginning on April 28, 2019, and continuing, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the “Stafford Act”). Therefore, I declare that such a major disaster exists in the State of Kansas.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to section 428 of the Stafford Act.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Jon K. Huss, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Kansas have been designated as adversely affected by this major disaster:

Allen, Anderson, Atchison, Barber, Barton, Butler, Chase, Chautauqua, Cherokee, Clark, Clay, Cloud, Coffey, Cowley, Doniphan, Elk, Ellsworth, Franklin, Geary, Greenwood, Harper, Harvey, Hodgeman, Jefferson, Kingman, Leavenworth, Lincoln, Linn, Lyon, Marion, Marshall, McPherson, Meade, Montgomery, Morris, Nemaha, Neosho, Osage, Ottawa, Pawnee, Phillips, Pottawatomie, Pratt, Reno, Rice, Rush, Russell, Saline, Sumner, Wabaunsee, Washington, Wilson, and Woodson Counties for Public Assistance.

All areas within the State of Kansas are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–16828 Filed 8–5–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF THE INTERIOR**Fish and Wildlife Service**

[FWS-HQ-ES-2019-N033;
FXES1113010000C4-190-FF02ENEH00]

Endangered and Threatened Wildlife and Plants; 28 Draft Recovery Plan Revisions for 53 Species in the Southeast, Mountain-Prairie, and Pacific Southwest Regions of the United States

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; opening of public comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability for public review and comment of 28 draft recovery plan revisions, which update recovery criteria for 53 endangered or threatened species located in 12 States (Alabama, Arizona, Arkansas, California, Florida, Georgia, Kentucky, Mississippi, Nevada, Oregon, Tennessee, and Utah) and the Commonwealth of Puerto Rico. We are updating recovery criteria to better assist in determining when an endangered species has recovered to the point that it may be reclassified as threatened, or that the protections afforded by the Endangered Species Act (ESA) are no longer necessary and the species may be removed from the ESA's protections. We request review of these draft recovery plan revisions and invite comments from local, State, Tribal, and Federal agencies, nongovernmental organizations, and the public.

DATES: We must receive comments on the draft recovery plan revisions on or before September 5, 2019.

ADDRESSES:

Reviewing documents: If you wish to review the draft recovery plan revisions, you may obtain copies from the website addresses in the table in **SUPPLEMENTARY INFORMATION**. You may also request copies of the draft recovery plan revisions by contacting the individuals listed in the table.

Submitting comments: If you wish to comment, see the table in **SUPPLEMENTARY INFORMATION** and submit your comments by one of the following methods:

1. *U.S. Mail or hand-delivery:* You may submit written comments and materials to the appropriate field office mailing address for the species in which you are interested;
2. *Email:* You may send comments by email to the identified contact person's

email address in the table, for each species. Please include "Draft Recovery Plan Revision Comments" in the subject line.

FOR FURTHER INFORMATION CONTACT: For information on a particular species, contact the appropriate person listed in the table for that species in **SUPPLEMENTARY INFORMATION**. Individuals who are hearing impaired may call the Federal Relay Service at 800-877-8339 for TTY assistance.

SUPPLEMENTARY INFORMATION:**Background**

In this notice, we announce for public review and comment the availability of 28 draft recovery plan revisions, which update recovery criteria for 53 endangered or threatened species located in 12 States (Alabama, Arizona, Arkansas, California, Florida, Georgia, Kentucky, Mississippi, Nevada, Oregon, Tennessee, and Utah) and the Commonwealth of Puerto Rico. This group of 28 draft recovery plan revisions is part of a larger effort underway to revise up to 182 recovery plans covering up to 305 species in order to achieve the following Department of the Interior Agency Priority Performance Goal outlined in the Department's Strategic Plan for Fiscal Years 2018–2022: "By September 30, 2019, 100 percent of all Fish and Wildlife Service recovery plans will have quantitative criteria for what constitutes a recovered species."

The purpose of a recovery plan is to provide a feasible and effective roadmap for a species' recovery, with the goal of improving its status and managing its threats to the point at which protections under the ESA are no longer needed. Recovery plans must be designed so that all stakeholders and the public understand the rationale behind the recovery program, whether they were involved in writing the plan or not, and recognize their role in its implementation. We are requesting submission of any information that enhances the necessary understanding of the (1) species' biology and threats and (2) recovery needs and related implementation issues or concerns, to ensure that we have assembled, considered, and incorporated the best available scientific and commercial information into the draft recovery plan revisions for these 53 species.

Recovery plans provide important guidance to the Service, States, other partners, and the general public on methods of minimizing threats to listed species and objectives against which to measure the progress towards recovery;

they are guidance and not regulatory documents. A recovery plan identifies, organizes, and prioritizes recovery actions and is an important guide that ensures sound scientific decision-making throughout the recovery process, which can take decades. Keeping recovery plans current ensures that threatened species and endangered species benefit through timely partner-coordinated implementation, based on the best available information.

A review of a recovery plan and its implementation may show that the plan is out of date or its usefulness is limited and that the plan warrants modification. The need for, and extent of, recovery plan modifications will vary considerably among recovery plans, depending on the scope and complexity of the initial plan, the structure of the document, and the involvement of stakeholders. Recovery plan modifications can range from relatively minor updates to a substantial rewrite that revises the existing plan in part (*i.e.*, an amendment to one of the sections that modifies the existing plan), or in full (*i.e.*, a full revision that completely replaces the existing plan). The need for a recovery plan revision may be triggered when, among other possibilities, (1) new information has been identified, such as population-level threats to the species or previously unknown life-history traits, which necessitates new or revised recovery strategy, actions, or criteria, or revision of all three in order to maintain the adequacy of the plan; and (2) the current plan is not achieving its objectives. Revisions benefit endangered and threatened species, our partners, and the public by incorporating the best available information on what is needed for species' recovery.

Revision of recovery plans requires public notice and comment under section 4(f)(4) of the ESA, including (1) a **Federal Register** notice of availability to give opportunity for public review and comment, (2) consideration of all information presented during the public comment period, and (3) approval by the Regional Director. When finalized, these recovery plan revisions will be made publicly available on the internet through our Environmental Conservation Online System (ECOS, <https://ecos.fws.gov>).

What plans are being made available for public review and comment?

This notice announces our draft recovery plan revisions for the species listed in the table below.

Common name	Scientific name	Listing status ¹	Current range	Recovery plan name	Internet availability of proposed recovery plan revision	Contact person, phone, email	Contact person's U.S. mail address
Southeast Region (Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Puerto Rico, and the U.S. Virgin Islands)							
Orangenacre mucket	<i>Lampsilis perovalis</i>	T	AL, MS	Mobile River Basin Aquatic Ecosystem Recovery Plan.	https://ecos.fws.gov/docs/recovery_plan/Orangenacre%20Mucket%20Recovery%20Plan%20Amendment.pdf	William J. Pearson, 251-441-5870, bill_pearson@fws.gov	Alabama Ecological Services Field Office, U.S. Fish and Wildlife Service, 1208-B Main Street, Daphne, AL 36526.
Alabama moccasinshell.	<i>Medionidus acutissimus</i>	T	AL, GA, MS, TN		https://ecos.fws.gov/docs/recovery_plan/Alabama%20Moccasinshell%20Recovery%20Plan%20Amendment.pdf		
Dark pigtoe	<i>Pleurobema furvum</i>	E	AL		https://ecos.fws.gov/docs/recovery_plan/Pleurobema%20rubellum%20Recovery%20Plan%20Amendment.pdf		
Triangular kidneyshell	<i>Ptychobranchus greenii</i>	E	AL, GA, TN		https://ecos.fws.gov/docs/recovery_plan/Triangular%20Kidneyshell%20Recovery%20Plan%20Amendment.pdf		
Red Hills salamander	<i>Phaeognathus hubrichti</i>	T	AL	Recovery Plan for the Red Hills <i>Phaeognathus hubrichti</i> .	https://ecos.fws.gov/docs/recovery_plan/Red%20Hills%20Salamander%20Recovery%20Plan%20Amendment.pdf		
Heavy pigtoe	<i>Pleurobema taitianum</i>	E	AL, MS	Five Tombigbee River Mussels Recovery Plan.	https://ecos.fws.gov/docs/recovery_plan/Heavy%20Pigtoe%20Recovery%20Plan%20Amendment.pdf		
Alabama sturgeon	<i>Scaphirhynchus suttkusi</i>	E	AL	Recovery Plan for the Alabama Sturgeon (<i>Scaphirhynchus suttkusi</i>).	https://ecos.fws.gov/docs/recovery_plan/Alabama%20Sturgeon%20Recovery%20Plan%20Amendment.pdf		
Palezone shiner	<i>Notropis albizonatus</i>	E	AL, KY	Recovery Plan for Palezone Shiner (<i>Notropis albizonatus</i>).	https://ecos.fws.gov/docs/recovery_plan/Palezone%20Shiner%20Recovery%20Plan%20Amendment.pdf	Lee Andrews 502-695-0468 lee_andrews@fws.gov	Kentucky Ecological Services Field Station, 330 West Broadway, Suite 265, Frankfort, KY 40601.
Pygmy madtom	<i>Noturus stanauli</i> ...	E	TN	Recovery Plan for Pygmy Madtom (<i>Noturus stanauli</i>).	https://ecos.fws.gov/docs/recovery_plan/Pygmy%20Madtom%20Recovery%20Plan%20Amendment.pdf		
Cahaba shiner	<i>Notropis cahabae</i>	E	AL	Cahaba Shiner (<i>Notropis cahabae</i>) Recovery Plan.	https://ecos.fws.gov/docs/recovery_plan/Cahaba%20Shiner%20Recovery%20Plan%20Amendment.pdf	Stephen Ricks, 601-321-1122 stephen_ricks@fws.gov	Mississippi Ecological Services Field Office, 6578 Dogwood View Pkwy, Suite A, Jackson, MS 39213.
Speckled pocketbook	<i>Lampsilis streckeri</i>	E	AR	Speckled Pocketbook Mussel (<i>Lampsilis streckeri</i>) Recovery Plan.	https://ecos.fws.gov/docs/recovery_plan/Speckled%20Pocketbook%20Recovery%20Plan%20Amendment.pdf	Melvin L. Tobin, 501-513-4473, melvin_tobin@fws.gov	Arkansas Ecological Services Field Office, 110 South Amity Road, Suite 300, Conway, AR 72032.
Fat threeridge	<i>Amblema neislerii</i>	E	FL, GA	Recovery Plan for Endangered Fat Threeridge, Shinyrayed Pocketbook, Gulf Moccasinshell, Ochlockonee Moccasinshell, Oval Pigtoe and Threatened Chipola Slabshell, and Purple Bankclimber.	https://ecos.fws.gov/docs/recovery_plan/Fat%20Threeridge%20Recovery%20Plan%20Amendment.pdf	Catherine T. Phillips, Ph.D., 850-769-0552, Catherine_phillips@fws.gov	Panama City Field Office, 1601 Balboa Avenue, Panama City, FL 32405.
Chipola slabshell	<i>Elliptio chipolaensis</i>	T	AL, FL		https://ecos.fws.gov/docs/recovery_plan/Chipola%20Slabshell%20Recovery%20Plan%20Amendment.pdf		
Cape Sable seaside sparrow.	<i>Ammodramus maritimus mirabilis</i>	E	FL	South Florida Multi-Species Recovery Plan.	https://ecos.fws.gov/docs/recovery_plan/Cape%20Sable%20Seaside%20Sparrow%20Recovery%20Plan%20Amendment.pdf	Roxanna Hinzman, 772-469-4309, SouthFL_recoveryplancomments@fws.gov	South Florida Ecological Services Field Office, 1339 20th Street, Vero Beach, FL 32960.
Florida grasshopper sparrow.	<i>Ammodramus savannarum floridanus</i>	E	FL		https://ecos.fws.gov/docs/recovery_plan/Florida%20Grasshopper%20Sparrow%20Recovery%20Plan%20Amendment.pdf		
Crenulate lead-plant ..	<i>Amorpha crenulata</i>	E	FL		https://ecos.fws.gov/docs/recovery_plan/Pine%20Rocklands%20Recovery%20Plan%20Amendment.pdf		
Deltoid surge	<i>Chamaesyce deltoidea</i> ssp. <i>deltoidea</i> .	E	FL				
Small's milkpea	<i>Galactia smallii</i>	E	FL				
Tiny polygala	<i>Polygala smallii</i>	E	FL				
Beautiful pawpaw	<i>Deeringothamnus pulchellus</i> .	E	FL		https://ecos.fws.gov/docs/recovery_plan/Beautiful%20Pawpaw_Recovery%20Plan%20Amendment.pdf		
Lakela's mint	<i>Dicerandra immaculata</i> .	E	FL		https://ecos.fws.gov/docs/recovery_plan/Lakelas%20Mint%20Recovery%20Plan%20Amendment.pdf		
Rice rat	<i>Oryzomys palustris natator</i> .	E	FL		https://ecos.fws.gov/docs/recovery_plan/Silver%20Rice%20Rat%20Recovery%20Plan%20Amendment.pdf		

Common name	Scientific name	Listing status ¹	Current range	Recovery plan name	Internet availability of proposed recovery plan revision	Contact person, phone, email	Contact person's U.S. mail address
Lower-keys marsh rabbit.	<i>Sylvilagus palustris hefneri</i> .	E	FL	https://ecos.fws.gov/docs/recovery_plan/Lower%20Keys%20Marsh%20Rabbit%20Recovery%20Plan%20Amendment.pdf .	Edwin E. Muñiz, 787-851-7297 edwin_muniz@fws.gov .	Caribbean Ecological Services Field Office, P.O. Box 1600, Rio Grande, PR 00745.
Capa rosa	<i>Callicarpa ampla</i> ..	E	Puerto Rico	<i>Callicarpa ampla</i> , <i>Ilex sintenisii</i> , <i>Styrax portoricensis</i> , <i>Temstroemia luquillensis</i> , and <i>Temstroemia subsessilis</i> Recovery Plan.	https://ecos.fws.gov/docs/recovery_plan/Five%20Plants%20Recovery%20Plan%20Amendment.pdf .		
No common name	<i>Ilex sintenisii</i>	E	Puerto Rico.				
Palo de jazmin	<i>Styrax portoricensis</i> .	E	Puerto Rico.				
Palo colorado	<i>Temstroemia luquillensis</i> .	E	Puerto Rico.				
No common name	<i>Temstroemia subsessilis</i> .	E	Puerto Rico.				
Wheeler's peperomia	<i>Peperomia wheeleri</i> .	E	Puerto Rico	<i>Peperomia wheeleri</i> Recovery Plan.	https://ecos.fws.gov/docs/recovery_plan/Peperomia%20wheeleri%20Recovery%20Plan%20Amendment.pdf .		
Uvillo	<i>Eugenia haematocarpa</i> .	E	Puerto Rico	Recovery Plan for <i>Pleodendron macranthum</i> and <i>Eugenia haematocarpa</i> .	https://ecos.fws.gov/docs/recovery_plan/Eugenia%20haematocarpa%20Pleodendron%20macranthum%20Recovery%20Plan%20Amendment.pdf .		
Chupacallos	<i>Pleodendron macranthum</i> .	E	Puerto Rico.				
Guajón	<i>Eleutherodactylus cooki</i> .	T	Puerto Rico	Recovery Plan for the Guajón or Puerto Rican Demon (<i>Eleutherodactylus cooki</i>).	https://ecos.fws.gov/docs/recovery_plan/Puerto%20Rican%20Demon%20Recovery%20Plan%20Amendment.pdf .		
No common name	<i>Elaphoglossum serpens</i> .	E	Puerto Rico	Puerto Rican Endangered Ferns Recovery Plan.	https://ecos.fws.gov/docs/recovery_plan/Puerto%20Rican%20Endangered%20Ferns%20Recovery%20Plan%20Amendment.pdf .		
No common name	<i>Polystichum calderonense</i> .	E	Puerto Rico.				
No common name	<i>Tectaria estremarana</i> .	E	Puerto Rico.				
No common name	<i>Thelypteris inabonensis</i> .	E	Puerto Rico.				
No common name	<i>Thelypteris vercunda</i> .	E	Puerto Rico.				
No common name	<i>Thelypteris yaucoensis</i> .	E	Puerto Rico.				
No common name	<i>Gesneria pauciflora</i> .	T	Puerto Rico	<i>Gesneria pauciflora</i> Recovery Plan.	https://ecos.fws.gov/docs/recovery_plan/Gesneria%20pauciflora%20Recovery%20Plan%20Amendment.pdf .		

Mountain-Prairie Region (Colorado, Kansas, Montana, Nebraska, North Dakota, South Dakota, Utah, Wyoming)

Virgin River chub	<i>Gila robusta seminuda</i> .	E	AZ, NV, UT	Recovery Plan for the Virgin River Fishes.	https://ecos.fws.gov/tess/plan/document/addendum/view.do?addendumId=1016601 .	Larry Crist, 801-975-3330, utahfieldoffice_esa@fws.gov .	Utah Ecological Services Field Office, 2369 West Orton Circle, Suite 50, West Valley City, UT 84119.
Barneby ridge-cress ..	<i>Lepidium barnebyanum</i> .	E	UT	Barneby Ridge-cress <i>Lepidium barnebyanum</i> Recovery Plan.	https://ecos.fws.gov/docs/recovery_plan/Barneby%20Ridge%20Cress%20*recovery%20criteria%2020181029%20FINAL.pdf .		
Clay phacelia	<i>Phacelia argillacea</i>	E	UT	<i>Phacelia argillacea</i> Atwood Recovery Plan.	https://ecos.fws.gov/docs/recovery_plan/Clay%20phacelia_recovery_criteria_20181210_FINAL_3.pdf .		
Maguire primrose	<i>Primula maguirei</i> ..	T	UT	Maguire Primrose (<i>Primula maguirei</i>) Recovery Plan.	https://ecos.fws.gov/docs/recovery_plan/Maguire_primrose_recovery_criteria_20181210_FINAL.pdf .		
Autumn buttercup	<i>Ranunculus acriformis</i> var. <i>aestivalis</i> .	E	UT	Autumn Buttercup <i>Ranunculus acriformis</i> A. Gray var. <i>aestivalis</i> L. Benson.	https://ecos.fws.gov/docs/recovery_plan/Autumnbuttercup_recovery_criteria_20181210_FINAL.pdf .		
Shrubby reed-mustard.	<i>Schoenocrambe suffrutescens</i> .	E	UT	Utah Reed-Mustards: Clay Reed-Mustard (<i>Schoenocrambe argillacea</i>), Barneby Reed-Mustard (<i>Schoenocrambe barnebyi</i>), Shrubby Reed-Mustard (<i>Schoenocrambe suffrutescens</i>) Recovery Plan.	https://ecos.fws.gov/docs/recovery_plan/Shrubby%20reed%20mustard%20recovery%20criteria_20181217_FINAL.pdf .		

Common name	Scientific name	Listing status ¹	Current range	Recovery plan name	Internet availability of proposed recovery plan revision	Contact person, phone, email	Contact person's U.S. mail address
Pacific Southwest Region (California, Nevada, and the Klamath Basin area of Oregon)							
Lange's metalmark butterfly.	<i>Apodemia mormo langei</i> .	E	CA	Recovery Plan for Three Endangered Species Endemic to Antioch Dunes, California.	https://ecos.fws.gov/docs/recovery_plan/Draft_RP_Amendment%20Antioch%20Dunes.pdf .	Kaylee Allen, 916-930-5603, kaylee_allen@fws.gov .	San Francisco Bay-Delta Fish and Wildlife Office, 650 Capitol Mall, Suite 8-300, Sacramento, CA 95814.
Contra Costa wall-flower.	<i>Erysimum capitatum</i> var. <i>angustatum</i> .	E	CA.				
Antioch Dunes evening-primrose.	<i>Oenothera deltoides</i> ssp. <i>howellii</i> .	E	CA.				
McDonald's rock-cress.	<i>Arabis mcdonaldiana</i> .	E	CA, OR	McDonald's Rock-Cress Recovery Plan (<i>Arabis mcdonaldiana</i> Eastwood).	https://ecos.fws.gov/docs/recovery_plan/DRAFT%20Recovery%20Plan%20Amendment%20MCRC.pdf .	Laurel Goldsmith, 707-822-7201, laurel_goldsmith@fws.gov .	Arcata Fish and Wildlife Office, 1655 Heindon Road, Arcata, CA 95521.
Howell's spineflower	<i>Chorizanthe howellii</i> .	E	CA	Seven Coastal Plants and the Myrtle's Silverspot Butterfly Recovery Plan.	https://ecos.fws.gov/docs/recovery_plan/Draft%20Recovery%20Plan%20Amendment%20Chorizanthe%20howellii.pdf .		
Western lily	<i>Lilium occidentale</i>	E	CA, OR	Recovery Plan for the Endangered Western lily (<i>Lilium occidentale</i>).	https://ecos.fws.gov/docs/recovery_plan/Draft%20Amendment%20to%20Western%20lily%20Recovery%20Plan.pdf .		
White River spinedace.	<i>Lepidomeda albivallis</i> .	E	NV	White River Spinedace (<i>Lepidomeda albivallis</i>) Recovery Plan.	https://ecos.fws.gov/docs/recovery_plan/Draft%20Recovery%20Plan%20Amendment%20for%20White%20River%20Spine%20dace.pdf .	Glen Knowles, 801-975-3330, glen_knowles@fws.gov .	Southern Nevada Fish and Wildlife Office, 4701 North Torrey Pines Drive, Las Vegas, NV 89130.
Amargosa vole	<i>Microtus californicus scirpensis</i> .	E	CA	Amargosa vole (<i>Microtus californicus scirpensis</i>) Recovery Plan.	https://ecos.fws.gov/docs/recovery_plan/Draft%20RP%20Amendment%20for%20AMVO.pdf .	Bradd Bridges, 760-431-9440, fw8chwocomments@fws.gov .	Carlsbad Fish and Wildlife Office, 2177 Salk Avenue, Suite 250, Carlsbad, CA 92008.

¹ E = endangered; T = threatened.

How do I ask questions or provide information?

For any species listed above, please submit your questions, comments, and materials to the appropriate contact in the table above. Individuals who are hearing impaired or speech impaired may call the Federal Relay Service at 800-877-8339 for TTY assistance.

Request for Public Comments

We request written comments on the draft recovery plan modifications. We will consider all comments we receive by the date specified in **DATES** prior to final approval of the plans.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

The authority for this action is section 4(f) of the Endangered Species Act (16 U.S.C. 1533 (f)).

Dated: July 19, 22019.

Margaret E. Everson,

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

[FR Doc. 2019-16749 Filed 8-5-19; 8:45 am]

BILLING CODE 4333-15-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R7-NWRS-2019-N167; FF07RYKD00 FXRS12610700000 189; OMB Control Number 1018-New]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; In-Season Subsistence Salmon Fishery Catch and Effort Survey

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, are proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before September 5, 2019.

ADDRESSES: Send written comments on this information collection request to the Office of Management and Budget's Desk Officer for the Department of the Interior by email at OIRA_Submission@omb.eop.gov; or via facsimile to (202) 395-5806. Please provide a copy of your comments to the 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-YDNWR Salmon Survey" in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT:

Madonna L. Baucum, Service Information Collection Clearance Officer, by email at Info_Coll@fws.gov, or by telephone at (703) 358-2503. 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.

On October 12, 2018, we published a **Federal Register** notice with a 60-day public comment period soliciting comments on this proposed new collection of information (83 FR 51695). In that notice, we solicited comments for 60 days, ending on December 11, 2018. We received one comment in response to that notice but it did not address the information collection requirements. We made no changes to the collection in response to that comment.

We are again soliciting comments on the information collection request (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. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your that your entire comment—including your personal identifying information—may be 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 administration and uses of national wildlife refuges and wetland management districts are governed by the National Wildlife Refuge System Administration Act of 1966 (16 U.S.C. 668dd–668ee) (Administration Act), as amended by the National Wildlife Refuge System Improvement Act of 1997; the Refuge Recreation Act of 1962 (16 U.S.C. 460k–460k–4) (Recreation Act); and, the Alaska National Interest Lands Conservation Act (16 U.S.C. 3101 *et seq.*) (ANILCA). ANILCA provides specific authorization and guidance for

the administration and management of national wildlife refuges within the State of Alaska.

The Service is requesting authorization to contribute to the design and implementation of subsistence fisher surveys for the purposes of informing in-season fisheries management decision-making in the Kuskokwim River subsistence salmon fishery at Yukon Delta National Wildlife Refuge (YDNWR). A program is already in place and is operated by tribal partners [the Orutsarmiut Traditional Native Council and the Kuskokwim River Inter-Tribal Fisheries Commission (KRITFC)], but the Service would like to be more involved in planning and administering the surveys.

The information collected by the survey includes the times individuals left and returned from boat launches, several characteristics of their fishing gear, broad classification of where the fishing activity occurred, for how long they actively fished, and how many of each of three salmon species they harvested. When coupled with aerial boat counts performed by the Service, these data can be used to obtain quantitative estimates of total fishing activity and salmon harvest occurring from short-duration subsistence harvest opportunities. The estimates are then used to inform the management strategy used jointly by the Service and the KRITFC.

Title of Collection: In-Season Subsistence Salmon Fishery Catch and Effort Survey.

OMB Control Number: 1018–New.

Form Number: None.

Type of Review: New.

Respondents/Affected Public: Subsistence fishers within the Yukon Delta National Wildlife Refuge.

Total Estimated Number of Annual Respondents: 1,014.

Total Estimated Number of Annual Responses: 1,014.

Estimated Completion Time per Response: 5 minutes.

Total Estimated Number of Annual Burden Hours: 85 hours.

Respondent's Obligation: Voluntary.

Frequency of Collection: On occasion.

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: July 31, 2019.

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2019–16723 Filed 8–5–19; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–ES–2019–N047;
FXES11130100000C4–190–FF02ENEH00]

Endangered and Threatened Wildlife and Plants; 21 Draft Recovery Plan Revisions for 25 Species in 15 States Across the United States

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; opening of public comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability for public review and comment of 21 draft recovery plan revisions, which update recovery criteria for 25 endangered or threatened species located in 15 States (Arizona, California, Colorado, Kentucky, Maine, New Hampshire, New Mexico, North Carolina, Oregon, Tennessee, Texas, Utah, Vermont, Virginia, West Virginia). We are updating recovery criteria to better assist in determining when an endangered species has recovered to the point that it may be reclassified as threatened, or that the protections afforded by the Endangered Species Act (ESA) are no longer necessary and the species may be removed from the ESA's protections. We request review of these draft recovery plan revisions and invite comments from local, State, Tribal, and Federal agencies, nongovernmental organizations, and the public.

DATES: We must receive comments on the draft recovery plan revisions on or before September 5, 2019.

ADDRESSES:

Reviewing documents: If you wish to review the draft recovery plan revisions, you may obtain copies from the website addresses in the table in **SUPPLEMENTARY INFORMATION**. You may also request copies of the draft recovery plan revisions by contacting the individuals listed in the table.

Submitting comments: If you wish to comment, see the table in **SUPPLEMENTARY INFORMATION** and submit your comments by one of the following methods:

1. *U.S. Mail or hand-delivery:* You may submit written comments and materials to the appropriate field office

mailing address for the species in which you are interested;

2. **Email:** You may send comments by email to the identified contact person's email address in the table, for each species. Please include "Draft Recovery Plan Revision Comments" in the subject line.

FOR FURTHER INFORMATION CONTACT: For information on a particular species, contact the appropriate person listed in the table for that species in

SUPPLEMENTARY INFORMATION.

Individuals who are hearing impaired may call the Federal Relay Service at 800-877-8339 for TTY assistance.

SUPPLEMENTARY INFORMATION:

Background

In this notice, we announce for public review and comment the availability of 21 draft recovery plan revisions, which update recovery criteria for 25 endangered or threatened species located in 15 States (Arizona, California, Colorado, Kentucky, Maine, New Hampshire, New Mexico, North Carolina, Oregon, Tennessee, Texas, Utah, Vermont, Virginia, and West Virginia). This group of 21 draft recovery plan revisions is part of a larger effort underway to revise up to 182 recovery plans covering up to 305 species in order to achieve the following Department of the Interior Agency Priority Performance Goal outlined in the Department's Strategic Plan for Fiscal Years 2018–2022: "By September 30, 2019, 100 percent of all Fish and Wildlife Service recovery plans will have quantitative criteria for what constitutes a recovered species."

The purpose of a recovery plan is to provide a feasible and effective roadmap for a species' recovery, with the goal of improving its status and managing its

threats to the point at which protections under the Endangered Species Act (ESA; 16 U.S.C. 1531 *et seq.*) are no longer needed. Recovery plans must be designed so that all stakeholders and the public understand the rationale behind the recovery program, whether they were involved in writing the plan or not, and recognize their role in its implementation. We are requesting submission of any information that enhances the necessary understanding of the (1) species' biology and threats and (2) recovery needs and related implementation issues or concerns, to ensure that we have assembled, considered, and incorporated the best available scientific and commercial information into the draft recovery plan revisions for these 25 species.

Recovery plans provide important guidance to the Service, States, other partners, and the general public on methods of minimizing threats to listed species and objectives against which to measure the progress towards recovery; they are guidance and not regulatory documents. A recovery plan identifies, organizes, and prioritizes recovery actions and is an important guide that ensures sound scientific decision-making throughout the recovery process, which can take decades. Keeping recovery plans current ensures that threatened species and endangered species benefit through timely partner-coordinated implementation, based on the best available information.

A review of a recovery plan and its implementation may show that the plan is out of date or its usefulness is limited and that the plan warrants modification. The need for, and extent of, recovery plan modifications will vary considerably among recovery plans, depending on the scope and complexity

of the initial plan, the structure of the document, and the involvement of stakeholders. Recovery plan modifications can range from relatively minor updates to a substantial rewrite that revises the existing plan in part (*i.e.*, an amendment to one of the sections that modifies the existing plan), or in full (*i.e.*, a full revision that completely replaces the existing plan). The need for a recovery plan revision may be triggered when, among other possibilities, (1) new information has been identified, such as population-level threats to the species or previously unknown life-history traits, which necessitates new or revised recovery strategy, actions, or criteria, or revision of all three in order to maintain the adequacy of the plan; and (2) the current plan is not achieving its objectives. Revisions benefit endangered and threatened species, our partners, and the public by incorporating the best available information on what is needed for species' recovery.

Revision of recovery plans requires public notice and comment under section 4(f)(4) of the ESA, including (1) a **Federal Register** notice of availability to give opportunity for public review and comment, (2) consideration of all information presented during the public comment period, and (3) approval by the Regional Director. When finalized, these recovery plan revisions will be made publicly available on the internet through our Environmental Conservation Online System (ECOS, <https://ecos.fws.gov>).

What plans are being made available for public review and comment?

This notice announces our draft recovery plan revisions for the species listed in the table below.

Common Name	Scientific name	Listing status ¹	Current range	Recovery plan name	Internet availability of proposed recovery plan revision	Contact person, phone, email	Contact person's U.S. mail address
Southwest Region (Arizona, New Mexico, Oklahoma, and Texas)							
Sonoran tiger salamander	<i>Ambystoma tigrinum stebbinsi</i>	E	AZ	Sonoran Tiger Salamander (<i>Ambystoma tigrinum stebbinsi</i>) Recovery Plan ² .	https://ecos.fws.gov/docs/recovery_plan/Draft%20APG%20RP%20Amendment_Sonoran%20tiger%20salamander_03152019.pdf	Field Supervisor, 602–242–0210, incomingazcorr@fws.gov	Arizona Ecological Services Field Office, 9828 North 31st Avenue, #C3, Phoenix, AZ 85051.
Navajo sedge	<i>Carex specuicola</i> ..	T	AZ, UT ..	Recovery Plan for Navajo Sedge <i>Carex specuicola</i> ² .	https://ecos.fws.gov/docs/recovery_plan/Draft%20APG%20RP%20Amendment_Navajo%20sedge_03152019.pdf		
Nichol's Turk's head cactus.	<i>Echinocactus horizonthalonius</i> var. <i>nicholii</i>	E	AZ	Recovery Plan for the Nichol's Turk's Head Cactus (<i>Echinocactus horizonthalonius</i> var. <i>nicholii</i>) ² .	https://ecos.fws.gov/docs/recovery_plan/Draft%20APG%20RP%20Amendment_Nichols%20turks%20head_03152019.pdf		
Little Colorado spinedace	<i>Lepidomeda vittata</i>	T	AZ	Little Colorado River Spinedace <i>Lepidomeda vittata</i> Recovery Plan ² .	https://ecos.fws.gov/docs/recovery_plan/Draft%20APG%20RP%20Amendment_Little%20Colorado%20spinedace_03202019.pdf		
Spikedace	<i>Meda fulgida</i>	E	AZ, NM ..	Spikedace, <i>Meda fulgida</i> Recovery Plan ² .	https://ecos.fws.gov/docs/recovery_plan/Draft%20APG%20RP%20Amendment_spikedace_03152019.pdf		

Common Name	Scientific name	Listing status ¹	Current range	Recovery plan name	Internet availability of proposed recovery plan revision	Contact person, phone, email	Contact person's U.S. mail address
Loach minnow	<i>Rhinichthys cobitis</i>	E	AZ, NM ..	Loach Minnow, <i>Tiaroga cobitis</i> Recovery Plan ² .	https://ecos.fws.gov/docs/recovery_plan/Draft%20APG%20RP%20Amendment_loach%20minnow_03152019.pdf .		
Masked bobwhite	<i>Colinus virginianus ridgwayi</i> .	E	AZ	Masked Bobwhite Recovery Plan, Second Revision ² .	https://ecos.fws.gov/docs/recovery_plan/Draft%20APG%20RP%20Amendment_masked%20bobwhite_03152019.pdf .	William Radke, 520-364-2104, bill_radke@fws.gov .	Buenos Aires, Leslie Canyon, & San Bernardino National Wildlife Refuges, P.O. Box 3509, Douglas, AZ 85607.
Texas poppy-mallow	<i>Callirhoe scabriuscula</i> .	E	TX	Texas Poppy-Mallow <i>Callirhoe scabriuscula</i> Recovery Plan ² .	https://ecos.fws.gov/docs/recovery_plan/Draft%20APG%20RP%20Amendment_Texas%20poppy%20mallow_03152019.pdf .	Adam Zerrenner, 512-490-0057, adam_zerrenner@fws.gov .	Austin Ecological Services Field Office, 10711 Burnet Road, Suite 200 Austin, TX 78758.
Fountain darter	<i>Etheostoma fonticola</i> .	E	TX	San Marcos and Comal Springs and Associated Aquatic Ecosystems (Revised) Recovery Plan ² .	https://ecos.fws.gov/docs/recovery_plan/Draft%20APG%20RP%20Amendment_San%20Marcos%20and%20Comal%20Springs_1.pdf .		
Texas blind salamander ..	<i>Typhlomolge rathbuni</i> .	E	TX.				
Texas wild-rice	<i>Zizania texana</i>	E	TX.				
Black lace cactus	<i>Echinocereus reichenbachii</i> var. <i>alberti</i> .	E	TX	Black Lace Cactus (<i>Echinocereus reichenbachii</i> var. <i>alberti</i>) Recovery Plan ² .	https://ecos.fws.gov/docs/recovery_plan/Draft%20APG%20RP%20Amendment_black%20lace%20cactus.pdf .	Chuck Ardizzone, 281-826-8282, chuck_ardizzone@fws.gov .	Texas Coastal Ecological Services Field Office, 17629 El Camino Real, Suite 211, Houston, TX 77058.
Walker's manioc	<i>Manihot walkerae</i>	E	TX	Walker's Manioc <i>Manihot walkerae</i> Recovery Plan ² .	https://ecos.fws.gov/docs/recovery_plan/Draft%20APG%20RP%20Amendment_Walkers%20manioc_03152019.pdf .		

Northeast Region (Connecticut, Delaware, the District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, and West Virginia)

Jesup's milk-vetch	<i>Astragalus robbinsii</i> var. <i>jesupi</i> .	E	NH, VT ..	Jesup's Milk-Vetch Recovery Plan (<i>Astragalus robbinsii</i> var. <i>jesupi</i>) Draft Revised Recovery Plan ³ .	https://ecos.fws.gov/docs/recovery_plan/20190228_Draft%20JMV%20Recovery%20Plan_1.pdf .	David Simmons, 603-227-6425, david_simmons@fws.gov .	New England Field Office, 70 Commercial St., Suite 300, Concord, NH 03301.
Virginia big-eared bat	<i>Corynorhinus townsendii virginianus</i> .	E	KY, NC, TN, VA, WV.	A Recovery Plan for the Ozark Big-Eared Bat and the Virginia Big-Eared Bat ² .	https://ecos.fws.gov/docs/recovery_plan/20190313_Draft%20VBE%20Recovery%20Plan%20Amendment.pdf .	Daphne Carlson Bremer, 304-636-6586, daphne_carlsonbremer@fws.gov .	West Virginia Field Office, 90 Vance Drive, Elkins, WV 26241.
Furbish lousewort	<i>Pedicularis furbishiae</i> .	E	ME	Recovery Plan for the Furbish's Lousewort (<i>Pedicularis furbishiae</i>), Draft Second Revision ³ .	https://ecos.fws.gov/docs/recovery_plan/20190306_Furbish%20lousewort%20RP_draft%20final.pdf .	Anna Harris, 207-469-7300, anna_harris@fws.gov .	Maine Field Office, 306 Hatchery Road East, Orland, ME 04431.

Mountain-Prairie Region (Colorado, Kansas, Montana, Nebraska, North Dakota, South Dakota, Utah, Wyoming)

Pawnee montane skipper	<i>Hesperia leonardus montana</i> .	T	CO	Pawnee Montane Skipper Recovery Plan ² .	https://ecos.fws.gov/docs/recovery_plan/Pawnee%20montane%20skipper_Draft%20Amendment%201.pdf .	Leslie Ellwood, 303-236-4747, leslie_ellwood@fws.gov .	Colorado Ecological Services Field Office, 134 Union Blvd., Suite 670, Lakewood, CO 80228.
Dudley Bluffs bladderpod	<i>Lesquerella congesta</i> .	T	CO	Dudley Bluffs Bladderpod (<i>Lesquerella congesta</i>) and Dudley Bluffs Twinpod (<i>Physaria obcordata</i>) Recovery Plan ³ .	https://ecos.fws.gov/docs/recovery_plan/20190318_DudleyBluffs_DraftRecoveryPlan.pdf .	Ann Timberman, 970-628-7181, ann_timmerman@fws.gov .	Colorado Ecological Services Field Office, Western Colorado Sub-Office, 445 W. Gunnison Ave., Suite 240, Grand Junction, CO 81504.
Dudley Bluffs twinpod	<i>Physaria obcordata</i> .	T	CO.				

Pacific Southwest Region (California, Nevada, and the Klamath Basin area of Oregon)

Applegate's milk-vetch	<i>Astragalus applegatei</i> .	E	CA, OR	Applegate's milk-vetch (<i>Astragalus applegatei</i>) Recovery Plan ² .	https://ecos.fws.gov/docs/recovery_plan/Draft%20RP%20Amendment%20Applegates%20MV_1.pdf .	Jeanne Spaur, kfalls@fws.gov , 541-885-8481.	Klamath Falls Fish and Wildlife Office, 1936 California Ave., Klamath Falls, OR 97601.
El Segundo blue butterfly	<i>Euphilotes battoides allyni</i> .	E	CA	El Segundo Blue Butterfly (<i>Euphilotes battoides allyni</i>) Recovery Plan ² .	https://ecos.fws.gov/docs/recovery_plan/Draft%20RP%20Amendment%20ESB_1.pdf .	Bradd Bridges, fw8chwocomments@fws.gov , 760-431-9440.	Carlsbad Fish and Wildlife Office, 2177 Salk Avenue, Suite 250, Carlsbad, CA 92008.
Quino checkerspot butterfly.	<i>Euphydryas editha quino</i> .	E	CA	Recovery Plan for the Quino Checkerspot Butterfly (<i>Euphydryas editha quino</i>) ² .	https://ecos.fws.gov/docs/recovery_plan/Draft%20RP%20Amendment%20for%20QCB_1.pdf .		
Palos Verdes blue butterfly.	<i>Glaucopteryx lygdamus palosverdesensis</i> .	E	CA	Palos Verdes Blue Butterfly Recovery Plan ² .	https://ecos.fws.gov/docs/recovery_plan/Draft%20RP%20Amendment%20PVB.pdf .		

Common Name	Scientific name	Listing status ¹	Current range	Recovery plan name	Internet availability of proposed recovery plan revision	Contact person, phone, email	Contact person's U.S. mail address
San Clemente logger-head shrike.	<i>Lanius ludovicianus mearnsi</i> .	E	CA	Recovery Plan for the Endangered and Threatened Species of the California Channel Islands ² .	https://ecos.fws.gov/docs/recovery_plan/Draft%20RP%20Amendment%20for%202%20SCI_shrike%20LIMA_1.pdf .		
San Clemente Island woodland-star.	<i>Lithophragma maximum</i> .	E	CA.				

¹ E = endangered; T = threatened.

² Denotes a partial revision (i.e., amendment) to the recovery plan.

³ Denotes a full revision of the recovery plan.

How do I ask questions or provide information?

For any species listed above, please submit your questions, comments, and materials to the appropriate contact in the table above. Individuals who are hearing impaired or speech impaired may call the Federal Relay Service at 800-877-8339 for TTY assistance.

Request for Public Comments

We request written comments on the draft recovery plan modifications. We will consider all comments we receive by the date specified in **DATES** prior to final approval of the plans.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

The authority for this action is section 4(f) of the Endangered Species Act (16 U.S.C. 1533 (f)).

Dated: July 25, 2019.

Margaret E. Everson,

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

[FR Doc. 2019-16748 Filed 8-5-19; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-HQ-ES-2019-N048;
FXES1113010000C4-190-FF02ENEH00]

Endangered and Threatened Wildlife and Plants; 21 Draft Recovery Plan Revisions for 43 Southeastern Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; opening of public comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability for public review and comment of 21 draft recovery plan revisions, which update recovery criteria for 43 endangered or threatened species located in Alabama, Arkansas, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Missouri, Mississippi, and Tennessee, the Commonwealth of Puerto Rico, and the U.S. and British Virgin Islands. We are updating recovery criteria to better assist in determining when an endangered species has recovered to the point that it may be reclassified as threatened, or that the protections afforded by the Endangered Species Act (ESA) are no longer necessary and the species may be removed from the ESA's protections. We request review of these draft recovery plan revisions and invite comments from local, State, Tribal, and Federal agencies, nongovernmental organizations, and the public.

DATES: We must receive comments on the draft recovery plan revisions on or before September 5, 2019.

ADDRESSES: *Reviewing documents:* If you wish to review the draft recovery plan revisions, you may obtain copies from the website addresses in the table in **SUPPLEMENTARY INFORMATION**. You may also request copies of the draft recovery plan revisions by contacting the individuals listed in the table.

Submitting comments: If you wish to comment, see the table in **SUPPLEMENTARY INFORMATION** and submit your comments by one of the following methods:

1. *U.S. Mail or hand-delivery:* You may submit written comments and materials to the appropriate field office mailing address for the species in which you are interested;

2. *Email:* You may send comments by email to the identified contact person's email address in the table, for each species. Please include "Draft Recovery Plan Revision Comments" in the subject line.

FOR FURTHER INFORMATION CONTACT: For information on a particular species,

contact the appropriate person listed in the table for that species in

SUPPLEMENTARY INFORMATION.

Individuals who are hearing impaired may call the Federal Relay Service at 800-877-8339 for TTY assistance.

SUPPLEMENTARY INFORMATION:

Background

In this notice, we announce for public review and comment the availability of 21 draft recovery plan revisions, which update recovery criteria for 43 endangered or threatened species located in Alabama, Arkansas, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Missouri, Mississippi, and Tennessee, the Commonwealth of Puerto Rico, and the U.S. and British Virgin Islands. This group of 21 draft recovery plan revisions is part of a larger effort underway to revise up to 182 recovery plans covering up to 305 species in order to achieve the following Department of the Interior Agency Priority Performance Goal outlined in the Department's Strategic Plan for Fiscal Years 2018-2022: "By September 30, 2019, 100 percent of all Fish and Wildlife Service recovery plans will have quantitative criteria for what constitutes a recovered species."

The purpose of a recovery plan is to provide a feasible and effective roadmap for a species' recovery, with the goal of improving its status and managing its threats to the point at which protections under the Endangered Species Act (ESA; 16 U.S.C. 1531 *et seq.*) are no longer needed. Recovery plans must be designed so that all stakeholders and the public understand the rationale behind the recovery program, whether they were involved in writing the plan or not, and recognize their role in its implementation. We are requesting submission of any information that enhances the necessary understanding of the (1) species' biology and threats and (2) recovery needs and related implementation issues or concerns, to ensure that we have assembled, considered, and incorporated the best available scientific and commercial information into the draft recovery plan revisions for these 43 species.

Recovery plans provide important guidance to the Service, States, other partners, and the general public on methods of minimizing threats to listed species and objectives against which to measure the progress towards recovery; they are guidance and not regulatory documents. A recovery plan identifies, organizes, and prioritizes recovery actions and is an important guide that ensures sound scientific decision-making throughout the recovery process, which can take decades. Keeping recovery plans current ensures that threatened species and endangered species benefit through timely partner-coordinated implementation, based on the best available information.

A review of a recovery plan and its implementation may show that the plan is out of date or its usefulness is limited and that the plan warrants modification. The need for, and extent of, recovery plan modifications will vary

considerably among recovery plans, depending on the scope and complexity of the initial plan, the structure of the document, and the involvement of stakeholders. Recovery plan modifications can range from relatively minor updates to a substantial rewrite that revises the existing plan in part (*i.e.*, an amendment to one of the sections that modifies the existing plan), or in full (*i.e.*, a full revision that completely replaces the existing plan). The need for a recovery plan revision may be triggered when, among other possibilities, (1) new information has been identified, such as population-level threats to the species or previously unknown life-history traits, which necessitates new or revised recovery strategy, actions, or criteria, or revision of all three in order to maintain the adequacy of the plan; and (2) the current plan is not achieving its objectives. Revisions benefit endangered and

threatened species, our partners, and the public by incorporating the best available information on what is needed for species' recovery.

Revision of recovery plans requires public notice and comment under section 4(f)(4) of the ESA, including (1) a **Federal Register** notice of availability to give opportunity for public review and comment, (2) consideration of all information presented during the public comment period, and (3) approval by the Regional Director. When finalized, these recovery plan revisions will be made publicly available on the internet through our Environmental Conservation Online System (ECOS, <https://ecos.fws.gov>).

What plans are being made available for public review and comment?

This notice announces our draft recovery plan revisions for the species listed in the table below.

Common name	Scientific name	Listing status ¹	Current range	Recovery plan name	Internet availability of proposed recovery plan revision	Contact person, phone, email	Contact person's U.S. mail address
Morefield's leather flower	<i>Clematis morefieldii</i>	E	AL, TN ...	Morefield's Leather Flower <i>Clematis morefieldii</i> Recovery Plan ² .	https://ecos.fws.gov/docs/recovery_plan/Morefields%20Leather%20Flower%20Recovery%20Plan%20Amendment.pdf	Stephen Ricks, 601-321-1122, stephen_ricks@fws.gov	Mississippi Ecological Services Field Office, 6578 Dogwood View Pkwy, Suite A, Jackson, MS 39213.
Southern combshell	<i>Epioblasma penita</i>	E	AL, MS ..	Five Tombigbee River Mussels Recovery Plan ² .	https://ecos.fws.gov/docs/recovery_plan/Southern%20Combshell%20and%20Black%20Clubshell%20Recovery%20Plan%20Amendment.pdf		
Black clubshell	<i>Pleurobema curtum</i>	E	AL, MS.				
Fat pocketbook	<i>Potamilus capax</i> ...	E	AR, IL, IN, KY, LA, MO, MS, TN.	A Recovery Plan for the Fat Pocketbook Pearly Mussel <i>Potamilus capax</i> ² .	https://ecos.fws.gov/docs/recovery_plan/Fat%20Pocketbook%20Mussel%20Recovery%20Plan%20Amendment.pdf		
Alabama redbellied turtle	<i>Pseudemys alabamensis</i>	E	AL, MS ..	Draft Revised Recovery Plan for the Alabama Red-Bellied Turtle (<i>Pseudemys alabamensis</i>) ³ .	https://ecos.fws.gov/docs/recovery_plan/Alabama%20Red%20Bellied%20Turtle%20Draft%20Revised%20Recovery%20Plan.pdf		
Dusky gopher frog	<i>Rana sevosa</i>	E	AL, MS ..	Dusky Gopher Frog (<i>Rana sevosa</i>) Recovery Plan ² .	https://ecos.fws.gov/docs/recovery_plan/Dusky%20Gopher%20Frog%20Recovery%20Plan%20Amendment.pdf		
Alabama canebrake pitcher-plant.	<i>Sarracenia rubra</i> ssp. <i>alabamensis</i> .	E	AL	Alabama Canebrake Pitcher Plant (<i>Sarracenia rubra</i> ssp. <i>alabamensis</i>) Recovery Plan ² .	https://ecos.fws.gov/docs/recovery_plan/Alabama%20Canebrake%20Pitcher%20Plant%20Recovery%20Plan%20Amendment_1.pdf		
Alabama cavefish	<i>Speoplatyrhinus poulsoni</i> .	E	AL	Alabama Cavefish <i>Speoplatyrhinus poulsoni</i> Recovery Plan (Second Revision) ² .	https://ecos.fws.gov/docs/recovery_plan/Alabama%20Cavefish%20Recovery%20Plan%20Amendment.pdf		
Alabama beach mouse ...	<i>Peromyscus polionotus ammobates</i> .	E	AL	Recovery Plan for the Alabama Beach Mouse (<i>Peromyscus polionotus ammobates</i>), Perdido Key Beach Mouse (<i>P. p. trissyllepsis</i>), and Choctawhatchee Beach Mouse (<i>P. p. allophrys</i>) ² .	https://ecos.fws.gov/docs/recovery_plan/Alabama%20Beach%20Mouse%20Recovery%20Plan%20Amendment.pdf	William J. Pearson, 251-441-5870, bill_pearson@fws.gov	Alabama Ecological Services Field Office, U.S. Fish and Wildlife Service, 1208-B Main Street, Daphne, AL 36526.
Choctawhatchee beach mouse.	<i>Peromyscus polionotus allophrys</i> .	E	FL		https://ecos.fws.gov/docs/recovery_plan/Choctawhatchee%20Beach%20Mouse%20Recovery%20Plan%20Amendment.pdf	Catherine T. Phillips, Ph.D., 850-769-0552, catherine_phillips@fws.gov	Panama City Field Office, 1601 Balboa Avenue, Panama City, FL 32405.
Perdido Key beach mouse.	<i>Peromyscus polionotus trissyllepsis</i> .	E	AL, FL ...		https://ecos.fws.gov/docs/recovery_plan/Perdido%20Key%20Beach%20Mouse%20Recovery%20Plan%20Amendment.pdf		

Common name	Scientific name	Listing status ¹	Current range	Recovery plan name	Internet availability of proposed recovery plan revision	Contact person, phone, email	Contact person's U.S. mail address
Apalachicola rosemary	<i>Conradina glabra</i>	E	FL	Recovery Plan for Apalachicola Rosemary (<i>Conradina glabra</i>) ² .	https://ecos.fws.gov/docs/recovery_plan/Apalachicola%20Rosemary%20Recovery%20Plan%20Amendment.pdf .		
Ochlockonee moccasinshell.	<i>Medionidus simpsonianus</i> .	E	FL, GA ..	Recovery Plan for Endangered Fat Threeridge, Shinyrayed Pocketbook, Gulf Moccasinshell, Ochlockonee moccasinshell, Oval Pigtoe and Threatened Chipola Slabshell, and Purple bankclimber ² .	https://ecos.fws.gov/docs/recovery_plan/Ochlockonee%20Moccasinshell%20Recovery%20Plan%20Amendment.pdf .		
Chapman rhododendron	<i>Rhododendron chapmanii</i> .	E	FL	Recovery Plan for Chapman's Rhododendron, <i>Rhododendron chapmanii</i> ² .	https://ecos.fws.gov/docs/recovery_plan/Chapmans%20Rhododendron%20Recovery%20Plan%20Amendment.pdf .		
Gentian pinkroot	<i>Spigelia gentianoides</i> .	E	AL, FL ...	Recovery Plan for <i>Spigelia gentianoides</i> (Gentian pinkroot) ² .	https://ecos.fws.gov/docs/recovery_plan/Gentian%20Pinkroot%20Recovery%20Plan%20Amendment.pdf .		
Florida scrub-jay	<i>Aphelocoma coerulescens</i> .	T	FL	Draft Revised Recovery Plan for the Florida Scrub-Jay (<i>Aphelocoma coerulescens</i>) ³ .	https://ecos.fws.gov/docs/recovery_plan/Florida%20Scrub-Jay%20Draft%20Revised%20Recovery%20Plan.pdf .	Jay B. Herrington, 904-731-3191, jay_herrington@fws.gov .	Northeast Florida Ecological Services Field Office, 7915 Baymeadows Way, Suite 200, Jacksonville, FL 32256.
Four-petal pawpaw	<i>Asimina tetramera</i>	E	FL	South Florida Multi-Species Recovery Plan ² .	https://ecos.fws.gov/docs/recovery_plan/Four%20Petal%20PawPaw%20Recovery%20Plan%20Amendment.pdf .	Roxanna Hinzman, 772-469-4309, SouthFL_recoveryplancomments@fws.gov .	South Florida Ecological Services Field Office, 1339 20th Street, Vero Beach, FL 32960.
Fragrant prickly-apple	<i>Cereus eriophorus</i> var. <i>fragrans</i> .	E	FL		https://ecos.fws.gov/docs/recovery_plan/Fragrant%20Prickly%20Apple%20Recovery%20Plan%20Amendment.pdf .		
Florida perforate cladonia	<i>Cladonia perforata</i>	E	FL		https://ecos.fws.gov/docs/recovery_plan/Florida%20Perforate%20Cladonia%20Recovery%20Plan%20Amendment.pdf .		
Short-leaved rosemary	<i>Conradina brevifolia</i> .	E	FL		https://ecos.fws.gov/docs/recovery_plan/Lake%20Wales%20Ridge%20Plants%20Recovery%20Plan%20Amendment.pdf .		
Avon Park harebells	<i>Crotalaria avonensis</i> .	E	FL.				
Garrett's mint	<i>Dicerandra christmanii</i> .	E	FL.				
Scrub mint	<i>Dicerandra frutescens</i> .	E	FL.				
Snakeroot	<i>Eryngium cuneifolium</i> .	E	FL.				
Highlands scrub hypericum.	<i>Hypericum cumulicola</i> .	E	FL.				
Scrub blazingstar	<i>Liatris ohlingerae</i> ..	E	FL.				
Lewton's polygala	<i>Polygala lewtonii</i> ..	E	FL.				
Wireweed	<i>Polygonella basiramia</i> .	E	FL.				
Sandlace	<i>Polygonella myriophylla</i> .	E	FL.				
Carter's mustard	<i>Warea carteri</i>	E	FL.				
Florida ziziphus	<i>Ziziphus celata</i>	E	FL.				
American crocodile [FL DPS].	<i>Crocodylus acutus</i>	T	FL		https://ecos.fws.gov/docs/recovery_plan/American%20Crocodile%20Recovery%20Plan%20Amendment.pdf .		
Okeechobee gourd	<i>Cucurbita okeechobeensis</i> ssp. <i>okeechobeensis</i> .	E	FL		https://ecos.fws.gov/docs/recovery_plan/Okeechobee%20Gourd%20Recovery%20Plan%20Amendment.pdf .		
Snail kite	<i>Rostrhamus sociabilis plumbeus</i> .	E	FL		https://ecos.fws.gov/docs/recovery_plan/Everglade%20Snail%20Kite%20Recovery%20Plan%20Amendment.pdf .		
Key tree-cactus	<i>Pilosocereus robinii</i> .	E	FL		https://ecos.fws.gov/docs/recovery_plan/Key%20Tree%20Cactus%20Recovery%20Plan%20Amendment.pdf .		
Eastern indigo snake	<i>Drymarchon corais couperi</i> .	T	AL, FL, GA.	Draft Revised Recovery Plan for the Eastern Indigo Snake ³ .	https://ecos.fws.gov/docs/recovery_plan/Eastern%20Indigo%20Snake%20Draft%20Revised%20Recovery%20Plan.pdf .	Donald W. Imm, Ph.D., cell: 850-532-2046, office: 706-208-7501, fax: 706-613-6059, donald_imm@fws.gov .	Georgia Ecological Services Field Office, 355 East Hancock Avenue, Room 320 Box 7, Athens, GA 30601.
Amber darter	<i>Percina antesella</i>	E	GA, TN ..	Draft Revised Recovery Plan for the Amber Darter (<i>Percina antesella</i>) ³ .	https://ecos.fws.gov/docs/recovery_plan/Amber%20Darter%20Draft%20Revised%20Recovery%20Plan.pdf .		

Common name	Scientific name	Listing status ¹	Current range	Recovery plan name	Internet availability of proposed recovery plan revision	Contact person, phone, email	Contact person's U.S. mail address
Conasauga logperch	<i>Percina jenkinsi</i>	E	GA, TN ..	Draft Revised Recovery Plan for the Conasauga Logperch (<i>Percina jenkinsi</i>) ³	https://ecos.fws.gov/docs/recovery_plan/Conasauga%20Logperch%20Draft%20Revised%20Recovery%20Plan.pdf .	
Louisiana pearlshell	<i>Margaritifera hembeli</i> .	T	AR, LA ..	Draft Revised Recovery Plan for the Louisiana Pearlshell (<i>Margaritifera hembeli</i>) ³ .	https://ecos.fws.gov/docs/recovery_plan/Louisiana%20Pearlshell%20Draft%20Revised%20Recovery%20Plan.pdf .	Joseph Ranson, 337-291-3113, joseph_ranson@fws.gov .	Louisiana Ecological Services Field Office, 200 Dulles Drive, Lafayette, LA 70506.
Puerto Rican sharp-shinned hawk.	<i>Accipiter striatus venator</i> .	E	Puerto Rico.	Puerto Rican Broad-Winged Hawk and Puerto Rican Sharp-Shinned Hawk Recovery Plan ² .	https://ecos.fws.gov/docs/recovery_plan/Puerto%20Rican%20Broad-Winged%20Hawk%20and%20Puerto%20Rican%20Sharp-Shinned%20Hawk%20Recovery%20Plan%20Amendment.pdf .	Edwin E. Muñoz, 787-851-7297, edwin_muniz@fws.gov .	Caribbean Ecological Services Field Office, P.O. Box 1600, Rio Grande, PR 00745.
Puerto Rican broad-winged hawk.	<i>Buteo platypterus brunescens</i> .	E	Puerto Rico.				
Puerto Rican boa	<i>Epicrates inornatus</i>	E	Puerto Rico.	Recovery Plan for the Puerto Rican Boa ² .	https://ecos.fws.gov/docs/recovery_plan/Puerto%20Rican%20Boa%20Recovery%20Plan%20Amendment.pdf .		
Virgin Islands tree boa	<i>Epicrates monensis granti</i> .	E	Puerto Rico, Virgin Islands.	Recovery Plan for the Virgin Islands Tree Boa (<i>Epicrates monensis granti</i>) ² .	https://ecos.fws.gov/docs/recovery_plan/Virgin%20Island%20Tree%20Boa%20Recovery%20Plan%20Amendment.pdf .		

¹ E = endangered; T = threatened.

² Denotes a partial revision (*i.e.*, amendment) to the recovery plan.

³ Denotes a full revision of the recovery plan.

How do I ask questions or provide information?

For any species listed above, please submit your questions, comments, and materials to the appropriate contact in the table above. Individuals who are hearing impaired or speech impaired may call the Federal Relay Service at 800-877-8339 for TTY assistance.

Request for Public Comments

We request written comments on the draft recovery plan modifications. We will consider all comments we receive by the date specified in **DATES** prior to final approval of the plans.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

The authority for this action is section 4(f) of the Endangered Species Act (16 U.S.C. 1533 (f)).

Dated: July 19, 2019.

Margaret E. Everson,

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

[FR Doc. 2019-16750 Filed 8-5-19; 8:45 am]

BILLING CODE 4333-15-P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[19XD4523WC DWCF00000.000000 DS68664000 DQ.QSO00.19WC0000; OMB Control Number 1084-0033]

Agency Information Collection Activities; Private Rental Survey

AGENCY: Office of the Secretary, Office of Acquisition and Property Management, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Acquisition and Property Management are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before October 7, 2019.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to Laura Walters, Quarters Rental Program Manager, Interior Business Center, 7301 W Mansfield Ave., MS D-2910, Denver, CO 80235, or by fax: 303-969-6336, or by email to laura_a_walters@ibc.doi.gov. Please

reference OMB Control Number 1084-0033 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Laura Walters by email at laura_a_walters@ibc.doi.gov, or by telephone at 303-969-5696.

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 Office of Acquisition and Property Management; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Office of Acquisition and Property Management enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Office of Acquisition and Property Management 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: Office of Management and Budget (OMB) regulations at 5 CFR 1320, which implement the Paperwork Reduction Act of 1995 (Pub. L. 104–131), require that interested members of the public and affected parties have an opportunity to comment on information collection and recordkeeping activities. This notice identifies an information collection activity that the Office of Acquisition and Property Management has submitted to OMB for renewal.

Title 5 of the U.S. Code section 5911 authorizes Federal agencies to provide housing for Government employees under specified circumstances. In compliance with OMB Circular A–45 (Revised), Rental and Construction of Government Quarters, a review of private rental market housing rates is required at least once every 5 years to ensure that the rental, utility charges, and charges for related services to occupants of Government Furnished Housing (GFH) are comparable to corresponding charges in the private sector. To avoid unnecessary duplication and inconsistent rental rates, the Department of the Interior, Office of the Secretary, Interior Business Center (on behalf of the Office of Acquisition and Property Management), conducts housing surveys in support of employee housing management programs for the Departments of the Interior (DOI), Agriculture, Commerce, Homeland Security, Justice, Transportation, Health and Human Services, and Veterans Affairs. In this survey, two collection forms are used: OS–2000 covering “Houses—Apartments—Mobile Homes,” and OS–2001 covering “Trailer Spaces.”

This collection of information provides data that is essential for DOI and the other Federal agencies to manage GFH in accordance with the requirements of OMB Circular A–45 (Revised). If this information were not collected from the public, DOI and the other Federal agencies providing GFH would be required to use professional

real estate appraisals of private market rental costs, again, in accordance with OMB Circular A–45.

Title of Collection: Private Rental Survey.

OMB Control Number: 1084–0033.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Individuals/households, businesses and other for-profit institutions.

Total Estimated Number of Annual Respondents: OS–2000: 3,841; OS–2001: 200; Total: 4,041.

Total Estimated Number of Annual Responses: OS–2000: 3,841; OS–2001: 200; Total: 4,041.

Estimated Completion Time per Response: 6 minutes for OS–2000 and 4 minutes for OS–2001.

Total Estimated Number of Annual Burden Hours: 353 hours.

Respondent's Obligation: Voluntary.

Frequency of Collection: Annually.

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.*).

Megan Olsen,

Director, Office of Acquisition and Property Management.

[FR Doc. 2019–16742 Filed 8–5–19; 8:45 am]

BILLING CODE 4334–63–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLAZG02200.L16100000.
DQ0000.LXSS206A0000]

Notice of Availability of Record of Decision for the San Pedro Riparian National Conservation Area Resource Management Plan Final Environmental Impact Statement, Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: The Bureau of Land Management (BLM) announces the availability of the Record of Decision (ROD) for the approved Resource Management Plan (RMP) for the San Pedro Riparian National Conservation Area (SPRNCA) located in Cochise County in southeastern Arizona. The Arizona State Director signed the ROD on July 30, 2019, which constitutes the final decision of the BLM and makes the approved RMP effective immediately.

ADDRESSES: Copies of the ROD/ approved RMP are available upon request from the Field Manager, Tucson Field Office, Bureau of Land Management, 3201 East Universal Way, Tucson, AZ 85756 or on the BLM ePlanning project website at <https://go.usa.gov/xQKFU>. Copies of the ROD/ approved RMP are available for public inspection at the Arizona State Office and the Tucson Field Office.

FOR FURTHER INFORMATION CONTACT:

Scott Feldhausen, Gila District Manager, telephone 520–258–7279; address 3201 East Universal Way, Tucson, AZ 85756; email blm_az_tfo_sprnca_rmp@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, 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: The SPRNCA RMP provides management for 55,990 acres of public land administered by the BLM Tucson Field Office. The approved RMP describes the goals, objectives, and management actions for the SPRNCA's resources and uses identified in the enabling legislation, including aquatic; wildlife; archaeological; paleontological; scientific; cultural; educational; and recreational resources and values. The approved RMP focuses on active resource management, provides a mix of recreational opportunities, allows for livestock grazing on existing allotments in the SPRNCA, increases acres available for hunting with firearms, and provides for additional opportunities for habitat restoration, water recharge projects, and species reintroductions. The SPRNCA RMP was developed with stakeholder dialogue throughout the planning process. The BLM regularly communicated with, and solicited input from the public, organizations, other agencies, state and local government, and the tribes through public meetings, newsletters, and electronic communications. The Proposed RMP/ Final EIS was published on April 26, 2019 (84 FR 17888). During the 30-day protest period, the BLM Director received 28 protest letters. All protests were resolved prior to the issuance of the ROD. No comments regarding potential inconsistencies with State and local plans, programs, and policies were received from the Governor's Office during the Governor's Consistency Review process. The approved RMP carries forward all decisions from the

Proposed Plan. The ROD summarizes clarifications and modifications included in the RMP. Minor changes were made in the RMP for clarity and to reduce redundancy. Minor inconsistencies, including the numbering of goals, objectives, allowable uses and management actions, were also rectified. There are not any appealable decisions included in the ROD.

(Authority: 40 CFR 1506.6)

Raymond Suazo,
State Director.

[FR Doc. 2019-16746 Filed 8-5-19; 8:45 am]

BILLING CODE 4310-32-P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731-TA-1455-1457 (Preliminary)]

Polyethylene Terephthalate (PET) Sheet From Korea, Mexico, and Oman; Revised Schedule for the Subject Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

DATES: July 31, 2019.

FOR FURTHER INFORMATION CONTACT:

Kristina Lara (202-205-3386), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202-205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION: On July 9, 2019, the Commission established a schedule for the conduct of the preliminary phase of the subject investigations (84 FR 33785, July 15, 2019). Subsequently, the Department of Commerce ("Commerce") extended the deadline for its initiation determinations from July 29, 2019 to August 19, 2019. The Commission, therefore, is revising its schedule to conform with Commerce's new schedule. The Commission must reach a preliminary determination by

September 13, 2019, and the Commission's views must be transmitted to Commerce within five business days thereafter, or by September 20, 2019.

For further information concerning this proceeding, see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

By order of the Commission.

Issued: July 31, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019-16698 Filed 8-5-19; 8:45 am]

BILLING CODE 7020-02-P

JUDICIAL CONFERENCE OF THE UNITED STATES

Meeting of the Judicial Conference; Advisory Committee on Civil Rules

AGENCY: Advisory Committee on Civil Rules, Judicial Conference of the United States.

ACTION: Notice of open meeting.

SUMMARY: The Advisory Committee on Civil Rules will hold a meeting on October 29, 2019. The meeting will be open to public observation but not participation. An agenda and supporting materials will be posted at least 7 days in advance of the meeting at: <http://www.uscourts.gov/rules-policies/records-and-archives-rules-committees/agenda-books>.

DATES: October 29, 2019 (9:00 a.m.–5:00 p.m.).

ADDRESSES: Thurgood Marshall Federal Judiciary Building, Mecham Conference Center, Administrative Office of the United States Courts, One Columbus Circle NE, Washington, DC 20544.

FOR FURTHER INFORMATION CONTACT:

Rebecca A. Womeldorf, Rules Committee Secretary, Rules Committee Staff, Administrative Office of the United States Courts, Washington, DC 20544, telephone (202) 502-1820.

Dated: August 1, 2019.

Rebecca A. Womeldorf,

Rules Committee Secretary.

[FR Doc. 2019-16735 Filed 8-5-19; 8:45 am]

BILLING CODE 2210-55-P

JUDICIAL CONFERENCE OF THE UNITED STATES

Meeting of the Judicial Conference; Advisory Committee on Criminal Rules

AGENCY: Advisory Committee on Criminal Rules, Judicial Conference of the United States.

ACTION: Notice of open meeting.

SUMMARY: The Advisory Committee on Criminal Rules will hold a meeting on September 24, 2019. The meeting will be open to public observation but not participation. An agenda and supporting materials will be posted at least 7 days in advance of the meeting at: <http://www.uscourts.gov/rules-policies/records-and-archives-rules-committees/agenda-books>.

DATES: September 24, 2019 (9:00 a.m.–5:00 p.m.).

ADDRESSES: National Constitution Center, 525 Arch Street, Philadelphia, PA 19106.

FOR FURTHER INFORMATION CONTACT:

Rebecca A. Womeldorf, Rules Committee Secretary, Rules Committee Staff, Administrative Office of the United States Courts, Washington, DC 20544, telephone (202) 502-1820.

Dated: August 1, 2019.

Rebecca A. Womeldorf,

Rules Committee Secretary.

[FR Doc. 2019-16734 Filed 8-5-19; 8:45 am]

BILLING CODE 2210-55-P

JUDICIAL CONFERENCE OF THE UNITED STATES

Meeting of the Judicial Conference; Advisory Committee on Evidence Rules

AGENCY: Advisory Committee on Evidence Rules, Judicial Conference of the United States.

ACTION: Notice of open meeting.

SUMMARY: The Advisory Committee on Evidence Rules will hold a meeting on October 25, 2019. The meeting will be open to public observation but not participation. An agenda and supporting materials will be posted at least 7 days in advance of the meeting at: <http://www.uscourts.gov/rules-policies/records-and-archives-rules-committees/agenda-books>.

DATES: October 25, 2019 (9:00 a.m.–5:00 p.m.).

ADDRESSES: Vanderbilt University, 131 21st Avenue South, Nashville, TN 37203.

FOR FURTHER INFORMATION CONTACT:

Rebecca A. Womeldorf, Rules

Committee Secretary, Rules Committee Staff, Administrative Office of the United States Courts, Washington, DC 20544, telephone (202) 502-1820.

Dated: August 1, 2019.

Rebecca A. Womeldorf,
Rules Committee Secretary.

[FR Doc. 2019-16739 Filed 8-5-19; 8:45 am]

BILLING CODE 2210-55-P

JUDICIAL CONFERENCE OF THE UNITED STATES

Meeting of the Judicial Conference; Advisory Committee on Appellate Rules

AGENCY: Advisory Committee on Appellate Rules, Judicial Conference of the United States.

ACTION: Notice of open meeting.

SUMMARY: The Advisory Committee on Appellate Rules will hold a meeting on October 30, 2019. The meeting will be open to public observation but not participation. An agenda and supporting materials will be posted at least 7 days in advance of the meeting at: <http://www.uscourts.gov/rules-policies/records-and-archives-rules-committees/agenda-books>.

DATES: October 30, 2019 (9:00 a.m.–5:00 p.m.).

ADDRESSES: Thurgood Marshall Federal Judiciary Building, Mecham Conference Center, Administrative Office of the United States Courts, One Columbus Circle NE, Washington, DC 20544.

FOR FURTHER INFORMATION CONTACT: Rebecca A. Womeldorf, Rules Committee Secretary, Rules Committee Staff, Administrative Office of the United States Courts, Washington, DC 20544, telephone (202) 502-1820.

Dated: August 1, 2019.

Rebecca A. Womeldorf,
Rules Committee Secretary.

[FR Doc. 2019-16737 Filed 8-5-19; 8:45 am]

BILLING CODE 2210-55-P

JUDICIAL CONFERENCE OF THE UNITED STATES

Meeting of the Judicial Conference

Advisory Committee on Bankruptcy Rules

AGENCY: Advisory Committee on Bankruptcy Rules, Judicial Conference of the United States.

ACTION: Notice of open meeting.

SUMMARY: The Advisory Committee on Bankruptcy Rules will hold a meeting on September 26, 2019. The meeting

will be open to public observation but not participation. An agenda and supporting materials will be posted at least 7 days in advance of the meeting at: <http://www.uscourts.gov/rules-policies/records-and-archives-rules-committees/agenda-books>.

DATES: September 26, 2019 (9:00 a.m.–5:00 p.m.).

ADDRESSES: Thurgood Marshall Federal Judiciary Building, Mecham Conference Center, Administrative Office of the United States Courts, One Columbus Circle NE, Washington, DC 20544.

FOR FURTHER INFORMATION CONTACT: Rebecca A. Womeldorf, Rules Committee Secretary, Rules Committee Staff, Administrative Office of the United States Courts, Washington, DC 20544, telephone (202) 502-1820.

Dated: August 1, 2019.

Rebecca A. Womeldorf,
Rules Committee Secretary.

[FR Doc. 2019-16736 Filed 8-5-19; 8:45 am]

BILLING CODE 2210-55-P

DEPARTMENT OF JUSTICE

[OMB Number 1123-0013]

Agency Information Collection Activities; Proposed eCollection eComments Requested; United States Victims of State Sponsored Terrorism Fund Application Form

Correction

Notice document 2019-14380, appearing on pages 32474 through 32475, in the issue of July 8, 2019, was inadvertently published in error and is hereby withdrawn.

[FR Doc. C1-2019-14380 Filed 8-5-19; 8:45 am]

BILLING CODE 1301-00-D

NUCLEAR REGULATORY COMMISSION

[NRC-2019-0146]

Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving Proposed No Significant Hazards Considerations and Containing Sensitive Unclassified Non-Safeguards Information and Safeguards Information and Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information and Safeguards Information

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment request; notice of opportunity to comment,

request a hearing, and petition for leave to intervene; order imposing procedures.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) received and is considering approval of one amendment request. The amendment request is for Fort Calhoun Station, Unit No. 1. For the amendment request, the NRC proposes to determine that it involves no significant hazards consideration. Because the amendment request contains sensitive unclassified non-safeguards information (SUNSI) and safeguards information (SGI), an order imposes procedures to obtain access to SUNSI and SGI for contention preparation.

DATES: Comments must be filed by September 5, 2019. A request for a hearing must be filed by October 7, 2019. Any potential party as defined in § 2.4 of title 10 of the *Code of Federal Regulations* (10 CFR), who believes access to SUNSI and/or SGI is necessary to respond to this notice must request document access by August 16, 2019.

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-2019-0146. 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: Paula Blechman, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001; telephone: 301-415-2242, email: Paula.Blechman@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2019-0146, facility name, unit number(s), plant docket number, application date, and subject when contacting the NRC about the availability of information for

this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website*: Go to <https://www.regulations.gov/> and search for Docket ID NRC-2019-0146.

- *NRC's Agencywide Documents Access and Management System (ADAMS)*: You may obtain publicly-available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

- *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-2019-0146, facility name, unit number(s), plant docket number, application date, and subject in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <https://www.regulations.gov/> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Pursuant to Section 189a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the NRC is publishing this notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make

immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This notice includes notices of amendments containing SUNSI and/or SGI.

III. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, or (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for the amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. If the Commission takes action prior to the expiration of either the comment period or the notice period, it will publish a notice of issuance in the **Federal Register**. If the Commission makes a final no significant hazards consideration determination, any hearing will take place after issuance. The Commission expects that the need

to take this action will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's "Agency Rules of Practice and Procedure" in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC's regulations are accessible electronically from the NRC Library on the NRC's website at <https://www.nrc.gov/reading-rm/doc-collections/cfr/>. Alternatively, a copy of the regulations is available at the NRC's Public Document Room, located at One White Flint North, Room O1-F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions which the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of

the proceeding. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to establish when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission no later than 60 days from the date of publication of this notice. The petition must be filed in accordance

with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document, and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(h)(2) a State, local governmental body, or Federally-recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. Alternatively, a State, local governmental body, Federally-recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a hearing is granted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC website at <https://www.nrc.gov/site-help/e-submittals.html>. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the

participant should contact the Office of the Secretary by email at hearing.docket@nrc.gov, or by telephone at 301-415-1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals/getting-started.html>. Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public website at <https://www.nrc.gov/site-help/electronic-sub-ref-mat.html>. A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the "Contact Us" link located on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals.html>, by email to

MSHD.Resource@nrc.gov, or by a toll-free call at 1-866-672-7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at <https://adams.nrc.gov/ehd>, unless excluded pursuant to an order of the Commission or the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click "Cancel" when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose

of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

For further details with respect to this license amendment application, see the application for amendment which is available for public inspection in ADAMS and at the NRC's PDR. For additional direction on accessing information related to this document, see the "Accessing Information and Submitting Comments" section of this document.

Omaha Public Power District, Docket No. 50-285, Fort Calhoun Station, Unit No. 1 (FCS), Washington County, Nebraska

Date of amendment request: February 28, 2019, as supplemented by letter dated May 20, 2019. Publicly-available versions are in ADAMS under Accession Nos. ML19065A055 and ML19140A390, respectively.

Description of amendment request: This amendment request contains SGL. The proposed amendment would revise the Security Plan, Training and Qualification Plan, and Safeguards Contingency Plan (the "Plan" or "Security Plan") at the FCS. The Security Plan will supersede the current Security Plan, Training and Qualification Plan, and Safeguards Contingency Plan at FCS. These changes will more fully reflect the permanently shutdown and defueled status of the facility, as well as the reduced scope of potential radiological accidents and security concerns, once all spent fuel has been permanently moved to dry cask storage within the onsite FCS independent spent fuel storage installation (ISFSI), an activity which is currently scheduled for completion in mid-2020.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The irradiated fuel at FCS is currently stored in the spent fuel pool (SFP) and at the ISFSI. In this condition, the number of credible accidents/transients is significantly smaller than for a plant authorized to operate the reactor or emplace or retain fuel in the reactor vessel. Accidents/transients that are no longer applicable in a permanently defueled condition have been deleted from the FCS Safety Analysis Report, as updated

(DSAR) Chapter 14. One of the remaining DSAR Chapter 14 accidents is the Fuel Handling Accident (FHA). However, as previously discussed, the Plan reflects the future site configuration where all the remaining spent fuel in the SFP has been moved to the ISFSI and there are no requirements to return spent fuel to the SFP. The FHA will no longer be credible after all fuel has been removed from the SFP.

The casks are maintained in accordance with the provisions of the general license for the FCS ISFSI, utilizing the TN Americas LLC, 32PT Dry Shield Canister (DSC), Certificate of Compliance No. 72-1004, and in accordance with the associated NUH-003 Updated Final Safety Analysis Report (UFSAR) for the Standardized NUHOMS® Horizontal Modular Storage System for Irradiated Nuclear Fuel. The 32PT DSC consists of spent nuclear fuel residing within a fuel basket structure contained within the sealed metallic canister. The Horizontal Storage Module 202 System (HSM-202) receives and contains the sealed DSC for long term storage, and provides gamma and neutron shielding, ventilation passages, missile protection, and protection against natural phenomena and accidents for the DSC. The NUH-003 UFSAR, Section 8.2, Accident Analysis, provides the evaluation of accidents for the 32PT and HSM-202 System which satisfies the minimum acceptance criteria. In which accident conditions are analyzed to demonstrate that the requirements of 10 CFR 72.122 are met and that adequate safety margins exist for the NUHOMS® system design.

The 32PT DSC and HSM-202 System provides the spent nuclear fuel and radioactive material in storage with confinement, radiation shielding, criticality and passive heat removal, independent of other facility structures, systems, and components (SSCs).

The proposed amendment has no effect on the capability of any facility SSC to perform its design function. The modifications associated with these changes do not significantly affect the ability of the DSC and HSM to perform their functions as described in the NUH-003 UFSAR. Hence, the proposed amendment has no effect on the ability of the Cask System to perform its design function nor would it increase the likelihood of an accident previously evaluated. The proposed amendment would not increase the likelihood of the malfunction of any plant SSC. Therefore, the proposed amendment does not involve a significant increase in the probability or consequences of a previously evaluated accident.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed amendment does not involve major physical alterations of any facility SSCs or Cask System components required to mitigate or prevent any accident previously evaluated and does not have a significant effect on the capability of any facility SSC or Cask System component to perform its design functions. Minor modifications are associated

with this proposed amendment (e.g. Vehicle Barrier System (VBS) relocation, wiring changes in security equipment, the addition of telecommunications equipment, and software changes to the security computer system). The proposed license amendment would not physically change any SSCs involved in the mitigation of any postulated accident. Thus, no new initiators or precursors of new or different kind of accident are created. Furthermore, the proposed amendment does not create the possibility of a new failure mode associated with any equipment failures. The credible events for the ISFSI remain unchanged.

Therefore, the proposed changes do not create the possibility of new or different kind of accident from any previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?
Response: No.

Because the 10 CFR part 50 license for FCS no longer authorizes operation of the reaction or emplacement or retention of fuel into the reactor vessel, as specified in 10 CFR 50.82(a)(2), the occurrence of postulated accidents associated with reactor operation is no longer credible. The modifications associated with the proposed amendment include lighting, intruder detection systems, protected area boundary fencing, access control system, telecommunications equipment, VBS relocation, and a central alarm station. The proposed amendment does not involve a significant change in any facility SSCs or Cask System component's design, configuration, or operation. Therefore, the modifications associated with this proposed amendment do not significantly affect the capability or manner in which facility SSCs or Cask System components perform their safety functions or the safety.

Therefore, the proposed amendment does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Stephen M. Bruckner, Attorney, Fraser Stryker PC LLO, 500 Energy Plaza, 409 South 17th Street, Omaha, NE 68102.

NRC Branch Chief: Bruce Watson, CHP.

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information and Safeguards Information for Contention Preparation

Omaha Public Power District, Docket No. 50-285, Fort Calhoun Station, Unit No. 1, Washington County, Nebraska

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing sensitive

unclassified information (including SUNSI and SGI). Requirements for access to SGI are primarily set forth in 10 CFR parts 2 and 73. Nothing in this Order is intended to conflict with the SGI regulations.

B. Within 10 days after publication of this notice of hearing and opportunity to petition for leave to intervene, any potential party who believes access to SUNSI or SGI is necessary to respond to this notice may request access to SUNSI or SGI. A "potential party" is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI or SGI submitted later than 10 days after publication will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requestor shall submit a letter requesting permission to access SUNSI, SGI, or both to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Deputy General Counsel for Hearings and Administration, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The email address for the Office of the Secretary and the Office of the General Counsel are *Hearing.Docket@nrc.gov* and *RidsOgcMailCenter.Resource@nrc.gov*, respectively.¹ The request must include the following information:

(1) A description of the licensing action with a citation to this **Federal Register** notice;

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1);

(3) If the request is for SUNSI, the identity of the individual or entity requesting access to SUNSI and the requestor's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly available versions of the information requested would not be sufficient to provide the

basis and specificity for a proffered contention; and

(4) If the request is for SGI, the identity of each individual who would have access to SGI if the request is granted, including the identity of any expert, consultant, or assistant who will aid the requestor in evaluating the SGI. In addition, the request must contain the following information:

(a) A statement that explains each individual's "need to know" the SGI, as required by 10 CFR 73.2 and 10 CFR 73.22(b)(1). Consistent with the definition of "need to know" as stated in 10 CFR 73.2, the statement must explain:

(i) Specifically why the requestor believes that the information is necessary to enable the requestor to proffer and/or adjudicate a specific contention in this proceeding;² and

(ii) The technical competence (demonstrable knowledge, skill, training or education) of the requestor to effectively utilize the requested SGI to provide the basis and specificity for a proffered contention. The technical competence of a potential party or its counsel may be shown by reliance on a qualified expert, consultant, or assistant who satisfies these criteria.

(b) A completed Form SF-85, "Questionnaire for Non-Sensitive Positions," for each individual who would have access to SGI. The completed Form SF-85 will be used by the Office of Administration to conduct the background check required for access to SGI, as required by 10 CFR part 2, subpart C, and 10 CFR 73.22(b)(2), to determine the requestor's trustworthiness and reliability. For security reasons, Form SF-85 can only be submitted electronically through the Electronic Questionnaires for Investigations Processing website, a secure website that is owned and operated by the Office of Personnel Management. To obtain online access to the form, the requestor should contact the NRC's Office of Administration at 301-415-3710.³

(c) A completed Form FD-258 (fingerprint card), signed in original ink,

² Broad SGI requests under these procedures are unlikely to meet the standard for need to know; furthermore, NRC staff redaction of information from requested documents before their release may be appropriate to comport with this requirement. These procedures do not authorize unrestricted disclosure or less scrutiny of a requestor's need to know than ordinarily would be applied in connection with an already-admitted contention or non-adjudicatory access to SGI.

³ The requestor will be asked to provide his or her full name, social security number, date and place of birth, telephone number, and email address. After providing this information, the requestor usually should be able to obtain access to the online form within one business day.

¹ While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's "E-Filing Rule," the initial request to access SUNSI and/or SGI under these procedures should be submitted as described in this paragraph.

and submitted in accordance with 10 CFR 73.57(d). Copies of Form FD-258 may be obtained by writing the Office of Administrative Services, Mail Services Center, Mail Stop P1-37, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by email to MAILSVC.Resource@nrc.gov. The fingerprint card will be used to satisfy the requirements of 10 CFR part 2, subpart C, 10 CFR 73.22(b)(1), and Section 149 of the Atomic Energy Act of 1954, as amended, which mandates that all persons with access to SGI must be fingerprinted for an Federal Bureau of Investigation identification and criminal history records check.

(d) A check or money order payable in the amount of \$357.00⁴ to the U.S. Nuclear Regulatory Commission for each individual for whom the request for access has been submitted.

(e) If the requestor or any individual(s) who will have access to SGI believes they belong to one or more of the categories of individuals that are exempt from the criminal history records check and background check requirements in 10 CFR 73.59, the requestor should also provide a statement identifying which exemption the requestor is invoking and explaining the requestor's basis for believing that the exemption applies. While processing the request, the Office of Administration, Personnel Security Branch, will make a final determination whether the claimed exemption applies. Alternatively, the requestor may contact the Office of Administration for an evaluation of their exemption status prior to submitting their request. Persons who are exempt from the background check are not required to complete the SF-85 or Form FD-258; however, all other requirements for access to SGI, including the need to know, are still applicable.

Note: Copies of documents and materials required by paragraphs C.(4)(b), (c), and (d) of this Order must be sent to the following address: U.S. Nuclear Regulatory Commission, ATTN: Personnel Security Branch, Mailstop TWFN-07D04M, 11555 Rockville Pike, Rockville, MD 20852. These documents and materials should *not* be included with the request letter to the Office of the Secretary, but the request letter should state that the forms and fees have been submitted as required.

D. To avoid delays in processing requests for access to SGI, the requestor should review all submitted materials for completeness and accuracy

(including legibility) before submitting them to the NRC. The NRC will return incomplete packages to the sender without processing.

E. Based on an evaluation of the information submitted under paragraphs C.(3) or C.(4) above, as applicable, the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI or need to know the SGI requested.

F. For requests for access to SUNSI, if the NRC staff determines that the requestor satisfies both E.(1) and E.(2) above, the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.⁵

G. For requests for access to SGI, if the NRC staff determines that the requestor has satisfied both E.(1) and E.(2) above, the Office of Administration will then determine, based upon completion of the background check, whether the proposed recipient is trustworthy and reliable, as required for access to SGI by 10 CFR 73.22(b). If the Office of Administration determines that the individual or individuals are trustworthy and reliable, the NRC will promptly notify the requestor in writing. The notification will provide the names of approved individuals as well as the conditions under which the SGI will be provided. Those conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order⁶ by each individual who will be granted access to SGI.

⁵ Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

⁶ Any motion for Protective Order or draft Non-Disclosure Agreement or Affidavit for SGI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 180 days of the deadline for the receipt of the written access request.

H. Release and Storage of SGI. Prior to providing SGI to the requestor, the NRC staff will conduct (as necessary) an inspection to confirm that the recipient's information protection system is sufficient to satisfy the requirements of 10 CFR 73.22.

Alternatively, recipients may opt to view SGI at an approved SGI storage location rather than establish their own SGI protection program to meet SGI protection requirements.

I. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI or SGI must be filed by the requestor no later than 25 days after receipt of (or access to) that information. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI or SGI contentions by that later deadline.

J. Review of Denials of Access.

(1) If the request for access to SUNSI or SGI is denied by the NRC staff either after a determination on standing and requisite need, or after a determination on trustworthiness and reliability, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) Before the Office of Administration makes a final adverse determination regarding the trustworthiness and reliability of the proposed recipient(s) for access to SGI, the Office of Administration, in accordance with 10 CFR 2.336(f)(1)(iii), must provide the proposed recipient(s) any records that were considered in the trustworthiness and reliability determination, including those required to be provided under 10 CFR 73.57(e)(1), so that the proposed recipient(s) have an opportunity to correct or explain the record.

(3) The requestor may challenge the NRC staff's adverse determination with respect to access to SUNSI or with respect to standing or need to know for SGI by filing a challenge within 5 days of receipt of that determination with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an Administrative Law Judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

(4) The requestor may challenge the Office of Administration's final adverse

⁴ This fee is subject to change pursuant to the Office of Personnel Management's adjustable billing rates.

determination with respect to trustworthiness and reliability for access to SGI by filing a request for review in accordance with 10 CFR 2.336(f)(1)(iv).

(5) Further appeals of decisions under this paragraph must be made pursuant to 10 CFR 2.311.

K. Review of Grants of Access. A party other than the requestor may challenge an NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed within 5 days of the notification by the NRC staff of its grant of access and must be filed with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an Administrative Law Judge

with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.⁷

L. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI or SGI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners

who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. The attachment to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

It is so ordered.

Dated at Rockville, Maryland, this 11th day of July, 2019.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

Attachment 1—General Target Schedule for Processing and Resolving Requests for Access to Sensitive Unclassified Non-Safeguards Information and Safeguards Information in This Proceeding

Day	Event/activity
0	Publication of Federal Register notice of hearing and opportunity to petition for leave to intervene, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified NonSafeguards Information (SUNSI) and/or Safeguards Information (SGI) with information: Supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding; demonstrating that access should be granted (e.g., showing technical competence for access to SGI); and, for SGI, including application fee for fingerprint/background check.
60	Deadline for submitting petition for intervention containing: (i) Demonstration of standing; (ii) all contentions whose formulation does not require access to SUNSI and/or SGI (+25 Answers to petition for intervention; +7 requestor/petitioner reply).
20	U.S. Nuclear Regulatory Commission (NRC) staff informs the requestor of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows (1) need for SUNSI or (2) need to know for SGI. (For SUNSI, NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents). If NRC staff makes the finding of need to know for SGI and likelihood of standing, NRC staff begins background check (including fingerprinting for a criminal history records check), information processing (preparation of redactions or review of redacted documents), and readiness inspections.
25	If NRC staff finds no "need," no "need to know," or no likelihood of standing, the deadline for requestor/petitioner to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds "need" for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI.
190	(Receipt +180) If NRC staff finds standing, need to know for SGI, and trustworthiness and reliability, deadline for NRC staff to file motion for Protective Order and draft Non-disclosure Affidavit (or to make a determination that the proposed recipient of SGI is not trustworthy or reliable). Note: Before the Office of Administration makes a final adverse determination regarding access to SGI, the proposed recipient must be provided an opportunity to correct or explain information.
205	Deadline for petitioner to seek reversal of a final adverse NRC staff trustworthiness or reliability determination under 10 CFR 2.336(f)(1)(iv).
A	If access granted: Issuance of a decision by a presiding officer or other designated officer on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI and/or SGI consistent with decision issuing the protective order.
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI and/or SGI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of opportunity to request a hearing and petition for leave to intervene), the petitioner may file its SUNSI or SGI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI and/or SGI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60	Decision on contention admission.

⁷Requestors should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007, as amended at 77 FR

46562; August 3, 2012) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as

applicable), but not to the initial SUNSI/SGI request submitted to the NRC staff under these procedures.

[FR Doc. 2019-15132 Filed 8-5-19; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

666th Meeting of the Advisory Committee on Reactor Safeguards (ACRS)

In accordance with the purposes of Sections 29 and 182b of the Atomic Energy Act (42 U.S.C. 2039, 2232b), the Advisory Committee on Reactor Safeguards (ACRS) will hold meetings on September 4–7, 2019, Two White Flint North, 11545 Rockville Pike, ACRS Conference Room T2D10, Rockville, MD 20852.

Wednesday, September 4, 2019, Conference Room T2D10

1:00 p.m.–1:05 p.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

1:05 p.m.–2:00 p.m.: Advanced Reactor SECY Policy Paper on Siting (Open)—The Committee will have briefings by and discussion with representatives of the NRC staff regarding the subject topic.

2:00 p.m.–4:30 p.m.: Turkey Point Subsequent License Renewal (Open)—The Committee will have briefings by and discussion with representatives of the NRC staff and Florida Power & Light Co. regarding the subject topic.

4:45 p.m.–6:00 p.m.: Preparation of ACRS Reports/Retreat (Open)—The Committee will continue its discussion of proposed ACRS reports and retreat items.

Thursday, September 5, 2019, Conference Room T2D10

8:30 a.m.–11:30 a.m.: Westinghouse Topical Report, WCAP-17794 Related to New D5 CPR Correlation for SVEA-96 Optima-3 Fuel Design (Open/Closed)—The Committee will have briefings by and discussion with representatives of the NRC staff and Westinghouse regarding the subject topic. [Note: A portion of this session may be closed in order to discuss and protect information designated as proprietary, pursuant to 5 U.S.C. 552b(c)(4)].

12:30 p.m.–2:30 p.m.: Topical Report-0716-50351, “NuScale Applicability of AREVA Method for the Evaluation of Fuel Assembly Structural Response to Externally Applied Forces” (Open/Closed)—The Committee will have briefings by and discussion with representatives of the NRC staff and NuScale regarding the subject topic. [Note: A portion of this session may be

closed in order to discuss and protect information designated as proprietary, pursuant to 5 U.S.C. 552b(c)(4)].

2:45 p.m.–6:00 p.m.: Preparation of ACRS Reports/Retreat (Open/Closed)—The Committee will continue its discussion of proposed ACRS reports and retreat items. [Note: A portion of this session may be closed in order to discuss and protect information designated as proprietary, pursuant to 5 U.S.C. 552b(c)(4)]. [Note: A portion of this meeting may be closed pursuant to 5 U.S.C. 552b (c) (2) and (6) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.]

Friday, September 6, 2019, Conference Room T2D10

8:30 a.m.–10:00 a.m.: Future ACRS Activities/Report of the Planning and Procedures Subcommittee and Reconciliation of ACRS Comments and Recommendations/Retreat (Open/Closed)—The Committee will hear discussion of the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the Full Committee during future ACRS meetings and retreat items. [Note: A portion of this meeting may be closed pursuant to 5 U.S.C. 552b (c) (2) and (6) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.] [Note: A portion of this session may be closed in order to discuss and protect information designated as proprietary, pursuant to 5 U.S.C. 552b(c)(4)].

10:15 a.m.–12:00 p.m.: Preparation of ACRS Reports/Retreat (Open/Closed)—The Committee will continue its discussion of proposed ACRS reports and retreat items. [Note: A portion of this session may be closed in order to discuss and protect information designated as proprietary, pursuant to 5 U.S.C. 552b(c)(4)]. [Note: A portion of this meeting may be closed pursuant to 5 U.S.C. 552b (c) (2) and (6) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.]

1:00 p.m.–6:00 p.m.: Preparation of ACRS Reports/Retreat (Open/Closed)—The Committee will continue its discussion of proposed ACRS reports and retreat items. [Note: A portion of

this session may be closed in order to discuss and protect information designated as proprietary, pursuant to 5 U.S.C. 552b(c)(4)]. [Note: A portion of this meeting may be closed pursuant to 5 U.S.C. 552b (c) (2) and (6) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy].

Saturday, September 7, 2019, Conference Room T2D10

8:30 a.m.–12:00 p.m.: Preparation of ACRS Reports/Retreat (Open/Closed)—The Committee will continue its discussion of proposed ACRS reports and retreat items. [Note: A portion of this session may be closed in order to discuss and protect information designated as proprietary, pursuant to 5 U.S.C. 552b(c)(4)]. [Note: A portion of this meeting may be closed pursuant to 5 U.S.C. 552b (c) (2) and (6) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy].

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on December 7, 2018 (83 FR 26506). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Persons desiring to make oral statements should notify Quynh Nguyen, Cognizant ACRS Staff (Telephone: 301-415-5844, Email: Quynh.Nguyen@nrc.gov), 5 days before the meeting, if possible, so that appropriate arrangements can be made to allow necessary time during the meeting for such statements. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the Cognizant ACRS staff if such rescheduling would result in major inconvenience. The bridgeline number for the meeting is 866-822-3032, passcode 8272423#.

Thirty-five hard copies of each presentation or handout should be provided 30 minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the Cognizant ACRS Staff one day before meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the Cognizant ACRS Staff with a CD containing each

presentation at least 30 minutes before the meeting.

In accordance with Subsection 10(d) of Public Law 92–463 and 5 U.S.C. 552b(c), certain portions of this meeting may be closed, as specifically noted above. Use of still, motion picture, and television cameras during the meeting may be limited to selected portions of the meeting as determined by the Chairman. Electronic recordings will be permitted only during the open portions of the meeting.

ACRS meeting agendas, meeting transcripts, and letter reports are available through the NRC Public Document Room at pdr.resource@nrc.gov, or by calling the PDR at 1–800–397–4209, or from the Publicly Available Records System (PARS) component of NRC's document system (ADAMS) which is accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html> or <http://www.nrc.gov/reading-rm/doc-collections/#ACRS/>.

Video teleconferencing service is available for observing open sessions of ACRS meetings. Those wishing to use this service should contact Ms. Paula Dorm, ACRS Audio Visual Technician (301–415–7799), between 7:30 a.m. and 3:45 p.m. (ET), at least 10 days before the meeting to ensure the availability of this service. Individuals or organizations requesting this service will be responsible for telephone line charges and for providing the equipment and facilities that they use to establish the video teleconferencing link. The availability of video teleconferencing services is not guaranteed.

Dated: July 31, 2019.

Russell E. Chazell,

Federal Advisory Committee Management Officer, Office of the Secretary.

[FR Doc. 2019–16714 Filed 8–5–19; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Notice of Submission for Approval: Declaration for Federal Employment (OF 306)

AGENCY: Office of Personnel Management.

ACTION: 30-day notice and request for comments.

SUMMARY: The Office of Personnel Management (OPM), Suitability Executive Agent Programs, is notifying the general public and other Federal agencies that OPM is seeking Office of Management and Budget (OMB) renewal

of a previously approved information collection, Declaration for Federal Employment (OF 306).

DATES: Comments are encouraged and will be accepted until September 5, 2019. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget by the following method: <http://www.regulations.gov>. Follow the instructions for submitting comments. All submissions received must include the agency name and docket number for this document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: A copy of this information collection, with applicable supporting documentation, may be obtained by contacting Office of Personnel Management, Suitability Executive Agent Programs, 1900 E Street NW, Suite 1435, Washington, DC 20415 or by electronic mail at SuitEA@opm.gov. Please contact Colleen Crowley at 202–606–2245 if you have questions.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3507(a)(1), OPM is providing an additional 30 days for public comments. OPM previously solicited comments for this collection, with a 60-day public comment period, at 84 FR 5733 (February 22, 2019). 2,748 comments were received. This notice announces that OPM has submitted to OMB a request to renew with no changes a previously approved information collection, OMB number 3206–0182, Declaration for Federal Employment (OF 306). The public has an additional 30-day opportunity to comment.

The Declaration for Federal Employment Optional Form (OF) 306 is completed by applicants who are under consideration for Federal or Federal contract employment. It collects information about an applicant's selective service registration, military service, and general background. The information collected on this form is mainly used to determine a person's acceptability for Federal and Federal contract employment, and his or her retirement status and life insurance enrollment. However, if necessary, and usually in conjunction with another

form or forms, the information on this form may be used in conducting an investigation to determine a person's suitability or ability to hold a security clearance, and it may be disclosed to authorized officials making similar, subsequent determinations. The OF 306 permits applicants to disclose and explain their personal history in advance of the background investigation, consistent with a Privacy Act requirement to “collect information to the greatest extent practicable directly from the subject individual when the information may result in adverse determinations about an individual's rights, benefits, and privileges under Federal programs.” See 5 U.S.C. 552a(3)(2).

The OF 306 requests that the applicant provide personal identifying data, including past convictions, imprisonments, probations, paroles or military court martial, delinquency on a Federal debt, Selective Service Registration, United States military service, Federal civilian or military retirement benefits received or applied for, and life insurance enrollment. To be clear, providing information regarding past criminal conduct does not in itself impact an individual's eligibility for most positions in the federal government. Renewal of the form is not changing any current policies.

In the February 22, 2019 **Federal Register** Notice, OPM proposed to change the form to provide clarification for respondents who may have completed pretrial diversionary programs.

OPM has decided to renew the form in its current state, without the modifications proposed in the February 22, 2019 **Federal Register** Notice. This will permit OPM time to carefully evaluate and consider the 2,748 comments submitted during the comment period by members of the public and other stakeholders. We will take these comments into consideration to evaluate the best way forward to allow for both continuing to support second chance hiring initiatives and providing federal agencies with the ability to make informed hiring and vetting decisions.

OPM supports efforts by the Administration and Congress to take steps to reform the criminal justice system and improve second chance hiring employment opportunities. For most federal jobs, questions regarding criminal history do not appear on initial job applications, and agencies do consider people with criminal records when filling most government positions if they are the best candidates and can comply with existing requirements.

Later in the process, generally after there has been a conditional offer of employment, individuals seeking admission to the civil service are asked to complete a Declaration for Federal Employment (OF 306) and undergo an investigation to establish “suitability” or fitness for employment. *See* 5 CFR 330.1300.

Past criminal conduct does not prohibit a person from being hired into the vast majority of federal jobs, and each decision is determined on a case by case basis.

Analysis

Agency: Office of Personnel Management, Suitability Executive Agent Programs.

Title: Declaration for Federal Employment, Optional Form (OF) 306.

OMB Number: 3206–0182.

Affected Public: Individuals.

Number of Respondents: 315,478.

Estimated Time per Respondent: 15 minutes.

Total Burden Hours: 78,870.

Office of Personnel Management.

Steve Hickman,

Federal Register Liaison.

[FR Doc. 2019–16696 Filed 8–5–19; 8:45 am]

BILLING CODE 6325–53–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86536; File No. SR–EMERALD–2019–27]

Self-Regulatory Organizations; MIAx Emerald, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 518, Complex Orders

July 31, 2019.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b–4 thereunder,² notice is hereby given that on July 18, 2019, MIAx Emerald, LLC (“MIAx Emerald” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend Exchange Rule 518, Complex

Orders, to amend subsection (d)(7) and to make a minor non-substantive change to correct a typographical error in subsection (f)(1) of Interpretation and Policy .05.

The text of the proposed rule change is available on the Exchange’s website at <http://www.miaxoptions.com/rule-filings/emerald> at MIAx Emerald’s principal office, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Exchange Rule 518, Complex Orders, to amend subsection (d)(7), Allocation at the Conclusion of a Complex Auction, to adopt a new parenthetical to existing rule text to state that orders and quotes executed in a Complex Auction ³ will be allocated first in price priority based on their original limit price (or protected price, as described in Interpretation and Policy .05., if price protection is engaged).

Currently, subsection (d)(7) of the Rule provides that orders and quotes executed in a Complex Auction will be allocated first in price priority based on their original limit price, and thereafter as follows, and the Rule lists six different scenarios which influence allocation. The Exchange is proposing to adopt the parenthetical, “or protected price if price protection, as described in Interpretation and Policy .05., is engaged” after the term “original limit price” to improve the fairness and consistency of allocations among participants at the end of a Complex Auction.

Under the proposal, allocations will continue to be calculated based on original limit price, with the exception that if price protection is engaged,

allocation will then be based on the order’s protected price as opposed to the order’s original limit price. The following examples using the MPC Protection better illustrate this scenario.⁴

Example #1A

End of Complex Auction Allocation Using Current Allocation Methodology

icEBBO ⁵/dcEBBO ⁶ 1.75 × 2.00

cNBBO ⁷ 1.85 × 1.95

MPC 0.05

MPC Protection:

cNBB ⁸ – MPC (1.85 – 0.05 = 1.80)

cNBO ⁹ + MPC (1.95 + 0.05 = 2.00)

Complex Order 1 (CO1) Buy 10 @2.00 (Auction on Arrival) ¹⁰

CO1 marked AOA initiates an auction upon receipt.

⁴ The Exchange notes that the System provides a number of price protections as described in Policy .05. of Interpretations and Policies to this Rule. Price protections include a Vertical Spread Variance price protection (.05.(a)); a Calendar Spread Variance price protection (.05.(b)); an Implied Away Best Bid or Offer (“ixABBO”) price protection. The ixABBO price protection feature is a price protection mechanism under which, when in operation as requested by the submitting Member, a buy order will not be executed at a price that is higher than each other single exchange’s best displayed offer for the complex strategy, and under which a sell order will not be executed at a price that is lower than each other single exchange’s best displayed bid for the complex strategy (.05.(d)); and a Complex MIAx Emerald Price Collar (“MPC”) price protection (.05.(f)).

⁵ Implied Complex MIAx Emerald Best Bid or Offer (“icEBBO”). The icEBBO is a calculation that uses the best price from the Simple Order Book for each component of a complex strategy including displayed and non-displayed trading interest. For stock-option orders, the icEBBO for a complex strategy will be calculated using the best price (whether displayed or non-displayed) on the Simple Order Book in the individual option component(s), and the NBBO in the stock component. *See* Exchange Rule 518(a)(12).

⁶ Displayed Complex MIAx Emerald Best Bid or Offer (“dcEBBO”). The dcEBBO is calculated using the best displayed price for each component of a complex strategy from the Simple Order Book. For stock-option orders, the dcEBBO for a complex strategy will be calculated using the Exchange’s best displayed bid or offer in the individual option component(s) and the NBBO in the stock component. *See* Exchange Rule 518(a)(8).

⁷ The Complex National Best Bid or Offer (“cNBBO”) is calculated using the NBBO for each component of a complex strategy to establish the best net bid and offer for a complex strategy. *See* Exchange Rule 100.

⁸ NBB means the National Best Bid.

⁹ NBO means the National Best Offer.

¹⁰ A “Complex Auction-on-Arrival” or “cAOA” order is a complex order designated to be placed into a Complex Auction upon receipt or upon evaluation. Complex orders that are not designated as cAOA will, by default, not initiate a Complex Auction upon arrival, but except as described herein will be eligible to participate in a Complex Auction that is in progress when such complex order arrives or if placed on the Strategy Book may participate in or may initiate a Complex Auction, following evaluation conducted by the System (as described in subparagraph (d) below).[sic] *See* Exchange Rule 518(b)(2)(i).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ *See* Exchange Rule 518(d).

Market Maker (“MM”) ¹¹ Complex Order 2 (CO2) Sell 10 @1.80 (MPC = 1.80)

MM Complex AOC eQuote ¹² 3 (CO3) Sell 10 @1.00 (MPC = 1.80)

Unrelated order CO2 and related response CO3 arrive during the auction and join the auction in progress. The Auction concludes with no further interest being received.

Upon conclusion of the Auction CO2 and CO3 are subject to MPC Protection and cannot trade more than 0.05 lower than the Away Best Bid (1.85); meaning that these orders cannot trade lower than 1.80. With allocation based upon the original limit price CO3 trades 10 with CO1 at 1.80 ahead of CO2 since CO3’s original limit price (1.00) was more aggressive than the original limit price of CO2 (1.80). CO2 does not trade and leaves a balance of 10 to sell at 1.80. cToM ¹³ 1.75×1.80 (10)

Example 1B below illustrates the same scenario but with allocation as proposed by the new rule language.

Example #1B

End of Complex Auction Allocation Using Proposed Allocation Methodology (Price Protection Engaged)

icEBBO/dcEBBO 1.75×2.00

cNBBO 1.85×1.95

MPC 0.05

MPC Protection:

cNBB – MPC ($1.85 - 0.05 = 1.80$)

cNBO + MPC ($1.95 + 0.05 = 2.00$)

Complex Order 1 (CO1) Buy 10 @2.00 (Auction on Arrival)

CO1 marked AOA initiates an auction upon receipt.

MM Complex Order 2 (CO2) Sell 10 @ 1.80 (MPC = 1.80)

MM Complex AOC eQuote 3 (CO3) Sell 10 @1.00 (MPC = 1.80)

Unrelated order CO2 and related response CO3 arrive during the auction and join the auction in progress. The Auction concludes with no further interest being received.

Upon conclusion of the Auction CO2 and CO3 are subject to MPC Protection and cannot trade more than 0.05 lower

than the Away Best Bid (1.85); meaning that these orders cannot trade lower than 1.80. With allocation priority based on the protected price CO3 trades a pro-rata share of 5 with CO1 at 1.80 based on its protected price. CO2 also trades a pro-rata share of 5 with CO1 at 1.80 based on its protected price. CO1 is filled, CO2 and CO3 each leave a balance of 5, booked at their protected price of 1.80.

cToM 1.75×1.80 (10)

The Exchange believes that using the protected price is more meaningful than using an order’s original limit price in the context of determining trade allocation priority as orders cannot be executed at prices that would violate their protected price. Additionally, changing the allocation priority in this fashion would align allocations for orders with the same protected price, when price protection is engaged, with allocations for orders with the same original limit price, when price protection is not engaged, which can be seen in the examples below.

Example #2A

End of Complex Auction Allocation Using Current Allocation Methodology

icEBBO/dcEBBO 1.75×2.00

cNBBO 1.85×1.95

MPC 0.05

MPC Protection:

cNBB – MPC ($1.85 - 0.05 = 1.80$)

cNBO + MPC ($1.95 + 0.05 = 2.00$)

Complex Order 1 (CO1) Buy 10 @2.00 (Auction on Arrival)

CO1 marked AOA initiates an auction upon receipt.

Market Maker (“MM”) Complex Order 2 (CO2) Sell 10 @1.90 (MPC = 1.80)

MM Complex AOC eQuote 3 (CO3) Sell 10 @1.90 (MPC = 1.80)

Unrelated order CO2 and related response CO3 arrive during the auction and joins the auction in progress. The Auction concludes with no further interest being received.

Upon conclusion of the Auction CO2 and CO3 when subject to MPC Protection cannot trade more than 0.05 lower than the Away Best Bid (1.85); meaning that these orders cannot trade lower than 1.80. However since the limit price of CO2 and CO3 is not through the MPC Protected Price, price protection is not engaged and the trade is based on the best limit price among CO2 and CO3. With allocation based upon the original limit price; CO3 trades a pro-rata share of 5 with CO1 at 1.90 based on its original price. CO2 also trades a pro-rata share of 5 with CO1 at 1.90 based on its original price. CO1 is filled, CO2 and CO3 each leave a balance of 5, booked at their limit price.

Example 2B below illustrates the same scenario but with allocation as proposed by the new rule language.

Example #2B

End of Complex Auction Allocation Using Proposed Allocation Methodology (Price Protection Not Engaged)

icMBBO/dcMBBO 1.75×2.00

cNBBO 1.85×1.95

MPC 0.05

MPC Protection = cNBB – MPC ($1.85 - 0.05 = 1.80$)

Complex Order 1 (CO1) Buy 10 @2.00 (Auction on Arrival)

CO1 marked AOA initiates an auction upon receipt.

Market Maker (“MM”) Complex Order 2 (CO2) Sell 10 @1.90 (MPC = 1.80)

MM Complex AOC eQuote 3 (CO3) Sell 10 @1.90 (MPC = 1.80)

Unrelated order CO2 and related response CO3 arrive during the auction and joins the auction in progress. The Auction concludes with no further interest being received.

Upon conclusion of the Auction CO2 and CO3 when subject to MPC Protection cannot trade more than 0.05 lower than the Away Best Bid (1.85); meaning that these orders cannot trade lower than 1.80. However since the limit price of CO2 and CO3 is not through the MPC Protected Price, price protection is not engaged and the trade is based on the best limit price among CO2 and CO3. With allocation based upon the original limit price; CO3 trades a pro-rata share of 5 with CO1 at 1.90 based on its original price. CO2 also trades a pro-rata share of 5 with CO1 at 1.90 based on its original price. CO1 is filled, CO2 and CO3 each leave a balance of 5, booked at their limit price.

There is no difference in the allocation results under the proposed allocation algorithm or the current allocation algorithm for orders with identical original limit prices when price protection is not engaged. Additionally, as demonstrated in Example 3A and 3B below, there is no difference in the allocation results under the proposed allocation algorithm or the current allocation algorithm for orders with differing original limit prices when price protection is not engaged.

Example #3A

End of Complex Auction Allocation Using Current Allocation Methodology

icEBBO/dcEBBO 1.75×2.00

cNBBO 1.85×1.95

MPC 0.05

MPC Protection:

cNBB – MPC ($1.85 - 0.05 = 1.80$)

cNBO + MPC ($1.95 + 0.05 = 2.00$)

¹¹ The term “Market Makers” refers to “Lead Market Makers”, “Primary Lead Market Makers” and “Registered Market Makers” collectively. See Exchange Rule 100.

¹² A “Complex Auction-or-Cancel eQuote” or “cAOC eQuote,” which is an eQuote submitted by a Market Maker that is used to provide liquidity during a specific Complex Auction with a time in force that corresponds with the duration of the Complex Auction. A cAOC eQuote with a size greater than the aggregate auctioned size (as defined in Rule 518(d)(4)) will be capped for allocation purposes at the aggregate auctioned size. See Exchange Rule 518.02(c)(1).

¹³ cToM is the Exchange’s Complex Top of Market data feed.

Complex Order 1 (CO1) Buy 10 @2.00 (Auction on Arrival)
 CO1 marked AOA initiates an auction upon receipt.
 Market Maker ("MM") Complex Order 2 (CO2) Sell 10 @1.95 (MPC = 1.80)
 MM Complex AOC eQuote 3 (CO3) Sell 10 @1.85 (MPC = 1.80)

Unrelated order CO2 and related response CO3 arrive during the auction and join the auction in progress. The Auction concludes with no further interest being received.

Upon conclusion of the Auction CO2 and CO3 when subject to MPC Protection cannot trade more than 0.05 lower than the Away Best Bid (1.85); meaning that these orders cannot trade lower than 1.80. However since the limit price of CO2 and CO3 is not through the MPC Protected Price, price protection is not engaged. With allocation based upon the original limit price; CO3 trades 10 with CO1 at 1.90 ahead of CO2 since its original limit price (1.85) was more aggressive than the original limit price of CO2 (1.95). CO2 does not trade and leaves a balance of 10 to sell at 1.95.

Example #3B

End of Complex Auction Allocation Using Proposed Allocation Methodology (Price Protection Not Engaged)

icMBBO/dcMBBO 1.75×2.00
 cNBB 1.85×1.95
 MPC 0.05

MPC Protection = cNBB – MPC
 $(1.85 - 0.05 = 1.80)$

Complex Order 1 (CO1) Buy 10 @2.00 (Auction on Arrival)
 CO1 marked AOA initiates an auction upon receipt.

Market Maker ("MM") Complex Order 2 (CO2) Sell 10 @1.95 (MPC = 1.80)
 MM Complex AOC eQuote 3 (CO3) Sell 10 @1.85 (MPC = 1.80)

Unrelated order CO2 and related response CO3 arrive during the auction and joins the auction in progress. The Auction concludes with no further interest being received.

Upon conclusion of the Auction CO2 and CO3 when subject to MPC Protection cannot trade more than 0.05 lower than the Away Best Bid; meaning that these orders cannot trade lower than 1.80. However since the limit price of CO2 and CO3 is not through the MPC Protected Price, price protection is not engaged. Allocation remains based upon original limit price as price protection is not engaged. CO3 trades 10 with CO1 at 1.90 ahead of CO2 since its original limit price (1.85) was more aggressive than the original limit price of CO2 (1.95). CO2 does not trade and leaves a balance of 10 to sell at 1.95.

As illustrated by the examples above, there is no difference in allocations under the proposal when orders have the same, or different, original limit prices when price protection is not engaged (Examples 2 and 3 respectively). Under the current rule there is a difference in allocation when orders have the same protected price but different original limit prices, as illustrated in Example 1. Under the Exchange's proposal, using the order's protected price, when price protection is engaged, to determine allocation, will provide the same allocation result as when orders have the same original limit price, but when price protection is not engaged (as demonstrated in Example 2). The Exchange believes that allocating interest at the conclusion of a Complex Auction based upon an order's protected price, when price protection is engaged, as opposed to its original limit price, provides a consistent allocation methodology when orders have the same price (either original limit price when price protection is not engaged, or protected price when price protection is engaged).

Additionally, the Exchange proposes to amend section (f) of Interpretation and Policy .05 to add an opening quotation to the term eQuotes in subsection (1), which states, [a]ll complex orders on the Exchange, together with cAOC eQuotes and cIOC eQuotes¹⁴ (as defined in Interpretations and Policies: 02.(c)(1) and (2) of this Rule) (collectively, "eQuotes"), are subject to the MPC Price Protection feature. This is non-substantive change to make a typographical correction to the rule text.

2. Statutory Basis

MIAX Emerald believes that its proposed rule change is consistent with Section 6(b) of the Act¹⁵ in general, and furthers the objectives of Section 6(b)(5) of the Act¹⁶ in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in

facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that determining priority for allocating interest at the conclusion of a Complex Auction based on an order's protected price, when price protection is engaged, removes impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest by providing a consistent allocation methodology. Basing trade allocation priority on an order's protected price provides for a more equitable allocation of interest at the conclusion of a Complex Auction versus using an order's original limit price to determine allocation priority. An order's original limit price is not relevant for determining allocation as the order cannot trade through its protected price. Therefore, the Exchange believes that when price protection is engaged, using the protected price as the basis for allocation priority at the conclusion of a Complex Auction is more appropriate.

As demonstrated in Example 1A, under the current rule an order with a limit price that is through its protected price supersedes an order with a limit price equal to its protected price. In Example 1A, the trade price is equal to the protected price, however the order with a more aggressive original limit price receives the first allocation. In Example 1A, the order's \$1.00 original limit price to sell is illusory in the sense that the order can never be executed below its protected price of \$1.80 due to price protection being engaged. With two orders that can be executed at \$1.80 the Exchange believes that basing allocation on the protected price promotes just and equitable principles of trade, as both orders receive an allocation. This aligns to the allocation that results when two orders can be executed at their original limit price without price protection being engaged, and provides consistency in the allocation process used on the Exchange, and prevents unfair allocations from occurring, which promotes just and equitable principles of trade.

The Exchange believes its proposal to make a non-substantive change to correct a typographical error protects investors and the public interest by providing accuracy in the Exchange's rules. Clarity and precision in the Exchange's rules helps avoid the

¹⁴ A "Complex Immediate-or-Cancel eQuote" or "cIOC eQuote," which is a complex eQuote with a time-in-force of IOC that may be matched with another complex quote or complex order for an execution to occur in whole or in part upon receipt into the System. cIOC eQuotes will not: (i) Be executed against individual orders and quotes resting on the Simple Order Book; (ii) be eligible to initiate a Complex Auction or join a Complex Auction in progress; (iii) rest on the Strategy Book; or (iv) be displayed. Any portion of a cIOC eQuote that is not executed will be immediately cancelled. See Exchange Rule 518.02(c)(2).

¹⁵ 15 U.S.C. 78f(b).

¹⁶ 15 U.S.C. 78f(b)(5).

potential for confusion which benefits investors and the public.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange's proposal will not impose any burden on inter-market competition as the proposal will only affect trade allocations performed at the conclusion of a Complex Auction on the Exchange, when price protection is engaged.

The Exchange does not believe the proposed rule change will impose any burden on intra-market competition as the rules of the Exchange are applicable to all Members¹⁷ equally, and will equally impact those Members who participate in Complex Auctions.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁸ and Rule 19b-4(f)(6) thereunder.¹⁹

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act²⁰ normally does not become operative for 30 days after the date of its filing. However, Rule 19b-4(f)(6)(iii)²¹ permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the

public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposed rule change may become operative upon filing. As discussed above, the Exchange believes that using an order's protected price when price protection is engaged, rather than an order's original limit price, is appropriate for determining allocation priority at the conclusion of a Complex Auction because an order cannot be executed at a price that would violate its protected price. Thus, an order's original limit price is not relevant for determining allocation priority when price protection is engaged, and the Exchange believes that using an order's protected price to determine auction allocations when price protection is engaged will prevent unfair Complex Auction allocations. The Commission believes that determining Complex Auction allocations based on an order's protected price when price protection is engaged, rather than on the order's original limit price, is appropriate because an order will never execute at a price that violates its protected price. The Commission believes that using an order's protected price when price protection is engaged will help to assure that orders are allocated fairly at the conclusion of a Complex Auction. Therefore, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.²²

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act.

²² For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-EMERALD-2019-27 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-EMERALD-2019-27. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-EMERALD-2019-27, and should be submitted on or before August 27, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²³

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019-16721 Filed 8-5-19; 8:45 am]

BILLING CODE 8011-01-P

²³ 17 CFR 200.30-3(a)(12).

¹⁷ The term "Member" means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed "members" under the Exchange Act. *See* Exchange Rule 100.

¹⁸ 15 U.S.C. 78s(b)(3)(A).

¹⁹ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

²⁰ 17 CFR 240.19b-4(f)(6).

²¹ 17 CFR 240.19b-4(f)(6)(iii).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-86533; File No. SR-EMERALD-2019-28]

Self-Regulatory Organizations; MIAX Emerald, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 515, Execution of Orders and Quotes

July 31, 2019.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b-4 thereunder,² notice is hereby given that on July 22, 2019, MIAX Emerald, LLC (“MIAX Emerald” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend Exchange Rule 515, Execution of Orders and Quotes, to make minor, non-substantive edits and clarifying changes to the rule text.

The text of the proposed rule change is available on the Exchange’s website at <http://www.miaxoptions.com/rule-filings/emerald> at MIAX Emerald’s principal office, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Exchange Rule 515, Execution of Orders and Quotes, to make minor, non-substantive edits and clarifying changes to the rule text in order to provide consistency and clarity within the rule text. Specifically, the Exchange proposes to make a number of minor non-substantive edits to references to “Rule 515” throughout the rule text. Currently, there are several references in Exchange Rule 515 where the rule refers back to itself generally as “Rule 515”. The Exchange proposes to amend all general references in Exchange Rule 515 that are to “Rule 515” that do not refer to any particular subsection or paragraph to be replaced with “this Rule” in order to provide consistency and clarity within the rule text. The proposed changes would be to references to “Rule 515” that are currently in the following subsections and paragraphs in Exchange Rule 515: Paragraph (a); paragraph (c); subsection (c)(1)(i); subsection (c)(1)(ii)(A); subsection (c)(1)(ii)(C)3.; proposed renumbered subsection (d)(3)(iii) (as described below); subsection (i)(3)(i); and Interpretation and Policy .04.

Next, the Exchange proposes to amend several paragraphs and subsections to make corrective changes to the numerical and alphabetical list item identifiers to properly conform to the hierarchical heading scheme used throughout the Exchange’s rulebook. Accordingly, subsections (a)(i) through (a)(iii) will be renumbered as (a)(1) through (a)(3); subsections (c)(1)(ii)(A)(A) through (c)(1)(ii)(A)(C) will be renumbered as (c)(1)(ii)(A)1. through (c)(1)(ii)(A)3.; subsections (c)(1)(ii)(B)(A) through (c)(1)(ii)(B)(D) will be renumbered as (c)(1)(ii)(B)1. through (c)(1)(ii)(B)4.; subsections (d)(i)(A) through (d)(i)(C) will be renumbered as (d)(1)(i) through (d)(1)(iii); subsection (d)(ii) will be renumbered as (d)(2); subsections (d)(iii)1. through (d)(iii)4. will be renumbered as (d)(3)(i) through (d)(3)(iv); subsections (d)(iv) through (d)(v) will be renumbered as (d)(4) through (d)(5); subsections (g)(i) through (g)(ii) will be renumbered as (g)(1) through (g)(2); Interpretation and Policy .02 subsections (b)(i) through (b)(iv) will be renumbered as (b)(1) through (b)(4); Interpretation and Policy .02 subsections (c)(i) through (c)(iii) will be renumbered as (c)(1) through (c)(3); and Interpretation and Policy .04

subsections (i) through (iii) will be renumbered as (a) through (c).

Next, the Exchange proposes to amend subsection (c)(1)(ii)(C)3. to provide a more accurate citation to the subsection that discusses the Managed Interest Process when the Exchange receives a new Post-Only OQ on the opposite side of the market from a Post-Only Order being managed and the new Post-Only OQ locks or crosses the Book price of the resting Post-Only Order. In this instance, subsection (c)(1)(ii)(C)3. currently provides a citation to subsection (c)(1)(ii), which is the general citation to the subsection for the Managed Interest Process. The Exchange now proposes to amend that citation to be to be “(c)(1)(ii)(B)” as that subsection is a more accurate citation for the Managed Interest Process in this scenario.

Finally, the Exchange proposes to amend Interpretation and Policy .01 to insert brackets around subsections that are to be “Reserved” to provide consistency throughout the rule text. Other subsections that are reserved throughout the Exchange’s rulebook are all bracketed [sic]. Accordingly, the Exchange proposes to insert brackets around “Reserved” in Interpretation and Policy .01.

2. Statutory Basis

The Exchange believes that its proposed rule change is consistent with Section 6(b) of the Act ³ in general, and furthers the objectives of Section 6(b)(5) of the Act ⁴ in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes the proposed changes promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed changes make clarifying edits to the rule text of Exchange Rule 515, and correct errors in the hierarchical heading scheme and to certain citations to provide uniformity in the Exchange’s rulebook. The Exchange believes that these proposed changes will provide greater clarity to Members and the public regarding the

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78f(b).

⁴ 15 U.S.C. 78f(b)(5).

Exchange's rules and that it is in the public interest for rules to be accurate and concise so as to eliminate the potential for confusion.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange believes the proposed changes will not impose any burden on intra-market competition as there is no functional change to the Exchange's System and because the rules of the Exchange apply to all MIAX Emerald participants equally. The proposed rule changes will have no impact on competition as they are not designed to address any competitive issues but rather are designed to remedy minor non-substantive issues and provide added clarity to the rule text of Exchange Rule 515. In addition, the Exchange does not believe the proposal will impose any burden on inter-market competition as the proposal does not address any competitive issues and is intended to protect investors by providing further transparency regarding the Exchange's functionality.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act⁵ and Rule 19b-4(f)(6)⁶ thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the

public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.^{IV} Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-EMERALD-2019-28 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-EMERALD-2019-28. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-EMERALD-2019-28 and

should be submitted on or before August 27, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁷

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019-16718 Filed 8-5-19; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 10:00 a.m. on Thursday, August 8, 2019.

PLACE: The meeting will be held at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at <https://www.sec.gov>.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

The subject matters of the closed meeting will consist of the following topics:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims;

Consideration of amicus participation; and

Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters

CONTACT PERSON FOR MORE INFORMATION: For further information; please contact

⁷ 17 CFR 200.30-3(a)(12).

⁵ 15 U.S.C. 78s(b)(3)(A).

⁶ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

Vanessa A. Countryman from the Office of the Secretary at (202) 551-5400.

Dated: August 1, 2019.

Vanessa A. Countryman,
Secretary.

[FR Doc. 2019-16860 Filed 8-2-19; 11:15 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-86532; File No. SR-NYSEArca-2019-02]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Granting Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To List and Trade the Shares of the ProShares UltraPro 3x Natural Gas ETF and ProShares UltraPro 3x Short Natural Gas ETF Under NYSE Arca Rule 8.200-E

July 31, 2019.

I. Introduction

On January 28, 2019, NYSE Arca, Inc. (“Exchange” or “NYSE Arca”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (“Act” or “Exchange Act”)² and Rule 19b-4 thereunder,³ a proposed rule change to list and trade shares (“Shares”) of the ProShares UltraPro 3x Natural Gas ETF and ProShares UltraPro 3x Short Natural Gas ETF (individually, “Fund,” and collectively, “Funds”) under NYSE Arca Equities Rule 8.200-E. The proposed rule change was published for comment in the **Federal Register** on February 15, 2019.⁴

On March 26, 2019, pursuant to Section 19(b)(2) of the Act,⁵ the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.⁶ On May 15, 2019, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act⁷ to determine whether to approve or disapprove the proposed

rule change.⁸ In the Order Instituting Proceedings, the Commission solicited comments on specified matters related to the proposal.⁹ On June 26, 2019, the Exchange filed Amendment No. 1 to the proposed rule change.¹⁰ The Commission has received no comments on the proposal. This order grants approval of the proposed rule change, as modified by Amendment No. 1.

II. Exchange’s Description of the Proposal, as Modified by Amendment No. 1¹¹

The Exchange proposes to list and trade the Shares of each Fund under NYSE Arca Rule 8.200-E, Commentary .02, which governs the listing and trading of Trust Issued Receipts.¹² Each

⁸ See Securities Exchange Act Release No. 85860, 84 FR 23103 (May 21, 2019) (“Order Instituting Proceedings”).

⁹ Specifically, the Commission instituted proceedings to allow for additional analysis of the proposed rule change’s consistency with Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be “designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade,” and “to protect investors and the public interest.” See *id.*, 84 FR at 23104.

¹⁰ In Amendment No. 1, which amended and replaced the proposed rule change in its entirety, the Exchange clarified: (a) That each Fund will seek to invest in Futures Contracts (as defined herein) listed on NYMEX (as defined herein); (b) the specific circumstances and conditions under which a Fund may obtain exposure to the Benchmark (as defined herein) through investments in Financial Instruments (as defined herein); (c) the trading volume and open interest in natural gas futures contracts; (d) the trading hours of the natural gas futures contracts, the designated settlement time of the natural gas futures contracts, and the daily Benchmark closing value calculation time; and (e) that prior to the commencement of trading, the Exchange will inform its ETP Holders (as defined herein) of the suitability requirements of NYSE Arca Equities Rule 9.2-E(a) in an information bulletin. In addition, the Exchange made other technical, conforming, and non-substantive changes to the proposal. Because the changes in Amendment No. 1 do not materially alter the substance of the proposed rule change or raise unique or novel regulatory issues, Amendment No. 1 is not subject to notice and comment. Amendment No. 1 is available on the Commission’s website at: <https://www.sec.gov/comments/sr-nysearca-2019-02/srnysearca201902-5736053-186688.pdf>.

¹¹ The Commission notes that additional information regarding, among other things, the Shares, Funds, investment objectives, permitted investments, investment strategies and methodologies, investment restrictions, creation and redemption procedures, availability of information, trading rules and halts, and surveillance procedures, can be found in the Notice (see *supra* note 4) and the Registration Statement (see *infra* note 13), as applicable.

¹² Commentary .02 to NYSE Arca Rule 8.200-E applies to Trust Issued Receipts that invest in “Financial Instruments.” The term “Financial Instruments,” as defined in Commentary .02(b)(4) to NYSE Arca Rule 8.200-E, means any combination of investments, including cash; securities; options on securities and indices; futures contracts; options on futures contracts; forward contracts; equity caps, collars, and floors; and swap agreements.

Fund is a series of the ProShares Trust II (“Trust”), a Delaware statutory trust.¹³ The Trust and the Funds are managed and controlled by ProShare Capital Management LLC (“ProShare Capital” or “Sponsor”). ProShare Capital is registered as a commodity pool operator with the Commodity Futures Trading Commission and is a member of the National Futures Association. The Bank of New York Mellon will be the custodian, transfer agent, and administrator for the Funds. SEI Investments Distribution Co. will serve as distributor for the Funds.

Overview of the Funds

The investment objective of the ProShares UltraPro 3x Natural Gas ETF is to seek daily¹⁴ investment results (before fees and expenses) that correspond to three times (3x) the performance of the Bloomberg Natural Gas Subindex (“Benchmark”). The investment objective of the ProShares UltraPro 3x Short Natural Gas ETF is to seek daily investment results (before fees and expenses) that correspond to three times the inverse (-3x) of the performance of the Benchmark. The Benchmark is intended to reflect the performance of a rolling position in natural gas futures contracts listed on the New York Mercantile Exchange (“NYMEX,” which is part of the CME Group, Inc.), without regard to income earned on cash positions.

Investments of the Funds

In seeking to achieve the Funds’ investment objectives, ProShare Capital will utilize a mathematical approach to determine the type, quantity, and mix of investment positions that ProShare Capital believes, in combination, should produce daily returns consistent with the Funds’ respective objectives. Each Fund will seek to meet its respective investment objective by investing, under normal market conditions,¹⁵ in NYMEX-

¹³ The Trust is registered under the Securities Act of 1933. On May 19, 2017, the Trust filed with the Commission a registration statement on Form S-1 under the Securities Act of 1933 relating to the Funds (File No. 333-218136) (“Registration Statement”).

¹⁴ Each Fund seeks to achieve its investment objective for a single day, and not for any other period. The Exchange states that the return of a Fund for a period longer than a single trading day is the result of its return for each day compounded over the period and thus will usually differ from a Fund’s multiple times the return of the Benchmark for the same period.

¹⁵ The term “normal market conditions” includes, but is not limited to, the absence of: trading halts in the applicable financial markets generally; operational issues (e.g., systems failure) causing dissemination of inaccurate market information; or force majeure type events such as natural or manmade disaster, act of God, armed conflict, act of terrorism, riot or labor disruption, or any similar

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

⁴ See Securities Exchange Act Release No. 85088 (Feb. 11, 2019), 84 FR 4573 (“Notice”).

⁵ 15 U.S.C. 78s(b)(2).

⁶ See Securities Exchange Act Release No. 85417, 84 FR 12304 (Apr. 1, 2019). The Commission designated May 16, 2019, as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to approve or disapprove, the proposed rule change.

⁷ 15 U.S.C. 78s(b)(2)(B).

listed futures contracts and NYMEX-listed options on such futures contracts (collectively, “Futures Contracts”).¹⁶ The Funds will not invest directly in natural gas. The Funds’ investments in Futures Contracts will be used to produce economically “leveraged” or “inverse leveraged” investment results for the Funds.

Each Fund may, to a lesser extent and in view of regulatory requirements and/or market conditions,¹⁷ obtain exposure to the Benchmark through investment in over-the-counter (“OTC”) swap transactions and forward contracts based on such Benchmark (“Financial Instruments”). A Fund may invest in Financial Instruments: (i) If position, price or accountability limits are reached with respect to Futures Contracts;¹⁸ (ii) if margin requirements or exposure limits are reached with a particular futures commission merchant; (iii) if the market for a specific futures contract experiences emergencies (e.g., natural disaster, terrorist attack or an act of God) or disruptions (e.g., trading halt or “flash crash”); (iv) to maintain or increase portfolio diversification or liquidity or to obtain more favorable pricing; (v) to mitigate credit risk or exposure; or (vi) if the Sponsor deems it impractical or otherwise not in the best interest of a Fund to buy or sell Futures Contracts (such as during periods of market volatility or illiquidity).

Each Fund will also hold cash or cash equivalents, such as U.S. Treasury

securities or other high credit quality, short-term fixed-income or similar securities (such as shares of money market funds and collateralized repurchase agreements), pending investment in Futures Contracts or Financial Instruments or as collateral for the Funds’ investments.

In addition, to the extent a Fund enters into swap agreements and other OTC transactions, it will do so only with large, established and well capitalized financial institutions that meet the Sponsor’s credit quality standards and monitoring policies. Each Fund will use various techniques to minimize credit risk including early termination or reset and payment, using different counterparties and limiting the net amount due from any individual counterparty.

The Funds do not intend to hold Futures Contracts through expiration, but instead intend to “roll” or close their respective positions before expiration.¹⁹ The Exchange states that the Funds do not expect to have exposure to Futures Contracts and Financial Instruments greater than three times (3x) the Funds’ net assets. The Exchange further represents that not more than 10% of the net assets of a Fund in the aggregate invested in Futures Contracts will consist of Futures Contracts whose principal market is not a member of the Intermarket Surveillance Group (“ISG”) or is a market with which the Exchange does not have a comprehensive surveillance sharing agreement (“CSSA”).

III. Discussion and Commission Findings

After careful review, the Commission finds that the Exchange’s proposal to list and trade the Shares is consistent with the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange.²⁰ In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with

Section 6(b)(5) of the Exchange Act,²¹ which requires, among other things, that the Exchange’s rules be designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission also finds that the proposal to list and trade the Shares on the Exchange is consistent with Section 11A(a)(1)(C)(iii) of the Exchange Act,²² which sets forth Congress’ finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities.

According to the Exchange, quotation and last-sale information regarding the Shares will be disseminated through the facilities of the Consolidated Tape Association. Quotation information for cash equivalents and OTC Financial Instruments may be obtained from brokers and dealers who make markets in such instruments. Quotation information for exchange-traded swaps will be available from the applicable exchange and major market vendors. The intraday, closing prices, and settlement prices of the Futures Contracts will be readily available from the applicable futures exchange websites, automated quotation systems, published or other public sources, or major market data vendors. Complete real-time data for the Futures Contracts is available by subscription through on-line information services. ICE Futures U.S. and NYMEX also provide delayed futures and options on futures information on current and past trading sessions and market news free of charge on their respective websites. The specific contract specifications for Futures Contracts are also available on such websites, as well as other financial informational sources. Intra-day price and closing price level information for the Benchmark will be available from major market data vendors.

The Funds’ website will display the applicable end of day closing net asset value (“NAV”). The daily holdings of each Fund will be available on the Funds’ website. The Funds’ website will also include a form of the prospectus for the Funds that may be downloaded. The website will include the Shares’ ticker and CUSIP information, along with

intervening circumstance. See NYSE Arca Rule 8.600-E(c)(5).

¹⁶ According to the Exchange, a Futures Contract is a standardized contract traded on, or subject to the rules of, an exchange that calls for the future delivery of a specified quantity and type of a particular underlying asset at a specified time and place or alternatively may call for cash settlement. The notional size and calendar term Futures Contracts on a particular underlying asset are identical and are not subject to any negotiation, other than with respect to price and the number of contracts traded between the buyer and seller. Natural gas futures contracts listed on NYMEX have significant volume and open interest. Year-to-date (as of 3/27/19) average daily dollar volume of the first and second month contracts combined is over \$6 billion per day and current open is over \$10 billion.

¹⁷ Market conditions that the Sponsor currently anticipates could cause a Fund to invest in Financial Instruments include, among others, conditions where the Sponsor believes the use of Financial Instruments would allow a Fund to obtain greater liquidity or more favorable pricing.

¹⁸ According to the Exchange, many designated contract markets, such as the NYMEX, have established accountability levels and position limits on the maximum net long or net short futures contracts in commodity interests that any person or group of persons under common trading control may hold, own or control. In addition, NYMEX also sets price fluctuation limits on futures contracts. Options do not have individual price limits but rather are linked to the price limit of Futures Contracts.

¹⁹ The Funds also may invest in options on Futures Contracts. Unlike Futures Contracts, which the Funds intend to roll before expiration, the Funds intend to hold “in-the-money” options on Futures Contracts to expiration. The Funds expect to exercise in-the-money options on Futures Contracts at expiration of the options contract and they would settle through receipt or delivery of the underlying Futures Contracts. The Funds expect to hold out-of-the-money options to expiration and that they will be expired worthless. Options on Futures Contracts are subject to the effects of contango and backwardation to the same general extent as their underlying Futures Contracts.

²⁰ In approving this proposed rule change, the Commission has considered the proposed rule’s impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

²¹ 15 U.S.C. 78f(b)(5).

²² 15 U.S.C. 78k-1(a)(1)(C)(iii).

additional quantitative information updated on a daily basis for each Fund.²³ The website disclosure of portfolio holdings will be made daily and will include, as applicable, (i) the name, quantity, value, expiration, and strike price of Futures Contracts, (ii) the counterparty to and value of swap agreements and forward contracts, and (iii) the aggregate net value of other assets (*i.e.*, Treasury securities, cash equivalents, and cash) held in each Fund's portfolio, if applicable. The Funds' website will be publicly available at the time of the public offering of Shares and accessible at no charge. The spot price of natural gas also is available on a 24-hour basis from major market data vendors.

Each Fund's NAV will be calculated on each day other than a day when the Exchange is closed for regular trading. The Funds will typically compute their NAVs as of 2:30 p.m. Eastern Time ("E.T."), which is the designated settlement time of the natural gas futures listed on NYMEX,²⁴ or an earlier time as set forth on www.ProShares.com, if necessitated by the Exchange or other exchange material to the valuation or operation of such Fund closing early. Each Fund's NAV is calculated only once each trading day. In order to provide updated information relating to a Fund for use by investors and market professionals, the Exchange will calculate an updated IFV, which will be calculated by using the prior day's closing NAV per Share of a Fund as a base and will be updated throughout the Core Trading Session of 9:30 a.m. E.T. to 4:00 p.m. E.T. to reflect changes in the approximate aggregate per Share value of the investments held by a Fund based on the most recently available prices for the Fund's investments. The IFV will be disseminated on a per Share basis every 15 seconds during the Exchange's Core Trading Session and be widely disseminated by one or more major

market data vendors during the NYSE Arca Core Trading Session. The NAV for the Shares will be disseminated daily to all market participants at the same time.

The Commission further believes that the proposal to list and trade the Shares is reasonably designed to promote fair disclosure of information that may be necessary to price the Shares appropriately and to prevent trading when a reasonable degree of transparency cannot be assured. If the Exchange becomes aware that the NAV with respect to the Shares is not disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the NAV is available to all market participants. Further, the Exchange may halt trading during the day in which an interruption to the dissemination of the IFV or the value of the Benchmark occurs. If the interruption to the dissemination of the IFV or the value of the Benchmark persists past the trading day in which it occurred, the Exchange will halt trading no later than the beginning of the trading day following the interruption. Trading in Shares of a Fund will be halted if the circuit breaker parameters in NYSE Arca Equities Rule 7.12-E have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. The Exchange states that it has a general policy prohibiting the distribution of material, non-public information by its employees. Moreover, trading of the Shares will be subject to NYSE Arca Equities Rule 8.200-E, Commentary .02(e), which sets forth certain restrictions on Equity Trading Permit ("ETP") Holders acting as registered Market Makers in Trust Issued Receipts to facilitate surveillance.

The Commission notes that the Exchange or the Financial Industry Regulatory Authority ("FINRA"), on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares and certain Futures Contracts with other markets and other entities that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares and certain Futures Contracts from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares and certain Futures Contracts from markets and other entities that are members of ISG or with which the Exchange has in

place a CSSA.²⁵ The Exchange is also able to obtain information regarding trading in the Shares, the physical commodities underlying Futures Contracts through ETP Holders, in connection with such ETP Holders' proprietary or customer trades which they effect through ETP Holders on any relevant market. The Exchange can obtain market surveillance information, including customer identity information, with respect to transactions (including transactions in Futures Contracts) occurring on US futures exchanges, which are members of the ISG.

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. In support of this proposal, the Exchange represented that:

- (1) The Shares will conform to the initial and continued listing criteria under NYSE Arca Equities Rule 8.200-E.
- (2) The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions.
- (3) Trading in the Shares will be subject to the existing trading surveillances administered by the Exchange, as well as cross-market surveillances administered by FINRA on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws, and these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange.

(4) Prior to the commencement of trading, the Exchange will inform its ETP Holders in an Information Bulletin of the special characteristics and risks associated with trading the Shares. Specifically, the Information Bulletin will discuss the following: (a) The risks involved in trading the Shares during the Early and Late Trading Sessions when an updated IFV will not be calculated or publicly disseminated; (b) the procedures for purchases and redemptions of Shares in Creation Units (and that Shares are not individually redeemable); (c) NYSE Arca Equities Rule 9.2(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (d) how information regarding the IFV is

²³ The Funds' website will include: (1) Daily trading volume, the prior business day's reported NAV and closing price, and a calculation of the premium and discount of the closing price or midpoint of the bid/ask spread at the time of NAV calculation ("Bid/Ask Price") against the NAV; and (2) data in chart format displaying the frequency distribution of discounts and premiums of the daily closing price or Bid/Ask Price against the NAV, within appropriate ranges, for at least each of the four previous calendar quarters.

²⁴ The daily closing value of the Benchmark is calculated as of 2:30 p.m. E.T. to coincide with the designated settlement time of the natural gas futures listed on NYMEX. These contracts generally trade 23 hours a day, Sunday through Friday from 6:00 p.m. E.T. with a 60-minute break each day beginning at 5:00 p.m. E.T. The Fund's Indicative Fund Value ("IFV") is updated to reflect the price of these contracts up until 4:00 p.m.

²⁵ For a list of the current members of ISG, see www.isgportal.org. According to the Exchange, not all components of a Fund may trade on markets that are members of ISG or with which the Exchange has in place a CSSA.

disseminated; (e) how information regarding portfolio holdings is disseminated; (f) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; (g) trading information; and (h) NYSE Arca suitability rules.

(5) Prior to the commencement of trading, the Exchange will inform its ETP Holders of the suitability requirements of NYSE Arca Equities Rule 9.2–E(a) in an Information Bulletin. Specifically, ETP Holders will be reminded in the Information Bulletin that, in recommending transactions in the Shares, they must have a reasonable basis to believe that (a) the recommendation is suitable for a customer given reasonable inquiry concerning the customer's investment objectives, financial situation, needs, and any other information known by such ETP Holder, and (b) the customer can evaluate the special characteristics, and is able to bear the financial risks, of an investment in the Shares. In connection with the suitability obligation, the Information Bulletin will also provide that ETP Holders must make reasonable efforts to obtain the following information: (i) The customer's financial status; (ii) the customer's tax status; (iii) the customer's investment objectives; and (iv) such other information used or considered to be reasonable by such ETP Holder or registered representative in making recommendations to the customer.

(6) FINRA has implemented increased sales practice and customer margin requirements for FINRA members applicable to inverse, leveraged and inverse leveraged securities (which include the Shares) and options on such securities, as described in FINRA Regulatory Notices 09–31 (June 2009), 09–53 (August 2009), and 09–65 (November 2009). ETP Holders that carry customer accounts will be required to follow the FINRA guidance set forth in these notices.

(7) For initial and continued listing, each Fund will be in compliance with Rule 10A–3 under the Act,²⁶ as provided by NYSE Arca Equities Rule 5.3–E.

(8) Each Fund will seek to meet its respective investment objective by investing, under normal market conditions, in NYMEX-listed Futures Contracts. The Funds will not invest directly in natural gas.

(9) Each Fund may, to a lesser extent and in view of regulatory requirements

and/or market conditions,²⁷ obtain exposure to the Benchmark through investment in OTC Financial Instruments. A Fund may invest in Financial Instruments: (i) If position, price or accountability limits are reached with respect to Futures Contracts;²⁸ (ii) if margin requirements or exposure limits are reached with a particular futures commission merchant; (iii) if the market for a specific futures contract experiences emergencies (e.g., natural disaster, terrorist attack or an act of God) or disruptions (e.g., trading halt or “flash crash”); (iv) to maintain or increase portfolio diversification or liquidity or to obtain more favorable pricing; (v) to mitigate credit risk or exposure; or (vi) if the Sponsor deems it impractical or otherwise not in the best interest of a Fund to buy or sell Futures Contracts (such as during periods of market volatility or illiquidity).

(10) The Funds do not expect to have exposure to Futures Contracts and Financial Instruments greater than three times (3x) the Funds' net assets as of the time the NAV is calculated.

(11) Not more than 10% of the net assets of a Fund in the aggregate invested in Futures Contracts shall consist of Futures Contracts whose principal market is not a member of the ISG or is a market with which the Exchange does not have a CSSA.

(12) To the extent a Fund enters into swap agreements and other OTC transactions, it will do so only with large, established and well capitalized financial institutions that meet the Sponsor's credit quality standards and monitoring policies. Each Fund will use various techniques to minimize credit risk including early termination or reset and payment, using different counterparties and limiting the net amount due from any individual counterparty.

(13) A minimum of 100,000 Shares of each Fund will be outstanding at the commencement of trading on the Exchange.

The Exchange represents that all statements and representations made in this filing regarding (a) the description of the portfolios of the Funds or Benchmark, (b) limitations on portfolio holdings or the Benchmark, or (c) the applicability of Exchange listing rules specified in this rule filing shall constitute continued listing requirements for listing the Shares on the Exchange. The issuer has represented to the Exchange that it will advise the Exchange of any failure by

the Funds to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements.²⁹ If a Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under NYSE Arca Equities Rule 5.5–E(m).

This approval order is based on all of the Exchange's representations and description of the Funds, including those set forth above and in Amendment No. 1. The Commission notes that the Shares must comply with the requirements of NYSE Arca Equities Rule 8.200–E and Commentary .02 thereto to be listed and traded on the Exchange on an initial and continuing basis.

For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act³⁰ and the rules and regulations thereunder applicable to a national securities exchange.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Exchange Act,³¹ that the proposed rule change (SR–NYSEArca–2019–02), as modified by Amendment No. 1, be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³²

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–16717 Filed 8–5–19; 8:45 am]

BILLING CODE 8011–01–P

²⁹ The Commission notes that certain other proposals for the listing and trading of Managed Fund Shares include a representation that the exchange will “surveil” for compliance with the continued listing requirements. *See, e.g.,* Securities Exchange Act Release No. 77499 (April 1, 2016), 81 FR 20428 (April 7, 2016) (Notice of Filing of Amendment No. 2, and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 2, to List and Trade Shares of the SPDR DoubleLine Short Duration Total Return Tactical ETF of the SSgA Active Trust), available at: <http://www.sec.gov/rules/sro/bats/2016/34-77499.pdf>. In the context of this representation, it is the Commission's view that “monitor” and “surveil” both mean ongoing oversight of the Fund's compliance with the continued listing requirements. Therefore, the Commission does not view “monitor” as a more or less stringent obligation than “surveil” with respect to the continued listing requirements.

³⁰ 15 U.S.C. 78f(b)(5).

³¹ 15 U.S.C. 78s(b)(2).

³² 17 CFR 200.30–3(a)(12).

²⁶ 17 CFR 240.10A–3.

²⁷ *See supra* note 17 and accompanying text.

²⁸ *See supra* note 18 and accompanying text.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86534; File No. SR–MIAX–2019–33]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 520, Limitations on Orders

July 31, 2019.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b–4 thereunder, ² notice is hereby given that on July 18, 2019, Miami International Securities Exchange, LLC (“MIAX Options” or the “Exchange”) filed with the Securities and Exchange Commission (“Commission”) a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend Exchange Rule 520, Limitations on Orders, to remove certain order entry restrictions prohibiting Electronic Exchange Members ³ from effectively operating as Market Makers ⁴ on the Exchange.

The text of the proposed rule change is available on the Exchange’s website at <http://www.miaxoptions.com/rule-filings/> at MIAX Options’ principal office, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set

forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Exchange Rule 520, Limitations on Orders, to remove certain order entry restrictions prohibiting EEMs from effectively operating as Market Makers on the Exchange. Currently, subsection (a)(1) of Exchange Rule 520 provides that the Exchange shall designate classes in which EEMs may enter into the System, ⁵ as principal or as agent, buy and sell limit orders in the same option series, for the account or accounts of the same or related beneficial owners. Currently, subsection (a)(2) of Exchange Rule 520 provides that, in all other classes, EEMs shall not enter into the System, as principal or agent, limit orders in the same options series, for the account or accounts of the same or related beneficial owners, in such a manner that the EEM or the beneficial owner(s) effectively is operating as a market maker by holding itself out as willing to buy and sell such option contract on a regular or continuous basis. Subsection (a)(2) further provides that in determining whether an EEM or beneficial owner effectively is operating as a Market Maker, the Exchange will consider, among other things: the simultaneous or near-simultaneous entry of limit orders to buy and sell the same option contract; the multiple acquisition and liquidation of positions in the same options series during the same day; and the entry of multiple limit orders at different prices in the same options series.

The Exchange now proposes to amend Exchange Rule 520(a) to delete current subsection (a)(1) and to modify current subsection (a)(2) such that, for all option classes, the restrictions prohibiting EEMs from effectively operating as Market Makers will only be applicable to Priority Customer Orders ⁶ since Priority Customer Orders have priority at any price over the bids and offers of

non-Priority Customer Orders. Current Exchange Rule 520(a)(2) was adopted to limit the ability of Members that are not Market Makers to compete on preferential terms within the Exchange’s System. Because Priority Customer Orders are provided with certain benefits such as priority of bids and offers, the Exchange believes that Priority Customer Orders should continue to be subject to the restrictions set out in current Exchange Rule 520(a)(2). However, because broker-dealer orders do not have priority over bids and offers of Market Makers, the Exchange no longer believes it is necessary to impose the restrictions set out in current Exchange Rule 520(a)(2) on the entry of broker-dealer orders. Similarly, because Voluntary Professional orders do not have priority over bids and offers of Market Makers, the Exchange does not believe it is necessary to impose the restrictions set out in current Exchange Rule 520(a)(2) on Voluntary Professional orders.⁷

Pursuant to this proposal, the Exchange will allow EEMs to enter buy and sell limit orders in the same options series for the account or accounts of the same beneficial owners, other than for

⁷ The Exchange notes that this rule change would only eliminate the restrictions of Exchange Rule 520(a)(2) in the manner proposed. Members would continue to remain subject to the requirements of Exchange Rule 303 (which requires Members to establish, maintain and enforce written policies and procedures reasonably designed, taking into consideration the nature of such Member’s business, to prevent the misuse of material, nonpublic information by such Member or persons associated with such Member), Exchange Rule 301, Interpretation and Policy .02 (which considers it conduct inconsistent with just and equitable principles of trade for any person associated with a Member who has knowledge of all material terms and conditions of: (a) An order and a solicited order, (b) an order being facilitated, or (c) orders being crossed, the execution of which are imminent, to enter, based on such knowledge, an order to buy or sell an option for the same underlying security as any option that is the subject of the order, or an order to buy or sell the security underlying such class, or any order to buy or sell any related instrument until (1) the terms of the order and any changes in the terms of the order of which the person associated with the Member has knowledge are disclosed to the trading crowd, or (2) the trade can no longer reasonably be considered imminent in view of the passage of time since the order was received); Exchange Rule 520(b) (which provides that EEMs may not execute as principal orders they represent as agent unless (i) agency orders are first exposed on the Exchange for at least one (1) second, (ii) the EEM has been bidding or offering on the Exchange for at least one (1) second prior to receiving an agency order that is executable against such bid or offer, or (iii) the EEM utilizes the MIAX PRIME pursuant to Rule 515A); and Exchange Rule 520(c) (which provides that EEMs may not execute orders they represent as agent on the Exchange against orders solicited from Members and non-member broker-dealers to transact with such orders unless the unsolicited order is first exposed on the Exchange for at least one (1) second, or the EEM utilizes the MIAX PRIME or the PRIME Solicitation Mechanism pursuant to Rule 515A).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ The term “Electronic Exchange Member” or “EEM” means the holder of a Trading Permit who is not a Market Maker. Electronic Exchange Members are deemed “members” under the Exchange Act. See Exchange Rule 100.

⁴ The term “Market Makers” refers to “Lead Market Makers”, “Primary Lead Market Makers” and “Registered Market Makers” collectively. See Exchange Rule 100.

⁵ The term “System” means the automated trading system used by the Exchange for the trading of securities. See Exchange Rule 100.

⁶ The term “Priority Customer Order” means an order for the account of a Priority Customer. See Exchange Rule 100. The term “Priority Customer” means a person or entity that (i) is not a broker or dealer in securities, and (ii) does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). The number of orders shall be counted in accordance with Interpretation and Policy .01 of Exchange Rule 100.

the account(s) of Priority Customers, and will no longer need to designate specific classes for EEMs to engage in this type of activity. Accordingly, the Exchange believes that subsection (a)(1) of the current rule is no longer necessary and is redundant. Therefore, the Exchange proposes to delete subsection (a)(1). Similarly, the Exchange proposes to delete the beginning text of subsection (a)(2), which states “In all other classes,” as this rule text is no longer necessary in accordance with the Exchange’s proposal to also delete subsection (a)(1).

Additionally, the Exchange proposes to insert text into the first sentence of current Exchange Rule 520(a)(2) to specify that Priority Customer Orders would continue to be subject to the restrictions of that subsection. The Exchange proposes to delete the text in the first sentence of current subsection (a)(2) regarding limit orders entered by EEMs as principal or agent to clarify that all Priority Customer Orders are subject to the restrictions of that subsection. The Exchange also proposes to amend the hierarchical scheme in the first sentence of current subsection (a)(2) to insert romanettes “(i)” and “(ii)” to clarify the two conditions that must exist for the entry of Priority Customer Orders to be subject to the restrictions of current subsection (a)(2). The Exchange further proposes to delete the text in the first sentence of current subsection (a)(2) that states “or related” when referring to the account or accounts of the same beneficial owner. The purpose of this change is to remove outdated rule text and to align the Exchange’s proposed rule with a competing options exchange that has a rule consistent with this proposal.⁸ The Exchange believes this is a non-substantive change and is consistent with the Exchange’s proposal to delete subsection (a)(1) of the rule. The Exchange does not believe that deleting the text “or related” will not [sic] have any impact to Members as the remaining text continues to apply to “the account or accounts of the same beneficial owner(s).” The Exchange also proposes to capitalize the term “Market Maker” throughout current subsection (a)(2) to harmonize the rule text to the definition of Market Maker in Exchange Rule 100 and clarify that the rule text of current

subsection (a)(2) refers to Market Makers on the Exchange. The Exchange proposes to delete the term “Electronic Exchange Member” in the second sentence of current subsection (a)(2) as the purpose of this proposed rule change is to remove the restrictions of current subsection (a)(2) as they currently pertain to EEMs effectively operating as Market Makers. Additionally, the Exchange proposes to replace the term “option contract” throughout current subsection (a)(2) with the term “security” or “securities,” where appropriately used in the singular or plural. The purpose of these proposed changes are to align the Exchange’s proposed rule with competing options exchanges that have rules consistent with this proposal.⁹

Further, Exchange Rule 520(a)(2) currently provides that, in determining whether an EEM or beneficial owner effectively is operating as a Market Maker, the Exchange will consider, among other things: The simultaneous or near-simultaneous entry of limit orders to buy and sell the same option contract; the multiple acquisition and liquidation of positions in the same options during the same day; and the entry of multiple limit orders at different prices in the same options series. The Exchange proposes to remove the second condition pertaining to the multiple acquisition and liquidation of positions from its list of factors used for determining whether an EEM or beneficial owner is operating as a Market Maker. In light of the proliferation of day trading activity and the fact that such a prohibition does not exist on other markets,¹⁰ the Exchange no longer believes this activity should be considered a factor in determining whether an EEM or beneficial owner is effectively acting as a Market Maker.

With the proposed changes, Exchange Rule 520(a) would be amended to state as follows:

Electronic Exchange Members shall not enter into the System Priority Customer Orders in the same options series if (i) the orders are limit orders for the account or accounts of the same beneficial owner(s) and (ii) the limit orders are entered in such a manner that the beneficial owner(s) effectively is operating as a Market Maker by holding itself out as willing to buy and sell such securities on a regular or continuous basis. In determining whether a

beneficial owner effectively is operating as a Market Maker, the Exchange will consider, among other things, the simultaneous or near-simultaneous entry of limit orders to buy and sell the same security and the entry of multiple limit orders at different prices in the same security.

Accordingly, the restrictions contained in current Exchange Rule 520(a)(2) against entering limit orders into the System would no longer be applicable to EEMs, except when entering Priority Customer Orders for account of the same beneficial owner. Further, current Exchange Rule 520(a)(1) would be deleted in its entirety.

2. Statutory Basis

The Exchange believes that its proposed rule change is consistent with Section 6(b) of the Act¹¹ in general, and furthers the objectives of Section 6(b)(5) of the Act¹² in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes its proposal promotes just and equitable principles of trade, removes impediments to and perfects the mechanisms of a free and open market and a national market system, and in general, protects investors and the public interest by removing the prohibition on EEMs from entering limit orders in such a manner to effectively operate as Market Makers will more freely permit the entry of orders by EEMs, resulting in more orders on the Exchange. The increase in more orders on the Exchange should increase liquidity on the Exchange, which would benefit all market participants.

The Exchange believes its proposal to prohibit EEMs from entering Priority Customer Orders for the account of the same beneficial owner such that the beneficial owner is effectively operating as a Market Maker continues to promote just and equitable principles of trade because Priority Customer Orders have priority over the bids and offers of non-Priority Customer Orders. Because Priority Customers are provided with

⁸ See Cboe Exchange, Inc. Rules, CHAPTER VI. DOING BUSINESS ON THE EXCHANGE FLOOR, Rule 6.8, Prohibition Against Customers Functioning as Market-Makers; Securities Exchange Act Release No. 59700 (April 2, 2009), 67 FR 16246 (April 9, 2009)(SR-CBOE-2009-009) (Order Approving a Proposed Rule Change To Amend its Rules Prohibiting Members From Functioning as Market Makers).

⁹ See *id.*; see also Nasdaq ISE, LLC, Options 3 Options Trading Rules, Section 22(a); Securities Exchange Act Release No. 63017 (September 29, 2010), 75 FR 61795 (October 6, 2010)(SR-ISE-2010-95).

¹⁰ See *id.*

¹¹ 15 U.S.C. 78f(b).

¹² 15 U.S.C. 78f(b)(5).

certain benefits such as priority of bids and offers, the Exchange believes its proposal to continue to subject Priority Customer Orders to the restrictions of current Exchange Rule 520(a)(2) will protect investors and the public interest. The Exchange believes its proposal to remove the restrictions of current subsection (a)(2) on EEMs entering broker-dealer and Voluntary Professional orders in such a manner that the EEM is effectively operating as a Market Maker promotes just and equitable principles of trade because those orders do not receive the same benefits as Priority Customer Orders, such as priority of bids and offers.

Similarly, the Exchange believes its proposal to delete subsection (a)(1) and specific text in subsection (a)(2) promotes just and equitable principles of trade, removes impediments to and perfects the mechanisms of a free and open market and a national market system, and in general, protects investors and the public interest by removing provisions of the rule text that no longer apply in light of the Exchange's proposal to allow EEMs to enter buy and sell limit orders in the same options series for the account or accounts of the same beneficial owners, other than for the account(s) of Priority Customers. Accordingly, the Exchange will no longer need to designate specific classes for EEMs to engage in this type of market making activity pursuant to subsection (a)(1). This proposed change will provide greater clarity to Members and the public regarding the Exchange's rules and it is in the public interest for rules to be accurate and concise so as to eliminate the potential for confusion.

The Exchange believes its proposal to remove the second condition pertaining to the multiple acquisition and liquidation of positions from its list of factors used for determining whether an EEM or beneficial owner is operating as a Market Maker promotes just and equitable principles of trade, removes impediments to and perfects the mechanisms of a free and open market and a national market system, and in general, protects investors and the public interest because of the proliferation of day trading activity and the fact that such a prohibition does not exist on other markets.¹³

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intra-Market Competition

Specifically, the Exchange believes that removing the prohibition on EEMs from entering limit orders such that EEMs may enter limit orders in such a manner to effectively operate as Market Makers will further promote competition on the Exchange, increase order flow and liquidity, leading to tighter, more efficient markets to the benefit of all market participants.

The Exchange believes that the prohibition on EEMs from entering Priority Customer Orders for the account of the same beneficial owner such that the beneficial owner is effectively operating as a Market Maker does not impose any burden on competition that is not necessary or appropriate because Priority Customers are provided with certain benefits such as priority of bids and offers that are not shared by other market participants.

Inter-Market Competition

The Exchange believes that its proposal to remove the prohibition on EEMs from entering limit orders such that EEMs may enter limit orders in such a manner to effectively operate as Market Makers will not impose any burden on intermarket competition not necessary or appropriate in furtherance of the purposes of the Act because of the proliferation of day trading activity and the fact that such a prohibition does not exist on other markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁴ and Rule 19b-4(f)(6) thereunder.¹⁵

¹⁴ 15 U.S.C. 78s(b)(3)(A).

¹⁵ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act¹⁶ normally does not become operative for 30 days after the date of its filing. However, Rule 19b-4(f)(6)(iii)¹⁷ permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposed rule change may become operative upon filing. Waiver of the operative delay would allow the Exchange to immediately harmonize with similar rules on other exchanges that allow EEMs to effectively operate as Market Makers. Therefore, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.¹⁸

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-MIAX-2019-33 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange

¹⁶ 17 CFR 240.19b-4(f)(6).

¹⁷ 17 CFR 240.19b-4(f)(6)(iii).

¹⁸ For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

¹³ See *supra* note 9.

Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-MIAX-2019-33. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-MIAX-2019-33, and should be submitted on or before August 27, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁹

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019-16719 Filed 8-5-19; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-86535; File No. SR-MRX-2019-16]

Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Options 2 (Options Market Participants) and Options 3 (Options Trading Rules) Relating to Certain Order Types

July 31, 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 July 24, 2019, Nasdaq MRX, LLC ("MRX" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Options 2 (Options Market Participants) and Options 3 (Options Trading Rules) relating to certain order types.

The text of the proposed rule change is available on the Exchange's website at <http://nasdaqmrxcchwallstreet.com/>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is amend Options 2 (Options Market Participants) and Options 3 (Options Trading Rules) relating to certain order types. Each change is described in more detail below.

Stopped Orders

The Exchange proposes to amend its rules to remove Stopped Orders as an order type. A Stopped Order is a limit order that meets the requirements of Options 5, Section 2(b)(8).³ As provided in Options 5, Section 2(b)(8), a "stopped order" is defined as an order for which, at the time of receipt for the order, a Member had guaranteed an execution at no worse than a specified price, where: (i) The stopped order was for the account of a Customer; (ii) the Customer agreed to the specified price on an order-by-order basis; and (iii) the price of the Trade-Through was, for a stopped buy order, lower than the national Best Bid in the options series at the time of execution, or, for a stopped sell order, higher than the national Best Offer in the options series at the time of execution. To execute Stopped Orders, Members must enter them into the Facilitation Mechanism or Solicited Order Mechanism pursuant to Options 3, Section 11.⁴

Due to a lack of demand for Stopped Orders, the Exchange plans to decommission the functionality supporting this order type.⁵ To reflect this elimination, the Exchange proposes to delete all references to Stopped Orders as follows:

- Options 2, Section 6(a), which currently allows Market Makers to enter all order types in the options classes to which they are appointed, except for Stopped Orders, Reserve Orders, and Customer Cross Orders.
- Options 3, Section 7(b)(5), which defines a Stopped Order.

The Exchange proposes to implement the amendments relating to Stopped Orders by November 1, 2019.

³ See Options 3, Section 7(b)(5).

⁴ Stopped orders were originally introduced on the Exchange as a Trade-Through exception under the Options Order Protection and Locked/Crossed Market Plan (the "Plan"). MRX adopted rules to implement the Trade-Through exception for stopped orders as an order type. See Securities Exchange Act Release No. 76998 (January 29, 2016), 81 FR 6066 (February 4, 2016) (File No. 10-221).

⁵ No member has used this order type since the Exchange's previous trading system migrated over to Nasdaq INET technology in 2017.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

¹⁹ 17 CFR 200.30-3(a)(12).

All-or-None Orders

The Exchange also proposes to amend Options 3, Section 8 (Opening) to remove specific references to the manner in which All-Or-None Orders⁶ ("AONs") will be treated in the Exchange's opening process. The Exchange previously amended its rules to provide that an AON may only be entered into the System with a time-in-force designation of Immediate-Or-Cancel,⁷ and deleted related rule text that described an AON as persisting in the Exchange's order book.⁸ The Exchange, however, inadvertently did not remove such AON references from the opening process rule in Options 3, Section 8. At the time the Exchange's opening process was adopted, AONs were not restricted and could trade as a limit or market order to be executed in its entirety or not at all.⁹ With the amendments in SR-MRX-2017-02, an AON does not persist in the order book and is therefore treated the same as any other Immediate-or-Cancel Order. As such, the carve-outs specified in Section 8(b), (g) and (j)(6) are unnecessary since an All-Or-None Order would execute immediately or cancel similar to other orders which trade in the same manner. The Exchange believes removing these references will eliminate confusion.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,¹⁰ in general, and furthers the objectives of Section 6(b)(5) of the Act,¹¹ in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

The Exchange believes that removing Stopped Orders as an order type is consistent with the Act because it would simplify the functionality available on the Exchange and reduce

the complexity of its order types. The Exchange's affiliated options markets, Nasdaq BX ("BX"), The Nasdaq Options Market ("NOM"), Nasdaq PHLX ("Phlx") and Nasdaq ISE, LLC do not offer stopped orders as an order type.

The Exchange also believes that it is consistent with the Act to remove unnecessary and confusing references to AONs in the opening rule set forth in Options 3, Section 8 as AONs will now immediately trade or cancel. The Exchange originally specified the manner in which AONs would trade in the opening because at the time the opening process was adopted, this order type traded differently as compared to other order types. That distinction has become unnecessary because AONs trade the same as other Immediate-or-Cancel Orders. Updating Options 3, Section 8 to remove an unnecessary and inaccurate distinction will protect investors and the public interest by clarifying the rule.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change would allow the Exchange to remove an order type that no Member uses today, and eliminate unnecessary and inaccurate references to AONs within its opening rule, thereby making clear the order types available for trading on the Exchange and reducing potential confusion.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act¹² and subparagraph (f)(6) of Rule 19b-4 thereunder.¹³

¹² 15 U.S.C. 78s(b)(3)(A)(iii).

¹³ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-MRX-2019-16 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-MRX-2019-16. 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

prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

⁶ An All-Or-None Order is a limit or market order that is to be executed in its entirety or not at all. An All-Or-None Order may only be entered as an Immediate-or-Cancel Order. See Options 3, Section 7(c).

⁷ An Immediate-Or-Cancel Order is a limit order that is to be executed in whole or in part upon receipt. Any portion not so executed is to be treated as cancelled. See Options 3, Section 7(b)(3). See Securities Exchange Act Release No. 81204 (July 25, 2017), 82 FR 35557 (July 31, 2017) (SR-MRX-2017-02).

⁸ See Securities Exchange Act Release No. 82129 (November 20, 2017), 82 FR 56084 (November 27, 2017) (SR-MRX-2017-24).

⁹ See Securities Exchange Act Release No. 80937 (June 15, 2017), 82 FR 28113 (June 20, 2017) (SR-MRX-2017-01).

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(5).

inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-MRX-2019-16 and should be submitted on or before August 27, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁴

Jill M. Peterson,
Assistant Secretary.

[FR Doc. 2019-16720 Filed 8-5-19; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94-409, the Securities and Exchange Commission will hold an Open Meeting on Thursday, August 8, 2019 at 10:00 a.m.

PLACE: The meeting will be held in Auditorium LL-002 at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will begin at 10:00 a.m. (ET) and will be open to the public. Seating will be on a first-come, first-served basis. Visitors will be subject to security checks. The meeting will be webcast on the Commission's website at www.sec.gov.

MATTERS TO BE CONSIDERED:

1. The Commission will consider whether to propose rule amendments to modernize the description of business, legal proceedings, and risk factor disclosures that registrants are required to make pursuant to Regulation S-K. The proposed amendments are intended to update these rules to account for developments since their adoption or last amendment, to improve these disclosures for investors, and to simplify compliance efforts for registrants.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

CONTACT PERSON FOR MORE INFORMATION: For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact

Vanessa A. Countryman, Office of the Secretary, at (202) 551-5400.

Dated: August 1, 2019.

Vanessa A. Countryman,
Secretary.

[FR Doc. 2019-16850 Filed 8-2-19; 11:15 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-86537; File No. SR-NASDAQ-2019-060]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing of Proposed Rule Change To Amend Rules 4120 and 4753

July 31, 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 July 18, 2019, The Nasdaq Stock Market LLC ("Nasdaq" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rules 4120 and 4753 to permit the Exchange to declare a regulatory halt in a security that traded in the over-the-counter market prior to the initial pricing on the Exchange and to allow for the initial pricing of such securities through the IPO Cross.

The text of the proposed rule change is available on the Exchange's website at <http://nasdaq.cchwallstreet.com>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set

forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq proposes to amend Rule 4120 to permit the Exchange to declare a regulatory halt in a security that traded in the over-the-counter market (the "OTC market") prior to the initial pricing on the Exchange. Nasdaq also proposes to amend Rule 4753 to allow for the initial pricing on the Exchange of such securities through the IPO Cross where a broker-dealer is willing to serve in the role of financial advisor to the issuer and perform the functions under Rule 4120(c)(8) that are ordinarily performed by an underwriter with respect to an initial public offering. Finally, the proposed change would state that where a security previously traded in the OTC market pursuant to FINRA Form 211 is initially priced using the IPO Cross, the fourth tie-breaker for each of the Current Reference Price disseminated in the Nasdaq Order Imbalance Indicator and the price at which the Nasdaq Halt Cross will occur shall be the most recent transaction price in the over-the-counter market.

Background

In 2014, Nasdaq first adopted rules to allow the use of the Nasdaq IPO Cross to initiate trading in securities that have not been listed on a national securities exchange or traded in the over-the-counter market pursuant to FINRA Form 211 (the "OTC market") immediately prior to the initial pricing and described the role of financial advisors in that process.³ At that time, the Exchange added new Rule 4120(c)(9)⁴ to set forth the process by which trading commences in such securities. Under that rule, securities of companies that have not previously been listed on a national securities exchange or traded in the OTC market pursuant to FINRA Form 211 immediately prior to listing on Nasdaq can be launched for trading using the same crossing mechanism

³ Securities Exchange Act Release No. 71931 (April 11, 2014), 79 FR 21829 (April 17, 2014) (SR-NASDAQ-2014-032) (the "2014 Rule Change").

⁴ In 2014, Nasdaq filed SR-NASDAQ-2014-081 modifying the functions that are performed by an underwriter with respect to an initial public offering and renumbered certain paragraphs of Rule 4120. Securities Exchange Act Release No. 73399 (October 21, 2014), 79 FR 63981 (October 27, 2014) (approving SR-NASDAQ-2014-81). All references in this filing are to the renumbered rules, as currently in effect.

¹⁴ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

available for IPOs outlined in Rule 4120(c)(8) and Rule 4753 (the "IPO Cross"). Prior to that rule change, securities of companies that were not conducting IPOs were released using the Halt Cross outlined in Rule 4120(c)(7), which differed from the IPO Cross.⁵

The 2014 Rule Change extended the safeguards contained in the IPO Cross to securities that have not been listed on a national securities exchange or traded in the OTC market immediately prior to the initial pricing and established that a broker-dealer serving in the role of financial advisor to the issuer could serve in the same capacity for such securities as the underwriter does for IPOs. Specifically, Rule 4120(c)(9) provides that the IPO Cross process described in Rules 4120 and 4753 is available to securities that have not been listed on a national securities exchange or traded in the OTC market immediately prior to the initial pricing where "a broker-dealer serving in the role of financial advisor to the issuer of the securities being listed is willing to perform the functions under Rule 4120(c)(8) that are performed by an underwriter with respect to an initial public offering."⁶ Rule 4753 provides the definition of Current Reference Price and a description of the calculation of the price at which the Nasdaq Halt Cross will occur.⁷

When Nasdaq added Rule 4120(c)(9) in 2014, it cross-referenced Rule 4753 but did not modify it. In 2019, Nasdaq amended Rule 4753 to elaborate the role of a financial advisor to the issuer of a security that has not been listed on a national securities exchange or traded in the OTC market immediately prior to the initial pricing.⁸ Nasdaq has successfully employed the IPO Cross for securities that have not been listed on a national securities exchange or traded in the OTC market pursuant to FINRA Form 211 immediately prior to the initial pricing since 2014 and continues

to believe that financial advisors to issuers seeking to utilize that process are well placed to perform the functions that are currently performed by underwriters with respect to an initial public offering.

Proposed Rule Change

Nasdaq now proposes to amend Rules 4120 and 4753, based on the same rationale that supported the 2014 Rule Change, to permit the Exchange to declare a regulatory halt in a security that traded in the over-the-counter market prior to the initial pricing on the Exchange.

The Exchange proposes to delete the clause "or traded in the over-the-counter market pursuant to FINRA Form 211" in Rule 4120 before "immediately prior to the initial pricing." The proposed amendment would thus enable the Exchange to declare a regulatory halt for a security that is having its initial listing on the Exchange that was traded in the OTC market immediately prior to its initial pricing on the Exchange.

Nasdaq believes that it would be consistent with the protection of investors and the public interest for the Exchange, as a primary listing exchange, to have to authority to declare a regulatory halt for a security that was previously traded in the OTC market prior to its initial pricing on Nasdaq. An OTC market security that will be listed on a primary listing exchange will be removed from the OTC trading list on the day prior to its initial pricing on the Exchange. However, on the day of its initial listing, such security can trade on an unlisted trading permit ("UTP") basis before the first transaction on the primary listing exchange. The Exchange believes that permitting the Exchange to declare a regulatory halt in such securities before trading on the Exchange begins would avoid potential price disparities or anomalies that may occur during any UTP trading before the first transaction on the primary listing exchange.

More specifically, the Exchange believes that quoting and trading in the pre-market of an OTC transfer can be erratic and investors may be harmed if their securities trade during this period. The Exchange believes that the proposed limited authority to declare a regulatory halt in the hours prior to the OTC transfer pricing on the Exchange would mitigate any potential price disparities and contribute to a fair and orderly market once the security opens on the Exchange. The Exchange believes that such authority would be consistent with the protection of investors and the public interest.

In addition, Nasdaq proposes to allow for the initial pricing of such securities through the IPO Cross where a broker-dealer is willing to serve in the role of financial advisor to the issuer and perform the functions under Rule 4120(c)(8) that are ordinarily performed by an underwriter with respect to an initial public offering. To that end, Nasdaq proposed to add Rules 4753(a)(3)(A)(iv)(e) and 4753(b)(2)(D)(v) to state that in the case of the initial pricing of a security that traded in the over-the-counter market pursuant to FINRA Form 211 immediately prior to the initial pricing, the fourth tie-breaker in calculating each of the Current Reference Price disseminated in the Nasdaq Order Imbalance Indicator and the price at which the Nasdaq Halt Cross will occur, respectively, shall be the most recent transaction price in that market. Nasdaq believes that such price is predictive of the price in the market for the common stock that will develop upon listing of the securities on Nasdaq and that it is therefore appropriate to use the price from such trading to determine the Current Reference Price and the price at which the Nasdaq Halt Cross will occur. Nasdaq also believes that the IPO Cross will be a better mechanism to open trading in these cases, given that these companies may attract significant interest upon listing on the Exchange from investors who previously could not invest in a security that was traded in the OTC market. In that way, the initial interest in the security upon its listing on the Exchange is similar to the interest in an initial public offering.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,⁹ in general, and furthers the objectives of Section 6(b)(5) of the Act,¹⁰ in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

The Exchange believes that the proposed amendment to Rules 4120 and 4753 to provide authority to declare a regulatory halt in a security that is an OTC transfer would remove impediments to and perfect the mechanism of a free and open market and a national market system by providing the Exchange with authority to halt trading across all markets for a security that has traded in the OTC

⁵ The Halt Cross process has a shorter quoting period (five minutes) and provides no ability to extend the quoting period in the event trading interest or volatility in the market appears likely to have a material impact on the security, unless there is an order imbalance as defined in the rule. See the 2014 Rule Change for additional details on the differences between the Halt Cross and the IPO Cross.

⁶ Subsequent to the 2014 Rule Change Nasdaq expanded and elaborated the functions that are performed by an underwriter with respect to an initial public offering. See footnote 4, above. Rule 4120(c)(9) requires a broker-dealer serving in the role of a financial advisor to the issuer of the securities being listed to perform all such functions in order for the issuer to utilize the IPO Cross for the initial pricing of the security.

⁷ Rules 4753(a)(3)(A) and 4753(b)(2)(D).

⁸ Securities Exchange Act Release No. 85156 (February 15, 2019), 84 FR 5787 (February 22, 2019) (SR-NASDAQ-2019-001).

⁹ 15 U.S.C. 78f(b).

¹⁰ 15 U.S.C. 78f(b)(5).

market and not previously listed on the Exchange, but for which a regulatory halt would promote fair and orderly markets. The Exchange believes that permitting the Exchange to declare a regulatory halt in such securities before trading on the Exchange begins would avoid potential price disparities or anomalies that may occur during any UTP trading before the first transaction on the primary listing exchange.¹¹ More specifically, the Exchange believes that quoting and trading in the pre-market of an OTC transfer can be erratic and investors may be harmed if their securities trade during this period. The Exchange therefore believes that having the authority to declare a regulatory halt for a security that is the subject of an OTC transfer is consistent with the protection of investors and the public interest and would promote fair and orderly markets by helping to protect against volatility in pricing before the initial transaction on the primary listing exchange.

The proposed rule change to clarify the fourth tie-breaker used in calculating the Current Reference Price disseminated in the Nasdaq Order Imbalance Indicator and the price at which the Nasdaq Halt Cross will occur, protects investors and the public interest by describing such fourth tie-breaker for a security that is not the subject of an IPO, but that has traded in the OTC market pursuant to FINRA Form 211 immediately prior to the initiation of trading on Nasdaq. The proposed rule change establishes that in such a case the Current Reference Price and price at which the Nasdaq Halt Cross will occur will be the most recent transaction price in the OTC market. Nasdaq believes the most recent price from such trading is predictive of the price that will develop upon listing of the securities on Nasdaq.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the benefit to

investors to halt trading in a security that transfers from an OTC market to a primary listing exchange outweighs any burden on competition that may result from a regulatory halt in such security before the initial listing on the primary listing exchange. The proposed rule change is consistent with existing authority for the Exchange to declare a regulatory halt in trading of a security before the initial pricing on the Exchange and would extend that authority to a transfer from the OTC market.

In addition, the proposed change is designed to more fully describe the application of the IPO Halt Cross to a security that has traded in the OTC market pursuant to FINRA Form 211 immediately prior to the initiation of trading on Nasdaq in the determination of the fourth tie-breaker in calculating the Current Reference Price for the security and the price at which the Nasdaq Halt Cross will occur. The proposed rule change will have no impact on competition as it is merely designed to improve the opening process for investors in securities of certain companies that have already chosen to list on the Exchange and to insure that the Current Reference Price and the price at which the Nasdaq Halt Cross will occur is appropriately calculated.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

- (A) By order approve or disapprove the proposed rule change, or
- (B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NASDAQ-2019-060 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-NASDAQ-2019-060. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NASDAQ-2019-060, and should be submitted on or before August 27, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹²

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019-16722 Filed 8-5-19; 8:45 am]

BILLING CODE 8011-01-P

¹¹ Approving similar changes to Rule 123D of the New York Stock Exchange (NYSE), the Commission stated that it "believes that extending the authority of the [NYSE] to declare a regulatory trading halt prior to the initial pricing on the [NYSE] of securities that were previously traded in the OTC market is consistent with the Act because it is reasonably designed to address any potential price disparities or anomalies that may occur during UTP trading before the first transaction on the [NYSE]." See Securities Exchange Act Release No. 86351 (July 11, 2019), 84 FR 34219 (July 17, 2019) (Approving SR-NYSE-2019-32).

¹² 17 CFR 200.30-3(a)(12).

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****[Summary Notice No. PE–2019–47]****Petition for Exemption; Summary of Petition Received; The Boeing Company****AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before August 26, 2019.

ADDRESSES: Send comments identified by docket number FAA–2019–0571 using any of the following methods:

- *Federal eRulemaking 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: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

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 the 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:

Deana Stedman, AIR–673, Federal Aviation Administration, 2200 South 216th Street, Des Moines, WA 98198, phone and fax 206–231–3187, email Deana.Stedman@faa.gov; or Alphonso Pendergrass, ARM–200, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591, phone 202–267–4713, email Alphonso.Pendergrass@faa.gov.

This notice is published pursuant to 14 CFR 11.85.

Issued in Des Moines, Washington, on July 31, 2019.

Victor Wicklund,*Manager, Transport Standards Branch.***Petition for Exemption***Docket No.:* FAA–2019–0571.*Petitioner:* The Boeing Company.*Section(s) of 14 CFR Affected:*

§ 25.1461.

Description of Relief Sought: Boeing Defense Space and Security is petitioning for an exemption of the affected section of 14 CFR to allow revision of Supplemental Type Certificate (STC) No. ST00157MC for the Model 767–2C military tanker airplane. The exemption would apply to the ram air turbine on the wing aerial refueling pod and would apply to military use only.

[FR Doc. 2019–16716 Filed 8–5–19; 8:45 am]

BILLING CODE 4910–13–P**DEPARTMENT OF TRANSPORTATION****Bureau of Transportation Statistics****[Docket ID Number: DOT–OST–2014–0031]****Agency Information Collection; Activity Under OMB Review; Passenger Origin-Destination Survey Report**

AGENCY: Office of the Assistant Secretary for Research and Technology (OST–R), Bureau of Transportation Statistics (BTS), DOT.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this notice announces that the Information Collection Request (ICR) abstracted below will be forwarded to the Office of Management and Budget (OMB) for extension of currently approved collections. The ICR describes the

nature of the information collection and its expected burden. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on April 30, 2019. No comments were received.

DATES: Written comments should be submitted by September 5, 2019.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, Attention: OST Desk Officer.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department. Comments should address whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT:

James Bouse, Office of Airline Information, RTS–42, Room E34–441, OST–R, BTS, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, Telephone Number (202) 366–4876, Fax Number (202) 366–3383 or EMAIL james.bouse@dot.gov.

Comments: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, Attention: OST Desk Officer.

SUPPLEMENTARY INFORMATION:*OMB Approval No.:* 2139–0013.*Title:* Passenger Origin-Destination Survey Report.*Form No.:* None.*Type of Review:* Extension of a currently approved collection.*Respondents:* Large certificated air carriers that provide scheduled passenger service.*Number of Respondents:* 47.*Total Number of Annual Responses:* 188.*Estimated Time per Response:* 60 hours.*Total Annual Burden:* 11,280 hours.

Needs and Uses: Survey data are used in monitoring the airline industry, negotiating international agreements, reviewing requests for the grant of anti-trust immunity for air carrier alliance agreements, selecting new international routes, selecting U.S. carriers to operate

limited entry foreign routes, and modeling the spread of contagious diseases. The Passenger Origin-Destination Survey Report is the only aviation data collection by DOT where the air carriers report the true origins and destinations of passengers' flight itineraries. The Department does have another aviation data collection (T-100) which (1) gives passenger totals for city-pairs served on a nonstop basis and (2) market totals for passengers traveling on a single flight number. If the passenger travels on multiple flight numbers, a new market is recorded for each change in flight number.

The Confidential Information Protection and Statistical Efficiency Act of 2002 (44 U.S.C. 3501 note), requires a statistical agency to clearly identify information it collects for non-statistical purposes. BTS hereby notifies the respondents and the public that BTS uses the information it collects under this OMB approval for non-statistical purposes including, but not limited to, publication of both Respondent's identity and its data, submission of the information to agencies outside BTS for review, analysis and possible use in regulatory and other administrative matters.

Issued in Washington, DC, on July 17, 2019.

William Chadwick, Jr.,

*Director, Office of Airline Information,
Bureau of Transportation Statistics.*

[FR Doc. 2019-16280 Filed 8-5-19; 8:45 am]

BILLING CODE 4910-9X-P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Department of the Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of persons whose property and interests in property have been unblocked and who have been removed from the list of Specially Designated Nationals and Blocked Persons.

DATES: See Supplementary Information section.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, tel.: 202-622-2420; Assistant Director for Licensing, tel.: 202-622-2480; Assistant Director for Regulatory Affairs, tel.: 202-622-4855; Assistant Director for Sanctions Compliance &

Evaluation, tel.: 202-622-2490; 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 (SDN List) and additional information concerning OFAC sanctions programs are available on OFAC's website (<https://www.treasury.gov/ofac>).

Notice of OFAC Actions

On August 1, 2019, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are unblocked, and removed these persons from the SDN List pursuant to the Foreign Narcotics Kingpin Designation Act.

Individuals

1. CHACON ROSSELL, Marllory Dadiana; DOB 04 Oct 1972; POB Guatemala City, Guatemala; nationality Guatemala (individual) [SDNTK].

2. GARZA RODRIGUEZ, Beatriz (a.k.a. GARZA RODRIGUEZ DE SANCHEZ, Beatriz), Av. Vallarta No. 3060, Colonia Vallarta San Jorge, Guadalajara, Jalisco, Mexico; 5151-37 A Av. Acueducto, La Colonia Residencial Pontevedra, Zapopan, Jalisco, Mexico; DOB 14 Nov 1948; POB Los Mochis, Sinaloa, Mexico; R.F.C. GARB481114965 (Mexico); C.U.R.P. GARB481114MSLRDT03 (Mexico) (individual) [SDNTK] (Linked To: INMOBILIARIA CORSANCH, S.A. DE C.V.).

3. PEREZ ALZATE, Guillermo (a.k.a. "PABLO SEVILLANO"), Diagonal 50 No. 49-14 of. 601, Medellin, Colombia; Calle 26A No. 70-35, Medellin, Colombia; Calle 30 No. 9-51, Monteria, Cordoba, Colombia; Calle 24 No. 1-52, B. Cta de Oro, Colombia; Calle 37 No. 2-40, Almacén Dulcino, Tumaco, Narino, Colombia; Cedula No. 71646827 (Colombia); Passport AF891052 (Colombia) (individual) [SDNTK].

4. QUINTERO NAVIDAD, Sajid Emilio (a.k.a. QUINTERO NAVIDAD, Sagid; a.k.a. "EL CADETE"); DOB 22 Nov 1980; POB Zapopan, Jalisco, Mexico; nationality Mexico; citizen Mexico; C.U.R.P. QUNS801122HJCNVJ00 (Mexico) (individual) [SDNTK].

5. RIEBELING CORDERO, Hilda, 3888 Calle Paseo de los Parques, Colonia Colinas de San Javier, Zapopan, Jalisco, Mexico; DOB 21 Jan 1972; POB Guadalajara, Jalisco, Mexico; Passport 99140083768 (Mexico); R.F.C. RICH7201214J3 (Mexico); C.U.R.P. RICH720121MJCBL08 (Mexico) (individual) [SDNTK].

6. SANCHEZ GARZA, Diego, Av. Vallarta No. 3060, Colonia Vallarta San Jorge, Guadalajara, Jalisco, Mexico; DOB 05 Apr 1976; POB Guadalajara, Jalisco, Mexico; R.F.C. SAGD760405A45 (Mexico); C.U.R.P. SAGD760405HJCNRG06 (Mexico) (individual) [SDNTK] (Linked To: GRUPO FRACSA, S.A. DE C.V.; Linked To: DBARDI,

S.A. DE C.V.; Linked To: GRUPO CONSTRUCTOR SEGUNDO MILENIO, S.A. DE C.V.; Linked To: BOCADOS DE AUTOR, S.A. DE C.V.).

7. SANCHEZ GARZA, Jose de Jesus, Av. Vallarta No. 3060, Colonia Vallarta San Jorge, Guadalajara, Jalisco, Mexico; DOB 12 Aug 1968; POB Guadalajara, Jalisco, Mexico; Passport 98140159994 (Mexico); R.F.C. SAGJ680812RE1 (Mexico); C.U.R.P. SAGJ680812HJCNRS08 (Mexico) (individual) [SDNTK] (Linked To: GRUPO FRACSA, S.A. DE C.V.; Linked To: DBARDI, S.A. DE C.V.).

8. SANCHEZ GARZA, Mauricio, Av. Vallarta No. 3060, Colonia Vallarta San Jorge, Guadalajara, Jalisco, Mexico; DOB 07 Dec 1970; POB Guadalajara, Jalisco, Mexico; Passport 99140083769 (Mexico); R.F.C. SAGM7012071B6 (Mexico); C.U.R.P. SAGM701207HJCNRR05 (Mexico) (individual) [SDNTK] (Linked To: DBARDI, S.A. DE C.V.; Linked To: GRUPO FRACSA, S.A. DE C.V.).

9. SANCHEZ BARBA, Jose de Jesus, Av. Vallarta No. 3060, Col. Vallarta San Jorge, Guadalajara, Jalisco, Mexico; 5151-37 A Avenida Acueducto, La Colonia Residencial Pontevedra, Zapopan, Jalisco, Mexico; DOB 02 Jul 1937; POB Tepatitlan de Morelos, Jalisco, Mexico; C.U.R.P. SABJ370702HJCNRS04 (Mexico) (individual) [SDNTK].

Entities

1. ALMACEN PICIS, 3 Avenida 19-59, Local 14, Zona 1, Guatemala City, Guatemala; Registration ID 80617 (Guatemala) [SDNTK].

2. ALQUILERES ROSSELL, Km 12.5 Carretera Al Salvador, Santa Rosalia, Condominio La Laguna, Casa 1, Guatemala, Guatemala; Registration ID 388175 (Guatemala) [SDNTK].

3. ANDREA YARI S.A. (a.k.a. ANDREAYARI, S.A.), 2 Calle 6AVE, Barrio El Centro San Pedro Sula, Cortes, Honduras; RUC #45476-12-300189 (Panama) [SDNTK].

4. AUTO HOTEL PUNTO CERO, Kilometro 49.5 Carretera A El Salvador, Aldea El Cernal, Barberena, Santa Rosa, Guatemala; Registration ID 404256 (Guatemala) [SDNTK].

5. BOCADOS DE AUTOR, S.A. DE C.V. (a.k.a. LUCRECIA BAR), Av. Pablo Neruda 3085, Colonia Providencia, Guadalajara, Jalisco 44630, Mexico; R.F.C. BAU810024J4 (Mexico) [SDNTK].

6. BODEGAS BANYOLAS, 14 Avenida 7-12 Zona 14, Centro Empresarial La Villa Bodega 23, Guatemala City, Guatemala; Registration ID 71152 (Guatemala) [SDNTK].

7. BOUTIQUE MARLLORY, KM 54.5 Carretera Al Salvador, Santa Rosa, Barberena, Guatemala; Registration ID 159497A (Guatemala) [SDNTK].

8. BROADWAY COMMERCE INC., 17 Calle A 7-21, Zona 10, Guatemala City, Guatemala; Registration ID 60832 (Guatemala) [SDNTK].

9. CABOMARZO, 3A Calle 3-46, Zona 2, Residenciales Valles De Maria, Villa Nueva, Guatemala; Registration ID 89276 (Guatemala) [SDNTK].

10. CASA VOGUE, Km 14.1 Carretera El Salvador, Centro Comercial Paseo San Sebastian Local 92, Guatemala City, Guatemala [SDNTK].

11. CORPORACION DAIMEX S.A., 14 Avenida 7-12, Zona 14, Bodega No. 22,

Empresarial La Villa, Guatemala City, Guatemala; Registration ID 36397 (Guatemala) [SDNTK].

12. DBARDI, S.A. DE C.V., Guadalajara, Jalisco C.P. 44540, Mexico; Folio Mercantil No. 4867-1 (Mexico) [SDNTK].

13. DELPSA, 2 Calle 25-80, Zona 15, Vista Hermosa II, Apt. 800, Guatemala City, Guatemala; Registration ID 200766 (Guatemala) [SDNTK].

14. DIGITAL SYS ADVISORS, 14 Avenida 7-12 Zona 14, Bodega 22, Empresarial La Villa, Guatemala City, Guatemala; Registration ID 68326 (Guatemala) [SDNTK].

15. DISTRIBUIDORA ROSSELL, Calzada Roosevelt KM, 13 40-31, Zona 11, Guatemala City, Guatemala; Registration ID 388221 (Guatemala) [SDNTK].

16. FARFAR, 14 Avenida 7-12 Zona 14, Bodega 22, Empresarial La Villa, Guatemala City, Guatemala; Registration ID 75563 (Guatemala) [SDNTK].

17. FERNAPLAST, Km 12-5 Ruta Al Atlantico, Apto. A, Zona 18, Guatemala City, Guatemala; Registration ID 188919A (Guatemala) [SDNTK].

18. FER'SEG S.A., 2 Calle 6AVE, Barrio El Centro San Pedro Sula, Cortes, Honduras; Registration ID 160766 (Panama) [SDNTK].

19. GRUPO CONSTRUCTOR SEGUNDO MILENIO, S.A. DE C.V., Av. Acueducto, s/n Col. Fraccionamiento Jardines del Country, Guadalajara, Jalisco C.P. 44210, Mexico; Folio Mercantil No. 5269-1 (Mexico) [SDNTK].

20. GRUPO FRACSA, S.A. DE C.V. (a.k.a. PONTEVEDRA; a.k.a. ZOTOGRADE), Av. Vallarta No. 3060, Col. Vallarta Norte, Guadalajara, Jalisco, Mexico; Acueducto 5300, Zapopan, Jalisco, Mexico; Acueducto 5151, Zapopan, Jalisco, Mexico; Folio Mercantil No. 19730-1 (Mexico) [SDNTK].

21. HACIENDA SANTA INES, 3 Avenida 13-46 Zona 1, Guatemala City, Guatemala; Registration ID 319945 (Guatemala) [SDNTK].

22. HUERTAS Y HORTALIZAS, Lote 10 Aldea Las Vacas, Zona 16, Guatemala City, Guatemala; Registration ID 49720 (Guatemala) [SDNTK].

23. IMPORTADORA BORRAYO LASMIBAT, 13 Av 26-49, San Jose Las Rosas Zona 8, Guatemala City, Guatemala; Registration ID 135027 [SDNTK].

24. INMOBILIARIA CORSANCH, S.A. DE C.V., Guadalajara, Jalisco, Mexico; Folio Mercantil No. 40778 (Mexico) [SDNTK].

25. INMOBILIARIA DATEUS, 1era Avenida 7-60, Zona 14, Apartamento 1602 Del Edificio Tadeus, Guatemala City, Guatemala; Registration ID 84101 (Guatemala) [SDNTK].

26. INVERSIONES A&E, 8 Avenida 16-49 Zona 10, Edificio San Ignacio Apto. 2-A, Guatemala City, Guatemala; Registration ID 43339 (Guatemala) [SDNTK].

27. RESTAURANT BAR LOS ANDARIEGOS, S.A. DE C.V. (a.k.a. BARBARESCO RESTAURANT), Buenos Aires No. 3090, esq. Montevideo, Col. Providencia, Guadalajara, Jalisco 44630, Mexico; R.F.C. RBA0504194T6 (Mexico) [SDNTK].

28. SISTEMAS CONSTRUCTORES (a.k.a. "SICONSA"), Lote 10, Aldea Las Vacas, Zona 16, Guatemala City, Guatemala; Registration ID 34279 (Guatemala) [SDNTK].

29. WALNUTHILL, Diagonal 6 10-01, Zona 10, Centro Gerencial Las Margaritas, Torre II, Of. 301-B, Guatemala City, Guatemala; Registration ID 80886 (Guatemala) [SDNTK].

Dated: August 1, 2019.

Andrea Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2019-16745 Filed 8-5-19; 8:45 am]

BILLING CODE 4810-AL-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Art Advisory Panel—Notice of Closed Meeting

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of closed meeting of Art Advisory Panel.

SUMMARY: Closed meeting of the Art Advisory Panel will be held in Washington, DC.

DATES: The meeting will be held September 18, 2019.

ADDRESSES: The closed meeting of the Art Advisory Panel will be held at 999 North Capitol Street NE, Washington, DC 20003.

FOR FURTHER INFORMATION CONTACT: Maricarmen Cuello, AP:SEPR:AAS, 51

SW 1st Avenue, Room 1014, Miami, FL 33130. Telephone (305) 982-5364 (not a toll free number).

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App., that a closed meeting of the Art Advisory Panel will be held at 999 North Capitol Street NE, Washington, DC 20003.

The agenda will consist of the review and evaluation of the acceptability of fair market value appraisals of works of art involved in Federal income, estate, or gift tax returns. This will involve the discussion of material in individual tax returns made confidential by the provisions of 26 U.S.C. 6103.

A determination as required by section 10(d) of the Federal Advisory Committee Act has been made that this meeting is concerned with matters listed in sections 552b(c)(3), (4), (6), and (7), of the Government in the Sunshine Act, and that the meeting will not be open to the public.

Donna Hansberry,

Chief, Appeals.

[FR Doc. 2019-16708 Filed 8-5-19; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF VETERANS AFFAIRS

Health Services Research and Development Service, Scientific Merit Review Board; Notice of Meetings

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act that the subcommittees of the Health Services Research and Development Service Scientific Merit Review Board will be held on the dates below from 8:00 a.m. to approximately 4:30 p.m. (unless otherwise listed) at the 20 F Street Conference Center, 20 F Street NW, Washington, DC 20001:

Meeting	Date(s)
HSR&D Long-Term Care, Aging and Support Services Subcommittee	August 20, 2019.
HSR&D Health Care and Clinical Management Subcommittee	August 20-21, 2019.
HSR&D Behavioral, Social, and Cultural Determinants of Health and Care Subcommittee	August 20-21, 2019.
HSR&D Mentored Research Subcommittee	August 20-22, 2019.
HSR&D Randomized Program Evaluations Subcommittee	August 21-22, 2019.
HSR&D QUERI Subcommittee	August 21-22, 2019.
HSR&D Healthcare Informatics Subcommittee	August 22-23, 2019.
HSR&D Mental and Behavioral Health Subcommittee	August 22-23, 2019.
HSR&D Health Care System Organization and Delivery Subcommittee	August 23, 2019.
HSR&D Learning Health Care System Initiative Subcommittee	August 23, 2019.

The purpose of the Board is to review health services research and development applications involving:

The measurement and evaluation of health care services; the testing of new methods of health care delivery and

management; and mentored research. Applications are reviewed for scientific and technical merit, mission relevance,

and the protection of human and animal subjects.

Each subcommittee meeting of the Board will be open to the public the first day for approximately one half-hour from 8:00 a.m. to 8:30 a.m. at the start of the meeting to cover administrative matters and to discuss the general status of the program. Members of the public who wish to attend the open portion of the subcommittee meetings may dial 1 (800) 767-1750, participant code 10443.

The remaining portion of each subcommittee meeting will be closed (8:30 a.m. to 4:30 p.m.) for the discussion, examination, reference to, and oral review of the intramural research proposals and critiques. During

the closed portion of each subcommittee meeting, discussion and recommendations will include qualifications of the personnel conducting the studies (the disclosure of which would constitute a clearly unwarranted invasion of personal privacy), as well as research information (the premature disclosure of which would likely compromise significantly the implementation of proposed agency action regarding such research projects). Closing the meetings is in accordance with 5 U.S.C. 552b (c)(6) and (c)(9)(B).

Oral or written comments will be accepted from the public only for the open portion of the meetings. Those

who plan to attend the open portion of a subcommittee meeting should contact Ms. Liza Catucci, MPH, HSR&D Administrative Officer, Department of Veterans Affairs, Health Services Research and Development Service (10X2H), 810 Vermont Avenue NW, Washington, DC 20420, or by email at Liza.Catucci@va.gov. For further information, please call Ms. Catucci at (202) 443-5797.

Dated: August 1, 2019.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2019-16774 Filed 8-5-19; 8:45 am]

BILLING CODE P



FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, et al.

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 413 and 414

[CMS-1713-P]

RIN 0938-AT70

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would update and make revisions to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2020. This rule also proposes to update the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury (AKI). This proposed rule also proposes to update requirements for the ESRD Quality Incentive Program (QIP). In addition, this rule proposes a methodology for calculating fee schedule payment amounts for new Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) items and services and making adjustments to the fee schedule amounts established using supplier or commercial prices if such prices decrease within 5 years of establishing the initial fee schedule amounts. This rule also proposes to revise existing regulations related to the competitive bidding program for DMEPOS. This proposed rule also would streamline the requirements for ordering DMEPOS items, and develop a new list of DMEPOS items potentially subject to a face-to-face encounter, written orders prior to delivery and/or prior authorization requirements. Finally, this proposed rule includes requests for information on data collection resulting from the ESRD PPS technical expert panel, changing the basis for the ESRD

PPS wage index, and new requirements for the competitive bidding of diabetic testing strips.

DATES: To be assured consideration, comments must be submitted at one of the addresses provided below, no later than September 27, 2019.

ADDRESSES: In commenting, please refer to file code CMS-1713-P. 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 submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.
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-1713-P, P.O. Box 8010, Baltimore, MD 21244-8010.

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 to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1713-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

ESRDPayment@cms.hhs.gov, for issues related to the ESRD PPS and coverage and payment for renal dialysis services furnished to individuals with AKI.

Delia Houseal, (410) 786-2724, for issues related to the ESRD QIP.

DMEPOS@cms.hhs.gov, for issues related to DMEPOS payment policy.

Julia Howard, (410) 786-8645, for issues related to DMEPOS CBP Amendments

Jennifer Phillips, (410) 786-1023; Olufemi Shodeke, (410) 786-1649;

Maria Ciccanti, (410) 786-3107; and Emily Calvert, (410) 786-4277, for issues related to the DMEPOS written order, face-to-face encounter, and prior authorization requirements.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in

a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a Table of Contents. Some of the issues discussed in this preamble affect the payment policies, but do not require changes to the regulations in the Code of Federal Regulations (CFR).

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I. Executive Summary*A. Purpose*

This proposed rule contains proposals related to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), payment for renal dialysis services furnished to individuals with acute kidney injury (AKI), the ESRD Quality Incentive Program (QIP), the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) proposed amendments, and the regulations governing DMEPOS orders, face-to-face encounters, and prior authorization.

In future rulemaking years, the DMEPOS provisions will be in a separate rule from the ESRD PPS, AKI and ESRD QIP provisions.

1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On January 1, 2011, we implemented the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14) (F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This rule proposes updates and revisions to the ESRD PPS for CY 2020.

2. Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

On June 29, 2015, the President signed the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27). Section 808(a) of TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with acute kidney injury (AKI). Section 808(b) of the TPEA amended section 1834 of the Act by adding a new subsection (r) that provides for payment for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate beginning January 1, 2017. This rule proposes to update the AKI payment rate for CY 2020.

3. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

The End-Stage Renal Disease Quality Incentive Program (ESRD QIP) is authorized by section 1881(h) of the Act. The Program fosters improved patient outcomes by establishing incentives for dialysis facilities to meet or exceed performance standards established by the Centers for Medicare & Medicaid Services (CMS). This proposed rule proposes several updates for the ESRD QIP.

4. DMEPOS Fee Schedule Payment Rules

a. Establishing Payment Amounts for New DMEPOS Items and Services (Gap-Filling)

This rule proposes to establish a gap-filling methodology in regulations for pricing new items and services in accordance with sections 1834(a), (h), (i) and 1833(o) of the Act for DME, prosthetic devices, orthotics, prosthetics, surgical dressings, and custom molded shoes, extra-depth shoes, and inserts, and section 1842(b) for parental and enteral nutrients (PEN) and medical supplies, including splints and casts and intraocular lenses inserted in a physician's office.

b. Adjusting Payment Amounts for DMEPOS Items and Services Gap-Filled Using Supplier or Commercial Prices

This rule proposes a one-time adjustment to the gap-filled fee schedule amounts in cases where prices decrease by less than 15 percent.

5. Conditions of Payment To Be Applied to the Proposed Master List of DMEPOS Items

This proposed rule would streamline the requirements for ordering DMEPOS items. It would also develop one Master List of DMEPOS items potentially subject to a face-to-face encounter, written orders prior to delivery and/or prior authorization requirements under the authority provided under sections 1834(a)(1)(E)(iv), 1834(a)(11)(B), and 1834(a)(15) of the Act.

B. Summary of the Major Provisions

1. ESRD PPS

- *Update to the ESRD PPS base rate for CY 2020:* The proposed CY 2020 ESRD PPS base rate is \$240.27. This proposed amount reflects a productivity-adjusted market basket increase as required by section 1881(b)(14)(F)(i)(I) of the Act (1.7 percent), and application of the wage index budget-neutrality adjustment factor (1.004180), equaling \$240.27 ($\$235.27 \times 1.017 \times 1.004180 = \240.27).

- *Annual update to the wage index:* We adjust wage indices on an annual basis using the most current hospital wage data and the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. For CY 2020, we are proposing to update the wage index values based on the latest available data.

- *Update to the outlier policy:* We are proposing to update the outlier policy using the most current data, as well as update the outlier services fixed-dollar loss (FDL) amounts for adult and pediatric patients and Medicare Allowable Payment (MAP) amounts for adult and pediatric patients for CY 2020 using CY 2018 claims data. Based on the use of the latest available data, the proposed FDL amount for pediatric beneficiaries would decrease from \$57.14 to \$44.91, and the MAP amount would decrease from \$35.18 to \$33.82, as compared to CY 2019 values. For adult beneficiaries, the proposed FDL amount would decrease from \$65.11 to \$52.50, and the MAP amount would decrease from \$38.51 to \$36.60. The 1.0 percent target for outlier payments was not achieved in CY 2018. Outlier payments represented approximately 0.5 percent of total payments rather than 1.0 percent. We believe using CY 2018 claims data to update the outlier MAP and FDL amounts for CY 2020 would increase payments for ESRD beneficiaries requiring higher resource utilization in accordance with a 1.0 percent outlier percentage.

- *Eligibility criteria for the transitional drug add-on payment adjustment (TDAPA):* We are proposing revisions to the drug designation process regulation at 42 CFR 413.234 for new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category. Specifically, we are proposing to exclude drugs approved by the Food and Drug Administration (FDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and drugs for which the new drug application (NDA) is classified by FDA as NDA Types 3, 5, 7 and 8, Type 3 in combination with Type 2 or Type 4, Type 5 in combination with Type 2, or Type 9 when the “parent NDA” is a Type 3, 5, 7 or 8—from being eligible for the transitional drug add-on payment adjustment (TDAPA), effective January 1, 2020.

- *Proposal to change the basis of payment for the TDAPA for calcimimetics:* We are continuing to pay the TDAPA for calcimimetics for a third year in CY 2020 in order to collect sufficient claims data for rate setting analysis, but are proposing to reduce the basis of payment for the TDAPA for calcimimetics for CY 2020 from the average sales price plus 6 percent (ASP+6) methodology to 100 percent of ASP. We believe that in paying the TDAPA for these products since 2018, we have provided sufficient time for ESRD facilities to address any administrative complexities and overhead costs that may have arisen with regard to furnishing the calcimimetics. We also believe we need to take into account the financial burden that increased payments place on beneficiaries and Medicare expenditures.

- *Average sales price (ASP) conditional policy for application of the TDAPA:* Under the policy finalized in the CY 2019 ESRD PPS final rule, effective January 1, 2020, the basis of payment for the TDAPA for all new renal dialysis drugs and biological products except calcimimetics is ASP+0, but if ASP data is not available, then we use Wholesale Acquisition Cost (WAC) +0, and if WAC is not available, then we use invoice pricing. We are concerned that if ASP data is not available to CMS, WAC or invoice pricing would likely increase Medicare expenditures more than the value of the ASP. We are proposing to no longer apply the TDAPA for a new renal dialysis drug or biological product if CMS does not receive a full calendar quarter of ASP data within 30 days of the last day of the 3rd calendar quarter after we begin applying the TDAPA for

that product. We would no longer apply the TDAPA for a new renal dialysis drug or biological product beginning no later than 2-calendar quarters after we determine a full calendar quarter of ASP data is not available. We are also proposing to no longer apply the TDAPA for a new renal dialysis drug or biological product if CMS does not receive the latest full calendar quarter of ASP data for the product, beginning no later than 2-calendar quarters after CMS determines that the latest full calendar quarter of ASP data is not available. We believe it is important to balance supporting ESRD facilities in their uptake of innovative new renal dialysis drugs and biological products with limiting increases to Medicare expenditures, and conditioning the TDAPA on the availability of ASP data would help us achieve that balance.

- *New and innovative renal dialysis equipment and supplies under the ESRD PPS:* We are proposing to pay a transitional add-on payment adjustment to support the use of certain new and innovative renal dialysis equipment or supplies furnished by ESRD facilities. We are proposing to include renal dialysis equipment and supplies (with the exception of capital-related assets) that are: (1) Granted marketing authorization by FDA on or after January 1, 2020, (2) commercially available, (3) have a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures, and (4) meet the substantial clinical improvement criteria specified in the Inpatient Prospective Payment System (IPPS) regulations at 42 CFR 412.87(b)(1). Specifically, under our proposal, the equipment or supply must represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. CMS would evaluate the application to determine eligibility for a transitional add-on payment adjustment. We are proposing that the payment adjustment for these new and innovative renal dialysis equipment and supplies would be based on 65 percent of the price established by the Medicare Administrative Contractors (MACs), using the information from the invoice and other relevant sources of information. We would pay the adjustment for 2-calendar years, after which the equipment or supply would qualify as an outlier service and no change to the ESRD PPS base rate would be made.

- *Discontinue the application of the erythropoiesis-stimulating agent (ESA) monitoring policy (EMP) under the*

ESRD PPS: We are proposing to discontinue the application of the erythropoiesis-stimulating agent (ESA) monitoring policy (EMP) under the ESRD PPS. Prior to implementation of the ESRD PPS, ESAs were paid separately, which resulted in gross overutilization. We continued to apply the EMP edits when we implemented the ESRD PPS so that we did not overvalue these biological products in determining eligibility for outlier payments. Since we bundled ESAs into the per treatment payment amount, overutilization and the incentive for overutilization have been eliminated from the ESRD PPS; therefore we believe the EMP is no longer necessary.

2. Payment for Renal Dialysis Services Furnished to Individuals With AKI

We are proposing to update the AKI payment rate for CY 2020. The proposed CY 2020 payment rate is \$240.27, which is the same as the base rate proposed under the ESRD PPS for CY 2020.

3. ESRD QIP

This proposed rule proposes several new requirements for the ESRD QIP beginning with payment year (PY) 2022, including but not limited to the following:

- Updates to the scoring methodology for the National Healthcare Safety Network (NHSN) Dialysis Event reporting measure to allow new facilities and facilities that are eligible to report data on the measure for less than 12 months to be able to receive a score on that measure.

- A proposal to convert the STRR clinical measure (NQF #2979) to a reporting measure while we examine concerns raised by stakeholders regarding the measure's validity.

We are not proposing any new requirements beginning with the PY 2023 ESRD QIP.

We are also proposing to make updates to our regulation text so that it better informs the public of the Program's requirements.

4. DMEPOS Fee Schedule Payment Rules

a. Establishing Payment Amounts for New DMEPOS Items and Services (Gap-Filling)

This rule proposes a specific methodology for calculating fee schedule amounts for new DMEPOS items. The fiscal impact of establishing payment amounts for new items based on our proposal cannot be estimated as these new items are not identified and would vary in uniqueness and costs. However, there is some inherent risk that the proposed methodology could

result in fee schedule amounts for new items that greatly exceed the costs of furnishing the items.

b. Adjusting Payment Amounts for DMEPOS Items and Services Gap-Filled Using Supplier or Commercial Prices

In cases where fee schedule amounts for new DMEPOS items and services are gap-filled using supplier or commercial prices, these prices may decrease over time. In cases where such prices decrease by less than 15 percent within 5 years of establishing the initial fee schedule amounts, this rule proposes a one-time adjustment to the gap-filled fee schedule amounts. We are not proposing these price adjustments in cases where prices increase.

5. Conditions of Payment To Be Applied to Certain DMEPOS Items

This proposed rule would streamline the requirements for ordering DMEPOS items. It would also develop one Master List of DMEPOS items potentially subject to a face-to-face encounter, written orders prior to delivery and/or prior authorization requirements under the authority provided under sections 1834(a)(1)(E)(iv), 1834(a)(11)(B), and 1834(a)(15) of the Act.

C. Summary of Costs and Benefits

In section XI of this proposed rule, we set forth a detailed analysis of the impacts that the proposed changes would have on affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Proposed ESRD PPS

The impact chart in section XI of this proposed rule displays the estimated change in payments to ESRD facilities in CY 2020 compared to estimated payments in CY 2019. The overall impact of the proposed CY 2020 changes is projected to be a 1.6 percent increase in payments. Hospital-based ESRD facilities have an estimated 1.9 percent increase in payments compared with freestanding facilities with an estimated 1.5 percent increase.

We estimate that the aggregate ESRD PPS expenditures would increase by approximately \$210 million in CY 2020 compared to CY 2019. This reflects a \$230 million increase from the payment rate update and a \$40 million increase due to the updates to the outlier threshold amounts, and a \$60 million decrease from the proposal to change the basis of payment for the TDAPA for calcimimetics from ASP+6 percent to ASP+0 percent. These figures do not reflect estimated increases or decreases in expenditures based on our proposals to refine the TDAPA eligibility criteria,

condition the TDAPA on the availability of ASP data, and provide a transitional add-on payment adjustment for new and innovative renal dialysis equipment and supplies. The fiscal impact of these proposals cannot be determined because these new renal dialysis drugs and biological products and new renal dialysis equipment and supplies are not yet identified and would vary in uniqueness and costs. As a result of the projected 1.6 percent overall payment increase, we estimate that there would be an increase in beneficiary co-insurance payments of 1.6 percent in CY 2020, which translates to approximately \$50 million.

2. Impacts of the Proposed Payment for Renal Dialysis Services Furnished to Individuals With AKI

The impact chart in section XI of this proposed rule displays the estimated change in proposed payments to ESRD facilities in CY 2020 compared to estimated payments in CY 2019. The overall impact of the proposed CY 2020 changes is projected to be a 1.7 percent increase in payments. Hospital-based ESRD facilities have an estimated 1.8 percent increase in payments compared with freestanding facilities with an estimated 1.7 percent increase.

We estimate that the aggregate payments made to ESRD facilities for renal dialysis services furnished to AKI patients at the proposed CY 2020 ESRD PPS base rate would increase by less than \$1 million in CY 2020 compared to CY 2019.

3. Impacts of the Proposed ESRD QIP

We estimate that the overall economic impact of the PY 2022 ESRD QIP would be approximately \$219 million as a result of the policies we have previously finalized and the proposals in this proposed rule. The \$219 million figure for PY 2022 includes costs associated with the collection of information requirements, which we estimate would be approximately \$205 million. We also estimate that the overall economic impact of the PY 2023 ESRD QIP would be approximately \$219 million as a result of the policies we have previously finalized. The \$219 million figure for PY 2023 includes costs associated with the collection of information requirements, which we estimate would be approximately \$205 million.

4. Impacts of the Proposed DMEPOS Fee Schedule Payment Rules

a. Establishing Payment Amounts for New DMEPOS Items and Services (Gap-Filling)

This rule proposes a specific methodology for calculating fee

schedule amounts for new DMEPOS items. The fiscal impact of establishing payment amounts for new items based on our proposal cannot be estimated as these new items are not identified and would vary in uniqueness and costs. However, there is some inherent risk that the proposed methodology could result in fee schedule amounts for new items that greatly exceed the costs of furnishing the items.

b. Adjusting Gap-Filled Payment Amounts for DMEPOS Items and Services Using Supplier or Commercial Prices

We are proposing a one-time adjustment to the gap-filled fee schedule amounts in cases where fee schedule amounts for new DMEPOS items and services are gap-filled using supplier or commercial prices, and these prices decrease by less than 15 percent within 5 years of establishing the initial fee schedule amounts. The one-time adjustment should generate savings although it would probably be a small offset to the potential increase in costs of establishing fee schedule amounts based on supplier invoices or prices from commercial payers. The fiscal impact for this provision is therefore considered negligible.

5. Conditions of Payment To Be Applied to Certain DMEPOS Items

This rule proposes to streamline the requirements for ordering DMEPOS items, and to identify the process for subjecting certain DMEPOS items to a face-to-face encounter and written order prior to delivery and/or prior authorization as a condition of payment. The fiscal impact of these requirements cannot be estimated as this rule only identifies all items that are potentially subject to the face-to-face encounter and written order prior to delivery requirements and/or prior authorization.

II. Calendar Year (CY) 2020 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background

1. Statutory Background

On January 1, 2011, we implemented the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), a case-mix adjusted bundled PPS for renal dialysis services furnished by ESRD facilities, as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the

Patient Protection and Affordable Care Act (the Affordable Care Act), established that beginning with calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2012, to reduce the single payment for renal dialysis services furnished on or after January 1, 2014 to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (excluding oral-only ESRD-related drugs). Consistent with this requirement, in the CY 2014 ESRD PPS final rule we finalized \$29.93 as the total drug utilization reduction and finalized a policy to implement the amount over a 3- to 4-year transition period (78 FR 72161 through 72170).

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1, 2016. And section 632(c) of ATRA required the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted. Section 217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amended sections 1881(b)(14)(F) and (I) of the Act and replaced the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170) with specific provisions that dictated the market basket update for CY 2015 (0.0 percent) and how the market basket should be reduced in CY 2016 through CY 2018.

Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oral-only ESRD-related drugs under the ESRD PPS prior to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the

most recent year available. Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

Finally, on December 19, 2014, the President signed the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295). Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis services cannot be made under the ESRD PPS bundled payment prior to January 1, 2025.

2. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single, per-treatment payment is made to an ESRD facility for all of the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to individuals for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definitions of renal dialysis services at § 413.171, which is in 42 CFR part 413, subpart H, along with other ESRD PPS payment policies. The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and accounts for patient case-mix variability. The adult case-mix adjusters include five categories of age, body surface area, low body mass index, onset of dialysis, four comorbidity categories, and pediatric patient-level adjusters consisting of two age categories and two dialysis modalities (§ 413.235(a) and (b)).

The ESRD PPS provides for three facility-level adjustments. The first payment adjustment accounts for ESRD facilities furnishing a low volume of dialysis treatments (§ 413.232). The second adjustment reflects differences in area wage levels developed from core based statistical areas (CBSAs) (§ 413.231). The third payment adjustment accounts for ESRD facilities furnishing renal dialysis services in a rural area (§ 413.233).

The ESRD PPS provides a training add-on for home and self-dialysis modalities (§ 413.235(c)) and an additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care when applicable (§ 413.237).

The ESRD PPS also provides for a transitional drug add-on payment adjustment (TDAPA) to pay for a new injectable or intravenous product that is not considered included in the ESRD

PPS bundled payment, meaning a product that is used to treat or manage a condition for which there is not an existing ESRD PPS functional category (§ 413.234). In the CY 2019 ESRD PPS final rule (83 FR 56929 through 56949), we expanded the TDAPA policy. Effective January 1, 2020, the TDAPA is available for all new renal dialysis drugs and biological products, not just those in new ESRD PPS functional categories.

3. Updates to the ESRD PPS

Policy changes to the ESRD PPS are proposed and finalized annually in the **Federal Register**. The CY 2011 ESRD PPS final rule was published on August 12, 2010 in the **Federal Register** (75 FR 49030 through 49214). That rule implemented the ESRD PPS beginning on January 1, 2011 in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA, over a 4-year transition period. Since the implementation of the ESRD PPS, we have published annual rules to make routine updates, policy changes, and clarifications.

On November 14, 2018, we published a final rule in the **Federal Register** titled, “Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS” (83 FR 56922 through 57073) (referred to as the CY 2019 ESRD PPS final rule). In that rule, we updated the ESRD PPS base rate for CY 2019, the wage index, the outlier policy, and we finalized revisions to the drug designation process and the low-volume payment adjustment. For further detailed information regarding these updates, see 83 FR 56922.

B. Provisions of the Proposed Rule

1. Eligibility Criteria for the Transitional Drug Add-On Payment Adjustment (TDAPA)

a. Background

Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment. Therefore, in the CY 2016 ESRD PPS final rule (80 FR 69013

through 69027), we finalized a process that allows us to recognize when an oral-only renal dialysis service drug or biological product is no longer oral-only, and a process to include new injectable and intravenous products into the ESRD PPS bundled payment, and when appropriate, modify the ESRD PPS payment amount.

In accordance with section 217(c)(1) of PAMA, we established § 413.234(d), which provides that an oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by the Food and Drug Administration (FDA). Additionally, in accordance with section 217(c)(2) of PAMA, we codified the drug designation process at § 413.234(b). We finalized a policy in the CY 2016 ESRD PPS final rule (80 FR 69017 through 69022) that, effective January 1, 2016, if a new injectable or intravenous product is used to treat or manage a condition for which there is an ESRD PPS functional category, the new injectable or intravenous product is considered included in the ESRD PPS bundled payment and no separate payment is available. The new injectable or intravenous product qualifies as an outlier service. The ESRD bundled market basket updates the PPS base rate annually and accounts for price changes of the drugs and biological products reflected in the base rate.

In the CY 2016 ESRD PPS final rule, we also established in § 413.234(b)(2) that, if the new injectable or intravenous product is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new injectable or intravenous product is not considered included in the ESRD PPS bundled payment and the following steps occur. First, an existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new injectable or intravenous product is used to treat or manage. Next, the new injectable or intravenous product is paid for using the TDAPA described in § 413.234(c). Then, the new injectable or intravenous product is added to the ESRD PPS bundled payment following payment of the TDAPA.

In the CY 2016 ESRD PPS final rule, we finalized a policy in § 413.234(c) to base the TDAPA on pricing methodologies under section 1847A of the Act and pay the TDAPA until sufficient claims data for rate setting analysis for the new injectable or intravenous product are available, but not for less than 2 years. During the time a new injectable or intravenous product is eligible for the TDAPA, it is not

eligible as an outlier service. Following payment of the TDAPA, the ESRD PPS base rate will be modified, if appropriate, to account for the new injectable or intravenous product in the ESRD PPS bundled payment.

After the publication of the CY 2016 ESRD PPS final rule, we continued to hear from the dialysis industry and other stakeholders with suggestions for improving the drug designation process. Therefore, in CY 2019 ESRD PPS rulemaking, we revisited the drug designation process to consider their concerns and we proposed policies that would mitigate these issues.

In the CY 2019 ESRD PPS final rule (83 FR 56929 through 56949), we finalized several provisions related to the drug designation process and the TDAPA under § 413.234, with an effective date of January 1, 2020. In particular, we finalized changes to the drug designation process regulation to: (1) Reflect that the process applies for all new renal dialysis drugs and biological products; (2) establish a definition for “new renal dialysis drug or biological product”; (3) expand the eligibility criteria for the TDAPA; (4) change the TDAPA’s basis of payment; and (5) extend the TDAPA to composite rate drugs and biological products that are furnished for the treatment of ESRD. We discuss these changes in detail in the next several paragraphs.

First, we revised the drug designation process regulation at § 413.234 to reflect that the drug designation process applies for all new renal dialysis drugs and biological products that are approved by FDA, regardless of the form or route of administration, that are used to treat or manage a condition associated with ESRD. In the CY 2019 ESRD PPS proposed rule (83 FR 34309 through 34312), we described the prior rulemakings in which we addressed how new drugs and biological products are implemented under the ESRD PPS and how we have accounted for renal dialysis drugs and biological products in the ESRD PPS base rate since its implementation on January 1, 2011. We explained that the drug designation process is dependent upon the ESRD PPS functional categories we developed, and is consistent with the policy we have followed since the inception of the ESRD PPS.

However, we noted in the CY 2019 ESRD PPS proposed rule (83 FR 34311 through 34312) that, because section 217(c)(2) of PAMA only required the Secretary to establish a process for including new injectable and intravenous drugs and biological products in the ESRD PPS bundled payment, such new products were the

primary focus of the regulation we adopted at § 413.234. We explained that we did not codify our full policy in the CY 2016 ESRD PPS final rule for other renal dialysis drugs, such as drugs and biological products with other forms of administration, including oral, which by law are included under the ESRD PPS (though oral-only renal dialysis drugs are excluded from the ESRD PPS bundled payment until CY 2025). Commenters were generally supportive of the proposal, and we finalized the changes to codify our drug designation policy with regard to all drugs.

Second, as part of our updates to the drug designation process regulation in the CY 2019 ESRD PPS final rule (83 FR 56929 through 56932), we replaced the definition of “new injectable or intravenous product” with a definition for “new renal dialysis drug or biological product.” Under the final definition, effective January 1, 2020, a “new renal dialysis drug or biological product” is an “injectable, intravenous, oral or other form or route of administration drug or biological product that is used to treat or manage a condition(s) associated with ESRD. It must be approved by the [FDA] on or after January 1, 2020 under section 505 of the [FD&C Act] or section 351 of the Public Health Service Act, commercially available, have an HCPCS application submitted in accordance with the official HCPCS Level II coding procedures, and designated by CMS as a renal dialysis service under § 413.171. Oral-only drugs are excluded until January 1, 2025.”

Third, we expanded the eligibility criteria for the TDAPA to include all new renal dialysis drugs and biological products, not just those in new ESRD PPS functional categories, in the CY 2019 ESRD PPS final rule (83 FR 56942 through 56843). In the CY 2019 ESRD PPS proposed rule (83 FR 34312 through 34314), we discussed a number of reasons why we were reconsidering our previous policy to limit the TDAPA to products for which there is not an ESRD PPS functional category. We described the concerns that commenters had raised during the CY 2016 ESRD PPS rulemaking regarding the eligibility criteria for the TDAPA, including concerns about inadequate payment for renal dialysis services and hindrance of high-value innovation, and noted that these are important issues that we contemplate while determining appropriate payment policies. We discussed that when new drugs and biological products are introduced to the market, ESRD facilities need to analyze their budget and engage in contractual agreements to accommodate

the new therapies into their care plans. We recognized that newly launched drugs and biological products can be unpredictable with regard to their uptake and pricing, which makes these decisions challenging for ESRD facilities. Furthermore, we stated that practitioners should have the ability to evaluate the appropriate use of a new product and its effect on patient outcomes.

We explained in the CY 2019 ESRD PPS proposed rule that this uptake period would be best supported by the TDAPA pathway because it would help ESRD facilities transition or test new drugs and biological products in their businesses under the ESRD PPS. We stated that the TDAPA could provide flexibility and target payment for the use of new renal dialysis drugs and biological products during the period when a product is new to the market so that we can evaluate if resource use can be aligned with payment. We further explained that we believe we need to be conscious of ESRD facility resource use and the financial barriers that may be preventing uptake of innovative new drugs and biological products. Thus, we proposed to revise § 413.234(c) to reflect that the TDAPA would apply for all new renal dialysis drugs and biological products regardless of whether they fall within an ESRD PPS functional category, and, for those products that fall within an existing functional category, the payment would apply for only 2 years and there would be no subsequent modification to the ESRD PPS base rate (83 FR 34314). At the end of the 2 years, the product would be eligible for outlier payment unless it is a renal dialysis composite rate drug or biological product.

As we discussed in the CY 2019 ESRD PPS final rule (83 FR 56934 through 56943), we received a variety of feedback from stakeholders on this proposal. Some commenters recommended delaying the expansion of the TDAPA and some urged CMS to consider different policy proposals. Some commenters were supportive of revising the drug designation process regulation to allow more drugs to be eligible for the TDAPA, while others expressed that the process needs to be further evaluated before any expansion. The Medicare Payment Advisory Commission (MedPAC) recommended that we not finalize the policy because it did not require that a new drug be more effective than current treatment and could undermine competition with existing drugs; or, if we do move forward with the policy, that we narrow eligibility to new drugs that fall into an existing ESRD PPS functional category

only if they substantially improve beneficiaries' outcomes.

Other commenters had similar concerns and recommended that we require that the TDAPA apply for new renal dialysis drugs and biological products that have clinical superiority over the existing products in the existing functional categories, and they provided suggestions on clinical value criteria. In addition, some commenters believed that the TDAPA should not apply to generic drugs and biosimilar biological products. Commenters asserted that generic drugs and biosimilar biological products seek to provide the same type of treatment and patient outcomes as existing drugs in the ESRD PPS bundled payment. Commenters further believed that these types of drugs and biological products have no clinically meaningful differences and that they should be treated equally in payment and coverage policies. We also received several comments on our proposal to apply the TDAPA for a new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate for 2 years, and to not modify the ESRD PPS base rate following payment of the TDAPA (83 FR 56934 through 56943).

After considering the public comments, we finalized the expansion of the eligibility criteria for the TDAPA to reflect the proposed policy in the CY 2019 ESRD PPS final rule (83 FR 56943). In that rule we explained that there are two purposes of providing the TDAPA. For renal dialysis drugs and biological products that fall into an existing ESRD PPS functional category, the purpose of the TDAPA is to help ESRD facilities to incorporate new drug and biological products and make appropriate changes in their businesses to adopt such products; provide additional payment for such associated costs, as well as promote competition among drugs and biological products within the ESRD PPS functional categories. For new renal dialysis drugs and biological products that do not fall within an existing ESRD PPS functional category and that are not considered to be reflected in the ESRD PPS base rate, the purpose of the TDAPA is to be a pathway toward a potential base rate modification (83 FR 56935).

In response to commenters that recommended clinical superiority of new renal dialysis drugs and biological products, we explained in the CY 2019 ESRD PPS final rule (83 FR 56938) that we believed allowing all new drugs and biological products to be eligible for the TDAPA would provide an ability for new drugs and biological products to compete with other drugs and biological

products in the market, which could mean lower prices for all such products. We also noted our belief that categorically limiting or excluding any group of drugs from the TDAPA would reduce the competitiveness because there would be less incentive for manufacturers to develop lower-priced drugs, such as generic drugs, to be able to compete with higher priced drugs during the TDAPA period. In addition, the question of whether one drug is more effective than another can be impacted by characteristics that vary across patients such as age, gender, race, genetic pre-disposition and comorbidities. We stated that innovation can provide options for those patients who do not respond to a certain preferred treatment regimen the same way the majority of patients respond.

In response to commenters who recommended that we not apply the TDAPA to generic drugs and biosimilar biological products, we explained in the CY 2019 ESRD PPS final rule (83 FR 56938) that the purpose of this policy is to foster a competitive marketplace in which all drugs within a functional category would compete for market share. We stated that we believed including generic drugs and biosimilar biological products under the TDAPA expansion would mitigate or discourage high launch prices. We further explained that we believed including these products would foster innovation of drugs within the current functional categories. We also noted that we believed including these products would give a financial boost to support their utilization, and ultimately lower overall drug costs since these products generally have lower prices. Because of this, we stated that we believed that generic drugs and biosimilar biological products would provide cost-based competition for new higher priced drugs during the TDAPA period and also afterward when they are bundled into the ESRD PPS.

In response to ESRD facilities that expressed concern regarding operational difficulties and patient access issues experienced for current drugs paid for using the TDAPA, we elected to make all of the changes to the drug designation process under § 413.234 and the expansion of the TDAPA eligibility effective January 1, 2020, as opposed to January 1, 2019, to address as many of those concerns as possible (83 FR 56937). We explained in the CY 2019 ESRD PPS final rule that the additional year provides us with the opportunity to address issues such as transitioning payment from Part D to Part B, coordinating issues involving Medicaid

and new Medicare Advantage policies, and working with the current HCPCS process as it applies to the ESRD PPS to accommodate the initial influx of new drugs and biological products. We also indicated that the additional year would allow more time for ESRD facility and beneficiary education about this new policy.

In addition, with regard to the HCPCS process, we explained the additional year would help us operationally in working with the HCPCS workgroup that manages the HCPCS process as it applies to the ESRD PPS to accommodate the initial influx of new renal dialysis drugs and biological products. We explained that in collaboration with the HCPCS workgroup we would make the determination of whether a drug or biological product is a renal dialysis service. We would also determine if the new renal dialysis drug or biological product falls within an existing functional category or if it represents a new functional category (83 FR 56937 through 56938).

With regard to our proposal to not modify the ESRD PPS base rate for new renal dialysis drugs and biological products that fall within existing ESRD PPS functional categories, we explained that we believe the intent of the TDAPA for these products is to provide a transition period for the unique circumstances experienced by ESRD facilities and to allow time for the uptake of the new product. We further explained that we did not believe it would be appropriate to add dollars to the ESRD PPS base rate for new renal dialysis drugs and biological products that fall within existing functional categories and that doing such would be in conflict with the fundamental principles of a PPS.

We also explained that the proposal would strike a balance of maintaining the existing functional category scheme of the drug designation process and not adding dollars to the ESRD PPS base rate when the base rate may already reflect costs associated with such services, while still supporting high-value innovation and allowing facilities to adjust or factor in new drugs through a short-term transitional payment.

We stated in the CY 2019 ESRD PPS final rule (83 FR 56940) that under our final policy, beginning January 1, 2020, for new renal dialysis drugs and biological products that fall within an existing functional category, the application of the TDAPA will begin with the effective date of subregulatory billing guidance and end 2 years from that date.

For new renal dialysis drugs and biological products that do not fall within an existing functional category, we continued the existing policy that application of the TDAPA will begin with the effective date of subregulatory billing guidance and end after we determine through notice-and-comment rulemaking how the drug will be recognized in the ESRD PPS bundled payment.

Fourth, in the CY 2019 ESRD PPS final rule, we changed the TDAPA's basis of payment (83 FR 34314 through 34316). We explained that if we adopted the proposals to expand the TDAPA eligibility criteria using the current basis of payment for the TDAPA—the pricing methodologies available under section 1847A of the Act—Medicare expenditures would increase, which would result in increases of cost sharing for ESRD beneficiaries, since we had not previously provided the TDAPA for all new renal dialysis drugs and biological products. We also discussed other reasons why we believed it may not be appropriate to base the TDAPA strictly on section 1847A of the Act methodologies (83 FR 34315).

Therefore, we proposed to base the TDAPA on 100 percent of ASP (ASP+0) instead of the pricing methodologies available under section 1847A of the Act (which includes ASP+6). For circumstances when ASP data is not available, we proposed that the TDAPA would be based on 100 percent of Wholesale Acquisition Cost (WAC) and, when WAC is not available, the TDAPA would be based on the drug manufacturer's invoice.

In the CY 2019 ESRD PPS final rule (83 FR 56943 through 56948), we discussed several comments received on this proposal. MedPAC supported the proposal to use ASP+0, stating that the ESRD PPS accounts for storage and administration costs and that ESRD facilities do not have acquisition price variation issues when compared to physicians. Conversely, industry stakeholders recommended the basis of payment remain at ASP+6 since they believe it assists with the administrative costs of packaging, handling, and staff. Commenters also recommended that CMS consider the impact of bad debt recovery and sequestration on payment when determining the basis of payment.

After considering public comments, in the CY 2019 ESRD PPS final rule (83 FR 56948), we finalized the policy as proposed, with one revision to change the effective date to CY 2020, and another revision to reflect that the basis of payment for the TDAPA for calcimimetics would continue to be based on the pricing methodologies

available under section 1847A of the Act (which includes ASP+6). We explained that we believe ASP+0 is reasonable for new renal dialysis drugs and biological products that fall within an existing functional category because there are already dollars in the per treatment base rate for a new drug's respective category. We also explained that we believe ASP+0 is a reasonable basis for payment for the TDAPA for new renal dialysis drugs and biological products that do not fall within the existing functional category because the ESRD PPS base rate has dollars built in for administrative complexities and overhead costs for drugs and biological products (83 FR 56946).

Fifth and finally, in the CY 2019 ESRD PPS final rule (83 FR 56948 through 56949), we finalized a policy to extend the TDAPA to composite rate drugs and biological products that are furnished for the treatment of ESRD. Specifically, beginning January 1, 2020, if a new renal dialysis drug or biological product as defined in § 413.234(a) is considered to be a composite rate drug or biological product and falls within an existing ESRD PPS functional category, it will be eligible for the TDAPA.

We explained that we believed by allowing all new renal dialysis drugs and biological products to be eligible for the TDAPA, we would provide an ability for a new drug to compete with other similar drugs in the market which could mean lower prices for all drugs. We further explained that we believed that new renal dialysis composite rate drugs and biological products could benefit from this policy as well. Additionally, we explained that we continue to believe that the same unique consideration for innovation and cost exists for drugs that are considered composite rate drugs. That is, the ESRD PPS base rate dollars allocated for these types of drugs may not directly address the costs associated with drugs in this category when they are newly launched and are finding their place in the market. We noted that we had not proposed to change the outlier policy and therefore these products will not be eligible for an outlier payment after the TDAPA period.

b. Basis for Proposed Refinement of the TDAPA Eligibility Criteria

Based on feedback received during and after the CY 2019 ESRD PPS rulemaking, we are proposing to make further refinements to the TDAPA eligibility criteria. As we discussed in the CY 2019 ESRD PPS final rule (83 FR 56935) and in section II.B.1.a of this proposed rule, we received many comments from all sectors of the

dialysis industry and other stakeholders on our proposal to expand the TDAPA eligibility to all new renal dialysis drugs and biological products, and each had their view on the direction the policy needed to go to support innovation. Commenters generally agreed that more drugs and biological products should be eligible for the TDAPA, that is, they agreed that drugs and biological products that fall within an ESRD PPS functional category should be eligible for a payment adjustment when they are new to the market. However, commenters also had specific policy recommendations for each element of the drug designation process, including which drugs should qualify for the TDAPA.

In the CY 2019 ESRD PPS final rule (83 FR 56938) some commenters recommended, among other suggestions, that CMS not apply the TDAPA to generic drugs or to biosimilar biological products. The commenters explained that they believe the rationale for the TDAPA is to allow the community and CMS to better understand the appropriate utilization of new products and their pricing. Commenters asserted that generic drugs and biosimilar biological products seek to provide the same type of treatment and patient outcomes as existing drugs in the ESRD PPS bundled payment. Thus, they expressed that the additional time for uptake is unnecessary for these drugs and biological products.

In addition, a drug manufacturer commented that a generic drug is not innovative because it must have the same active ingredient, strength, dosage form, and route of administration as the innovator drug it references in its abbreviated new drug application (ANDA). Further, a biosimilar biological product is not innovative because it is required under the Public Health Service Act (the PHS Act) to be highly similar and have no clinically meaningful differences to the reference product and cannot be licensed for a condition of use that has not been previously approved for the reference product or for a dosage form, strength, or route of administration that differs from that of the reference product. The commenter stated that because they have no clinically meaningful differences, biosimilar biological products and reference products should be treated equally in payment and coverage policies; a biosimilar biological product should not be eligible for the TDAPA when its reference product would not qualify for the payment.

Some commenters recommended that CMS require that the new renal dialysis drug or biological product, in order to

be eligible for the TDAPA, have a clinical superiority over existing drugs in the ESRD PPS bundled payment and provided suggestions on clinical value criteria. A dialysis facility organization expressed concern that the proposed policy would encourage promotion of so called “me too” drugs and higher launch prices, even if moderated after 2 years (83 FR 56938). A drug manufacturer recommended that CMS consider when FDA may re-profile a drug (83 FR 56939). The commenter further explained that re-profiling a drug may occur when its utility and efficacy are further elucidated or expanded once on-market. The commenter recommended that CMS establish a pathway as part of the drug designation process that would allow for manufacturers or other stakeholders to request that CMS reconsider how a particular drug is classified with regard to the functional categories.

MedPAC recommended that CMS not proceed with its proposal to apply the TDAPA policy to new renal dialysis drugs that fit into an existing functional category for several reasons (83 FR 56936). For example, MedPAC stated that paying the TDAPA for new dialysis drugs that fit into a functional category would be duplicative of the payment that is already made as part of the ESRD PPS bundle. MedPAC also asserted that applying the TDAPA to new dialysis drugs that fit into an existing functional category undermines competition with existing drugs included in the PPS payment bundle since the TDAPA would effectively unbundle all new dialysis drugs, removing all cost constraints during the TDAPA period and encouraging the establishment of high launch prices.

Since publishing the CY 2019 ESRD PPS final rule, we have continued to hear concerns about expanding the TDAPA policy from numerous stakeholders, including ESRD facilities and their professional associations, beneficiaries and their related associations, drug manufacturers, and beneficiary groups.

Also, our data contractor held a Technical Expert Panel (TEP) in December 2018, and gathered input regarding the expanded TDAPA policy at that time. More information about the TEP is discussed in section VIII.A of this proposed rule. Some ESRD facility associations participating in the TEP generally expressed concern that the TDAPA policy, as finalized in the CY 2019 ESRD PPS final rule, would inappropriately direct Medicare dollars to drugs and biological products that may be new to the market but not new with regard to certain characteristics of

the drug itself. For example, commenters noted that section 505 of the FD&C Act is broad and includes FDA approval of new drug applications (NDA), which is the vehicle through which drug sponsors formally propose that FDA approve a new pharmaceutical for sale and marketing in the U.S.¹ Section 505 of the FD&C Act includes FDA approval of NDAs for drugs that have a new dosage form, a reformulation, or a re-engineering of an existing product. These types of drugs are referred to in the pharmaceutical industry as line extensions, follow-on products, or me-too drugs.

Due to the feedback received following publication of the CY 2019 ESRD PPS final rule, we continued to analyze certain aspects of the policies finalized in the CY 2019 ESRD PPS final rule and are revisiting these issues as part of this proposed rule. Specifically, since ESRD facilities and other dialysis stakeholders have expressed concern about the broad nature of including all new renal dialysis drugs and biological products as eligible for the TDAPA, we are reconsidering whether all new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category should be eligible for the TDAPA.

As noted previously, in the CY 2019 ESRD PPS final rule (83 FR 56932) we finalized that effective January 1, 2020, a new renal dialysis drug or biological product is defined in § 413.234 as “[a]n injectable, intravenous, oral or other form or route of administration drug or biological product that is used to treat or manage a condition(s) associated with ESRD. It must be approved by the FDA on or after January 1, 2020, under section 505 of the [FD&C Act] or section 351 of the [PHS Act], commercially available, have an HCPCS application submitted in accordance with the official Level II HCPCS coding procedures, and designated by CMS as a renal dialysis service under § 413.171. Oral-only drugs are excluded until January 1, 2025.” While there are several parts of this definition, in this proposed rule we are focusing on the requirement that the product be approved by FDA “under section 505 of the [FD&C Act] or section 351 of the [PHS Act].” Specifically, we are proposing that certain new renal dialysis drugs approved by FDA under those authorities would not be eligible for the TDAPA under § 413.234(c)(1).

Section 505 of the FD&C Act and section 351 of the PHS Act provide the

¹ FDA. New Drug Application (NDA). Available at: <https://www.fda.gov/drugs/types-applications/new-drug-application-nda>.

authority to FDA for approving drugs and biological products, respectively, and provide several pathways for drug manufacturers to submit NDAs and biologics license applications (BLAs). Therefore, we have consulted with FDA and studied the different categories of NDAs and the different biological product pathways to consider whether the full breadth of these authorities aligned with our goals for the TDAPA policy under the ESRD PPS. As we explained in the CY 2019 ESRD PPS final rule (83 FR 56935), the purpose of the TDAPA for new renal dialysis drugs and biological products that fall within an existing functional category is to support innovation and help ESRD facilities to incorporate new products and make appropriate changes in their businesses to adopt such products; provide additional payment for such associated costs, as well as promote competition among drugs and biological products within the ESRD PPS functional categories.

FDA approves certain new drugs under section 505(c) of the FD&C Act, which includes NDAs submitted pursuant to section 505(b)(1) or 505(b)(2) of the FD&C Act. Section 505(b)(1) of the FD&C Act is a pathway for “stand-alone” applications and is used for drugs that have been discovered and developed with studies conducted by or for the applicant or for which the applicant has a right of reference, and are sometimes for new molecular entities and new chemical entities that have not been previously approved in the U.S.

Section 505(b)(2) of the FD&C Act is another pathway for NDAs, but where at least some of the information for an approved drug comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. A 505(b)(2) application may rely on FDA’s finding of safety and/or effectiveness for a listed drug (an approved drug product) or published literature provided that such reliance is scientifically justified and the 505(b)(2) applicant complies with the applicable statutory and regulatory requirements, including patent certification if appropriate. (See section 505(b)(2) of the FD&C Act and 21 CFR 314.54.) NDAs submitted pursuant to section 505(b)(1) or 505(b)(2) of the FD&C Act are then subdivided into categories by FDA.

The Office of Pharmaceutical Quality in FDA’s Center for Drug Evaluation and Research’s (CDER) has an NDA categorizing system that utilizes NDA classification codes. As explained in FDA/CDER Manual of Policies and Procedures (MAPP) 5018.2, “NDA

Classification Codes”, the code evolved from both a management and a regulatory need to identify and group product applications based on certain characteristics, including their relationships to products already approved or marketed in the U.S. FDA tentatively assigns an NDA classification code (that is, Type 1 NDA through Type 10 NDA) by the filing date for an NDA and reassesses the code at the time of approval. The reassessment is based upon relationships of the drug product seeking approval to products already approved or marketed in the U.S. at the time of approval. FDA may also reassess the code after approval. The NDA classification code is not indicative of the extent of innovation or therapeutic value that a particular drug represents. More information regarding the NDA classification code is available in FDA/CDER MAPP 5018.2 on FDA website at: <https://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/manualofpoliciesprocedures/ucm470773.pdf> and summarized in Table 1.

TABLE 1—NDA CLASSIFICATION CODES

Classification	Meaning
Type 1	New molecular entity.
Type 2	New active ingredient.
Type 3	New dosage form.
Type 4	New combination.
Type 5	New formulation or other differences.
Type 6	New indication or claim, same applicant [no longer used].
Type 7	Previously marketed but without an approved NDA.
Type 8	Prescription to Over-the-Counter.
Type 9	New indication or claim, drug not to be marketed under type 9 NDA after approval.
Type 10	New indication or claim, drug to be marketed under type 10 NDA after approval.
Type 1/4	Type 1, New molecular entity, and Type 4, New combination.
Type 2/3	Type 2, New active ingredient, and Type 3, New dosage form.
Type 2/4	Type 2, New active ingredient and Type 4, New combination.
Type 3/4	Type 3, New Dosage Form, and Type 4, New combination.

An ANDA is an application submitted by drug manufacturers and approved by FDA under section 505(j) of the FD&C Act for a “duplicate”² of a previously approved drug product. ANDAs are used for generic drugs. An ANDA relies on FDA’s finding that the previously

² The term *duplicate* generally refers to a “drug product that has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use as a listed drug,” that is, a previously approved drug product. See 54 FR 28872 (July 10, 1989).

approved drug product, that is, the reference listed drug, is safe and effective.

Biological products are approved by FDA under section 351 of the PHS Act. There are two pathways for biological products, one under section 351(a) and the other under section 351(k) of the PHS Act. A BLA submitted under section 351(a) of the PHS Act is the pathway for “stand-alone BLAs” that contains all information and data necessary to demonstrate that (among other things) the proposed biological product is safe, pure and potent. The 351(k) BLA pathway requires that the application contain information demonstrating that the biological product is biosimilar to or interchangeable with an FDA-licensed reference product. FDA does not assign classification codes for BLAs like it does for NDAs.

In addition to consulting with FDA, pharmaceutical statisticians within CMS have provided insight on the potential outcomes of providing payment incentives for promoting competition among drugs and biological products within the ESRD PPS functional categories. Specifically, we have learned that certain unintended consequences could arise from providing payment incentives for drugs with innovative qualities (for example, new molecular entities) in the same way as drugs with non-innovative qualities (for example, generic drugs). For example, more attention might be diverted to the less costly duplication of drugs that are already available rather than those that may be more expensive to develop and bring to market. This could cause an influx of non-innovative drugs to the dialysis space, potentially crowding out innovative drugs.

c. Proposed Refinement of the TDAPA Eligibility Criteria

We analyzed the information we gathered since the publication of the CY 2019 ESRD PPS final rule and contemplated the primary goal of the TDAPA policy for new renal dialysis drugs and biological products that fall within ESRD PPS functional categories, which is to support innovation and encourage development of these products. We continue to believe that this is accomplished by providing payment to ESRD facilities during the uptake period for a new renal dialysis drug or biological product to help the facilities incorporate new drugs and make appropriate changes in their businesses to adopt such drugs. We also continue to believe that the TDAPA provides additional payment for costs associated with these changes.

In addition to supporting innovation, we are mindful of the increase in Medicare expenditures associated with the expanded TDAPA policy. We note that the first year in which we paid the TDAPA, CY 2018, resulted in an estimated \$1.2 billion increase in ESRD PPS expenditures for two calcimimetic drugs used by approximately 25 percent of the Medicare ESRD population. We recognized that the policy we finalized in the CY 2019 ESRD PPS final rule would mean that each new renal dialysis drug and biological product eligible for the TDAPA would result in an increase in Medicare expenditures. However, we were balancing an increase in Medicare expenditures with the rationale for fostering a competitive marketplace. In the CY 2019 ESRD PPS final rule (83 FR 56937), we stated that we believed that by expanding the eligibility to all new drugs and biological products we would promote competition among drugs and biological products within the ESRD PPS functional categories which could result in lower prices for all drugs.

In response to ESRD facility and other dialysis stakeholders' concerns raised during and after the CY 2019 ESRD PPS rulemaking, and after conducting a closer study of FDA's NDA process, we are reconsidering the eligibility criteria that we finalized effective January 1, 2020. Since there are not unlimited Medicare resources, we believe those resources should not be expended on additional payments to ESRD facilities for drugs and biological products that are not truly innovative, and may facilitate perverse incentives for facilities to choose new products simply for financial gain. Since we have the ability to be more selective, through FDA's NDA classification codes, with the categories of renal dialysis drugs that would be eligible for the TDAPA for products in existing ESRD PPS functional categories, we believe that we can balance supporting innovation, incentivizing facilities with uptake of new and innovative renal dialysis products, and fostering competition for renal dialysis drugs and biological products that are new and innovative, rather than just new.

We acknowledge that the definition finalized in the CY 2016 ESRD PPS final rule (80 FR 69015 through 69027), which includes products "approved by [FDA] . . . under section 505 of the [FD&C Act] or section 351 of the [PHS Act]" has been part of the TDAPA eligibility criteria since the inception of the policy. We also acknowledge that this may be too expansive for purposes of determining eligibility for the TDAPA for new renal dialysis drugs and

biological products that fall within an existing functional category. For example, there may be new renal dialysis drugs approved by FDA under section 505 of the FD&C Act that may not be innovative.

We also acknowledge that while dialysis industry stakeholders recommended that we adopt significant clinical improvement standards for the TDAPA eligibility, we believe that unlike many Medicare beneficiaries, the Medicare ESRD beneficiary is significantly complex, with each patient having a unique and challenging profile for medical management of drugs and biological products. Practitioners should have the opportunity to evaluate the appropriate use of a new drug or biological product and its effect on patient outcomes and interactions with other medications the patient is currently taking. Further, the question of whether one drug is more effective than another can be impacted by characteristics that vary across patients such as age, gender, race, genetic predisposition and comorbidities. Innovation of drugs and biological products can provide options for those patients who do not respond to a certain preferred treatment regimen the same way the majority of patients respond.

In section II.B.1.c.i of this proposed rule we discuss categories of drugs that we are proposing to exclude from eligibility for the TDAPA under § 413.234(b)(1)(ii) and our proposed revisions to the drug designation process regulation in § 413.234 to reflect those categories.

We are also proposing to rely on, as a proxy, the NDA classification code, as it exists as of November 4, 2015, which is part of FDA/CDER MAPP 5018.2. The FDA/CDER MAPP 5018.2 is available at FDA website <https://www.fda.gov/media/94381/download>. We recognize that FDA's NDA classification codes do not necessarily reflect the extent of innovation or therapeutic advantage that a particular drug product represents. However, we believe FDA's NDA classification codes would provide an objective basis that we can use to distinguish innovative from non-innovative renal dialysis service drugs. We believe that distinguishing drugs would help us in our effort to support innovation by directing Medicare resources to renal dialysis drugs and biological products that are not reformulations or new dosage forms, while simultaneously balancing our goal to foster competition within the ESRD PPS functional categories by supporting products that advance the treatment for ESRD beneficiaries at a lower cost.

As discussed in section II.B.1.b of this proposed rule, the classification code assigned to an NDA generally describes FDA's classification of the relationship of the drug to drugs already marketed or approved in the U.S. If FDA makes changes to the NDA classification code in FDA/CDER MAPP 5018.2, we are proposing that we would assess FDA changes at the time they are publicly available and we would analyze those changes with regard to their implications for the TDAPA policy under the ESRD PPS. We would plan to propose in the next rulemaking cycle, any necessary revisions to the exclusions set forth in proposed § 413.234(e). We are soliciting comment on the proposal to rely on, as a proxy, the NDA classification code, as it exists as of November 4, 2015, which is part of the FDA/CDER MAPP 5018.2. We are also soliciting comments on the proposal that we would assess FDA changes to the NDA classification code at the time they are publicly available to analyze the changes with regard to their implications for the TDAPA policy and propose in the next rulemaking cycle, any necessary revisions to the proposed exclusions.

Currently, stakeholders must notify the Division of Chronic Care Management in our Center for Medicare of the interest for eligibility for the TDAPA and provide the information requested (83 FR 56932) for CMS to make a determination as to whether the new renal dialysis drug or biological product is eligible for the adjustment. With regard to operationalizing the proposed exclusions, in addition to the information currently described on the CMS ESRD PPS TDAPA web page under the Materials Required for CMS Determination Purposes, we would request that the stakeholder provide the FDA NDA Type classified at FDA approval or state if the drug was approved by FDA under section 505(j) of the FD&C Act.³ If the FDA NDA Type classified at FDA approval changes subsequently to the submission of the TDAPA application into CMS, we would expect that the submitter would resubmit the TDAPA request, and we would re-evaluate the submission. We note that we plan to have quarterly meetings with FDA to discuss new renal dialysis drugs and biological products that are eligible for the TDAPA.

As we discuss in the CY 2019 ESRD PPS final rule (83 FR 56932), once the information requested by CMS is

³ CMS. ESRD PPS Transitional Drug Add-on Payment Adjustment. Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug.html>.

received and reviewed, for new renal dialysis drugs and biological products eligible for the TDAPA, we will issue a change request with billing guidance that will provide notice that the product is eligible for the TDAPA as of a certain date and guidance on how to report the new drug or biological product on the ESRD claim. The effective date of this change request will initiate the TDAPA payment period and, for drugs that do not fall within a functional category, the data collection period.

For new renal dialysis drugs and biological products that are not eligible for the TDAPA, we indicated that a change request would be issued that will provide notice that the drug is included in the ESRD PPS bundle, qualifies as an outlier service, and is available for use, allowing patients to have access to the new product.

i. Proposed Exclusions From the TDAPA Eligibility

Using the current categories in FDA/CDER MAPP 5018.2 effective November 4, 2015, we are proposing to exclude Types 3, 5, 7 and 8, Type 3 in combination with Type 2 or Type 4, Type 5 in combination with Type 2, and Type 9 when the “parent NDA” is a Type 3, 5, 7 or 8 from being eligible for the TDAPA under § 413.234(c)(1). A Type 9 NDA is for a new indication or claim for a drug product that is currently being reviewed under a different NDA (the “parent NDA”), and the applicant does not intend to market this drug product under the Type 9 NDA after approval. We would use the NDA classification code Type identified at FDA approval. If FDA changes the classification type after we start applying the TDAPA with respect to a particular new renal dialysis drug, we would re-evaluate TDAPA eligibility. We are also proposing to exclude generic drugs from being eligible for the TDAPA under § 413.234(c)(1). In the following paragraphs we describe each NDA Type, as distinguished by FDA through the NDA classification code, and generic drugs proposed for exclusion and explain why we believe these products should not be eligible for the TDAPA for new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category.

(a) Type 3 NDA—New Dosage Form

Some dialysis stakeholders expressed concern that we would be paying the TDAPA for changes that did not reflect a product being significantly innovative, such as a pill size, pill scoring, oral solutions and suspensions of drugs that were previously only approved as solid

oral dosage forms, time-release forms, chewable or effervescent pills, orally disintegrating granules or adsorptive changes, or routes of administration. In response to these concerns, we are proposing to exclude Type 3 NDAs, which is for a new dosage form of an active ingredient that has been approved or marketed in the U.S. by the same or another applicant but has a different dosage form, as well as Type 3 in combination with Type 2 or Type 4, from being eligible for the TDAPA under § 413.234(b)(1). In addition, we are proposing to exclude Type 9 NDAs, as discussed in section II.B.1.ii.(d), when the “parent NDA” is a Type 3 NDA.

FDA’s regulation defines an active ingredient as a component of the drug product that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals (21 CFR 314.3(b)), which is incorporated in FDA/CDER MAPP 5018.2).

FDA’s regulation defines dosage form as the physical manifestation containing the active and inactive ingredients that delivers a dose of the drug product (21 CFR 314.3(b)), which is incorporated in FDA/CDER MAPP 5018.2). This includes such factors as: (1) The physical appearance of the drug product, (2) the physical form of the drug product prior to dispensing to the patient, (3) the way the product is administered, and (4) the design features that affect the frequency of dosing.

For Type 3 NDA drugs, the indication does not need to be the same as that of the already approved drug product. Once the new dosage form has been approved for an active ingredient, subsequent applications for the same dosage form and active ingredient should be classified as Type 5 NDA.

For purposes of the ESRD PPS, we do not want to incentivize the use of one dosage form of the drug over another. In addition to not being innovative, these drugs that are new to the market may not be innovative with regard to certain characteristics of the drug itself. Although these drugs may provide an expansion of patient treatment options, we believe these changes are not innovative and these drugs should not be paid for using the TDAPA. However, these drugs are still accounted for in the ESRD PPS base rate and would be eligible for an outlier payment. This type of research, development and marketing activity has been termed “product hopping” and can help manufacturers prolong revenue

streams.⁴ We do not believe these products should be eligible for the TDAPA because we do not want to provide perverse incentives for facilities to choose a new dosage form in order to obtain the TDAPA. In addition, we do not want to encourage the practice of companies moving drug research and development dollars from one branded drug to another, very similar drug with a longer patent life, thus increasing its market exclusivity for many years. This practice is counter to our goal of not only increasing competition among drugs in the ESRD functional categories so there are better drugs at lower cost, but also making the best use of Medicare resources and directing of those resources to payment for the utilization of high value, innovative drugs. For these reasons we are proposing to exclude Type 3 NDA drugs as being eligible for the TDAPA.

(b) Type 5 NDA—New Formulation or Other Differences

We are proposing to exclude Type 5 NDA drugs, which can be a new formulation or new manufacturer, from being eligible for the TDAPA. In addition, we are proposing to exclude Type 9 NDAs, as discussed in section II.B.1.ii.(d) of this proposed rule, when the “parent NDA” is a Type 5 NDA. Drugs that are classified as a Type 5 NDA are sometimes referred to as reformulations or follow-on products. Specifically, a Type 5 NDA is for a product, other than a new dosage form, that differs from a product already approved or marketed in the U.S. because of one of the seven following product characteristics.

The first characteristic involves changes in inactive ingredients that require either bioequivalence studies or clinical studies for approval and the product is submitted as an original NDA rather than as a supplement by the applicant of the approved product.

The second characteristic is that the product is a “duplicate” of a drug product by another applicant (same active ingredient, same dosage form, same or different indication, or same combination, and requires one of the following 4 items: (a) Bioequivalence testing, including bioequivalence studies with clinical endpoints, but is not eligible for submission as a section 505(j) application; (b) safety or effectiveness testing because of novel inactive ingredients; (c) full safety or effectiveness testing because the

⁴ Reed F. Beall et al. New Drug Formulations and Their Respective Generic Entry Dates, JMCP. February, 2019, 25(2): 218–224. Available at: <https://www.jmcp.org/doi/pdf/10.18553/jmcp.2019.25.2.218>.

product is one of the following four items: (i) Is subject to exclusivity held by another applicant; (ii) is a product of biotechnology and its safety and/or effectiveness are not assessable through bioequivalence testing, (iii) it is a crude natural product, or, (iv) it is ineligible for submission under section 505(j) of the FD&C Act because it differs in bioavailability, for example, products with different release patterns or (d) the applicant has a right of reference to the application.

The third characteristic is that the product contains an active ingredient or active moiety that has been previously approved or marketed in the U.S. only as part of a combination. This applies to active ingredients previously approved or marketed as part of a physical or chemical combination, or as part of a mixture derived from recombinant deoxyribonucleic acid technology or natural sources. An active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance (21 CFR 314.3(b)).

The fourth characteristic is that the product is a combination product that differs from a previous combination product by removal of one or more active ingredients or by substitution of a new ester or salt or other noncovalent derivative of an active ingredient for one of more of the active ingredients. In the case of a substitution of a noncovalent derivative of an active ingredient for one or more of the active ingredients, the NDA would be classified as a Type 2, 5 combination and we would propose to exclude it from eligibility for the TDAPA under § 413.234(b)(1).

The fifth characteristic is that the product contains a different strength of one or more active ingredients in a previously approved or marketed combination. A Type 5 NDA would generally be submitted by an applicant other than the holder of the approved application for the approved product. A similar change in an approved product by the applicant of the approved product would usually be submitted as a supplemental application.

The sixth characteristic is that the product differs in bioavailability (for example, superbioavailable or different controlled-release pattern) and, therefore, is ineligible for submission as an ANDA under section 505(j) of the FD&C Act.

The seventh characteristic is that the product involves a new plastic container that requires safety studies beyond limited confirmatory testing (see 21 CFR 310.509, Parenteral drugs in plastic containers, and FDA/CDER MAPP 6020.2, Applications for Parenteral Products in Plastic Immediate Containers).

Some commenters have characterized the types of drugs that are often approved in Type 5 NDAs as reformulations or line extensions. A line extension is a variation of an existing product.⁵ The variation can be a new formulation (reformulation) of an existing product, or a new modification of an existing molecular entity.⁶ A line extension has been defined as a branded pharmaceutical product that: (1) Includes the same active ingredient (either alone or in combination with other active ingredients) as an original product, (2) is manufactured by the same pharmaceutical company that makes the original product, or by one of its partners or subsidiaries, and, (3) is launched after the original product.⁷ An NME is discussed in section II.B.1.c.ii.(a) of this proposed rule. Line extensions were few in number prior to 1984, when the Drug Price Competition and Patent Term Restoration Act was passed following public outcry over high drug prices and rising drug expenditures, and following passage of that law, line extensions became prevalent in the pharmaceutical drug industry. We are aware that one of the acknowledged criticisms of pharmaceutical line extensions is their use as a strategy to extend the patent protections for products that have patents that are about to expire, by developing a new formulation and taking out new patents for the new formulation.⁸ It has been noted that line extensions through new formulations are not being developed for significant therapeutic advantage, but rather for the company's economic advantage.⁹

We do not believe that the characteristics of Type 5 NDA drugs would advance the intent of the TDAPA

for new renal dialysis drugs and biological products that fall within an existing functional category. While Type 5 NDA drugs may have clinical benefits to patients over previously approved products, we do not make that assessment as part of ESRD PPS payment policy. We do not believe that the types of changes represented by Type 5 NDAs enhance our goal of increased competition with the overarching goal of lowering drug prices. To the contrary, it seems that a goal of line extensions can be to thwart competition. Studies indicate that there is no lowering of prices through competition from line extensions. Rather, it has been reported that prices remain rigid and are not lowered. In fact, not only can product line extensions thwart competition, but they inherit the market success of the original brand, sometimes with little quality improvement over the original brand.¹⁰ For these reasons, we do not believe that providing a payment adjustment to ESRD facilities to support the uptake of a drug that is a line extension in their business model is a judicious use of Medicare resources. In addition, a study published in February 2019, concluded that the pattern of a considerable subset of reformulations prolonged the consumption of costly brand-name products at the expense of timely market entry of low cost generics.¹¹ This and other recent publications this past year have been helpful to inform policy proposals by demonstrating that reformulations frequently kept drug prices high, which does not meet our goal of increased competition assisting in the lowering of drug prices, at the expense of Medicare resources being directed to innovative drugs that advance the treatment of ESRD. Consequently, we believe it is important to propose to install guardrails to ensure that sufficient incentives exist for timely innovative drugs for the ESRD patients, that competition for lowering drug prices is not thwarted, and that perverse incentives do not exist for patients to receive a drug because it is financially rewarding, through the TDAPA, for the ESRD facilities. For these reasons, we do not believe Type 5 NDA drugs should be eligible for the TDAPA, and we are

⁵ V. Kadiyali et al. Product line extensions and competitive market interactions: An empirical analysis. *J Econometrics*. 1998, 89 (1–2): 339–63.

⁶ S.H. Hong et al. Product Line Extensions and Pricing Strategies of Brand-Name Drugs Facing Patent Expirations, *J MCP*. 2005, 11(9): 746–754.

⁷ A.C. Fowler, October 6, 2017, White Paper—Pharmaceutical Line Extensions in the United States, <http://www.nber.org/aging/valmed/WhitePaper-Fowler10.2017.pdf>.

⁸ S.H. Hong et al. Product Line Extensions and Pricing Strategies of Brand-Name Drugs Facing Patent Expirations, *J MCP*. 2005, 11(9): 746–754.

⁹ R. Collier Drug patents: The evergreening problem. *CMAJ*. 2013 Jun11; 185(9):E385–6. doi: 10.1503/cmaj.109–4466. Epub 2013 Apr 29.

¹⁰ S.H. Hong et al. Product Line Extensions and Pricing Strategies of Brand-Name Drugs Facing Patent Expirations, *J MCP*. 2005, 11(9): 746–754.

¹¹ Reed F. Beall et al. New Drug Formulations and Their Respective Generic Entry Dates, *JMCP*. February, 2019, 25(2): 218–224. Available at: <https://www.jmcp.org/doi/pdf/10.18553/jmcp.2019.25.2.218>.

proposing to exclude them in new § 413.234(e).

(c) Type 7 NDA—Previously Marketed but Without an Approved NDA

We are proposing to exclude Type 7 NDA, which is for a drug product that contains an active moiety that has not been previously approved in an application but has been marketed in the U.S., from being eligible for the TDAPA for renal dialysis drugs and biological products in existing functional categories. In addition, we are proposing to exclude Type 9 NDAs, as discussed in section II.B.1.ii.(d) of this proposed rule, when the “parent NDA” is a Type 7 NDA. This classification only applies to the first NDA approved for a drug product containing this (these) active moiety(ies). They include, but are not limited to the following four items: (1) The first post-1962 application for an active moiety marketed prior to 1938; (2) The first application for an active moiety first marketed between 1938 and 1962 that is identical, related or similar (IRS) to a drug covered by a Drug Efficacy Study Implementation (DESI) notice (FDA’s regulation at 21 CFR 310.6(b)(1) states that, “[a]n identical, related, or similar drug includes other brands, potencies, dosage forms, salts, and esters of the same drug moiety as well as any of drug moiety related in chemical structure or known pharmacological properties”); (3) The first application for an IRS drug product first marketed after 1962; and (4) The first application for an active moiety that was first marketed without an NDA after 1962.

We do not believe that the characteristics of Type 7 NDA drugs would advance the intent of the TDAPA policy because these drugs were already on the market. For example, FDA received an application for calcium gluconate, which is on the Consolidated Billing List and is already recognized as a renal dialysis service included in the ESRD PPS base rate. The NDA for calcium gluconate was classified by FDA in 2017 to be a Type 7 NDA. This drug is not innovative and does not significantly advance the treatment options for ESRD. If the Type 7 NDA drug is determined to be a renal dialysis service, it is likely it is already being used by the facility, so paying the TDAPA for it does not assist the facilities in uptake for their business model, which was one of the goals of the TDAPA. In addition, paying the TDAPA for Type 7 NDA drugs uses Medicare resources that ultimately could be used to pay for innovative drugs and services that result from

research and development in areas of high value innovation.

Therefore, we do not consider Type 7 NDA drugs to be eligible for the TDAPA.

(d) Type 8 NDA—Prescription to Over-the-Counter (OTC)

We are proposing to exclude Type 8 NDA, which is when a prescription drug product changes to an over-the-counter (OTC) drug product, from being eligible for the TDAPA. In addition, we are proposing to exclude Type 9 NDAs, as discussed in section II.B.1.ii.(d) of this proposed rule, when the “parent NDA” is a Type 8 NDA. A Type 8 NDA is for a drug product intended for OTC marketing that contains an active ingredient that has been approved previously or marketed in the U.S. only for dispensing by prescription. A Type 8 NDA may provide for a different dosing regimen, different strength, different dosage form, or different indication from the product approved previously for prescription sale.

If the proposed OTC switch would apply to all indications, uses, and strengths of an approved prescription dosage form (leaving no prescription-only products of that particular dosage form on the market), then FDA indicates that the application holder should submit the change as a supplement to the approved application. If the applicant intends to switch only some indications, uses, or strengths of the dosage form to OTC status (while continuing to market other indications, uses, or strengths of the dosage form for prescription-only sale), FDA indicates that the applicant should submit a new NDA for the OTC products, which would be classified as Type 8 NDA.

We do not believe that the characteristics of Type 8 NDA drugs would advance the intent of the TDAPA policy for renal dialysis drugs and biological products in existing functional categories because Type 8 NDAs are for drugs transitioning from prescription to OTC, and Medicare does not provide coverage of OTC drugs. Although certain innovative approaches may help increase access to a broader selection of nonprescription drugs for ESRD beneficiaries, we do not consider the transition from prescription to OTC to be innovative for purposes of the TDAPA policy. We believe that making the TDAPA available for Type 8 NDAs may defeat the intent of lowering overall costs for both the ESRD beneficiary and for Medicare, is not needed by the facilities to provide additional support during an uptake period so they can be incorporated into the business model. Over the counter drugs have already gone through safety trials if they were

previously prescription drugs and their end-point physiologic activity had been recognized and documented. Therefore, the newness is a reflection of accessibility to the general public without having to obtain a prescription through a licensed practitioner. We believe that these drugs, though new to the market, are not sufficiently innovative to qualify for TDAPA eligibility.

(e) Generic Drugs

We are proposing to exclude drugs approved by FDA under section 505(j) of the FD&C Act, which are generic drugs, from being eligible for the TDAPA. As discussed previously in section II.B.1.b of this proposed rule, an ANDA is an application submitted by drug manufacturers and approved by FDA under section 505(j) of the FD&C Act for a duplicate of a previously approved drug product.

An ANDA generally must contain information to show that the proposed generic product: (1) Is the same as the reference listed drug (RLD) with respect to the active ingredient(s), conditions of use, route of administration, dosage form, strength, and labeling (with certain permissible differences) and (2) is bioequivalent to the RLD. See section 505(j)(2)(A) of the FD&C Act. An ANDA may not be submitted if clinical investigations are necessary to establish the safety and effectiveness of the proposed product. A drug product approved in an ANDA is presumed to be therapeutically equivalent to its RLD. A drug product that is therapeutically equivalent to an RLD can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the RLD when administered to patients under the conditions specified in the labeling.

In the CY 2019 ESRD PPS final rule (83 FR 56931), we included generic drugs in the definition of a new renal dialysis drug or biological product eligible for the TDAPA because we believed this would foster both a competitive marketplace and innovation of drugs within functional categories, mitigate high launch prices, and provide a financial boost to support utilization. During the CY 2019 ESRD PPS rulemaking, we were aware of the pricing strategies being used by certain pharmaceutical companies to block the entry of generic drugs into the market in order to keep drug prices high. Though generic drugs are not considered innovative products, our primary intent in making generic drugs eligible for the TDAPA was to increase competition so that drug prices would be lower for the

beneficiary. However, we have since learned that bringing more generic drugs to market, though a significant component in lowering drug prices, is not in and of itself the solution.

For example, in June 2018, a report examined increased generic drug competition as the primary impetus to curtail skyrocketing drug prices, and found that though it is helpful, there is a ceiling on its impact. It found that generic competition would not affect 46 percent of the estimated sales revenue of the top 100 drugs through 2023.¹²

In June 2018, an article noted that competition has a limited impact on American health care, particularly when it comes to expensive interventions like prescription drugs. Notably, when an expensive drug's competition within the same family of drugs came on the market the prices did not go down. Rather, the prices increased approximately 675 percent. Each new entrant cost more than its predecessors, and their makers then increased their prices to match the newcomer's. When the first generic finally entered the market, its list price was only slightly less at 539 percent above the original entrant. Economists call this "sticky pricing" and the article notes that this is common in pharmaceuticals, and has raised the prices in the U.S. of drugs for serious conditions even when there are multiple competing drugs. Compounding this problem, the article states that companies have decided it is not in their interest to compete.¹³

For purposes of the ESRD PPS, we believe that we need to strike a balance between enhancing significant renal dialysis drug innovation and encouraging competition through support of innovative drugs that would become optimal choices for ESRD patients and advance their care through improved treatment choices. Our goal in supporting competition among drugs in the ESRD PPS functional categories was to ultimately affect the launch price of new drugs. We now question whether including all new renal dialysis drugs and biological products as eligible for the TDAPA would help us meet that goal. Rather, we believe reining in launch prices by placing guardrails on line extensions, reformulations and "sticky pricing" while staying mindful

of the Medicare trust fund would better enable us to achieve our goals for the TDAPA policy.

Therefore, we are proposing to revise the drug designation process regulation at § 413.234 by revising paragraph (b)(1)(ii) and adding paragraph (e), effective January 1, 2020, to specify that a new renal dialysis drug used to treat or manage a condition for which there is an ESRD PPS functional category is not eligible for payment using the TDAPA if it is a generic drug or if the NDA for the drug is classified by FDA as a certain type—specifically, if the drug is approved under section 505(j) of the FD&C Act or the NDA for the drug is classified by FDA as Type 3, 5, 7 or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the "parent NDA" is a Type 3, 5, 7 or 8.

We are soliciting comments as to whether any NDA Types that would remain eligible for the TDAPA under our proposal should be excluded, and whether any NDA Types that we are proposing to exclude should be included, for example, within the NDA Type 3 (new dosage form) the inclusion of intravenous to oral route of administration.

We are also proposing a technical change to § 413.234(a) to revise the definitions "ESRD PPS functional category" and "Oral-only drug" to be consistent with FDA nomenclature. We are proposing to change the definition of "ESRD PPS functional category" to replace "biologicals" with "biological products." We are also proposing to change the definition of "Oral-only drug" to replace "biological" with "biological product."

As compared to the TDAPA policy finalized in the CY 2019 ESRD PPS final rule, we believe that these proposed revisions would reduce CY 2020 Medicare expenditures for new renal dialysis drugs and biological products, which would also have a better downstream impact for beneficiary coinsurance. Specifically, in the CY 2019 ESRD PPS final rule (83 FR 56932), we finalized that, effective January 1, 2020, the TDAPA would apply for all new renal dialysis drugs and biological products. Since the proposed policy would carve out certain drug types from being eligible for the TDAPA and would be more limited than the expansive policy finalized in the CY 2019 ESRD PPS final rule for CY 2020, there would be lower Medicare expenditures in CY 2020. Further, the downstream effect of lower Medicare expenditures is lower coinsurance for beneficiaries.

We solicit comment on the proposals to revise the drug designation process

regulation at § 413.234 to reflect that certain new renal dialysis drugs would be excluded from eligibility for the TDAPA.

ii. Examples of New Renal Dialysis Drugs and Biological Products That Would Remain Eligible for the TDAPA

Under our proposal, any new renal dialysis drug or biological product that we are not proposing for exclusion in section II.B.1.c.i of this proposed rule, would continue to be eligible for the TDAPA. In the following paragraphs we provide some examples of the types of renal dialysis drugs and biological products that we believe would continue to be eligible for the TDAPA under our proposal, using the descriptions in the NDA classification code referenced in section II.B.1.c of this proposed rule. We note that under our proposal, FDA approvals under section 351 of the PHS Act, which includes biological products and biological products that are biosimilar to, or interchangeable with, a reference biological product, also would continue to be eligible for the TDAPA.

(a) Type 1 NDA—New Molecular Entity

Type 1 NDA refers to drugs containing an NME. An NME is an active ingredient that contains no active moiety that has been previously approved by FDA in an application submitted under section 505(b) of the FD&C Act or has been previously marketed as a drug in the U.S.

We believe the new renal dialysis drugs that are classified by FDA as a Type 1 NDA should continue to be eligible for the TDAPA because they generally fall within the 505(b)(1) pathway typically used for novel drugs, meaning they have not been previously studied or approved, and their development requires the sponsor to conduct all studies needed to demonstrate the safety and efficacy of the drug. Unlike the drugs proposed to be excluded from the TDAPA as described above, these drugs are generally not line extensions of previously existing drugs. There will be expenses with uptake by ESRD facilities of Type 1 NDA drugs, and one of the goals of the TDAPA is to provide additional support to ESRD facilities during the uptake period for these innovative drugs and help incorporate them into their business model.

(b) Type 2 NDA—New Active Ingredient

Type 2 NDA is for a drug product that contains a new active ingredient, but not an NME. A new active ingredient includes those products whose active moiety has been previously approved or

¹² B. Isgur et al., Health Research Institute, The FDA is approving more generic drugs than ever before. Faster than ever before. Is it enough to lower drug costs? June 2018. Available at: <https://www.pwc.com/us/en/health-industries/health-research-institute/pdf/pwc-health-research-institute-generic-drug-pricing-june-2018.pdf>.

¹³ E. Rosenthal, New York Times, Why Competition Won't Bring Down Drug Prices. June 21, 2018. Available at: <https://www.nytimes.com/2018/06/21/opinion/competition-drug-prices.html>.

marketed in the U.S., but whose particular ester, salt, or noncovalent derivative of the unmodified parent molecule has not been approved by FDA or marketed in the U.S., either alone, or as part of a combination product. Similarly, if any ester, salt, or noncovalent derivative has been marketed first, the unmodified parent molecule would also be considered a new active ingredient, but not an NME. Furthermore, if the active ingredient is a single enantiomer and a racemic mixture (the name for a 50:50 mixture of 2 enantiomers) containing that enantiomer has been previously approved by FDA or marketed in the U.S., or if the active ingredient is a racemic mixture containing an enantiomer that has been previously approved by FDA or marketed in the U.S., the NDA will be classified as a Type 2 NDA. Enantiomers are chiral molecules that are non-superimposable, mirror images of one another.

We believe the new renal dialysis drugs classified by FDA as Type 2 NDAs should be eligible for the TDAPA because, in part, it covers a single enantiomer active ingredient for which a racemic mixture containing that enantiomer has been approved by FDA. Single enantiomer drugs can lead to fewer drug interactions in the ESRD population, which already has a significant medication burden.¹⁴ We believe these drugs are innovative and it is important to support their development because of their lower development cost burden, coupled with enhancement of patient choice, which supports not only innovation, but the ability of the product to successfully launch and compete. We believe having the Type 2 NDA drugs be eligible for the TDAPA would support our goal of providing support to the ESRD facilities for 2 years while the drug is being incorporated into their business model.

(c) Type 4 NDA—New Combination

Type 4 NDA is a new drug-drug combination of two or more active ingredients. An application for a new drug-drug combination product may have more than one classification code if at least one component of the combination is an NME or a new active ingredient.

We are proposing that new renal dialysis drugs that are classified as a Type 4 NDA should continue to be

eligible for the TDAPA if at least one of the components is a Type 1 NDA (NME) or a Type 2 NDA (new active ingredient), both of which merit the TDAPA as previously discussed. An added advantage is that while introducing an innovative product, which is not the case for Type 3 NDA drugs, it reduces the pill burden to a patient population challenged with multiple medications and a complex drug regimen. Medication adherence is thought to be around 50 percent in the dialysis population and reducing this burden can improve adherence and should lead to improvement in treatment outcomes.¹⁵

We believe the advantages of Type 1 NDA and Type 2 NDA drugs, coupled with the possibility of improved adherence, merits eligibility for the TDAPA in that it encourages both innovators to develop competitive drugs at lower prices for this NDA classification code, and ESRD facilities to use the products with the boost that the TDAPA will provide in facilitating uptake of these new products.

(d) Type 9 NDA—New Indication or Claim, Drug Not To Be Marketed Under Type 9 NDA After Approval

Type 9 NDA is for a new indication or claim for a drug product that is currently being reviewed under a different NDA (the “parent NDA”), and the applicant does not intend to market this drug product under the Type 9 NDA after approval. Generally, a Type 9 NDA is submitted as a separate NDA so as to be in compliance with the guidance for industry on Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees.¹⁶ When the Type 9 NDA is submitted, it is given the same NDA classification code as the pending NDA. When one application is approved, the other application will be reclassified as a Type 9 NDA regardless of whether it was the first or second NDA actually submitted. After the approval of a Type 9 NDA, FDA will “administratively close” the Type 9 NDA and thereafter only accept submissions to the “parent” NDA.

Since Type 9 NDA is a new clinical indication, this suggests that a drug company is pioneering a new approach

to provide better pharmacologic care for vulnerable ESRD patients with complex medical needs, and we consider this to be sufficiently innovative to warrant TDAPA eligibility.

We believe renal dialysis drugs that are classified as NDA Types 1, 2, and 4 are all innovative and therefore we propose that these drugs should continue to be eligible for the TDAPA as discussed in sections II.B.1.c.ii.(a), II.B.1.c.ii.(b), and II.B.1.c.ii.(c), of this proposed rule. When the “parent NDA” is Type 1, 2, or 4, Type 9 NDA would be a new indication of those innovative drugs. Therefore we believe Type 9 NDA, when the “parent” is Type 1, 2, or 4, is just as innovative as Type 1, 2, or 4 and therefore should also be eligible for the TDAPA. We believe applying the TDAPA with respect to Type 9 NDA new renal dialysis drugs would assist ESRD facilities in adopting these drugs into their treatment protocols for patients, when these drugs are warranted for use in that subset of patients.

(e) Type 10 NDA—New Indication or Claim, Drug To Be Marketed Under Type 10 NDA After Approval

Type 10 NDA is for a drug product that is a duplicate of a drug product that is the subject of either a pending or approved NDA, and the applicant intends to market the drug product under this separate Type 10 NDA after approval. A Type 10 NDA is typically for a drug product that has a new indication or claim, and it may have labeling and/or a proprietary name that is distinct from that of the original NDA. When the Type 10 NDA is submitted, it would be given the same NDA classification code as the original NDA unless that NDA is already approved. When one application is approved, the other would be reclassified as Type 10 NDA regardless of whether it was the first or second NDA actually submitted.

We believe renal dialysis drugs with the Type 10 NDA classification code are sufficiently innovative and should be eligible for the TDAPA because a new indication for a previously submitted drug that is applicable to renal dialysis advances the field and suggests the drug company is pioneering a new approach to provide better pharmacologic care for vulnerable ESRD patients with complex medical needs. We believe this could provide savings in terms of time-to-market and research and development, which could be reflected in the launch price of the drug. We further believe applying the TDAPA with respect to Type 10 NDA new renal dialysis drugs will assist ESRD facilities in adopting these drugs into their treatment

¹⁴ A Calcaterra and I D'Acquarica, J Pharmaceutical and Biomedical Analysis, “The market of chiral drugs: Chiral switches versus de novo enantiomerically pure compounds,” 147(2018). Pages 323–340. Available at: <https://www.sciencedirect.com/science/article/pii/S0731708517314838?via%3Dihub>.

¹⁵ K Parker et al., Medication Burden in CKD–5D: Impact of dialysis modality and setting, Clin Kidney J. 2014, 7: 557–561. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4389130/pdf/sfu091.pdf>.

¹⁶ FDA. Guidance for Industry. Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees. Available at: <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079320.pdf>.

protocols for patients when these drugs are warranted for use in that subset of patients.

(f) FDA Approvals Under Section 351 of the PHS Act

Under our proposal, products that receive FDA approval under section 351 of the PHS Act, which occurs for new biological products and biological products that are biosimilar to, or interchangeable with, a reference biological product, would continue to be eligible for the TDAPA.

A BLA submitted under section 351(a) of the PHS Act is a “stand-alone BLA” that contains all information and data necessary to demonstrate that (among other things) the proposed biological product is safe, pure, and potent.

An application for licensure of a proposed biosimilar biological product submitted in a BLA under section 351(k) of the PHS Act must contain information demonstrating that the biological product is biosimilar to a reference product. ‘Biosimilar’ means “that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components” and that “there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product” (see section 351(i)(2) of the PHS Act).

An application for licensure of a proposed interchangeable product submitted in a BLA under section 351(k) of the PHS Act must meet the standards of “interchangeability.” To meet the additional standard of “interchangeability,” an applicant must provide sufficient information to demonstrate biosimilarity, and also to demonstrate that the biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch (see section 351(k)(4) of the PHS Act). Interchangeable products may be substituted for the reference product without the intervention of the prescribing healthcare provider (see section 351(i)(3) of the PHS Act). Further information regarding

biosimilar biological products is available on the FDA website.^{17 18 19}

CMS continues to support the development and the utilization of these products that contain innovative technology for the treatment of ESRD. The approval process for biosimilar biological products is a different pathway than that for generic drugs and has different requirements. We believe that a categorical exclusion from TDAPA eligibility for all biological products that are biosimilar to or interchangeable with a reference biological product, would disadvantage this sector of biological products in a space where we are trying to support technological innovation. While the products themselves may not be innovative, CMS believes the technology used to develop the products is sufficiently new and innovative to warrant TDAPA payment at this time.

However, unlike NDAs submitted pursuant to sections 505(b)(1) or 505(b)(2) of the FD&C Act, we do not have a categorical system to use as a proxy for assistance in determining which types of applications would meet the intent of the TDAPA policy. Therefore, we are proposing to continue to allow all biosimilar to or interchangeable with a reference biological products to remain eligible for the TDAPA instead of proposing to exclude all of them.

We are aware, however, that there are similar concerns about providing the TDAPA for these products that there are with generics. Specifically, according to a recent report, increased drug class competition for biosimilar biological products did not translate into pricing reductions, and there was a market failure contributing to the rising costs of prescription drugs. The researchers noted that the increases were borne solely by Medicare.²⁰ We will continue

to monitor future costs of biosimilar biological products as they pertain to renal dialysis, the TDAPA, and the ESRD PPS.

In summary, with regard to new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category, we believe that continuing to include these drugs and biological products as eligible for the TDAPA focuses payment to those products that are innovative in a way that meets the intent of the adjustment. That is, our intention is to support innovation by helping ESRD facilities make appropriate changes in their businesses to adopt such products, provide additional payment for such associated costs, incorporate these drugs and biological products into their beneficiaries’ care plans and potentially promote competition among drugs and biological products within the ESRD PPS functional categories. We plan to continue to monitor the use of the TDAPA for new renal dialysis drugs and biological products that fall within an existing functional category and will carefully evaluate the products that qualify for the payment adjustment. We note that for new renal dialysis drugs and biological products that do not fall within an existing ESRD PPS functional category, the purpose of the TDAPA continues to be a pathway toward a potential base rate modification.

Based on our past experience and our expectation of detailed analysis of future drug product utilization, pricing and payment, CMS anticipates proposing further refinements to the TDAPA policy through notice and comment rulemaking in the future.

d. Proposal To Modify the Basis of Payment for the TDAPA for Calcimimetics in CY 2020

In the CY 2016 ESRD PPS final rule (80 FR 69025 through 69026), we finalized an exception to the drug designation process for calcimimetics. Specifically, we identified phosphate binders and calcimimetics as oral-only drugs and, in accordance with § 413.234(d), an oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by FDA. We stated that under § 413.234(b)(1), if injectable or intravenous forms of phosphate binders or calcimimetics are approved by FDA, these drugs would be considered reflected in the ESRD PPS bundled

¹⁷ FDA. Guidance for Industry—Questions and Answers on Biosimilar Development and the BPCI Act. December, 2018. Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/questions-and-answers-biosimilar-development-and-bpci-act-guidance-industry>.

¹⁸ FDA. Draft guidance for industry—New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2) (when final, this guidance will represent FDA’s current thinking on this topic). Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/new-and-revised-draft-qas-biosimilar-development-and-bpci-act-revision-2>.

¹⁹ FDA. Webinar. Overview of the Regulatory Framework and FDA’s Guidance for the Development and Approval of Biosimilar and Interchangeable Products in the US. Available at: <https://www.fda.gov/drugs/biosimilars/fda-webinar-overview-regulatory-framework-and-fdas-guidance-development-and-approval-biosimilar-and>.

²⁰ A San-Juan-Rodriguez et al. “Assessment of Price Changes of Existing Tumor Necrosis Factor

Inhibitors After the Market Entry of Competitors.” JAMA Intern Med 2019. Feb18 <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2724390>.

payment because these drugs are included in an existing functional category, so no additional payment would be available for inclusion of these drugs.

However, we recognized the uniqueness of these drugs and finalized in the CY 2016 ESRD PPS final rule that we will not apply this process to injectable or intravenous forms of phosphate binders and calcimimetics when they are approved because payment for the oral forms of these drugs was delayed and dollars were never included in the base rate to account for these drugs. We further stated that we intend to use notice-and-comment rulemaking to include the oral and non-oral forms of calcimimetics and phosphate binders in the ESRD PPS bundled payment after the payment of the TDAPA. We explained that when these drugs are no longer oral-only drugs, we will pay for them under the ESRD PPS using the TDAPA based on the payment methodologies in section 1847A of the Act for a period of at least 2 years.

Change Request 10065, Transmittal 1889 issued August 4, 2017, replaced by Transmittal 1999 issued January 10, 2018, implemented the TDAPA for calcimimetics effective January 1, 2018. As discussed previously, calcimimetics will be paid using the TDAPA for a minimum of 2 years. Since payments have been made beginning January 1, 2018, a 2-year period would end December 31, 2019. We are still in the process of collecting utilization claims data for both the oral and non-oral form of calcimimetics, which will be used for a rate setting analysis. Therefore, we will continue to pay for calcimimetics using the TDAPA in CY 2020.

We stated in the CY 2019 ESRD PPS final rule (83 FR 56943) that we would continue to pay the TDAPA using the pricing methodologies under section 1847A of the Act (which includes ASP+6 percent) until sufficient claims data for rate setting analysis for the new injectable or intravenous product are available, but not for less than 2 years. Calcimimetics were the first drugs for which we paid the TDAPA (83 FR 56931), and this increased Medicare expenditures by \$1.2 billion in CY 2018. It is clear, therefore, that ESRD facilities are furnishing these innovative drugs. We explained in the CY 2019 ESRD PPS final rule (83 FR 56943) that one of the rationales for the 6 percent add-on to ASP has been to cover administrative and overhead costs. We explained that the ESRD PPS base rate has dollars built in for administrative complexities and overhead costs for drugs and biological products (83 FR 56944). We have

provided the TDAPA for calcimimetics for 2-full years, and we believe that is sufficient time for ESRD facilities to address any administrative complexities and overhead costs that may have arisen with regard to furnishing the calcimimetics. We also believe this proposal strikes a balance between supporting ESRD facilities in their uptake of these products and limiting the financial burden that increased payments place on beneficiaries and Medicare expenditures. Finally, this policy is consistent with the policy finalized for all other new renal dialysis drugs and biological products in the CY 2019 ESRD PPS final rule (83 FR 56948). We therefore propose that the basis of payment for the TDAPA for calcimimetics, beginning in CY 2020, will be 100 percent of ASP. That is, we propose to modify § 413.234(c) by removing the clause “except that for calcimimetics it is based on the pricing methodologies under section 1847A of the Social Security Act.”

In addition, under the proposal discussed in section II.B.2.c of this proposed rule, since we currently receive ASP data for calcimimetics, beginning January 1, 2020, we would no longer apply the TDAPA for calcimimetics if we stop receiving the latest full calendar quarter of ASP data for calcimimetics during the TDAPA payment period.

e. Proposed Revision to 42 CFR 413.230

In the CY 2011 ESRD PPS final rule (75 FR 49200), we added § 413.230 to 42 CFR part 413, subpart H to codify that the per treatment payment amount is the sum of the per treatment base rate established in § 413.220, adjusted for wages as described in § 413.231, and adjusted for facility-level and patient-level characteristics described in §§ 413.232 and 413.235; any outlier payment under § 413.237; and any training adjustment add-on under § 414.335(b). The per treatment payment amount is Medicare's payment to ESRD facilities under the ESRD PPS for furnishing renal dialysis services to Medicare ESRD beneficiaries.

In the CY 2016 ESRD PPS final rule (80 FR 69024), we codified the drug designation process regulation in § 413.234, which provides a TDAPA under § 413.234(c) when certain eligibility criteria are met. We apply the TDAPA at the end of the calculation of the ESRD PPS payment, which is similar to the application of the outlier payment (§ 413.237(c)) and the training add-on adjustment (§ 413.235(c)). That is, once the ESRD PPS base rate is adjusted by any applicable patient- and facility-level adjustments we add to it

any applicable outlier payment, training add-on adjustment, or the TDAPA.

In CY 2016 ESRD PPS rulemaking, we did not propose a corresponding revision to § 413.230 to reflect that the TDAPA is a component in the determination of the per treatment payment amount. In this proposed rule, we are proposing a revision to § 413.230 to add paragraph (d) to reflect the TDAPA. We believe this modification is necessary so the regulation appropriately reflects all inputs in the calculation of the per treatment payment amount. This revision to the regulation would not change how the ESRD PPS per treatment payment amount is currently calculated. We are also proposing to revise § 413.230 to include, as part of the calculation of the per treatment payment amount, any Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) as proposed in section II.B.3.b.iii of this proposed rule.

We are also proposing a technical change to § 413.230(c) to replace “§ 414.335(b)” with a more appropriate reference to the training adjustment add-on requirement, which is “§ 413.235(c).” In the CY 2011 ESRD PPS final rule (75 FR 49202) we inadvertently referred to § 414.335(b), which states, “After January 1, 2011, a home and self-training amount is added to the per treatment base rate for adult and pediatric patients as defined in § 413.230” when finalizing § 413.230. Section 413.235(c) similarly states “CMS provides a wage-adjusted add-on per treatment adjustment for home and self-dialysis training.” However, § 414.335(b) describes the training adjustment add-on when erythropoietin (EPO) is furnished to home dialysis patients, whereas § 413.235(c) describes the training adjustment add-on applicable, generally, even when EPO is not furnished. When we finalized § 413.230 in the CY 2011 ESRD PPS final rule, we intended for the training adjustment to apply more generally, rather than just when EPO is furnished and therefore, we are proposing to refer to § 413.235(c). We solicit comment on these proposed changes to § 413.230 to (1) add paragraph (d) to reflect that the TDAPA is a component in the determination of the per treatment payment amount and (2) replace the reference to “§ 414.335(b)” in § 413.230(c) with a more appropriate reference to the training adjustment add-on requirement, which is “§ 413.235(c).”

2. Proposed Average Sales Price (ASP) Conditional Policy for the TDAPA

a. Background

In the CY 2005 Physician Fee Schedule (PFS) final rule, published on November 15, 2004 (69 FR 66299 through 66302) in the **Federal Register**, we discussed that section 303(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) added section 1847A to the Act and established a payment methodology for certain drugs and biological products not paid on a cost or prospective payment basis furnished on or after January 1, 2005. Payments made under this methodology are primarily based on quarterly data submitted to CMS by drug manufacturers, and most payments under this methodology are based on the ASP. ASP-based payments are determined from manufacturer's sales to all purchasers (with certain exceptions) net of manufacturer rebates, discounts, and price concessions. Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of "best price" in the Medicaid Drug Rebate Program. ASP-based payments are determined for individual HCPCS codes. To allow time for manufacturers to submit quarterly data and for CMS to determine, check and disseminate payment limits to contractors that pay claims, the ASP-based payment limits are subject to a 2 quarter lag, which means that sales from January to March are used to determine payment limits in effect from July to September.²¹

Section 1847A(b)(1)(A) of the Act requires that the Medicare payment for a multiple source drug included within the same HCPCS code be equal to 106 percent of the ASP for the drug products included in the HCPCS code. Section 1847A(b)(1)(B) of the Act also requires that the Medicare payment for a single source drug HCPCS code be equal to the lesser of 106 percent of the ASP for the HCPCS code or 106 percent of the Wholesale Acquisition Cost (WAC) of the HCPCS code (83 FR 56929). The WAC is defined in section 1847A(c)(6)(B) of the Act as the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the U.S., not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale

price guides or other publications of drug or biological pricing data.

Section 1847A(c)(4) of the Act further provides a payment methodology in cases where the ASP during 1st quarter of sales is unavailable, stating that in the case of a drug or biologicals during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug or biological product are not sufficiently available from the manufacturer to compute an ASP for the biological product, the Secretary may determine the amount payable under this section for the drug or biological product based on the WAC or the methodologies in effect under Medicare Part B on November 1, 2003, to determine payment amounts for drugs or biological products. For further guidance on how Medicare Part B pays for certain drugs and biological products, see Medicare Claims Processing Manual (Pub. L. 100-04) (chapter 17, section 20) (<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf>).

We have used the payment methodology under section 1847A of the Act since the implementation of the ESRD PPS when pricing ESRD related drugs and biological products previously paid separately under Part B (prior to the ESRD PPS) for purposes of ESRD PPS policies or calculations (82 FR 50742 through 50743). In the CY 2016 ESRD PPS final rule (80 FR 69024), we adopted § 413.234(c), which requires that the TDAPA is based on payment methodologies available under section 1847A of the Act (including 106 percent of ASP). We also use such payment methodologies for Part B ESRD related drugs or biological products that qualify as an outlier service (82 FR 50745). For the purposes of the ESRD PPS, we use "payment methodology" interchangeably with "pricing methodology."

In the CY 2019 ESRD PPS final rule (83 FR 56948) we finalized a revision to § 413.234(c) under the authority of section 1881(b)(14)(D)(iv) of the Act, to base the TDAPA on 100 percent of ASP (ASP+0) instead of the pricing methodologies available under section 1847A of the Act (which includes ASP+6). We also explained in the CY 2019 ESRD PPS final rule (83 FR 56944) that there are times when the ASP is not available. For example, when a new drug or biological product is brought to the market, sales data is not sufficiently available from the manufacturer to compute an ASP. Therefore, we finalized a change to § 413.234(c) to specify that if ASP is not available, the TDAPA is based on 100 percent of WAC

(WAC+0) and, when WAC is not available, the payment is based on the drug manufacturer's invoice. We also modified § 413.234(c) to reflect that the basis of payment for the TDAPA for calcimimetics would continue to be based on the pricing methodologies available under section 1847A of the Act (which includes ASP+6). We specified that these changes to § 413.234(c) would be effective January 1, 2020.

In the CY 2019 ESRD PPS final rule (83 FR 56943), we discussed that the TDAPA is a payment adjustment under the ESRD PPS and is not intended to be a mechanism for payment for new drugs and biological products under Medicare Part B. We further explained that we believe it may not be appropriate under section 1881(b)(14)(D)(iv) of the Act to base the TDAPA strictly on the pricing methodologies under section 1847A of the Act. We explained that, in the CY 2019 ESRD PPS proposed rule (83 FR 34315), we considered options on which to base payment under the TDAPA, for example, maintaining the policy as is or potentially basing payments on the facility cost of acquiring drugs and biological products. We found that while the pricing methodologies under 1847A of the Act, and specifically ASP, could encourage certain unintended consequences, ASP data continues to be the best data available since it is commonly used to facilitate Medicare payment across care settings and is based on the manufacturer's sales to all purchasers (with certain exceptions) and is net of manufacturer rebates, discounts, and price concessions (83 FR 34315).

b. Basis for Conditioning the TDAPA on the Availability of ASP Data

As noted previously, under the change to § 413.234(c) finalized in the CY 2019 ESRD PPS final rule (83 FR 56948), effective January 1, 2020, the basis of payment for the TDAPA is ASP+0, but if ASP is not available, then it is WAC+0, and if WAC is not available, then it is based on the drug manufacturer's invoice. We also modified § 413.234(c) to reflect that the basis of payment for the TDAPA for calcimimetics would continue to be based on the pricing methodologies available under section 1847A of the Act (which includes ASP+6). We also note that as discussed in section II.B.1.d of this proposed rule, we are now proposing to modify the basis of payment for the TDAPA for calcimimetics for CY 2020 to ASP+0.

Following publication of the CY 2019 ESRD PPS final rule, we have continued to assess our policy allowing for WAC

²¹ ASPE, Issue Brief, Medicare Part B Drugs: Pricing and Incentives. March 2016. Available at: <https://aspe.hhs.gov/system/files/pdf/187581/PartBDrug.pdf>.

or invoice pricing if ASP is not available, and we have become concerned that it could lead to drug manufacturers who are not otherwise required to submit ASP data to CMS to delay submission or withhold ASP data from CMS so that ESRD facilities would receive a higher basis of payment for the TDAPA and be incentivized to purchase drugs from those manufacturers.

Calcimimetics were the first drugs for which we paid the TDAPA (83 FR 56931), and this increased Medicare expenditures by \$1.2 billion in CY 2018. We note that the TDAPA for one form of the calcimimetics was based on WAC for 2 quarters, and was more expensive than ASP. In addition, there were delays in the submission of ASP data for that drug, but we are now receiving ASP data for both calcimimetics. We are concerned about the significant increase in Medicare expenditures that resulted from paying the TDAPA for calcimimetics, and about this trend continuing with new renal dialysis drugs and biological products that become eligible for the TDAPA in the future. We therefore believe we need to limit the use of WAC (or invoice pricing) as the basis of the TDAPA to as few quarters as practicable to help limit increases to Medicare expenditures while maintaining our goals for the TDAPA policy—namely, supporting ESRD facilities in their uptake of innovative new renal dialysis drugs and biological products for those products that fall within a functional category and providing a pathway towards a potential base rate modification for those products that do not fall within a functional category.

Further, we are concerned that ASP will not be made available to CMS by drug manufacturers not currently required by statute to do so. Drug manufacturers who have Medicaid Drug Rebate Agreements as part of the Medicaid Drug Rebate Program are required by section 1927(b)(3) of the Act to submit ASP sales data into CMS quarterly. However, we anticipate there could be drugs marketed in the future that are eligible for the TDAPA, but may not be associated with ASP reporting requirements under section 1927(b) of the Act. While manufacturers that do not have Medicaid Drug Rebate Agreements may voluntarily submit ASP data into CMS,²² we are concerned manufacturers may not elect to do so. MedPAC and the Office of the Inspector General (OIG) have both noted concerns

about manufacturers not reporting ASP data for Part B drugs. As discussed in MedPAC's June 2017 Report to Congress,²³ the OIG found that for the 3rd quarter of 2012, out of 45 drug manufacturers who were not required to submit ASP for Part B drugs, only 22 voluntarily submitted ASP data.²⁴

We point out that even for those drug manufacturers who are required to submit ASP data into CMS, not all may fully comply. For the same 3rd quarter of 2012, the OIG found that at least 74 out of the 207 drug manufacturers with Medicaid Drug Rebate Agreements in place did not submit all of their required ASP data for their Part B drugs.²⁵ MedPAC's recommendations in its June 2017 report²⁶ would require that all Part B drug manufacturers submit ASP data into CMS, whether or not those manufacturers have a Medicaid Drug Rebate Agreement.²⁷ Based on this data and our own experience with the calcimimetics, we are concerned that manufacturers may not voluntarily report ASP data into CMS. We continue to believe that ASP is the best data currently available for the basis of payment for the TDAPA, because it is commonly used to facilitate Medicare payment across care settings and is based on the manufacturer's sales to all purchasers (with certain exceptions) net of all manufacturer rebates, discounts, and price concessions (83 FR 56943). Therefore, we believe conditioning the TDAPA on the availability of ASP data is appropriate and necessary to ensure that we are basing the amount of the TDAPA on the best data available.

In addition to our concerns about ASP data reporting generally, we are concerned that the TDAPA policy finalized in the CY 2019 ESRD PPS final rule effective January 1, 2020, could potentially incentivize drug manufacturers who do not have a Medicaid Drug Rebate Agreement to delay or to never submit ASP data in

order for ESRD facilities to receive an increased TDAPA for their products. As noted in section II.B.2.a of this proposed rule, under § 413.234(c), effective January 1, 2020, if ASP is not available to CMS, the basis of payment for the TDAPA is WAC+0 and when WAC is not available, then the TDAPA is based on invoice pricing. As MedPAC discussed in its June 2017 Report to Congress, WAC-based payments would likely increase Medicare expenditures as compared to ASP-based payments. As stated in section 1847A(c)(5) of the Act, ASP is calculated to include discounts and rebates. WAC is ultimately controlled by the manufacturer, and its statutory definition in section 1847A(c)(6)(B) of the Act does not include the discounts that ASP includes.²⁸ Similarly, invoice pricing may not reliably capture all available discounts and thus may be inflated. This means if a drug manufacturer chooses not to submit ASP data into CMS, the TDAPA would be based on an inflated amount beyond what the average cost to ESRD facilities to acquire those drugs. This additional amount would also then increase the coinsurance for the beneficiaries who receive those drugs. We believe conditioning the TDAPA on the availability of ASP data is necessary to mitigate this potential incentive and limit increases to Medicare expenditures.

c. Proposal To Condition the TDAPA Application on the Availability of ASP Data

We are proposing to revise § 413.234(c) to address the following concerns: (1) Increases to Medicare expenditures by the calcimimetics; (2) drug manufacturers not reporting ASP data; and (3) our TDAPA policy potentially incentivizing drug manufacturers to withhold ASP data from CMS. Under our proposed revisions, we would no longer apply the TDAPA for a new renal dialysis drug or biological product if CMS does not receive a full calendar quarter of ASP data within 30 days of the last day of the 3rd calendar quarter after we begin paying the TDAPA for the product. We note that we are not proposing to modify the current ASP reporting process²⁹ and our proposals are

²³ Report to Congress, MedPAC, June 2017, page 42. Available at: http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf.

²⁴ Limitations in Manufacturer Reporting of Average Sales Price Data for Part B Drugs, Office of the Inspector General, page 7. Available at: <https://oig.hhs.gov/oei/reports/oei-12-13-00040.pdf>.

²⁵ Limitations in Manufacturer Reporting of Average Sales Price Data for Part B Drugs, Office of the Inspector General, pages 7–8. Available at: <https://oig.hhs.gov/oei/reports/oei-12-13-00040.pdf>.

²⁶ Report to Congress, MedPAC, June 2017, pages 10–12. Available at: http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf.

²⁷ OMB. A Budget for a Better America. Fiscal Year 2020, page 41. Available at: <https://www.whitehouse.gov/wp-content/uploads/2019/03/budget-fy2020.pdf>.

²² MedPAC. Part B Drugs Payment Systems. October 2017. Page 2. Available at: http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_17_partb_final.pdf?sfvrsn=0.

²⁸ MedPAC. Part B Drugs Payment Systems. October 2017. Pages 43–44. Available at: http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf.

²⁹ CMS. Medicare Part B Drug Average Sales Price. Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html>.

consistent with this process. Since it is possible for a drug manufacturer to begin sales of its product in the middle of a calendar quarter, it may take approximately 2 to 3 quarters for CMS to obtain a full calendar quarter of ASP data. We believe that 3-calendar quarters is a reasonable amount of time for drug manufacturers to submit a full calendar quarter of ASP data to CMS; therefore, we are proposing to allow 3-calendar quarters for drug manufacturers to make ASP available to CMS to enable ESRD facilities to continue to receive the TDAPA for a product.

As discussed in section II.B.2.a of the proposed rule, there is a 2 quarter lag between the sales period for which ASP is reported and the effective date of the rate based on that ASP data. During this period between when the TDAPA is initiated for a product and the effective date of the rate based on the full quarter of ASP data made available to CMS, consistent with the policy finalized in the CY 2019 ESRD PPS final rule (83 FR 56948), the basis of the TDAPA would be WAC+0, and if WAC is not available, then invoice pricing. Once the drug manufacturer begins submitting ASP data, the basis of the TDAPA would be ASP+0. We are proposing that if we have not received a full calendar quarter of ASP data for a new renal dialysis drug or biological product by 30 days after the last day of the 3rd calendar quarter of applying the TDAPA for that product, we would stop applying the TDAPA within the next 2-calendar quarters. For example, if we begin applying the TDAPA on January 1, 2021 for an eligible new renal dialysis drug or biological product, and a full calendar quarter of ASP data for that product has not been made available to CMS by October 30, 2021 (30 days after the last day of the 3rd quarter of paying the TDAPA), we would stop applying the TDAPA for that product no later than March 31, 2022 (2 quarters after the 3rd quarter of paying the TDAPA).

We are therefore proposing to revise the regulatory text at § 413.234(c) to provide that, notwithstanding the time periods for payment of the TDAPA specified in paragraphs (c)(1) and (c)(2), we would no longer apply the TDAPA for a new renal dialysis drug or biological product if CMS has not received a full calendar quarter of ASP data for the product within 30 days after the last day of the 3rd calendar quarter after the TDAPA is initiated for the product.

We expect that once drug manufacturers begin submitting ASP data into CMS, they would continue to do so for the duration of the TDAPA

period as set forth in § 413.234(c). We continue to believe that basing the TDAPA on ASP+0, as compared to WAC+0 or invoice pricing, is the most appropriate choice for the ESRD PPS, and strikes the right balance of supporting ESRD facilities in their uptake of innovative new renal dialysis drugs and biological products and limiting increases to Medicare expenditures. If drug manufacturers were to stop submitting full quarters of ASP data for products that are eligible for the TDAPA, and we had to revert to basing the TDAPA on WAC or invoice pricing, we believe we would be overpaying for the TDAPA for those products.

Therefore, we are also proposing to revise the regulatory text at § 413.234(c) to no longer apply the TDAPA for a new renal dialysis drug or biological product if a drug manufacturer submits a full calendar quarter of ASP data into CMS within 30 days after the close last day of the 3rd calendar quarter after the TDAPA is initiated for the product, but at a later point during the applicable TDAPA period specified in § 413.234(c)(1) or (c)(2), stops submitting a full calendar quarter of ASP data into CMS. We assess pricing for new renal dialysis drugs and biological products eligible for the TDAPA on a quarterly basis. Once we determine that the latest full calendar quarter of ASP is not available, we would stop applying the TDAPA for the new renal dialysis drug or biological product within the next 2-calendar quarters. For example, if we begin paying the TDAPA on January 1, 2021 for an eligible new renal dialysis drug or biological product, and a full calendar quarter of ASP data is made available to CMS by October 30, 2021 (30 days after the close of the 3rd quarter of paying the TDAPA), but a full calendar quarter of ASP data is not made available to CMS as of January 30, 2022 (30 days after the close of the 4th quarter of paying the TDAPA), we would stop applying the TDAPA for the product no later than June 30, 2022 (2 quarters after the 4th quarter of paying the TDAPA).

3. New and Innovative Renal Dialysis Equipment and Supplies Under the ESRD PPS

a. Background on Renal Dialysis Equipment and Supplies Under the ESRD PPS

In the CY 2011 ESRD PPS final rule (75 FR 49075), we stated that when we computed the ESRD PPS base rate, we used the composite rate payments made under Part B in 2007 for dialysis in

computing the ESRD PPS base rate. These are identified in Table 19 of the CY 2011 ESRD PPS final rule (75 FR 49075) as “Composite Rate Services”. Sections 1881(b)(14)(A)(i) and 1881(b)(14)(B) of the Act specify the renal dialysis services that must be included in the ESRD PPS bundled payment, which includes items and services that were part of the composite rate for renal dialysis services as of December 31, 2010. As we indicated in the CY 2011 ESRD PPS proposed rule (74 FR 49928), the case-mix adjusted composite payment system represents a limited PPS for a bundle of outpatient renal dialysis services that includes maintenance dialysis treatments and all associated services including historically defined dialysis-related drugs, laboratory tests, equipment, supplies and staff time (74 FR 49928). In the CY 2011 ESRD PPS final rule (75 FR 49062), we noted that total composite rate costs in the per treatment calculation included costs incurred for training expenses, as well as all home dialysis costs. Currently, ESRD facilities are required to report their use of syringes on claims in order to receive separate payment, as discussed in the CY 2011 final rule (75 FR 49141). However, historically, ESRD facilities were not required to report any other renal dialysis equipment and supplies on claims (with the exception of syringes) because these items were paid through the composite rate and did not receive separate payment. As discussed in the Medicare Claims Processing Manual (chapter 8, section 50.3), CMS directs ESRD facilities to report a dialysis treatment and their charge for the treatment. That charge is intended to reflect the cost of the dialysis treatment (equipment, supplies, and staff time) as well as routine drugs and laboratory tests. This manual is available on the CMS website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c08.pdf>.

In the CY 2019 ESRD PPS final rule (83 FR 56942 through 56943), we finalized an expansion of the TDAPA to all new renal dialysis drugs and biological products, not just those in new ESRD PPS functional categories, including composite rate drugs and biological products that fall within an ESRD PPS functional category. A detailed discussion of the TDAPA policy is found in section II.B.1.a of this proposed rule. As part of the CY 2019 ESRD PPS rulemaking, we received several comments regarding payment under the ESRD PPS for certain new, innovative equipment and supplies used in the treatment of ESRD. For

example, as we described in the CY 2019 ESRD PPS final rule (83 FR 56972), a device manufacturer and device manufacturer association asked CMS to establish a transitional add-on payment adjustment for new FDA approved devices. They commented on the lack of FDA approved or authorized new devices for use in an ESRD facility, highlighting the need to promote dialysis device innovation. The commenters indicated they believed the same rationale CMS used to propose broadening the TDAPA eligibility also would apply to new medical devices. Specifically, the commenters noted that CMS has discretionary authority under section 1881(b)(14)(D)(iv) of the Act to adopt payment adjustments determined appropriate by the Secretary, and stated that precedent supports CMS' authority to use non-budget neutral additions to the ESRD PPS base rate for adjustments under specific circumstances.

A professional association urged CMS and other relevant policymakers to prioritize the development of a clear pathway to add new devices to the ESRD PPS bundled payment (83 FR 56973). The association stated that additional money should be made available to appropriately reflect the costs of new devices under the ESRD PPS bundled payment. A national dialysis organization and a large dialysis organization (LDO) asked CMS to clarify how it incentivizes the development of new dialysis devices. The organization asked CMS to describe how such a device would be included in the ESRD PPS bundle, and suggested the initial application of a pass-through payment, which would be evaluated later, based on the data. The organization stated that this evaluation would determine if the device should be included in the ESRD PPS base rate and whether or not additional funds should be added to the ESRD PPS bundled payment.

In addition, as we discussed in the CY 2019 ESRD PPS final rule (83 FR 56973), an LDO requested CMS plan appropriately for innovative devices or other new innovative products and asked CMS to work with the kidney care community to consider if and how new devices or other new innovative products delivering high clinical value, can be made available to beneficiaries, whether through the ESRD PPS or through other payment systems. A home dialysis patient group also expressed concern regarding the absence of a pathway for adding new devices to the ESRD PPS bundled payment, stating that it left investors and industry wary of investing in the development of new devices for patients. In response, we expressed appreciation for the

commenters' thoughts regarding payment for new and innovative devices, and stated that we did not include any proposals regarding this issue in the CY 2019 ESRD PPS proposed rule, so we considered these suggestions to be beyond the scope of that rule.

Also, in the CY 2019 ESRD PPS proposed rule, we solicited comment on whether we should expand the outlier policy to include composite rate drugs and supplies (83 FR 34332). We noted that under the proposed expansion to the drug designation process, such expansion of the outlier policy could support appropriate payment for composite rate drugs once the TDAPA period has ended. Additionally, with regard to composite rate supplies, an expansion of the outlier policy could support use of new innovative devices or items that would otherwise be considered in the ESRD PPS bundled payment. We stated that if commenters believe such an approach is appropriate, we requested they provide input on how we would effectuate such a shift in policy. For example, we noted, the reporting of these services may be challenging since they have never been reported on ESRD claims previously. We specifically requested feedback about how such items might work under the existing ESRD PPS outlier framework or whether specific changes to the policy to accommodate such items are needed.

We received mixed feedback in response to the comment solicitation, which was summarized in the CY 2019 ESRD PPS final rule (83 FR 56969 through 56970). Some LDOs and national dialysis organizations stated that they would prefer a smaller outlier pool with more money in the per treatment base rate while other ESRD facilities agreed that the outlier policy should be more comprehensive and expanded to include more items and services. In our response, we stated we recognized that the commenters' concerns regarding the expansion of outlier eligibility to include composite rate drugs and supplies are inextricably linked to their views on the effectiveness of our broader outlier policy or other payment adjustments. We indicated we would take these views into account as we consider the outlier policy and payment adjustments for future rulemaking.

In light of these comments, we are considering whether additional payment may be warranted for certain new and innovative renal dialysis equipment and supplies. In sections II.B.3.a.i and II.B.3.a.ii of this proposed rule is a general description of the IPPS

new technology add-on payment (NTAP) and its substantial clinical improvement (SCI) criteria. We believe a process similar to the IPPS process for establishing SCI for the NTAP described in section II.B.3.a.ii of this proposed rule could be used to identify the innovative renal dialysis equipment and supplies for which commenters were requesting additional payment under the ESRD PPS. We believe an NTAP-like payment adjustment under the ESRD PPS would be appropriate in order to support innovation while being responsive to stakeholders.

i. Add-On Payments for New Technology Under the Inpatient Prospective Payment System

In the CMS Innovators' Guide to Navigating Medicare,³⁰ we explain that the hospital IPPS makes payments to acute care hospitals for each Medicare patient or case treated. Hospitals are paid based on the average national resource use for treating patients in similar circumstances, not the specific cost of treating each individual patient. With few exceptions, Medicare does not pay separately for individual items or services. Physicians and hospital staff determine the appropriate course of treatment, and hospitals receive a bundled payment for the covered inpatient facility services provided to the Medicare patient. Hospitals receive one IPPS payment per Medicare case at discharge that equates to the total Medicare payment for the facility costs of caring for that Medicare patient. More information on determining IPPS payment is located on the CMS website: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>.

Also as discussed in the CMS Innovators' Guide to Navigating Medicare,³¹ the IPPS is designed to adapt to changing technology through year-to-year adjustments in Medicare Severity—Diagnosis Related Groups (MS-DRG) weights based on historical cost data. In theory, if new technologies lead to better care but are more expensive, or if they lead to more efficient care and are less expensive, hospitals will eventually receive appropriate payment as the MS-DRG weights are adjusted over time to reflect the impact of fluctuating costs. In practice, however, there are concerns that the system may be slow to react to

³⁰ <https://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/Downloads/Innovators-Guide-Master-7-23-15.pdf>.

³¹ <https://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/Downloads/Innovators-Guide-Master-7-23-15.pdf>.

rapidly evolving technological advancements.

Hospitals may experience a financial disadvantage as they provide more expensive products and services to Medicare beneficiaries while waiting for MS-DRG payments to reflect the higher costs. Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies under the IPPS. As an incentive for hospitals to adopt new technologies during the period before their costs are recognized in the MS-DRG weights, certain new medical services or technologies may be eligible for new technology add-on payments. The new technology add-on payment policy provides additional payments for eligible high cost cases without significantly eroding the incentives provided by a payment system based on averages. To qualify for add-on payments, the regulations at § 412.87 specify a service or technology must be: (1) New, (2) demonstrate a SCI over existing technology, and (3) be high cost such that the MS-DRG payment that would normally be paid is inadequate. For a complete discussion on the new technology add-on payment criteria, we refer readers to the fiscal year (FY) 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574).

Since it can take 2 to 3 years for reflection of cost data in the calculation of the MS-DRG weights, technologies generally are considered new for 2 to 3 years after they become available. Applicants must demonstrate that their product offers SCI and the other NTAP requirements.

Under the cost criterion, consistent with the formula specified in section 1886(d)(5)(K)(ii)(I) of the Act, to assess the adequacy of payment for a new technology paid under the applicable MS-DRG prospective payment rate, we evaluate whether the charges for cases involving the new technology exceed the threshold amount for the MS-DRG (or the case-weighted average of all relevant MS-DRGs, if the new technology could be assigned to many different MS-DRGs).

Although any interested party may submit an application for a new technology add-on payment, applications often come from the manufacturer of a new drug or device. Preliminary discussions on whether or not new technologies qualify for add-on payments are published in the annual IPPS proposed rules and are open to public comment.

The actual add-on payments are based on the cost to hospitals for the new technology. A new technology add-on payment is made if the total covered

costs of the patient discharge exceed the MS-DRG payment of the case (including adjustments for indirect medical education (IME) and disproportionate share hospital (DSH), but excluding outlier payments). The total covered costs are calculated by applying the cost-to-charge ratio (that is used for inpatient outlier purposes) to the total covered charges of the discharge.

Under § 412.88, if the costs of the discharge exceed the full MS-DRG payment, the additional payment amount equals the lesser of the following: (1) 50 percent of the costs of the new medical service or technology; (2) or 50 percent of the amount by which the total covered costs of the case (as determined above) exceed the standard MS-DRG payment, plus any applicable outlier payments if the costs of the case exceed the MS-DRG, plus adjustments for IME and DSH. More information on IPPS new technology add-on payments, including the deadline to submit an application, is located on the CMS website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html>.

ii. SCI Criteria for the New Technology Add-On Payment Under the IPPS

Under section 1886(d)(5)(K)(vi) of the Act, a medical service or technology will be considered a “new medical service or technology” if the service or technology meets criteria established by the Secretary after notice and an opportunity for public comment. For a more complete discussion of the establishment of the current criteria for the new technology add-on payment, we refer readers to the IPPS final rule published on September 7, 2001 in the **Federal Register** (66 FR 46913), referred to as “FY 2001 IPPS final rule,” where we finalized the “substantial improvement” criterion to limit new technology add-on payments under the IPPS to those technologies that afford clear improvements over the use of previously available technologies. Specifically, we stated that we would evaluate a request for new technology add-on payments against the following criteria to determine if the new medical service or technology would represent a SCI over existing technologies:

- The device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
- The device offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population

than allowed by currently available methods. There must also be evidence that use of the device to make a diagnosis affects the management of the patient.

- Use of the device significantly improves clinical outcomes for a patient population as compared to currently available treatments. We also noted examples of outcomes that are frequently evaluated in studies of medical devices. For example,
 - ++ Reduced mortality rate with use of the technology.
 - ++ Reduced rate of technology related complications.
 - ++ Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
 - ++ Decreased number of future hospitalizations or physician visits.

More rapid beneficial resolution of the disease process treatment because of the use of the device.

- ++ Decreased pain, bleeding, or other quantifiable symptom.
- ++ Reduced recovery time.

In the FY 2001 IPPS final rule (66 FR 46913), we stated that we believed the special payments for new technology should be limited to those new technologies that have been demonstrated to represent a substantial improvement in caring for Medicare beneficiaries, such that there is a clear advantage to creating a payment incentive for physicians and hospitals to utilize the new technology. We also stated that where such an improvement is not demonstrated, we continued to believe the incentives of the DRG system would provide a useful balance to the introduction of new technologies. In that regard, we also pointed out that various new technologies introduced over the years have been demonstrated to have been less effective than initially thought, or in some cases even potentially harmful. We stated that we believe that it is in the best interest of Medicare beneficiaries to proceed very carefully with respect to the incentives created to quickly adopt new technology.

We noted in the FY 2020 IPPS proposed rule (84 FR 19274 through 19275), that applicants for add-on payments for new medical services or technologies must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a SCI, along with a significant sample of cost data to demonstrate that the medical service or technology meets the cost criterion.

Complete application information, along with final deadlines for submitting a full application, is posted on the CMS website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html>.

Per section 1886(d)(5)(K)(i) of the Act, the Secretary is required to establish a mechanism to recognize the costs of new medical services and technologies under the payment system after notice and opportunity for public comment. The payment rate updates and policy changes including new technology add-on payments under the IPPS are completed through the annual notice-and-comment rulemaking process with an October 1 effective date. In the proposed rule, CMS reviews each application and the information and clinical evidence provided by the applicant on how it meets each of the new technology add-on payment criteria. Regarding substantial clinical improvement, we work with our medical officers to evaluate whether a technology represents a substantial clinical improvement. Under the IPPS, public input before publication of a notice of proposed rulemaking on add-on payments is required by section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of Public Law 108–173, and provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a SCI or advancement. In the final rule, we make a determination whether an applicant has met the new technology add-on payment criteria and is eligible for the add-on payment.

The IPPS proposed and final rules go on display around April and August, respectively, each year. The FY 2020 IPPS proposed rule is available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/IPPS-Regulations-and-Notices-Items/CMS-1716.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending>.

b. Proposed Additional Payment for New and Innovative Renal Dialysis Equipment and Supplies Under the ESRD PPS

Following publication of the CY 2019 ESRD PPS final rule (83 FR 56969 through 56970), which discussed the comment solicitation on expanding the outlier policy to include composite rate drugs and supplies, we have received additional information from dialysis equipment and supply manufacturers and a Technical Expert Panel (TEP) meeting held in December 2018

regarding composite rate equipment and supplies. Discussions of the key findings from the TEP meeting can be found in section VIII.A of this proposed rule. In addition, some manufacturers have informed us that there is little incentive for them to develop innovative equipment and supplies for the treatment of ESRD primarily because ESRD facilities have no incentive to adopt innovative dialysis equipment and supplies since they are included in the ESRD PPS bundled payment and currently no additional payment is made.

In addition we believe innovations in kidney care are likely as a result of the Kidney Innovation Accelerator (known as KidneyX). KidneyX is a public-private partnership between the Department of Health and Human Services and the American Society of Nephrology to accelerate innovation in the prevention, diagnosis, and treatment of kidney diseases.

KidneyX seeks to improve the lives of dialysis patients by accelerating the development of drugs, devices, biologics and other therapies across the spectrum of kidney care including prevention, diagnostics, and treatment. KidneyX's first round of prize funding focused on accelerating the commercialization of next-generation dialysis products, aiming to reduce the risk of innovation by streamlining processes, reducing regulatory barriers, and modernizing the way we pay for treatment. More than 150 applications were reviewed, covering a full-range of innovative proposals, including advances in access, home hemodialysis and peritoneal dialysis, adjuncts to current in-center dialysis, and proposals for implantable devices, externally-worn devices and prototypes for an artificial kidney. More information regarding KidneyX is available at the following link: <http://www.kidneyx.org/>.

We believe some of the prototypes developed as part of the KidneyX will be the type of innovation the commenters requested and we want to incentivize ESRD facility use of those products. We note that in order for equipment and supplies awarded through the KidneyX to be eligible for the additional payment under the ESRD PPS proposals in this section of the proposed rule, the items would also need to be determined by CMS to be a renal dialysis service and meet other eligibility criteria described in section II.B.3.b.i of this proposed rule. We also note that the goals for KidneyX and our proposal in this section are different but complementary; KidneyX is focused on accelerating innovation in the prevention, diagnosis, and treatment of

kidney disease, at the beginning stages of the development of an innovative product, while our proposals in this section are intended to support uptake of new and innovative renal dialysis products after they have been authorized for marketing by FDA and meet other requirements, all of which happen after the development stage.

In addition, on July 10, 2019, the President signed an Executive Order³² aimed at transforming kidney care in America. The executive order established many initiatives, including the launch of a public awareness campaign to prevent patients from going into kidney failure and proposals for the Secretary to support research regarding preventing, treating, and slowing progression of kidney disease and encouraging the development of breakthrough technologies to provide patients suffering from kidney disease with better options for care than those that are currently available.

i. Proposed Eligibility Criteria for Additional Payment for New and Innovative Renal Dialysis Equipment and Supplies

In consideration of the feedback we have received, we agree that additional payment for certain renal dialysis equipment and supplies may be warranted under specific circumstances outlined in this section of the proposed rule. We are proposing to provide additional payment for new and innovative renal dialysis equipment and supplies furnished by ESRD facilities (with the exception of capital-related assets), through a transitional add-on payment adjustment as described further in this proposed rule.

Renal dialysis equipment and supplies are medically necessary equipment and supplies used to furnish renal dialysis services in a facility or in a patient's home. We are proposing that "new" renal dialysis equipment and supplies are those that are granted marketing authorization by FDA on or after January 1, 2020. By including FDA marketing approvals on or after January 1, 2020, we intend to support ESRD facility use and beneficiary access to the latest technological improvements to renal dialysis equipment and supplies. We solicit comment on this aspect of our proposal and whether a different FDA marketing approval date—for example, on or after January 1, 2019—might be appropriate.

For new and innovative equipment and supplies, we believe the IPPS SCI

³² <https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/>.

criteria and the process used to evaluate SCI can be used as a proxy for identifying new and innovative items worthy of additional payment under the ESRD PPS. Under the IPPS, CMS has been assessing new technologies for many years to assure that the additional new technology add-on payments to hospitals are made only for truly innovative and transformative products. CMS is proposing to adopt the IPPS SCI criteria under the ESRD PPS for the same reason. We want to ensure that additional payments made under the ESRD PPS are limited to new equipment and supplies that are truly innovative. In addition, since renal dialysis services are routinely furnished to hospital inpatients and outpatients, we believe the same SCI criteria should be used to assess whether a new renal dialysis equipment or supply warrants additional payment under Medicare.

Therefore, we are proposing to adopt IPPS's SCI criteria specified in § 412.87(b)(1) including modifications finalized in future IPPS final rules, to determine when a new and innovative renal dialysis equipment or supply is eligible for additional payment under the ESRD PPS. That is, we would adopt IPPS's SCI criteria in § 412.87(b)(1) and any supporting policy around this criteria as discussed in IPPS preamble language. We believe that by incorporating the SCI criteria for new and innovative renal dialysis equipment under the ESRD PPS, we would be consistent with IPPS and innovators would have a standard for criteria to meet for both settings. We are also proposing to establish a process modeled after IPPS's process of determining if a new medical technology meets the SCI criteria specified in § 412.87(b)(1) discussed in section II.B.3.a.ii of this proposed rule. That is, we propose that CMS would determine whether the renal dialysis equipment or supply meets the eligibility criteria proposed in newly added § 413.236(b). Similar to how we evaluate whether a new drug or biological product is eligible for the TDAPA as discussed in the CY 2016 ESRD PPS final rule (80 FR 69019), we would need to determine whether the renal dialysis equipment and supply meets our eligibility criteria.

We note that as described in section II.B.3.a.i of this proposed rule, IPPS has additional criteria that is specific to its payment system, that is, a high cost criteria relative to the MS-DRG payment. We would not adopt the specific IPPS high cost criteria requirements under § 412.87(b)(3) under the ESRD PPS since the basis of payment is different. Specifically, under

the ESRD PPS, the basis of payment is the per treatment payment amount that is updated annually by the ESRD bundled market basket and the multifactor productivity adjustment. Since the elements of the IPPS payment system differ from that of the ESRD PPS, we are only proposing to adopt the SCI criteria in § 412.87(b)(1) at this time.

We are proposing to exclude capital-related assets from the additional payment, which we would define based on the Provider Reimbursement Manual (Pub. L. 15–1) (chapter 1, section 104.1) as assets that a provider has an economic interest in through ownership (regardless of the manner in which they were acquired). The Provider Reimbursement Manual is available on the CMS website at <https://www.cms.gov/NoRegulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.html>. This would include certain renal dialysis equipment and supplies. Examples of capital-related assets for ESRD facilities are dialysis machines, water purification systems and systems designed to clean dialysis filters for reuse. We do not believe that we should provide additional payment for capital-related assets because the cost of these items are captured in cost reports, depreciate over time, and are generally used for multiple patients. Since the costs of these items are reported in the aggregate, there is considerable complexity in establishing a cost on a per treatment basis. We therefore believe capital-related assets should be excluded from additional payment at this time, and we have proposed an exclusion to the eligibility criteria in new § 413.236(b)(2). However, we note that capital-related cost data from cost reports are used by CMS in regression analyses to refine the ESRD PPS so that the cost of any new capital-related assets is accounted for in the ESRD PPS payment adjustments.

Under our proposal, in addition to having marketing authorization by FDA on or after January 1, 2020, and meeting SCI criteria as determined under § 412.87(b)(1) as described in section II.B.3.a.ii of this proposed rule, the equipment or supply must be commercially available, have a HCPCS application submitted in accordance with the official Level II HCPCS coding procedures, and have been designated by CMS as a renal dialysis service under § 413.171. Following FDA marketing authorization, in order to establish a mechanism for payment, the equipment or supply would then go through a process to establish a billing code, specifically a HCPCS code. This information is necessary to conform to

the requirements for both CMS and provider billing systems. Information regarding the HCPCS process is available on the CMS website at <https://www.cms.gov/medicare/coding/MedHCPCSGenInfo/Index.html>.

Under our proposal, we would model our determination process similar to that of IPPS's NTAP. That is, manufacturers would submit all information necessary for determining that the renal dialysis equipment or supply meets the eligibility criteria listed in § 413.236(b). That would include FDA marketing authorization information, the HCPCS application information, and studies submitted as part of these two standardized processes, an approximate date of commercial availability, and any information necessary for SCI criteria evaluation. For example, clinical trials, peer reviewed journal articles, study results, meta-analyses, systematic literature reviews, and any other appropriate information sources can be considered. We would provide a description of the equipment or supply and pertinent facts related to it that can be evaluated through notice-and-comment rulemaking. We would consider whether a new renal dialysis equipment or supply meets the eligibility criteria specified in newly added § 413.236(b) and announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS. We would only consider, for additional payment for a particular calendar year, an application for which the renal dialysis equipment or supply is considered new by February 1 prior to the particular calendar year.

For example, in order to receive additional payment under the ESRD PPS in CY 2022 we would require that a complete application meeting our requirements be received by CMS no later than February 1, 2021. Then, we would include a discussion of the renal dialysis equipment or supply requesting additional payment in the CY 2022 ESRD PPS proposed rule. The evaluation of the eligibility criteria would be in the CY 2022 ESRD PPS final rule. If the renal dialysis equipment or supply qualifies for the additional payment, payment would begin January 1, 2022.

Alternatively, we considered an application deadline of September 1, however, we are proposing an earlier timeframe so that this additional policy would be implemented sooner. However, a September 1 deadline would provide more time initially for manufacturers to submit applications. We solicit comment on the proposed deadline date for the application.

We also solicit comment on the proposed criteria to determine new and innovative renal dialysis equipment and supplies that would be eligible for additional payment. In addition, we are soliciting comment on the use of different evaluative criteria and, where applicable, payment methodologies, for renal dialysis supplies and equipment that may be eligible for an additional payment under the ESRD PPS. These criteria could include cost thresholds for high cost items. We solicit comment on whether any of the IPPS SCI criteria would not be appropriate for the ESRD facility setting and whether there should be additional criteria specific to ESRD. We seek comment on whether to use FDA's pre-market approval and De Novo pathways as a proxy for or in place of the proposed SCI criteria. In addition, we are soliciting comment on potential implementation challenges, such as what sources of data that CMS should utilize to assess SCI. We are also soliciting comment on the proposed process that would be used to determine SCI. Also, we are soliciting comment on the benefits and drawbacks of the SCI criteria proposed in this rulemaking.

ii. Pricing of New and Innovative Renal Dialysis Equipment and Supplies

With respect to the new and innovative renal dialysis equipment and supplies discussed in section II.B.3.b.i of this proposed rule, we are not aware of pricing compendia currently available to price these items for the transitional add-on payment adjustment proposal discussed in this section. We also note that, unlike for new renal dialysis drugs and biological products eligible for the TDAPA, ASP and WAC pricing do not exist for renal dialysis equipment and supplies. Unlike the IPPS NTAP methodology, which uses MS-DRG payment and cost-to-charge ratios in their high cost criteria payment calculation, the ESRD PPS has a single per treatment payment amount. Therefore, we must propose a pricing method in the absence of data indicating a true market price.

In accordance with ESRD billing instructions of the Medicare Claims Processing Manual (chapter 8, section 50.3), we are proposing that ESRD facilities would report the HCPCS code, when available, and their corresponding charge for the item. In accordance with the Provider Reimbursement Manual (chapter 22, section 2203), Medicare does not dictate a provider's charge structure or how it itemizes charges but it does determine whether charges are acceptable for Medicare purposes. Charges should be reasonably and consistently related to the cost of

services to which they apply and are uniformly applied. In addition, the Provider Reimbursement Manual (chapter 22, section 2202.4) specifies that charges refer to the regular rates established by the provider for services rendered to both beneficiaries and to other paying patients. Charges should be related consistently to the cost of the services and uniformly applied to all patients whether inpatient or outpatient. All patients' charges used in the development of apportionment ratios should be recorded at the gross value; that is, charges before the application of allowances and discounts deductions.

Since we require charges to be reported at the gross value, we are not proposing to use charges as the basis of payment. The ESRD PPS does not have a charge structure or a gap-filling policy similar to the DMEPOS policy. We are proposing to obtain a pricing indicator that requires the item to be priced by Medicare Administrative Contractors (MACs). We propose to adopt a process that utilizes invoice-based pricing. We note that there are instances that invoice pricing is also used for DMEPOS. Specifically, in the Medicare Claims Processing Manual, (chapter 23, section 60.3), we state that "potential appropriate sources for such commercial pricing information can . . . include verifiable information from supplier invoices."

In addition, in the CY 2019 Physician Fee Schedule final rule (83 FR 59663), we discuss that invoice based pricing is used to pay for Part B drugs and biologicals in certain circumstances as described in the Medicare Claims Processing Manual (chapter 17, section 20.1.3). For example, if a payment allowance limit for a drug or biological is not included in the quarterly ASP Drug Pricing File or Not Otherwise Classified Pricing File, MACs are permitted to use invoice pricing. MACs may also use invoice based pricing for new drugs and biologicals that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified Pricing File. The new drug provision may be applied during the period just after a drug is marketed, that is before ASP data has been reported to CMS. We believe using invoices for new drugs and drugs without national pricing is a similar situation to dealing with new and innovative renal dialysis equipment and supplies that do not have a national price.

We believe that an invoice-based approach could be applied to the renal dialysis equipment and supplies that are the focus of our proposal. As noted previously, ESRD facility charges are gross values; that is, charges before the

application of allowances and discounts deductions. We believe the MAC-determined price should reflect the discounts, rebates and other allowances the ESRD facility (or parent company) receives. These terms are defined in the Provider Reimbursement Manual (chapter 8).³³ If the MAC-determined price does not reflect discounts, rebates and other allowances, the price would likely exceed the facility's cost for the item and result in higher coinsurance obligations for beneficiaries. For this reason, we believe it is important for MACs to develop a payment rate taking into consideration the invoice amount, the facility's charge for the item on the claim, discounts, allowances, rebates, the price established for the item by other MACs and the sources of information used to establish that price, payment amounts from other payers and the information used to establish those payment amounts, and information on pricing for similar items used to develop a payment rate. We believe the information that ESRD facilities would supply to the MACs should be verifiable, so that we can more appropriately establish the actual facility cost of the items.

The specific amounts would be established for the new and innovative renal dialysis equipment or supply HCPCS code using verifiable information from the following sources of information, if available: The invoice amount, facility charges for the item, discounts, allowances, and rebates; the price established for the item by other MACs and the sources of information used to establish that price; payment amounts determined by other payers and the information used to establish those payment amounts; and charges and payment amounts, required for other equipment and supplies that may be comparable or otherwise relevant.

Once there is sufficient payment data across MACs, we would consider establishing a national price for the item through notice and comment rulemaking. We are inviting public comment on this proposed approach for pricing new and innovative renal dialysis equipment and supplies for the transitional add-on payment adjustment proposal discussed in section II.B.3.b.iii of this proposed rule. We also solicit comment on other pricing criteria and other verifiable sources of information that should be considered.

As discussed in section II.B.3.a.i of this proposed rule, under the IPPS's

³³ Medicare Provider Reimbursement Manual, Chapter 8. Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R450PR1.pdf>.

NTAP payment policy, the additional payment for cases with high costs involving eligible new technologies preserves some of the incentives under the average-based payment system. The payment mechanism is based on the cost to hospitals for the new technology. Under § 412.88, Medicare pays a marginal cost factor of 50 percent for the costs of the new technology in excess of the full DRG payment. If the costs of the discharge exceed the full MS-DRG payment, the additional payment amount equals the lesser of the following: 50 percent of the costs of the new medical service or technology; or 50 percent of the amount by which the total covered costs of the case (as determined above) exceed the standard MS-DRG payment, plus any applicable outlier payments if the costs of the case exceed the MS-DRG, plus adjustments for IME and DSH.

To mitigate the Medicare expenditures incurred as a result of the transitional add-on payment adjustment proposal discussed later in this section of the proposed rule, we are proposing to base the additional payment on 65 percent of the MAC-determined price. We noted in the FY 2020 IPPS proposed rule (84 FR 19162) a 50 percent capped add-on amount was considered low with regard to providing hospitals with a sufficient incentive to use the new technology. In that rule, we proposed to modify the current payment mechanism to increase the amount of the maximum add-on payment amount to 65 percent. We believe that we have the same goal as IPPS with regard to supporting ESRD facility use of new and innovative renal dialysis equipment and supplies. Therefore, we are proposing to base the transitional add-on payment adjustment for new and innovative equipment and supplies on 65 percent of the MAC-determined price. We are also soliciting comment on whether we should explicitly link to the IPPS NTAP mechanism's maximum add-on payment amount percentage so that any change in that percentage would also change for the proposed transitional add-on payment adjustment paid to ESRD facilities for furnishing new and innovative renal dialysis equipment and supplies.

iii. Proposed Use of a Transitional Add-On Payment Adjustment for New and Innovative Renal Dialysis Equipment and Supplies

We are proposing to provide a transitional add-on payment adjustment for new and innovative renal dialysis equipment and supplies furnished by ESRD facilities that meet the eligibility criteria described in section II.B.3.b.i of

this proposed rule. That is, the payment adjustment would only be available for renal dialysis equipment and supplies that meet the proposed eligibility criteria discussed in section II.B.3.b.i of this proposed rule. We would refer to the adjustment as the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES).

We would establish the TPNIES based on our authority under section 1881(b)(14)(D)(iv) of the Act, which provides in relevant part that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate. We believe this authority is broad enough to support the creation of the TPNIES.

We acknowledge that ESRD facilities have unique challenges with regard to implementing new renal dialysis drugs and biological products as discussed in section II.B.1.a of this proposed rule, and we believe that the same issues would apply with respect to incorporating new and innovative equipment and supplies into their standards of care. For example, when new and innovative equipment and supplies are introduced to the market, ESRD facilities would need to analyze their budgets and engage in contractual agreements to accommodate the new items into their care plans. Newly marketed equipment and supplies can be unpredictable with regard to their uptake and pricing, which makes these decisions challenging for ESRD facilities. Furthermore, practitioners should have the ability to evaluate the appropriate use of a product and its effect on patient outcomes. We believe this uptake period would be supported by the proposed TPNIES because it would help facilities transition or test new and innovative equipment and supplies in their businesses under the ESRD PPS. The proposed TPNIES would target payment for the use of new and innovative renal dialysis equipment and supplies during the period when a product is new to the market.

We are proposing to apply the TPNIES for 2-calendar years from the effective date of the change request, which would coincide with the effective date of the CY ESRD PPS final rule. We would monitor renal dialysis service utilization trends, after which we are proposing that the item would become an eligible outlier service as provided in § 413.237. Therefore, we are proposing revisions to § 413.237(a)(1) to reflect outlier eligibility once the TPNIES period ends. We believe that 2 years would be a sufficient timeframe for ESRD facilities to set up or adjust business practices so that there is

seamless access to the new and innovative equipment and supplies. In addition, historically when we have implemented policy changes whereby facilities need to adjust their system modifications or protocols, we have provided a transition period. We believe that this 2-year timeframe is similar in that facilities are making changes to their systems and care plans to incorporate the new renal dialysis equipment and supplies into their standards of care and this could be supported by a transition period.

We further believe providing the TPNIES for 2 years would address the stakeholders' concerns regarding additional payment to account for higher cost of more new and innovative equipment and supplies that they believe may not be adequately captured by the dollars allocated in the ESRD PPS base rate. That is, this transitional add-on payment adjustment would give the new and innovative equipment and supplies a foothold in the market so that when the timeframe is complete, they are able to compete with the other equipment and supplies also accounted for in the ESRD PPS base rate. Once the 2-year timeframe is complete, we propose that the equipment or supply would then qualify as an outlier service, if applicable, and the facility would no longer receive the TPNIES for that particular item. Instead, in the outlier policy space, there is a level playing field where products could gain market share by offering the best practicable combination of price and quality.

We note that this proposal would increase Medicare expenditures, which would result in increases to ESRD beneficiary coinsurance, since we have not previously provided a payment adjustment for renal dialysis equipment and supplies in the past. However, to support agency initiatives and to be consistent with both our TDAPA policy and inpatient hospital payment policies, we believe that the proposed TPNIES would be appropriate to support ESRD facility uptake in furnishing new and innovative renal dialysis equipment and supplies.

The intent of the TPNIES for new and innovative equipment and supplies would be to provide a transition period for the unique circumstances experienced by ESRD facilities when incorporating certain new and innovative equipment and supplies into their businesses and to allow time for the uptake of the new and innovative equipment and supplies. At this time, we do not believe that it would be appropriate to add dollars to the ESRD PPS base rate for new and innovative renal dialysis equipment and supplies

because, as noted previously, the ESRD PPS base rate includes the cost of equipment and supplies used to furnish a dialysis treatment. As we have stated in CY 2019 ESRD PPS proposed rule (83 FR 34314), we believe that increasing the base rate for these items could be in conflict with the fundamentals of a PPS. That is, under a PPS, Medicare makes payments based on a predetermined, fixed amount that reflects the average cost and the facility retains the profit or suffers a loss resulting from the difference between the payment rate and the facility's resource use which creates an incentive for facilities to control their costs. It is not the intent of a PPS to add dollars to the base whenever something new is made available.

Therefore, we propose to add § 413.236, Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies. We propose to add § 413.236(a) to state that the basis for the TPNIES is to establish a payment adjustment to support ESRD facilities in the uptake of new and innovative renal dialysis equipment and supplies under the ESRD PPS under the authority of section 1881(b)(14)(D)(iv) of the Act. We also propose to add § 413.236(b) to require that a renal dialysis equipment or supply meet the following eligibility criteria in order to receive the TPNIES: (1) Has been designated by CMS as a renal dialysis service under § 413.171, (2) is new, meaning it is granted marketing authorization by FDA on or after January 1, 2020, (3) is commercially available, (4) has a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures, (5) is innovative, meaning it meets the criteria specified in § 412.87(b)(1) and related guidance in that it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries, and (6) is not a capital-related asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired).

We also propose to add § 413.236(c) to establish a process for SCI determination and deadline for consideration of new renal dialysis equipment or supply applications under the ESRD PPS. That is, we propose that we would consider whether a new renal dialysis supply or equipment meets the eligibility criteria specified in § 413.236(b) and announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS. We propose that we would

only consider a complete application received by CMS by February 1 prior to the particular calendar year.

We also propose to add § 413.236(d) to provide a payment adjustment for a new and innovative renal dialysis equipment or supply based on 65 percent of the MAC-determined price, as described in proposed § 413.236(e). The TPNIES would be paid for 2-calendar years. Following payment of the TPNIES, the ESRD PPS base rate would not be modified and the new and innovative renal dialysis equipment or supply would be an eligible outlier service as provided in § 413.237.

We also propose to add § 413.236(e) to require that the MAC on behalf of CMS would establish prices for the new and innovative renal dialysis equipment and supplies described in newly added § 413.236(b), and that we would use these prices for the purposes of determining the TPNIES. The specific amounts would be established for the new and innovative renal dialysis equipment or supply HCPCS code using verifiable information from the following sources of information, if available: The invoice amount, facility charges for the item, discounts, allowances, and rebates; the price established for the item by other MACs and the sources of information used to establish that price; payment amounts determined by other payers and the information used to establish those payment amounts; and charges and payment amounts, required for other equipment and supplies that may be comparable or otherwise relevant.

We are also proposing to add paragraph (e) to § 413.230 to reflect the TPNIES. We believe this modification is necessary so the regulation appropriately reflects all inputs in the calculation of the per treatment payment amount.

Since we are adding paragraphs (d) (discussed in section II.B.1.e of this proposed rule) and (e) to § 413.230, we also propose a technical change to remove “and” from the end of § 413.230(b). We propose that the “and” would be added to the end of § 413.230(d).

In addition, we are proposing to revise the definition of ESRD outlier services at § 413.237(a)(1) by adding a new paragraph (a)(1)(v) to include renal dialysis equipment and supplies that receive the TPNIES as specified in § 413.236 after the payment period has ended. We propose to redesignate existing paragraph (a)(1)(v) as paragraph (a)(1)(vi) and revise the paragraph to state “As of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry

panel are excluded from the definition of outlier services.” We are proposing this technical edit to reflect an order in the definition of ESRD outlier services as first, items and services included and second, items and services that are excluded.

We are also proposing technical changes to § 413.237(a)(1)(i) through (iv) to replace the phrases “ESRD-related” and “used in the treatment of ESRD” with “renal dialysis” to reflect the current terminology used under the ESRD PPS and to replace the word “biologicals” with “biological products” to reflect FDA's preferred terminology.

c. Comment Solicitation on Payment for Renal Dialysis Humanitarian Use Devices (HUD)

Medical devices and related innovations are integral in meeting the needs of patients, especially the most vulnerable patients, such as ESRD patients and those with rare medical conditions. While FDA determines which devices are authorized for marketing, public healthcare programs such as Medicare determine how these products will be covered and paid, which affects patient access to new and innovative products. We are soliciting comments on Medicare payment for renal dialysis services that have a Humanitarian Use Device (HUD) designation. Under FDA regulations (21 CFR 814.3(n)), a HUD is a “medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year.” Medicare has no specific rules, regulations or instructions with regard to HUDs. We are particularly interested in receiving comments on HUDs that would be considered renal dialysis services under the ESRD PPS, any barriers to payment encountered, and past experience in obtaining Medicare payment for these items through the MACs.

4. Proposal To Discontinue the ESA Monitoring Policy (EMP) Under the ESRD PPS

a. Background

In the CY 2011 ESRD PPS final rule (75 FR 49067, 49145 through 49147), CMS adopted the ESA monitoring policy (EMP) under the ESRD PPS for purposes of calculating the base rate and for establishing the outlier policy's percentage and thresholds.

For purposes of calculating the CY 2011 ESRD PPS base rate, payments for ESAs were capped based on determined dose limits as discussed in the Medicare Claims Processing Manual (chapter 8,

section 60.4.1). Payments for epoetin alfa in excess of 500,000 units per month in 2007 were capped at 500,000 units and a similar cap was applied to claims for darbepoetin alfa, in which the caps were based on 1500 mcg per month in 2007 (75 FR 49067).

With regard to the application of the outlier policy, since ESAs are considered to be an ESRD outlier service under § 413.237(a)(1)(i), covered units are priced and considered toward the eligibility for outlier payment consistent with § 413.237(b). That is, we apply dosing reductions and ESA dose limits consistent with the EMP prior to any calculation of outlier eligibility. Medicare contractors apply a 25 percent reduction in the reported ESA dose on the claim when the hemoglobin (or hematocrit) level exceeded a certain value, unless the ESRD facility reported a modifier to indicate the dose was being decreased. Also under the EMP, ESRD facilities are required to report other modifiers to indicate a patient's 3-month rolling average hemoglobin (or hematocrit) level so that the Medicare contractor knows when to apply a 50 percent reduction in the reported ESA dose on the claim. In addition to these dosing reductions, we also apply ESA dose limits as discussed in the Medicare Claims Processing Manual (chapter 8, section 60.4.1) prior to any calculation of outlier eligibility.

When we adopted the EMP for the ESRD PPS in the CY 2011 ESRD PPS final rule, we explained that we believed that the continued application of the EMP would help ensure the proper dosing of ESAs and provide a safeguard against the overutilization of ESAs, particularly where the consumption of other separately billable services may be high, in order to obtain outlier payments (75 FR 49146). Due to implementation of the ESRD PPS and FDA relabeling of epoetin alfa, which stated that the individualized dosing should be that which would achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL, we no longer believe application of the EMP is necessary to control utilization of ESAs in the ESRD population. That is, the impact of no longer paying separately for ESAs, which discourages overutilization, along with practitioners prescribing the biological product to maintain a lower hemoglobin level, has resulted in a decline in its utilization and a stringent monitoring of the biological product's levels in patients.

b. Proposal To Discontinue the Application of the EMP to Outlier Payments Under the ESRD PPS

Effective January 1, 2020, CMS is proposing to no longer apply the EMP under the ESRD PPS. Since the implementation of the ESRD PPS, ESA utilization has decreased significantly because the structure of the PPS removed the incentives to overuse these biological products. ESRD facilities would no longer be required to report the EMP-related modifiers and Medicare contractors would no longer apply dosing reduction or dose limit edits to ESA dosing. Therefore, these edits would no longer be applied prior to calculation of outlier eligibility and would no longer be reflected in outlier payments.

We would continue to require ESRD facilities to report all necessary information for the ESRD Quality Incentive Program. As part of managing the ESRD PPS, CMS has a monitoring program in place that studies the trends and behaviors of ESRD facilities under the ESRD PPS and the health outcomes of the beneficiaries who receive their care.³⁴ If we finalize this proposal, we would continue to monitor the utilization of ESAs to determine if additional medically unlikely edits are necessary. In addition, with the increased use of certain phosphate binders that have the secondary effect of anemia management, CMS would closely monitor ESA usage in conjunction with phosphate binder prescribing and usage.

We believe that discontinuing this policy would reduce burden for ESRD facilities because the EMP provides an opportunity for appeal to address those situations where there might be medical justification for higher hematocrit or hemoglobin levels. Beneficiaries, physicians, and ESRD facilities are required to submit additional documentation to justify medical necessity, and any outlier payment reduction amounts are subsequently reinstated when documentation supports the higher hematocrit or hemoglobin levels. Thus, we believe this proposal would reduce the documentation burden on ESRD facilities because they would no longer have to go through the EMP appeal process and submit additional documentation regarding medical necessity.

³⁴ ESRD PPS Claims-Based Monitoring Program. Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Claims-Based-Monitoring.html>.

We request public comments on our proposal to discontinue the application of the EMP under the ESRD PPS.

5. Proposed CY 2020 ESRD PPS Update

a. Proposed CY 2020 ESRD Bundled (ESRDB) Market Basket Update, Productivity Adjustment, and Labor-Related Share for ESRD PPS

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket increase factor and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. The statute also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services used to furnish renal dialysis services.

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRD Bundled (ESRDB) input price index (75 FR 49151 through 49162). In the CY 2015 ESRD PPS final rule we rebased and revised the ESRDB input price index to reflect a 2012 base year (79 FR 66129 through 66136). Subsequently, in the CY 2019 ESRD PPS final rule, we finalized a rebased ESRDB input price index to reflect a 2016 base year (83 FR 56951 through 56962).

Although "market basket" technically describes the mix of goods and services used for ESRD treatment, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from a market basket. Accordingly, the term "ESRDB market basket," as used in this document, refers to the ESRDB input price index.

We propose to use the CY 2016-based ESRDB market basket as finalized and described in the CY 2019 ESRD PPS final rule (83 FR 56951 through 56962) to compute the CY 2020 ESRDB market basket increase factor based on the best available data. Consistent with historical practice, we propose to estimate the ESRDB market basket update based on IHS Global Inc.'s (IGI), forecast using the most recently available data. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS

to forecast the components of the market baskets. Using this methodology and the IGI first quarter 2019 forecast of the CY 2016-based ESRDB market basket (with historical data through the fourth quarter of 2018), the proposed CY 2020 ESRDB market basket increase factor is 2.1 percent.

Under section 1881(b)(14)(F)(i) of the Act, for CY 2012 and each subsequent year, the ESRD market basket percentage increase factor shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The multifactor productivity (MFP) is derived by subtracting the contribution of labor and capital input growth from output growth. We finalized the detailed methodology for deriving the MFP projection in the CY 2012 ESRD PPS final rule (76 FR 40503 through 40504). The most up-to-date MFP projection methodology is available on the CMS website at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/MFPMethodology.pdf>. Using this methodology and the IGI first quarter 2019 forecast, the proposed MFP adjustment for CY 2020 (the 10-year moving average of MFP for the period ending CY 2020) is projected to be 0.4 percent.

As a result of these provisions, the proposed CY 2020 ESRD market basket adjusted for MFP is 1.7 percent. This market basket increase is calculated by starting with the proposed CY 2020 ESRDB market basket percentage increase factor of 2.1 percent and reducing it by the proposed MFP adjustment (the 10-year moving average of MFP for the period ending CY 2020) of 0.4 percent.

As is our general practice, if more recent data are subsequently available (for example, a more recent estimate of the market basket update or MFP adjustment), we propose to use such data to determine the final CY 2020 market basket update and/or MFP adjustment.

For the CY 2020 ESRD payment update, we propose to continue using a labor-related share of 52.3 percent for the ESRD PPS payment, which was finalized in the CY 2019 ESRD PPS final rule (83 FR 56963).

b. The Proposed CY 2020 ESRD PPS Wage Indices

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD

PPS final rule (75 FR 49200), we finalized an adjustment for wages at § 413.231. Specifically, CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. We use the Office of Management and Budget's (OMB's) core-based statistical area (CBSA)-based geographic area designations to define urban and rural areas and their corresponding wage index values (75 FR 49117). OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. The bulletins are available online at <https://www.whitehouse.gov/omb/bulletins/>.

For CY 2020, we would update the wage indices to account for updated wage levels in areas in which ESRD facilities are located using our existing methodology. We use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. The proposed CY 2020 wage index values for urban areas are listed in Addendum A (Wage Indices for Urban Areas) and the proposed CY 2020 wage index values for rural areas are listed in Addendum B (Wage Indices for Rural Areas). Addenda A and B are located on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html>.

We have also adopted methodologies for calculating wage index values for ESRD facilities that are located in urban and rural areas where there is no hospital data. For a full discussion, see CY 2011 and CY 2012 ESRD PPS final rules at 75 FR 49116 through 49117 and 76 FR 70239 through 70241, respectively. For urban areas with no hospital data, we compute the average wage index value of all urban areas within the state and use that value as the wage index. For rural areas with no hospital data, we compute the wage index using the average wage index values from all contiguous CBSAs to represent a reasonable proxy for that rural area. We apply the statewide urban average based on the average of all urban areas within the state to Hinesville-Fort Stewart, Georgia (78 FR

72173), and we apply the wage index for Guam to American Samoa and the Northern Mariana Islands (78 FR 72172). Beginning in CY 2020, we are proposing that the statewide urban average based on the average of all urban areas within the state also be applied to the Carson City, Nevada CBSA.

A wage index floor value is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values. Currently, all areas with wage index values that fall below the floor are located in Puerto Rico. However, the wage index floor value is applicable for any area that may fall below the floor.

In the CY 2011 ESRD PPS final rule (75 FR 49116 through 49117), we finalized a policy to reduce the wage index floor by 0.05 for each of the remaining years of the ESRD PPS transition, that is, until CY 2014. We applied a 0.05 reduction to the wage index floor for CYs 2012 and 2013, resulting in a wage index floor of 0.5500 and 0.5000, respectively (CY 2012 ESRD PPS final rule, 76 FR 70241). We continued to apply and reduce the wage index floor by 0.05 in CY 2013 (77 FR 67459 through 67461). Although we only intended to provide a wage index floor during the 4-year transition in the CY 2014 ESRD PPS final rule (78 FR 72173), we decided to continue to apply the wage index floor and reduce it by 0.05 per year for CY 2014 and for CY 2015.

In the CY 2016 ESRD PPS final rule (80 FR 69006 through 69008), however, we decided to maintain a wage index floor of 0.4000, rather than further reduce the floor by 0.05. We stated that we needed more time to study the wage indices that are reported for Puerto Rico to assess the appropriateness of discontinuing the wage index floor (80 FR 69006).

In the CY 2017 ESRD PPS proposed rule (81 FR 42817), we presented the findings from analyses of ESRD facility cost report and claims data submitted by facilities located in Puerto Rico and mainland facilities. We solicited public comments on the wage index for CBSAs in Puerto Rico as part of our continuing effort to determine an appropriate policy. We did not propose to change the wage index floor for CBSAs in Puerto Rico, but we requested public comments in which stakeholders could provide useful input for consideration in future decision-making. Specifically, we solicited comment on the suggestions that were submitted in the CY 2016 ESRD PPS final rule (80 FR 69007). After considering the public comments we received regarding the

wage index floor, we finalized a wage index floor of 0.4000 in the CY 2017 ESRD PPS final rule (81 FR 77858).

In the CY 2018 ESRD PPS final rule (82 FR 50747), we finalized a policy to permanently maintain the wage index floor of 0.4000, because we believed it was appropriate and provided additional payment support to the lowest wage areas. It also obviated the need for an additional budget-neutrality adjustment that would reduce the ESRD PPS base rate, beyond the adjustment needed to reflect updated hospital wage data, in order to maintain budget neutrality for wage index updates.

In the CY 2019 ESRD PPS final rule (83 FR 56964 through 56967), we finalized an increase to the wage index floor from 0.4000 to 0.5000 for CY 2019 and subsequent years. We explained that we revisited our evaluation of payments to ESRD facilities located in the lowest wage areas to be responsive to stakeholder comments and to ensure payments under the ESRD PPS are appropriate. We provided statistical analyses that supported a higher wage index floor and finalized an increase from 0.4000 to 0.5000 to safeguard access to care in those areas. We further explained that we believe a wage index floor of 0.5000 strikes an appropriate balance between providing additional payments to areas that fall below the wage floor while minimizing the impact on the ESRD PPS base rate. Currently, all areas with wage index values that fall below the floor are located in Puerto Rico. However, the wage index floor value is applicable for any area that may fall below the floor.

A facility's wage index is applied to the labor-related share of the ESRD PPS base rate. In the CY 2019 ESRD PPS final rule (83 FR 56963), we finalized a labor-related share of 52.3 percent, which is based on the 2016-based ESRDB market basket. Thus, for CY 2020, the labor-related share to which a facility's wage index would be applied is 52.3 percent.

We were recently made aware of a minor calculation error in the file used to compute the ESRD PPS wage index values for this proposed rule. We are posting the corrected wage index values on the ESRD PPS payment page and we will correct this error when computing the ESRD PPS wage index values and payment rates for the final rule.

c. Proposed CY 2020 Update to the Outlier Policy

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary

care, including variability in the amount of ESAs necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care would be frailty, obesity, and comorbidities, such as cancer. The ESRD PPS recognizes high cost patients, and we have codified the outlier policy and our methodology for calculating outlier payments at § 413.237. The policy provides that the following ESRD outlier items and services are included in the ESRD PPS bundle: (1) ESRD-related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (2) ESRD-related laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (3) medical/surgical supplies, including syringes, used to administer ESRD-related drugs that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; and (4) renal dialysis services drugs that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including ESRD-related oral-only drugs effective January 1, 2025.

In the CY 2011 ESRD PPS final rule (75 FR 49142), we stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the facility to identify the actual ESRD outlier services furnished to the patient by line item (that is, date of service) on the monthly claim. Renal dialysis drugs, laboratory tests, and medical/surgical supplies that are recognized as outlier services were originally specified in Attachment 3 of Change Request 7064, Transmittal 2033 issued August 20, 2010, rescinded and replaced by Transmittal 2094, dated November 17, 2010. Transmittal 2094 identified additional drugs and laboratory tests that may also be eligible for ESRD outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011, which included one technical correction.

Furthermore, we use administrative issuances and guidance to continually update the renal dialysis service items available for outlier payment via our quarterly update CMS Change Requests, when applicable. We use this separate guidance to identify renal dialysis service drugs that were or would have been covered under Medicare Part D for outlier eligibility purposes and in order to provide unit prices for calculating imputed outlier services. In addition, we also identify through our monitoring

efforts items and services that are either incorrectly being identified as eligible outlier services or any new items and services that may require an update to the list of renal dialysis items and services that qualify as outlier services, which are made through administrative issuances.

Under § 413.237, an ESRD facility is eligible for an outlier payment if its actual or imputed MAP amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted and described in the following paragraphs) plus the FDL amount. In accordance with § 413.237(c) of our regulations, facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule and at § 413.220(b)(4), using 2007 data, we established the outlier percentage, which is used to reduce the per treatment base rate to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments, at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the FDL amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and FDL amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140). As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis to compute the payment adjustments.

For CY 2020, we propose that the outlier services MAP amounts and FDL amounts would be derived from claims data from CY 2018. Because we believe that any adjustments made to the MAP amounts under the ESRD PPS should be based upon the most recent data year available in order to best predict any

future outlier payments, we propose the outlier thresholds for CY 2020 would be based on utilization of renal dialysis items and services furnished under the ESRD PPS in CY 2018. We recognize that the utilization of ESAs and other outlier services have continued to decline under the ESRD PPS, and that we have lowered the MAP amounts and FDL amounts every year under the ESRD PPS.

In the CY 2019 ESRD PPS final rule (83 FR 56968), we stated that based on the CY 2017 claims data, outlier payments represented approximately 0.80 percent of total payments. For this

proposed rule, as discussed in section II.B.5.c.ii of this proposed rule, CY 2018 claims data show outlier payments represented approximately 0.5 percent of total payments.

i. CY 2020 Update to the Outlier Services MAP Amounts and FDL Amounts

For CY 2020, we propose to update the outlier services MAP amounts and FDL amounts to reflect the utilization of outlier services reported on 2018 claims. For this proposed rule, the outlier services MAP amounts and FDL amounts were updated using 2018

claims data. We note that, beginning in CY 2020, the total expenditure amount includes payments made for calcimimetics under the TDAPA policy (calculated to be \$21.15 per treatment). The impact of this update is shown in Table 2, which compares the outlier services MAP amounts and FDL amounts used for the outlier policy in CY 2019 with the updated proposed estimates for this rule. The estimates for the proposed CY 2020 outlier policy, which are included in Column II of Table 2, were inflation adjusted to reflect projected 2020 prices for outlier services.

TABLE 2—OUTLIER POLICY: IMPACT OF USING UPDATED DATA TO DEFINE THE OUTLIER POLICY

	Column I Final outlier policy for CY 2019 (based on 2017 data, price inflated to 2019)*		Column II Proposed outlier policy for CY 2020 (based on 2018 data, price inflated to 2020)	
	Age < 18	Age >= 18	Age < 18	Age >= 18
Average outlier services MAP amount per treatment	\$34.18	\$40.18	\$32.27	\$38.15
Adjustments:				
Standardization for outlier services	1.0503	0.9779	1.0692	0.9789
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	\$35.18	\$38.51	\$33.82	\$36.60
FDL amount that is added to the predicted MAP to determine the outlier threshold	\$57.14	\$65.11	\$44.91	\$52.50
Patient-months qualifying for outlier payment	7.2%	8.2%	10.8%	9.9%

* Note that Column I was obtained from Column II of Table 11 from the CY 2019 ESRD PPS final rule (83 FR 56968).

As demonstrated in Table 2, the estimated FDL amount per treatment that determines the CY 2020 outlier threshold amount for adults (Column II; \$52.50) is lower than that used for the CY 2019 outlier policy (Column I; \$65.11). The lower threshold is accompanied by a decrease in the adjusted average MAP for outlier services from \$38.51 to \$36.60. For pediatric patients, there is a decrease in the FDL amount from \$57.14 to \$44.91. There is a corresponding decrease in the adjusted average MAP for outlier services among pediatric patients, from \$35.18 to \$33.82.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2020 would be 9.9 percent for adult patients and 8.2 percent for pediatric patients, based on the 2018 claims data. The pediatric outlier MAP and FDL amounts continue to be lower for pediatric patients than adults due to the continued lower use of outlier services (primarily reflecting lower use of ESAs and other injectable drugs).

ii. Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081) and under § 413.220(b)(4), we reduced the per

treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments as described in § 413.237. Based on the 2018 claims, outlier payments represented approximately 0.5 percent of total payments, which is below the 1 percent target due to declines in the use of outlier services. Recalibration of the thresholds using 2018 data is expected to result in aggregate outlier payments close to the 1 percent target in CY 2020. We believe the update to the outlier MAP and FDL amounts for CY 2020 would increase payments for ESRD beneficiaries requiring higher resource utilization and move us closer to meeting our 1 percent outlier policy because we are using more current data for computing the MAP and FDL which is more in line with current outlier services utilization rates. We note that recalibration of the FDL amounts in this proposed rule would result in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments, but would increase payments to ESRD facilities for beneficiaries with renal dialysis items and services that are eligible for outlier

payments, as well as co-insurance obligations for beneficiaries with renal dialysis services eligible for outlier payments.

d. Proposed Impacts to the CY 2020 ESRD PPS Base Rate

i. ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), we established the methodology for calculating the ESRD PPS per-treatment base rate, that is, ESRD PPS base rate, and the determination of the per-treatment payment amount, which are codified at § 413.220 and § 413.230. The CY 2011 ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year as required by section 1881(b)(14)(A)(ii) of the Act), updated to CY 2011, and represented the average per treatment MAP for composite rate

and separately billable services. In accordance with section 1881(b)(14)(D) of the Act and our regulation at § 413.230, the per-treatment payment amount is the sum of the ESRD PPS base rate, adjusted for the patient specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, any applicable outlier payment and training adjustment add-on, the TDAPA (as proposed in section II.B.1.e of this proposed rule), and the TPNIES (as proposed in section II.B.3.b.iii of this proposed rule).

ii. Annual Payment Rate Update for CY 2020

We are proposing an ESRD PPS base rate for CY 2020 of \$240.27. This update reflects several factors, described in more detail as follows:

- **Market Basket Increase:** Section 1881(b)(14)(F)(i)(I) of the Act provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by the ESRD market basket percentage increase factor. The latest CY 2020 projection for the proposed ESRDB market basket is 2.1 percent. In CY 2020, this amount must be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as required by section 1881(b)(14)(F)(i)(II) of the Act. As discussed previously, the proposed MFP adjustment for CY 2020 is 0.4 percent, thus yielding a proposed update to the base rate of 1.7 percent for CY 2020. Therefore, the proposed ESRD PPS base rate for CY 2020 before application of the wage index budget-neutrality adjustment factor would be \$239.27 ($\$235.27 \times 1.017 = \239.27).

- **Wage Index Budget-Neutrality Adjustment Factor:** We compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2020, we are not proposing any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the proposed CY 2020 wage index budget-neutrality adjustment factor using treatment counts from the 2018 claims and facility-specific CY 2019 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2019. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2020. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the ESRD wage index for CY 2020. The total of these payments becomes the new CY 2020 amount of

wage-adjusted expenditures for all ESRD facilities. The wage index budget-neutrality factor is calculated as the target amount divided by the new CY 2020 amount. When we multiplied the wage index budget-neutrality factor by the applicable CY 2020 estimated payments, aggregate payments to ESRD facilities would remain budget neutral when compared to the target amount of expenditures. That is, the wage index budget-neutrality adjustment factor ensures that wage index adjustments do not increase or decrease aggregate Medicare payments with respect to changes in wage index updates.

The CY 2020 proposed wage index budget-neutrality adjustment factor is 1.004180. This application would yield a CY 2020 ESRD PPS proposed base rate of \$240.27 ($\$239.27 \times 1.004180 = \240.27).

In summary, we are proposing a CY 2020 ESRD PPS base rate of \$240.27. This amount reflects a proposed market basket increase of 1.7 percent and the proposed CY 2020 wage index budget-neutrality adjustment factor of 1.004180.

III. CY 2020 Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

A. Background

The Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27) was enacted on June 29, 2015, and amended the Act to provide coverage and payment for dialysis furnished by an ESRD facility to an individual with acute kidney injury (AKI). Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a new paragraph (r) to provide payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and adjusted (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under section 1881(b)(14)(D) of the Act that the Secretary elects.

In the CY 2017 ESRD PPS final rule, we finalized several coverage and payment policies in order to implement subsection (r) of section 1834 of the Act

and the amendments to section 1881(s)(2)(F) of the Act, including the payment rate for AKI dialysis (81 FR 77866 through 77872, and 77965). We interpret section 1834(r)(1) of the Act as requiring the amount of payment for AKI dialysis services to be the base rate for renal dialysis services determined for a year under the ESRD base rate as set forth in § 413.220, updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment as set forth in § 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373. We codified this policy in § 413.372 (81 FR 77965).

B. Proposed Annual Payment Rate Update for CY 2020

1. CY 2020 AKI Dialysis Payment Rate

The payment rate for AKI dialysis is the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act, which is the finalized ESRD PPS base rate, including market basket adjustments, wage adjustments and any other discretionary adjustments, for such year. We note that ESRD facilities have the ability to bill Medicare for non-renal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis.

As discussed in section II.B.5.d of this proposed rule, the CY 2020 proposed ESRD PPS base rate is \$240.27, which reflects a proposed market basket increase of 2.1 percent reduced by the multifactor productivity adjustment of 0.4 percentage points, that is, 1.7 percent, and application of the proposed CY 2020 wage index budget-neutrality adjustment factor of 1.004180. Accordingly, we are proposing a CY 2020 per treatment payment rate of \$240.27 for renal dialysis services furnished by ESRD facilities to individuals with AKI. This payment rate is further adjusted by the wage index as discussed below.

2. Geographic Adjustment Factor

Under section 1834(r)(1) of the Act and § 413.372, the amount of payment for AKI dialysis services is the base rate for renal dialysis services determined for a year under section 1881(b)(14) of the Act (updated by the ESRD bundled market basket and multifactor productivity adjustment), as adjusted by any applicable geographic adjustment factor applied under section 1881(b)(14)(D)(iv)(II) of the Act. Accordingly, we apply the same wage index under § 413.231 that is used under the ESRD PPS and discussed in

section II.B.5.b of this proposed rule. The AKI dialysis payment rate is adjusted by the wage index for a particular ESRD facility in the same way that the ESRD PPS base rate is adjusted by the wage index for that facility (81 FR 77868). Specifically, we apply the wage index to the labor-related share of the ESRD PPS base rate that we utilize for AKI dialysis to compute the wage adjusted per-treatment AKI dialysis payment rate. As stated above, we are proposing a CY 2020 AKI dialysis payment rate of \$240.27, adjusted by the ESRD facility's wage index.

IV. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

A. Background and Proposed Regulation Text Update

For a detailed discussion of the ESRD QIP's background and history, including a description of the Program's authorizing statute and the policies that we have adopted in previous final rules, we refer readers to the following final rules: 75 FR 49030, 76 FR 628, 76 FR 70228, 77 FR 67450, 78 FR 72156, 79 FR 66120, 80 FR 68968, 81 FR 77834, 82 FR 50738, and 83 FR 56922. We have also

codified many of our policies for the ESRD QIP at 42 CFR 413.177 and 178.

As we discuss in section IV.C.2 of this proposed rule, we are proposing to adopt the baseline period and performance period for each payment year automatically by advancing each period by 1 year from the baseline and performance period that were adopted for the previous payment year.

We propose to revise the requirements at § 413.178 by redesignating paragraphs (d) through (f) as paragraphs (e) through (g), respectively. In addition, we propose to add a new paragraph (d) to specify the data submission requirements for calculating measure scores. Specifically, we are proposing to codify the requirement that facilities must submit measure data to CMS on all measures. This proposed regulation text codifies previously finalized policies and will make it easier for the public to locate and understand the Program's quality data submission requirements.

Additionally, the proposed text in new paragraph (d)(2) would codify our proposed policy to adopt the performance period and baseline period for each payment year automatically by advancing 1 year from the previous payment year. At § 413.178(d)(3)

through (d)(7), we are proposing to codify requirements for the Extraordinary Circumstances Exception (ECE) process, including a new option for facilities to reject an extraordinary circumstance exception granted by CMS under certain circumstances. This new option will provide facilities with flexibility under the ECE process. We are proposing this provision to provide clear guidance to the public on the scope of our ECE process.

We invite public comments on these proposals.

B. Proposed Update to Requirements Beginning With the PY 2022 ESRD QIP

1. PY 2022 ESRD QIP Measure Set

The PY 2022 ESRD QIP measure set includes 14 measures, which are described in Table 3. For more information on these measures, including the two measures that are new beginning with PY 2022 (the Percentage of Prevalent Patients Waitlisted (PPPW) clinical measure and the Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) reporting measure), please see the CY 2019 ESRD QIP final rule (83 FR 57003 through 57010).

TABLE 3—PY 2022 ESRD QIP MEASURE SET

NQF No.	Measure title and description
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure. Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple testing tools.
2496	Standardized Readmission Ratio (SRR), a clinical measure. Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.
2979	Standardized Transfusion Ratio (STrR), a clinical measure. Risk-adjusted STrR for all adult Medicare dialysis patients. Ratio of the number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected.
N/A	(Kt/V) Dialysis Adequacy Comprehensive, a clinical measure. A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. Percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.
2977	Hemodialysis Vascular Access: Standardized Fistula Rate clinical measure. Measures the use of an AV fistula as the sole means of vascular access as of the last hemodialysis treatment session of the month.
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure. Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.
1454	Hypercalcemia, a clinical measure. Proportion of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL.
1463*	Standardized Hospitalization Ratio (SHR), a clinical measure. Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.
Based on NQF #0418	Clinical Depression Screening and Follow-Up, a reporting measure. Facility reports in CROWNWeb one of six conditions for each qualifying patient treated during performance period.
N/A	Ultrafiltration Rate, a reporting measure. Number of months for which a facility reports elements required for ultrafiltration rates for each qualifying patient.
Based on NQF #1460	NHSN Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure. The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
N/A	NHSN Dialysis Event reporting measure. Number of months for which facility reports NHSN Dialysis Event data to CDC.
N/A	Percentage of Prevalent Patients Waitlisted (PPPW), a clinical measure.

TABLE 3—PY 2022 ESRD QIP MEASURE SET—Continued

NQF No.	Measure title and description
2988	Percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period. Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec), a reporting measure. Percentage of patient-months for which medication reconciliation was performance and documented by an eligible professional.

2. Estimated Performance Standards for the PY 2022 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as required by section 1881(h)(4)(B) of the Act, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer

readers to the CY 2013 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We recently codified definitions for the terms “achievement threshold,” “benchmark,” “improvement threshold,” and “performance standard” in our regulations at § 413.178(a)(1), (3), (7), and (12), respectively.

In the CY 2019 ESRD PPS final rule (83 FR 57010), we set the performance period for the PY 2022 ESRD QIP as CY 2020 and the baseline period as CY

2018. In this proposed rule, we are estimating in Table 4 the achievement thresholds, 50th percentiles of the national performance, and benchmarks for the PY 2022 clinical measures using data from 2016 and 2017. We intend to update these standards, using CY 2018 data, in the CY 2019 ESRD PPS final rule. We also note that we are proposing in this proposed rule to convert the STRR measure from a clinical measure to a reporting measure and that if that proposal is finalized, we would not update these standards for the STRR measure.

TABLE 4—ESTIMATED PERFORMANCE STANDARDS FOR THE PY 2022 ESRD QIP CLINICAL MEASURES USING THE MOST RECENTLY AVAILABLE DATA

Measure	Achievement threshold (15th percentile of national performance)	Median (50th percentile of national performance)	Benchmark (90th percentile of national performance)
Vascular Access Type:			
Standardized Fistula Rate	52.61%	63.69%	76.11%.
Catheter Rate	18.24%	11.15%	5.02%.
Kt/V Comprehensive	92.98% (92.75%) *	96.88% (96.83%) *	99.14% (99.10%). *
Hypercalcemia	1.81%	0.57%	0.00%.
Standardized Readmission Ratio	1.268 (1.273) *	0.998	0.629 (0.642). *
Standardized Transfusion Ratio	1.684 (1.695) *	0.840	0.194.
NHSN Bloodstream Infection	1.477	0.694 (0.698) *	0.
Standardized Hospitalization Ratio	1.248	0.967 (0.971) *	0.670 (0.687). *
PPPW	8.75%	17.77%	34.29%.
ICH CAHPS: Nephrologists' Communication and Caring ..	58.09%	67.81%	78.53%.
ICH CAHPS: Quality of Dialysis Center Care and Operations.	54.16%	62.34%	72.03%.
ICH CAHPS: Providing Information to Patients	73.90% (73.89%) *	80.38%	87.08%.
ICH CAHPS: Overall Rating of Nephrologists	49.33% (47.85%) *	62.22% (60.37%) *	76.57% (74.50%). *
ICH CAHPS: Overall Rating of Dialysis Center Staff	49.12% (49.10%) *	63.04% (63.03%) *	77.48%.
ICH CAHPS: Overall Rating of the Dialysis Facility	53.98% (53.97%) *	67.93%	82.48% (82.34%). *

* If the PY 2022 final numerical value is worse than the PY 2021 finalized value, we will substitute the PY 2022 final numerical value for the PY 2021 finalized value. We have provided the PY 2021 finalized value as a reference for clinical measures whose PY 2022 estimated value is worse than the PY 2021 finalized value.

Data sources: VAT measures: 2017 CROWNWeb; SRR, STRR, SHR: 2017 Medicare claims; Kt/V: 2017 CROWNWeb; Hypercalcemia: 2017 CROWNWeb; NHSN: 2017 CDC; ICH CAHPS: CMS 2017; PPPW: 2017 CROWNWeb and 2017 OPTN.

3. Proposed Changes to the Scoring Methodology Previously Finalized for the PY 2022 ESRD QIP

a. Proposed Update to the Scoring Methodology for the National Healthcare Safety Network (NHSN) Dialysis Event Reporting Measure

There are currently two similar measures in the ESRD QIP that assess dialysis events: (1) The National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) clinical

measure, and (2) the NHSN Dialysis Event reporting measure. For the NHSN BSI clinical measure, facilities must be eligible to report 12 months of data to the NHSN on a quarterly basis in order to receive a score on the measure, and are scored based on whether they submitted data for that 12-month period and how many dialysis events they reported during that 12-month period. For the NHSN Dialysis Event reporting measure, facilities must enroll in the

NHSN, complete any required training, and report monthly dialysis event data on a quarterly basis to the NHSN. The current scoring methodology for the NHSN Dialysis Event reporting measure was finalized in the CY 2017 ESRD PPS final rule, and it was selected for two reasons. First, due to the seasonal variability of bloodstream infection rates, we stated that we wanted to incentivize facilities to report the full 12 months of data and reward reporting

consistency over the course of the entire performance period. Second, we stated that from the perspective of national prevention strategies and internal quality improvement initiatives, there was still value in collecting fewer than 12 months of data from facilities. For those reasons, we finalized a policy in the CY 2017 ESRD PPS final rule to award facilities 10 points for submitting 12 months of data, 2 points for reporting between 6 and 11 months of dialysis event data, and 0 points for reporting fewer than 6 months of data. See Table 5 for the current scoring distribution.

TABLE 5—CURRENT SCORING DISTRIBUTION FOR THE NHSN DIALYSIS EVENT REPORTING MEASURE

Number of reporting months	Points awarded to facility
12 months	10
6–11 months	2
0–5 months	0

As we have accumulated experience with this policy, we are concerned that new facilities and facilities for which CMS grants an ECE for part of the performance period that applies for a payment year are not eligible to receive a score on the NHSN Dialysis Event reporting measure because they are not eligible to report data for the full 12-month period. As a result, we do not believe that this policy appropriately accounts for the effort made by these facilities to report these data for the months in which they are eligible to report. For example, for PY 2020, the number of new facilities certified during the performance year (CY 2018) was 390 and the number of facilities granted an ECE during CY 2018 was 31, but none of those facilities was eligible to receive a score on the measure. In addition, if a facility is aware that it will not be eligible to receive a score on the NHSN Dialysis Event reporting measure, we are concerned that the facility will not be incentivized to report data at all for that payment year.

We have therefore reconsidered our previous policy. We propose to remove the NHSN Dialysis Event reporting measure's exclusion of facilities with fewer than 12 eligible reporting months. Beginning with the PY 2022 ESRD QIP, we propose to assess successful reporting based on the number of months facilities are eligible to report the measure. Under this proposal, facilities would receive credit for scoring purposes based on the number of months they successfully report data out of the number of eligible months.

For example, if a facility had 10 eligible reporting months because it was granted an ECE for 2 months of the performance period, and reported data for those 10 eligible months, the facility would receive a score, whereas under the current policy, the facility would not receive a score. To accommodate this proposed change and to ensure that our scoring methodology appropriately incentivizes facilities to report data on the NHSN Dialysis Event reporting measure, even if they are not eligible to report data for all 12 months of a performance period, we also propose to assign scores for reporting different quantities of data as summarized in Table 6.

TABLE 6—PROPOSED SCORING DISTRIBUTION FOR THE NHSN DIALYSIS EVENT REPORTING MEASURE

Percentage of eligible months* reported	Points awarded to facility
100% of eligible months	10
Less than 100% but no less than 50% of eligible months	2
Less than 50% of eligible months	0

* We define the term “eligible months” to mean the months in which dialysis facilities are required to report dialysis event data to NHSN per the measure eligibility criteria. This includes facilities that offer in-center hemodialysis and facilities that treat at least 11 eligible in-center hemodialysis patients during the performance period.

We believe that it is important to encourage new facilities and facilities with an approved ECE to report complete and accurate dialysis event data to the NHSN for all the months in which they are eligible to submit data so that we have as comprehensive as possible a view of these facilities' performance on this important clinical topic. We continue to believe that complete and accurate reporting of NHSN data is critical to maintaining the integrity of the NHSN surveillance system, enables facilities to implement their own quality improvement initiatives, and enables the Centers for Disease Control and Prevention (CDC) to design and disseminate prevention strategies. We believe the fairest way to balance these goals is to adopt a new NHSN Dialysis Event reporting measure policy focused more specifically on considering reporting successful based on the number of months that a facility is eligible to report the measure. We are not proposing changes to the NHSN BSI clinical measure's scoring methodology and will continue to require that facilities report data for the full 12

months of data in order to receive a score on that measure.

We seek comment on these proposals.

b. Proposal To Convert the Standardized Transfusion Ratio (STrR) Clinical Measure to a Reporting Measure

In the CY 2015 ESRD PPS final rule (79 FR 66192 through 66197) we finalized the adoption of the Standardized Transfusion Ratio (STrR) clinical measure to address gaps in the quality of anemia management, beginning with the PY 2018 ESRD QIP. We also finalized policies to score facility performance on the STrR clinical measure based on achievement and improvement in the PY 2018 ESRD QIP (79 FR 66209). We finalized identical scoring policies for the STrR clinical measure in the PY 2019 ESRD QIP and the PY 2020 ESRD QIP in the CY 2016 ESRD PPS final rule (80 FR 69060 through 69061) and the CY 2017 ESRD PPS final rule (81 FR 77916), respectively.

After finalizing the STrR clinical measure in the CY 2015 ESRD PPS final rule, we submitted the measure to the NQF for consensus endorsement, but the Renal Standing Committee did not recommend it for endorsement, in part due to concerns that variability in hospital coding practices with respect to the use of 038 and 039 revenue codes might unduly bias the measure rates. Upon reviewing the committee's feedback, we revised the STrR clinical measure's specifications to address those concerns. The updated measure specifications for the STrR clinical measure contain a more restricted definition of transfusion events than was previously used in the STrR clinical measure. Specifically, the revised definition excludes inpatient transfusion events for claims that include only 038 or 039 revenue codes without an accompanying International Statistical Classification of Diseases and Related Health Problems—9 (ICD–9) or ICD–10 procedure code or value code. As a result, the measure can identify transfusion events more specifically and with less bias related to regional coding variation, which means that the measure assesses a smaller number of events as well as a smaller range of total events.

Following this revision, we resubmitted the STrR clinical measure (NQF #2979) to NQF for consensus endorsement. The NQF endorsed the revised STrR clinical measure in 2016, and in the CY 2018 ESRD PPS final rule (82 FR 50771 through 50774), we finalized changes to the STrR clinical measure that aligned the measure specifications used for the ESRD QIP with the measure specifications that

NQF endorsed in 2016 (NQF #2979), beginning with the PY 2021 ESRD QIP. We also finalized policies to score facility performance on the revised STTr clinical measure based on achievement and improvement (82 FR 50779 through 50780), and we subsequently finalized that those policies would continue for PY 2022 and in subsequent payment years (83 FR 57011).

Commenters to the CY 2019 ESRD PPS proposed rule raised concerns about the validity of the modified STTr measure (NQF #2979) finalized for adoption beginning with PY 2021. Commenters specifically stated that due to the new level of coding specificity required under the ICD-10-CM/PCS coding system, many hospitals are no longer accurately coding blood transfusions. The commenters further stated that because the STTr measure is calculated using hospital data, the rise of inaccurate blood transfusion coding by hospitals has negatively affected the validity of the STTr measure (83 FR 56993 through 56994).

We are currently in the process of examining the concern raised by commenters about the validity of the modified STTr measure, and we considered three alternatives for scoring the measure until we complete that process: (1) Assign the score that a facility would need to earn if it performed at the 50th percentile of national ESRD performance during the baseline year to every facility that would otherwise earn a score during the performance period below that median score, (2) align the measure specifications with those used for the measure prior to the PY 2021 ESRD QIP, and (3) convert the STTr clinical measure to a reporting measure.

We considered the second alternative because the previously adopted measure specifications for the STTr clinical measure include a more expansive definition of transfusions. However, we rejected the second policy alternative because that version of the STTr clinical measure was not endorsed by the NQF due to the concern expressed by the Renal Standing Committee that variability in hospital coding practices with respect to the use of 038 and 039 revenue codes might unduly bias the

measure rates. We are in the process of evaluating the concern raised by commenters to the CY 2019 ESRD PPS proposed rule, and we intend present our analyses and measure changes to the NQF under an ad hoc review of the STTr clinical measure later this year before making a final decision regarding implementation in the ESRD QIP. Additionally, any substantive changes to the STTr that result from this process may require a MAP review prior to any future implementation effort. Under the first policy alternative, the Program would continue use of a measure endorsed by NQF, and if a facility does receive a payment reduction, it would not be due to its performance on the STTr clinical measure. Facilities would have to score below the median score used in the minimum TPS (mTPS) for a different measure in order to receive a payment reduction. If a facility scores at the median used in the mTPS calculation for all measures, it will receive the same TPS as the mTPS and therefore not receive a payment reduction. However, we rejected the first policy alternative because it would score facilities based on their performance on a measure whose validity we are currently examining.

Under the third policy alternative, we would be using a reporting measure that is based on an NQF-endorsed measure, but we would not be scoring facilities on the measure based on their performance. While the current concerns regarding measure validity may call into question the capacity for current data to adequately capture transfusion rates attributable to facilities, we believe that the transfusions captured by the measure are a conservative estimate of the number of events that actually occur, and that those events represent an undesirable health outcome for patients that is potentially modifiable by the dialysis facility through appropriate anemia management.

In light of the concerns raised about the validity of the STTr clinical measure, we are continuing to examine this issue. We would like to ensure that the Program's scoring methodology results in fair and reliable STTr measure scores because those scores are linked to

dialysis facilities' TPS and possible payment reductions. We believe that the most appropriate way to continue fulfilling the statutory requirement to include a measure of anemia management in the Program while ensuring that dialysis facilities are not adversely affected during our continued examination of the measure is to convert the STTr clinical measure to a reporting measure for the reasons discussed above.

We are also proposing that, beginning with PY 2022, we would score the STTr reporting measure as follows: facilities that meet previously finalized minimum data and eligibility requirements will receive a score on the STTr reporting measure based on the successful reporting of data, not on the values actually reported. We are proposing that in order to receive 10 points on the measure, a facility would need to report the data required to determine the number of eligible patient-years at risk and have at least 10 eligible patient-years at risk. A patient-year at risk is a period of 12-month increments during which a single patient is treated at a given facility. A patient-year at risk can be comprised of more than 1 patient if, when added together, their time in treatment equals a year. For example, if 1 patient is treated at the same facility for 4 months and a second patient is treated at a facility for 8 months, then the two patients would combine to form a full patient year.

We believe this scoring adjustment policy would enable us to retain an anemia management measure in the ESRD QIP measure set while we continue to examine the measure's validity concerns raised by stakeholders.

We seek comments on these proposals.

c. Proposed Update to the MedRec Reporting Measure's Scoring Methodology

In the CY 2019 ESRD PPS final rule (83 FR 57011), we finalized a policy to score the MedRec reporting measure using the following equation, beginning with the PY 2022 ESRD QIP.

$$\left(\frac{\text{Number of patient-months successfully reporting data}}{\text{Number of eligible patient-months}} \times 12 \right) - 2$$

We also stated that this equation was similar to the equation used for the

Ultrafiltration reporting measure (81 FR 77917):

$$\left(\frac{\text{\# months successfully reporting data}}{\text{\# eligible months}} \times 12 \right) - 2$$

However, we inadvertently used the term “patient-months” in the MedRec reporting measure’s scoring equation. We calculate a subset of our clinical measures using patient-months (the Kt/V Comprehensive clinical measure, the Standard Fistula Rate clinical measure, the Catheter Rate clinical measure, and the Hypercalcemia clinical measure) because patient-months is the unit of analysis based on their measure specifications. Facility-months are generally used for a reporting measure

because they assess the proportion of months in a year that a facility reported to CMS the data necessary to calculate the measure.

The use of facility-months for the MedRec reporting measure is also consistent with the scoring methodology we have used for all other reporting measures which require monthly reporting, including the Anemia Management reporting measure (finalized for removal beginning with the PY 2021 ESRD QIP measure), the

Serum Phosphorus reporting measure (finalized for removal beginning with the PY 2021 ESRD QIP measure), and the Ultrafiltration reporting measure.

We are therefore proposing to revise the scoring equation for the MedRec reporting measure so that the scoring methodology accurately describes our intended policy. We propose to score the MedRec reporting measure using the following equation, beginning with the PY 2022 ESRD QIP.

$$\left(\frac{\text{\# months successfully reporting data}}{\text{\# eligible months}} \times 12 \right) - 2$$

We seek public comment on this proposal.

Additionally, in section IV.B.4 of the CY 2019 ESRD PPS final rule, we finalized a requirement for PY 2021 and beyond for facilities to begin collecting data for purposes of the ESRD QIP beginning with services furnished on the first day of the month that is 4 months after the month in which the CMS Certification Number (CCN) becomes effective (83 FR 56999 through 57000). In section IV.C.4.c of the CY 2019 ESRD PPS final rule (83 FR 57013 through 57014), we applied the updated reporting requirement for new facilities finalized in section IV.B.4 of the CY 2019 ESRD PPS final rule to the MedRec reporting measure

eligibility requirements finalized in section IV.C.4.c of the CY 2019 ESRD PPS final rule. We specified in Table 23 of the CY 2019 ESRD PPS final rule that facilities with a CCN Open Date before October 1, 2019 would meet the eligibility requirements for the MedRec reporting measure.

In order to ensure that there is no confusion regarding these requirements, we are clarifying that for the MedRec reporting measure, facilities with a CCN Open Date before the October 1st prior to the performance period (which, for the PY 2022 ESRD QIP, would be a CCN Open Date before October 1, 2019) must begin collecting data on that measure.

4. Proposed Update to the Eligibility Requirements for the PY 2022 ESRD QIP

In the CY 2019 ESRD PPS final rule, we finalized a policy where, with respect to the NHSN Dialysis Event reporting measure, facilities are required to have a CCN Open Date on or before the October 1 prior to the performance

period to be eligible to receive a score, beginning with the PY 2021 ESRD QIP (83 FR 56999 through 57000). In section IV.B.3.a of this proposed rule, we are proposing to remove the NHSN Dialysis Event reporting measure’s exclusion of facilities with fewer than 12 eligible reporting months and to assess successful reporting based on the number of months facilities are eligible to report the measure, beginning with the PY 2022 ESRD QIP. To accommodate this proposed policy, we are proposing to remove the requirement that, to be eligible to receive a score on the NHSN Dialysis Event reporting measure, new facilities must have a CCN Open Date before October 1 prior to the performance period that applies to the payment year. Table 7 summarizes the ESRD QIP’s minimum eligibility requirements for scoring, including the proposed change to the eligibility requirement for the NHSN Dialysis Event reporting measure.

TABLE 7—PROPOSED ELIGIBILITY REQUIREMENTS FOR SCORING ON ESRD QIP MEASURES

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Comprehensive (Clinical)	11 qualifying patients	N/A	11–25 qualifying patients.
Vascular Access Type: Long-term Catheter Rate (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.
Vascular Access Type: Standardized Fistula Rate (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.
Hypercalcemia (Clinical)	11 qualifying patients	N/A	11–25 qualifying patients.

TABLE 7—PROPOSED ELIGIBILITY REQUIREMENTS FOR SCORING ON ESRD QIP MEASURES—Continued

Measure	Minimum data requirements	CCN open date	Small facility adjuster
NHSN BSI (Clinical)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	11–25 qualifying patients.
NHSN Dialysis Event (Reporting)	11 qualifying patients	N/A as proposed	11–25 qualifying patients.
SRR (Clinical)	11 index discharges	N/A	11–41 index discharges.
STrR (Clinical)	10 patient-years at risk	N/A	10–21 patient-years at risk.
SHR (Clinical)	5 patient-years at risk	N/A	5–14 patient-years at risk.
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities will not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period.	Before October 1 prior to the performance period that applies to the program year.	N/A.
Depression Screening and Follow-Up (Reporting)	11 qualifying patients	Before April 1 of the performance period that applies to the program year.	N/A.
Ultrafiltration (Reporting)	11 qualifying patients	Before April 1 of the performance period that applies to the program year.	N/A.
MedRec (Reporting)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	N/A.
PPPW (Clinical)	11 qualifying patients	N/A	11–25 qualifying patients.

5. Estimated Payment Reduction for the PY 2022 ESRD QIP

Under our current policy, a facility will not receive a payment reduction in connection with its performance the ESRD QIP for a payment year if it achieves a TPS that is at or above the minimum TPS that we establish for the payment year. We have defined the minimum TPS in our regulations at § 413.178(a)(8) as, with respect to a payment year, the TPS that an ESRD facility would receive if, during the baseline period, it performed at the 50th percentile of national performance on all clinical measures and the median of national ESRD facility performance on all reporting measures.³⁵

Our current policy, which is codified at § 413.177 of our regulations, is also to implement the payment reductions on a sliding scale using ranges that reflect payment reduction differentials of 0.5 percent for each 10 points that the facility's TPS falls below the minimum TPS (76 FR 634 through 635).

³⁵ We recently codified definitions for the terms “achievement threshold,” “benchmark,” “improvement threshold,” and “performance standard” in our regulations at 42 CFR 413.178(a)(1), (3), (7), and (12), respectively. When we codified the definition of the “performance standard,” we declined to include a reference to the 50th percent of national performance in that definition because the term “performance standards” applies more broadly to levels of achievement and improvement and is not a specific reference to the 50th percentile of national performance. Instead, we have incorporated the concept of the 50th percentile of national performance into recently codified definition of the minimum TPS.

For PY 2022, we estimate using available data that a facility must meet or exceed a minimum TPS of 53 in order to avoid a payment reduction. We note that the mTPS estimated in this proposed rule is based on data from CY 2017 instead of the PY 2022 baseline period (CY 2018) because CY 2018 data are not yet available. We will update and finalize the mTPS using CY 2018 data in the CY 2020 ESRD PPS final rule.

We refer the reader to Table 4 for the estimated values of the 50th percentile of national performance for each clinical measure. Under our current policy, a facility that achieves a TPS below 53 would receive a payment reduction based on the TPS ranges indicated in Table 8.

TABLE 8—PAYMENT REDUCTION SCALE FOR PY 2022 BASED ON THE MOST RECENTLY AVAILABLE DATA

Total performance score	Reduction (%)
100–53	0
52–43	0.5
42–33	1.0
32–23	1.5
22–0	2.0

We intend to update the minimum TPS for PY 2022, as well as the payment reduction ranges for that payment year, in the CY 2020 ESRD PPS final rule.

6. Data Validation Proposals for PY 2022 and Beyond

One of the critical elements of the ESRD QIP's success is ensuring that the data submitted to calculate measure scores and TPSs are accurate. The ESRD QIP currently includes two validation studies for this purpose: the CROWNWeb data validation study (OMB Control Number 0938–1289) and the NHSN validation study (OMB Control Number 0938–1340). In the CY 2019 ESRD PPS final rule, we adopted the CROWNWeb data validation study as a permanent feature of the Program (83 FR 57003). Under that policy, we will continue validating CROWNWeb data in PY 2022 and subsequent payment years, and we will deduct 10 points from a facility's TPS if it is selected for validation but does not submit the requested records.

We also adopted a methodology for the PY 2022 NHSN validation study, which targets facilities for NHSN validation by identifying facilities that are at risk for under-reporting. A sample of 300 facilities will be selected, and each facility will be required to submit 20 patient records covering 2 quarters of data reported in the performance year (for PY 2022, this would be CY 2020). For additional information on this methodology, we refer readers to the CY 2018 ESRD PPS final rule (82 FR 50766 through 50767).

We are proposing to continue using this methodology for the NHSN validation study for PY 2023 and

subsequent years because based on a recent statistical analysis conducted by the CDC, we have concluded that to achieve the most reliable results for a payment year, we would need to review approximately 6,072 charts submitted by 303 facilities. This sample size would produce results with a 95 percent confidence level and a 1 percent margin of error. Based on those results and our desire to ensure that dialysis event data reported to the NHSN for purposes of the ESRD QIP are accurate, we are proposing to continue use of this methodology in the PY 2023 NHSN validation study and for subsequent years.

Additionally, as we finalized for CROWNWeb validation, we are proposing to adopt NHSN validation as a permanent feature of the ESRD QIP with the methodology we first finalized for PY 2022 and are proposing to continue for PY 2023 and subsequent years. We continue to believe that the purpose of our validation programs is to ensure the accuracy and completeness of data that are scored under the ESRD QIP, and we believe that validating NHSN data using this methodology achieves that goal. Now that we have adopted a larger sample size of 300 facilities for the NHSN validation study and have thus ensured enough precision within the study, we believe that making the validation study permanent will signal our commitment to accurate reporting of the important clinical topics covered by the NHSN measures that we have adopted.

We welcome public comments on these proposals.

C. Proposals for the PY 2023 ESRD QIP

1. Continuing Measures for the PY 2023 ESRD QIP

Under our previously-adopted policy, we are continuing all measures from the PY 2022 ESRD QIP for PY 2023. We are not proposing to adopt any new measures beginning with the PY 2023 ESRD QIP.

2. Proposed Performance Period for the PY 2023 ESRD QIP and Subsequent Years

We continue to believe that 12-month performance and baseline periods provide us sufficiently reliable quality measure data for the ESRD QIP. We therefore propose to establish CY 2021 as the performance period for the PY 2023 ESRD QIP for all measures. Additionally, we propose to establish CY 2019 as the baseline period for the PY 2023 ESRD QIP for all measures for purposes of calculating the achievement threshold, benchmark, and the

minimum TPS, and CY 2020 as the baseline period for the PY 2023 ESRD QIP for purposes of calculating the improvement threshold. Beginning with PY 2024, we propose to adopt automatically a performance and baseline period for each year that is 1-year advanced from those specified for the previous payment year. For example, under this policy, we would automatically adopt CY 2022 as the performance period for the PY 2024 ESRD QIP. We would also automatically adopt CY 2020 as the baseline period for purposes of calculating the achievement threshold, benchmark, and minimum TPS and CY 2021 as the baseline period for purposes of calculating the improvement threshold, for the PY 2024 ESRD QIP.

We welcome comment on these proposals.

3. Performance Standards for the PY 2023 ESRD QIP and Subsequent Years

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as required by section 1881(h)(4)(B) of the Act, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer readers to the CY 2013 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We recently codified definitions for the terms “achievement threshold,” “benchmark,” “improvement threshold,” and “performance standard” in our regulations at § 413.178(a)(1), (3), (7), and (12), respectively.

a. Performance Standards for Clinical Measures in the PY 2023 ESRD QIP

At this time, we do not have the necessary data to assign numerical values to the achievement thresholds, benchmarks, and 50th percentiles of national performance for the clinical measures because we do not have CY 2019 data. We intend to publish these numerical values, using CY 2019 data, in the CY 2021 ESRD PPS final rule.

b. Performance Standards for the Reporting Measures in the PY 2023 ESRD QIP

In the CY 2019 ESRD PPS final rule, we finalized the continued use of existing performance standards for the Screening for Clinical Depression and

Follow-Up reporting measure, the Ultrafiltration Rate reporting measure, the NHSN Dialysis Event reporting measure, and the MedRec reporting measure (83 FR 57010 through 57011). We will continue use of these performance standards in PY 2023.

4. Scoring the PY 2023 ESRD QIP

a. Scoring Facility Performance on Clinical Measures

In the CY 2014 ESRD PPS final rule, we finalized policies for scoring performance on clinical measures based on achievement and improvement (78 FR 72215 through 72216). In the CY 2019 ESRD PPS final rule, we finalized a policy to continue use of this methodology for future payment years (83 FR 57011) and we codified these scoring policies at § 413.178(d).³⁶

We are not proposing to change our scoring policies.

b. Scoring Facility Performance on Reporting Measures

In the CY 2019 ESRD PPS final rule, we codified our policy for scoring performance on reporting measures at § 413.178(d),³⁷ and we finalized the continued use of existing policies for scoring performance on the Ultrafiltration Rate reporting measure and the MedRec reporting measure (83 FR 57011). We will continue use of the Ultrafiltration Rate reporting measure's scoring policy in PY 2023. In section IV.B.3.c of this proposed rule, we propose to use facility-months instead of patient-months when scoring the MedRec reporting measure and clarify our intention to begin scoring new facilities with a CCN Open date before the October 1st of the year prior to the performance period rather than before the January 1st of the performance period. Those proposals, if finalized, would apply to PY 2023 and subsequent payment years.

5. Proposals for Weighting the Measure Domains, and for Weighting the TPS for PY 2023

Under our current policy, we assign the Patient & Family Engagement Measure Domain a weight of 15 percent of TPS, the Care Coordination Measure Domain a weight of 30 percent of TPS, the Clinical Care Measure Domain a weight of 40 percent of TPS, and the Safety Measure domain a weight of 15 percent of TPS, for the PY 2022 ESRD QIP (83 FR 57011 through 57012).

³⁶ Please note that we are proposing to redesignate paragraph (d) as subparagraph (e) in this proposed rule.

³⁷ As noted above, we are proposing to redesignate paragraph (d) as subparagraph (e) in this proposed rule.

In the CY 2019 ESRD PPS final rule, we finalized a policy to assign weights to individual measures and a policy to redistribute the weight of unscored measures in the PY 2022 ESRD QIP (83 FR 57011 through 57012). We are proposing to continue use of the PY 2022 measure weights for the PY 2023 ESRD QIP and subsequent payment years. We also proposing to continue use of the PY 2022 measure weight redistribution policy in the PY 2023 ESRD QIP and subsequent payment years.

We welcome comments on these proposals.

Under our current policy, a facility must be eligible to be scored on at least one measure in two of the four measures domains in order to be eligible to receive a TPS (83 FR 57012).

V. Establishing Payment Amounts for New Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Items and Services (Gap-Filling)

A. Background

1. Calculating Fee Schedule Amounts for DMEPOS Items and Services

Section 1834(a) of the Act mandates payment based on the lesser of the supplier's actual charge or a fee schedule amount for DME other than customized items defined at 42 CFR 414.224 and items included in a competitive bidding program in a competitive bidding area under section 1847(a) of the Act. Section 1834(h) of the Act mandates payment based on the lesser of the supplier's actual charge or a fee schedule amount for most prosthetic devices, orthotics, and prosthetics other than off-the-shelf orthotics included in a competitive bidding program in a competitive bidding area under section 1847(a) of the Act. Section 1834(i) of the Act mandates payment based on the lesser of the supplier's actual charge or a fee schedule amount for surgical dressings. Section 1833(o)(2)(A) of the Act mandates payment based on the lesser of the supplier's actual charge or a fee schedule amount in accordance with section 1834(h) of the Act for custom molded shoes, extra-depth shoes, and inserts. Section 1842(s) of the Act authorizes payment based on the lesser of the supplier's actual charge or a fee schedule amount for parenteral and enteral nutrients, equipment, and supplies (PEN), other than enteral nutrients, equipment, and supplies included in a competitive bidding program in a competitive bidding area under section 1847(a) of the Act, and medical supplies, including splints and

casts and intraocular lenses inserted in a physician's office. The fee schedule amounts established for these items and services are based on payments made previously under the reasonable charge payment methodology, which is set forth in section 1842(b) of the Act and in our regulations at 42 CFR 405.502. Generally, reasonable charge determinations are based on customary and prevailing charges derived from historic charge data. The fee schedule amounts for DME, prosthetic devices, orthotics, prosthetics, and custom molded shoes, extra-depth shoes, and inserts are based on average reasonable charges from 1986 and 1987. The fee schedule amounts for surgical dressings are based on average reasonable charges from 1992. The fee schedule amounts for PEN are calculated on a nationwide basis and are the lesser of the reasonable charges for 1995, or the reasonable charges that would have been used in determining payment for these items in 2002 under the former reasonable charge payment methodology (§ 414.104(b)). The fee schedule amounts for splints and casts are based on reasonable charges for 2013 and the fee schedule amounts for intraocular lenses inserted in a physician's office are based on reasonable charges for 2012. In accordance with sections 1834(a)(14)(L), 1834(h)(4)(xi), and 1842(s)(1)(B)(ii) of the Act, the DMEPOS fee schedule amounts are generally adjusted annually by the percentage increase in the CPI-U for the 12-month period ending with June 30 of the preceding year reduced by a productivity adjustment. The Medicare payment amount for a DMEPOS item is generally equal to 80 percent of the lesser of the actual charge or the fee schedule amount for the item, less any unmet Medicare Part B deductible. The beneficiary coinsurance for such items is generally equal to 20 percent of the lesser of the actual charge or the fee schedule amount for the item once the deductible is met.

The statute does not specify how to calculate fee schedule amounts when the base reasonable charge data does not exist. As discussed later on, since 1989, we have used a process referred to as "gap-filling" to fill the gap in the reasonable charge data for new DMEPOS items, which are newly covered items or technology or items paid under Healthcare Common Procedure Coding System (HCPCS) codes for miscellaneous items. The gap-filling process is used to estimate what Medicare would have paid for the item under the reasonable charge payment methodology during the period of time

from which reasonable charge data is used to calculate the fee schedule amounts, or the fee schedule "base period" (for example, 1986 and 1987 for DME). Various methods have been used by CMS and its contractors to gap-fill DMEPOS fee schedule amounts including use of fees for comparable items, supplier prices, manufacturer's suggested retail prices (MSRPs), wholesale prices plus a markup percentage to convert the prices to retail prices, or other methods. In any case where prices are used for gap-filling, the prices are deflated to the fee schedule base period by the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the price is in effect to the mid-point of the fee schedule base period. Program guidance containing instructions for contractors (mainly for use by the Durable Medical Equipment Medicare Administrative Contractors (DME MACs)) for gap-filling DMEPOS fee schedule amounts is found at section 60.3 of chapter 23 of the Medicare Claims Processing Manual (Pub. L. 100-04). The instructions indicate that the DMEPOS fee schedule for items for which reasonable charge data were unavailable during the fee schedule base period are to be gap-filled using the fee schedule amounts for comparable items or supplier price lists with prices in effect during the fee schedule base period. The instructions specify that supplier price lists include catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include verifiable information from supplier invoices and non-Medicare payer data (for example, fee schedule amounts comprised of the median of the commercial pricing information adjusted as described below). Mail order catalogs are suitable sources of routinely available price information for items such as urological and ostomy supplies which require frequent replacement. We issued Transmittal 4130, Change Request 10924 dated September 14, 2018 which updated the manual instruction to clarify that supplier price lists can include internet retail prices or verifiable information from supplier invoices and non-Medicare payer data. Prior to 2018, non-Medicare payer data had not been included to establish gap-filled DMEPOS fee schedule amounts. CMS and its contractors have used internet retail prices in the past in addition to catalogue prices, as well as wholesale prices plus a retail price mark up, and on one occasion hospital

invoices plus a 10 percent markup as a source for commercial pricing information.

In 2015, in revising the DME MAC statement of work, CMS clarified to the DME MACs that manufacturer's suggested retail prices (MSRP) should not be used for gap-filling due to CMS's concerns that MSRPs may not represent routinely available supplier price lists, which are incorporated for supplier charges in calculating fee schedule amounts that the statute mandates be based on historic reasonable charges. Although MSRPs were used in certain cases in the past to gap-fill DMEPOS fee schedule amounts, our experience has revealed the retail prices suggested by manufacturers often are inflated and do not reflect commercial competitive pricing, or a price that is paid to a supplier for furnishing items and services. Using MSRPs to gap-fill DMEPOS fee schedule amounts led to excessive fee schedule amounts compared to fees established for other DMEPOS items paid for in 1986, 1987, 1992, 2001, or other fee schedule base periods. In many cases, a single manufacturer may produce a new item, and pricing information may therefore be limited to the MSRP. In these situations, unlike other items and services paid for under Medicare, there is not yet independently substantiated pricing information. In addition, similar items are not available to create competition and to potentially limit the price a sole source manufacturer charges for the new item. We believe the MSRP may represent the amount the manufacturer charges to Medicare and other health insurance payers before pricing is established in a competitive market by suppliers furnishing the product and competitor products.

Currently, when we release our program instruction to the DME MACs to update the DMEPOS fee schedule, we include a list of new HCPCS codes, which are then added to the DMEPOS fee schedule. Also, we release updated DMEPOS fee schedule amounts in fee schedule files to our contractors and available online at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule.html>.

If a HCPCS code for a new item is added and takes effect, and the fee schedule amounts for the new code have not yet been added to the DMEPOS fee schedule file, our contractors establish payment on an interim basis using local fee schedule amounts gap-filled in accordance with the program instructions at section 60.3 of chapter 23 of the Medicare Claims Processing

Manual until the fee schedule amounts on the national files are available.

2. Coding for New DMEPOS Items

The HCPCS is a standardized coding system used to process claims submitted to Medicare, Medicaid, and other health insurance programs. Level I of the HCPCS codes is comprised of Current Procedural Terminology (CPT) codes identifying primarily medical services and procedures furnished by physicians and other health care practitioners, published and maintained by the American Medical Association. Level II of the HCPCS codes primarily identifies items, supplies, services and certain drugs used outside the practitioner setting. Assignment of a HCPCS code is not a coverage determination and does not imply that any payer will cover the items in the code category.

In 2001, section 531(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) mandated procedures that permit public consultation for coding and payment determinations for new DMEPOS items under Medicare Part B in a manner consistent with the procedures established for implementing ICD–9–CM coding modifications. As a result, beginning in 2002, after the HCPCS Workgroup's preliminary decision has been developed, the preliminary decisions are made available to the public via our website and public meetings are scheduled to receive public comment on the preliminary decisions.

Following the HCPCS public meetings, we make a final decision on each new DMEPOS code request and payment category. Then, we prepare and release the HCPCS and DMEPOS fee schedule files and program instructions for the next applicable update (annual or quarterly) to our contractors and via our website. Also, a summary of the final coding and payment category decisions is made available on our website. See the following websites for more information:

- HCPCS Files: <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html>;
- DMEPOS Fee Schedule Files: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule.html>;
- Program Instructions: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/index.html>; and
- Public Meeting Summaries: <https://www.cms.gov/Medicare/Coding/>

MedHCPCSGenInfo/HCPCS PublicMeetings.html.

Typically, more than 100 applications are submitted to the CMS HCPCS Workgroup each year, with approximately one-third requesting new or revised DMEPOS codes. The number of approved new DMEPOS codes is not finalized until shortly before the release of the HCPCS dataset, which in some cases, leaves very short timeframes to prepare and release the updated DMEPOS fee schedule.

3. Continuity of Pricing

Instructions for contractors addressing how to establish DMEPOS payment amounts following updates to HCPCS codes are contained at section 60.3.1 of chapter 23 of the Medicare Claims Processing Manual. When an item receives a new HCPCS code, it does not necessarily mean that Medicare payment on a fee schedule basis has never been made for the item described by the new code. If a new code is established, contractors are instructed to make every effort to determine whether the item has a pricing history and profile. If there is a pricing history, that is, the items and services described by the new code were paid for in the past under other codes based on the fee schedule amounts for the other codes, the fee schedule amounts used to pay for the item previously are mapped or cross walked to the new code(s) for the item to ensure continuity of pricing. Since there are different kinds of coding changes, there are various ways pricing is cross walked from old codes to new codes, which is addressed in our program instructions at section 60.3.1 of chapter 23 of the Medicare Claims Processing Manual. For example, when the code for an item is divided into multiple codes for the components of that item, the total of the separate fee schedule amounts established for the components must not be higher than the fee schedule amount for the original item. However, when there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts for the single code are applied to each of the new codes. Conversely, when the codes for the components of a single item are combined in a single global code, the fee schedule amounts for the new code are established by totaling the fee schedule amounts used for the components (that is, use the total of the fee schedule amounts for the components as the fee schedule amount for the global code). However, when the codes for several

different items are combined into a single code, the fee schedule amounts for the new code are established using the average (arithmetic mean), weighted by allowed services, of the fee schedule amounts for the formerly separate codes. These instructions are used to ensure continuity of pricing under the Medicare program, but do not apply to items when a pricing history does not exist, that is, in situations where an item was not paid for under a HCPCS code or codes with an established DMEPOS fee schedule amount(s). The gap-filling process only applies to items not assigned to existing HCPCS codes with established fee schedule amounts and items that were not previously paid for by Medicare under either a deleted or revised HCPCS code.

4. Authority for Establishing Special Payment Limits

Section 1842(b)(8) of the Act authorizes CMS to adjust payment amounts if, subject to the factors described in the statute and the regulations, CMS determines that such payment amounts are grossly excessive or grossly deficient, and therefore are not inherently reasonable. CMS may make a determination that would result in an increase or decrease of more than 15 percent of the payment amount for a year only if it follows all of the requirements under paragraphs (B), (C), and (D) of section 1842(b)(8) of the Act. Under these requirements, CMS must take certain factors into account, such as whether the payment amount does not reflect changing technology. In addition, section 1842(b)(9) of the Act mandates a specific process that CMS must follow when using this “inherent reasonableness” authority (IR authority) to adjust payment amounts by more than 15 percent a year. CMS has established the methodology and process for using the IR authority at §§ 405.502(g) and (h). Use of the IR authority involves many steps mandated under sections 1842(b)(8) and (9) of the Act, which can include consulting with supplier representatives before making a determination that a payment amount is not inherently reasonable; publishing a notice of a proposed determination in the **Federal Register** which explains the factors and data taken into account; a 60-day comment period; and publishing a final notice, again explaining the factors and data taken into account in making the determination. Medicare can only make payment adjustments for “inherent reasonableness” that would result in a change of more than 15 percent per year by going through the process outlined in the statute and at §§ 405.502(g) and (h). As a result, the

requirements under sections 1842(b)(8) and (9) of the Act regarding “inherent reasonableness” adjustments are applicable to special payment limits established in cases where supplier or commercial prices used for gap-filling decrease by more than 15 percent.

Examples of factors that may result in grossly excessive or grossly deficient payment amounts are set forth at § 405.502(g)(1)(vii) and include, but are not limited to, the following:

- The market place is not competitive.
- Medicare and Medicaid are the sole or primary sources of payment for a category of items and services.
- The payment amounts for a category of items and services do not reflect changing technology, increased facility with that technology, or changes in acquisition, production, or supplier costs.
- The payment amounts for a category of items or services in a particular locality are grossly higher or lower than payment amounts in other comparable localities for the category of items or services.
- Payment amounts for a category of items and services are grossly higher or lower than acquisition or production costs for the category of items and services.
- There have been increases in payment amounts for an item or service that cannot be explained by inflation or technology.
- Payment amounts for a category of items or services are grossly higher or lower than payments made for the same category of items or services by other purchasers in the same locality.
- A new technology exists which is not reflected in the existing payment allowances.

Prior to making a determination pursuant to section 1842(b)(8) of the Act that would result in an increase or decrease of more than 15 percent in a payment amount for a year, CMS is required to consult with representatives of suppliers or other individuals who furnish an item or service. In addition, section 1842(b)(8)(D) of the Act mandates that CMS consider the potential impact of a determination pursuant to section 1842(b)(8) that would result in a payment amount increase or decrease of more than 15 percent for a year on quality, access, beneficiary liability, assignment rates, and participation of suppliers. In establishing a payment limit for a category of items or services, we consider the available information relevant to the category of items or services in order to establish a payment amount that is realistic and equitable.

Under § 405.502(g)(2), the factors we may consider in establishing a payment limit include the following:

- Price markup. The relationship between the retail and wholesale prices or manufacturer's costs of a category of items and services. If information on a particular category of items and services is not available, we may consider the price markup on a similar category of items and services and information on general industry pricing trends.
- Differences in charges. The differences in charges for a category of items and services made to non-Medicare and Medicare patients or to institutions and other large volume purchasers.
- Costs. Resources (for example, overhead, time, acquisition costs, production costs, and complexity) required to produce a category of items and services.
- Use. Imputing a reasonable rate of use for a category of items or services and considering unit costs based on efficient use.
- Payment amounts in other localities. Payment amounts for a category of items and services furnished in another locality.

In determining whether a payment amount is grossly excessive or grossly deficient, and in establishing an appropriate payment amount, we use valid and reliable data. To ensure the use of valid and reliable data, we must meet the criteria set forth at § 405.502(g)(4), to the extent applicable. This includes, but is not limited to, considering the cost of the services necessary to furnish a product to beneficiaries if wholesale costs are used.

If we make a determination that a special payment limit is warranted to adjust a grossly excessive or grossly deficient payment amount for a category of items and services by more than 15 percent within a year, CMS must publish in the **Federal Register** a proposed and final notice of any special payment limits before we adopt the limits, with at least a 60-day period for public comments on the proposed notice. The proposed notice must explain the factors and data considered in determining the payment amount is grossly excessive or deficient and the factors and data considered in determining the special payment limits. The final notice must explain the factors and data considered and respond to public comment.

5. The 2006 Proposed Rule and 2018 Solicitation of Comments on Gap-Filling

On May 1, 2006, we published several proposed changes for the gap-filling process in our rule titled “Medicare

Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues” (71 FR 25687 through 25689). The May 2006 proposed rule discussed the existing gap-filling process and the results of pilot assessments conducted by two CMS contractors to assess the benefits, effectiveness, and costs of several products. The purpose of the pilot assessments was to compile the technical information necessary to evaluate the technologies of the studied products with the objective of making payment and HCPCS coding decisions for new items. The contractors evaluated the products based on: (1) A functional assessment; (2) a price comparison analysis; and (3) a medical benefit assessment. The functional assessment involved evaluating a device’s operations, safety, and user documentation relative to the Medicare population. The price comparison analysis involved determining how the cost of the product compared with similar products on the market or alternative treatment modalities. The medical benefit assessment focused on the effectiveness of the product in doing what it claims to do.

As a result of the pilot studies, we proposed to use what we referred to as the “functional technology assessment” process, in part or in whole, to establish payment amounts for new items (71 FR 25688). We also suggested that we would make every effort to use existing fee schedule amounts or historic Medicare payment amounts for new HCPCS codes; that we would retain the method of using payment amounts for comparable items (properly calculated fee schedule amounts, or supplier price lists); but that we would discontinue the practice of deflating supplier prices and manufacturer suggested retail prices to the fee schedule base period. In response to our proposal, many commenters recommended a delay for finalizing regulations for the gap-filling process due to an overwhelming number of new proposals in the rule, including the DMEPOS competitive bidding program. In our final rule published on April 10, 2007 in the **Federal Register** titled “Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues,” we did not finalize our proposals for regulations for the gap-filling process, as a result of commenters feedback. We stated that we would address comments and address regulations for the gap-

filling process in future rulemaking (72 FR 17994).

In our CY 2019 ESRD PPS proposed rule titled “Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS”, we issued a request for information on the gap-filling process for establishing fees for newly covered DMEPOS items paid on a fee schedule basis. We solicited comments for information on how the gap-filling process could be revised in terms of what data sources or methods could be used to estimate historic allowed charges for new technologies in a way that satisfies the exclusive payment rules for DMEPOS items and services, while preventing excessive overpayments or underpayments for new technology items and services. In the final rule, we summarized the comments received and stated we would consider these comments carefully as we contemplate future policies (83 FR 57046 through 57047). The majority of the comments focused on the aspects of transparency, sources of information, and comparable items in the gap filling process. Overall, the commenters recommended that CMS increase transparency for stakeholders during the gap-filling process for establishing fees for new DMEPOS items and revise the process for filling the gap in the data due to the lack of historic reasonable charge payments by estimating what the historic reasonable charge payments would have been for the items from a base year of 1986 and 1987 and inflating to the current year. Also, some commenters did not want CMS to include internet or catalog pricing in the gap-filling process unless there is evidence that the price meets all Medicare criterion and includes all Medicare required services. The commenters stated that internet and catalog prices do not reflect the costs to suppliers of compliance with the many Medicare requirements such as supplier accreditation, in-the-home assessment, beneficiary training, and documentation, and thereby do not contribute to a reasonable payment level. Furthermore, commenters suggested developing additional guidelines and definitions for

determining whether a Medicare covered DMEPOS item is comparable to a new item for the purpose of assigning a fee schedule amount to a new item. The commenters elaborated that in order for an item to be comparable to another item, both should have similar features and function, should be intended for the same patient population, for the same clinical indicators, and to fill the same medical need. In addition, some commenters endorsed the addition of a weighting calculation to apply to a median price that would factor in the existing market demand/share/utilization of each product and price included in the array of retail prices used for gap-filling using supplier price lists. The commenters expressed concern that the current gap-filling methodology assumes that all products within a given HCPCS code have equal characteristics, minimum specifications, and the gap-filling method does not account for relative quality, durability, clinical preference, and overall market demand. Thus, the commenters were concerned that the calculation of a gap-filled amount for a new item does not reflect the utilization of an existing item.

B. Current Issues

Concerns have been raised by manufacturers and stakeholders about CMS’ processes for establishing fees for new DMEPOS items. In particular, our process for reviewing information and data when establishing fee schedule amounts for new DMEPOS items in some instances has led to confusion among some stakeholders. For example, some manufacturers have been confused in the past about why fee schedule amounts for comparable items are sometimes used to establish fee schedule amounts for new items and what CMS considers when determining whether new items are comparable to other DMEPOS items. Some have asked for a process that is more predictable in determining what sources of data CMS would use to establish fee schedule amounts for new DMEPOS items and services, given the amount of time and money associated with investing in the development of new technology for DMEPOS items and services.

Major stakeholder concerns related to gap-filling DMEPOS fee schedule amounts have been: (1) How CMS determines that items and services are comparable; (2) sources of pricing data other than fees for comparable items; (3) timing of fee schedule calculations and use of interim fees; (4) public consultation; (5) pricing data and information integrity; and (6)

adjustment of newly established fees over time.

1. Code or Item Comparability Determinations

We have heard frequently from manufacturers that do not agree that their newly developed DMEPOS item is comparable to older technology DMEPOS items and services. Using fee schedule amounts for comparable items to establish fee schedule amounts for new items can involve a number of pricing combinations including, but not limited to: (1) A one to one mapping where the fees for one code are used to establish the fees for a new code, (2) the use of fees for a combination of codes with established fee schedule amounts; (3) the use of fees for one or more codes minus the fees for one or more other codes identifying a missing feature(s) the newer item does not include; or (4) the use of one or more codes plus additional amounts for the costs of an additional feature(s) the newer items has that the older item(s) does not include. The benefit of using fee schedule amounts for comparable items, especially items that CMS paid for

during the fee schedule base period, is that average reasonable charge data or pricing data that is closer to the fee schedule base period is used in establishing the fee schedule amounts, and this better reflects the requirements of the statute than using more recent supplier prices as a proxy for reasonable charge data from the past. In addition, establishing fees for a new item that are significantly higher than fees for comparable items based on reasonable charge data can result in a competitive advantage for the new item because the suppliers of the older item are paid considerably less than the suppliers of the new item even though the new item is comparable to the older item. This could create an incentive for suppliers to furnish the new item more often than the older item, which would create an unfair advantage for the manufacturer(s) of the new item.

We undertook a review of the major components and attributes of DMEPOS items that we evaluate when determining whether items are comparable in order to develop and propose a standard for when and how fees for comparable items would be

used to establish fees for new items. We identified five main categories upon which new DMEPOS items can be compared to older DMEPOS items: Physical components; mechanical components; electrical components (if applicable); function and intended use; and additional attributes and features.

As shown in Table 9, a comparison can be based on, but not limited to, these five main components and various attributes falling under the five main components. When examining whether an item is comparable to another item, the analysis can be based on the items as a whole or its subcomponents. A new product does not need to be comparable within each category, and there is no prioritization of the categories. The attributes listed in Table 9 under the five main components are examples of various attributes CMS evaluates within each category. We believe that establishing a set framework and basis for identifying comparable items in regulation would improve the transparency and predictability of establishing fees for new DMEPOS items.

TABLE 9—COMPARABLE ITEM ANALYSIS
[Any combination of, but not limited to, the categories below for a device or its subcomponents]

Components	Attributes
Physical Components	Aesthetics, Design, Customized vs. Standard, Material, Portable, Size, Temperature Range/ Tolerance, Weight.
Mechanical Components	Automated vs. Manual, Brittleness, Ductility, Durability, Elasticity, Fatigue, Flexibility, Hard-ness, Load Capacity, Flow-Control, Permeability, Strength.
Electrical Components	Capacitance, Conductivity, Dielectric Constant, Frequency, Generator, Impedance, Piezo-electric, Power, Power Source, Resistance.
Function and Intended Use	Function, Intended Use.
Additional Attributes and Features	“Smart”, Alarms, Constraints, Device Limitations, Disposable Parts, Features, Invasive vs. Non-Invasive.

We believe that by establishing a basis for comparability, stakeholders would be better informed on how these analyses are performed, creating a more transparent process that stakeholders would better understand and which would facilitate a more efficient exchange of information between stakeholders and CMS on the various DMEPOS items and services, both old and new. We believe this would also help avoid situations where comparable DMEPOS items have vastly different fee schedule amounts or where items that are not comparable have equal fee schedule amounts.

2. Sources of Pricing Data Other Than Fees for Comparable Items

When CMS is establishing the fee schedule amount for a new item that lacks a Medicare pricing history and

CMS is unable to identify comparable items with existing fee schedule amounts, other sources of pricing data must be used to calculate the DMEPOS fee schedule amount for the new item. Current program instructions in section 60.3 of chapter 23 of the Medicare Claims Processing Manual specify that supplier price lists may be used in these cases, and that supplier price lists can include catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. In 2018, we clarified in the instructions in section 60.3 of the Medicare Claims Processing Manual that potential appropriate sources for such commercial pricing information can also include verifiable information from supplier invoices and non-Medicare payer data. Our rationale for using supplier price lists for gap-

filling purposes is that supplier price lists provide the best estimate of what suppliers would have routinely charged for furnishing DMEPOS items during the fee schedule base period (if reasonable charge data for the new item is not available and comparable items with existing fee schedule amounts are not identified). When using supplier price lists to estimate what reasonable charge amounts would have been during the base period, CMS deflates the prices listed in supplier price lists to the fee schedule base period. For example, section 1834(a)(2)(B) of the Act mandates fee schedule amounts for inexpensive DME items based on the average reasonable charges for the item(s) from July 1, 1986 through June 30, 1987. If supplier price lists are used to estimate what these average reasonable charges would have been

during the base period of 1986/87, the 2018 (for example) prices listed in the supplier price lists are converted to 1986/87 dollars by multiplying the 2018 prices by a deflation factor (.439 in this example) that is listed in section 60.3 of chapter 23 of the Medicare Claims Processing Manual. The deflation factor is equal to the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the price is in effect (June of 2018 in this example) to the mid-point of the fee schedule base period (December of 1986 in this example). So, if the 2018 price is \$100, this price is multiplied by .439 to compute a 1986/87 price of \$43.90. CMS then applies the covered items update factors mandated by section 1834(a)(14) of the Act for use in updating the data from the base period to establish current fee schedule amounts. In the example above, the \$43.90 base fee is updated to \$66.80 for 2019 if the device is a class II device or \$74.16 if it is a class III device, after applying the update factors mandated by section 1834(a)(14) of the Act.

In addition to using information from supplier or commercial price lists, CMS can determine the relative supplier costs of furnishing new DMEPOS items compared to other DMEPOS items with existing fee schedule amounts by using technology assessments to determine the relative cost of a new DMEPOS item versus older items for which Medicare fee schedule amounts have been established. Under this option for obtaining pricing information, the cost of new DMEPOS items relative to the cost of items with existing fee schedule amounts would be assessed and used to establish fee schedule amounts for the new DMEPOS items. The assessment would be made by biomedical engineers, certified orthotists/prosthetists and other experts at CMS and its contractors. Payment amounts for new items and services under the old reasonable charge payment methodology were sometimes gap-filled using relative value scales, which filled gaps in charge data for an item based on the relative value or cost of the item compared to other items with charge data. This same concept can be used to price new DMEPOS items relative to existing DMEPOS items under the fee schedule. In the past, we have contracted with companies to conduct technology assessments, and the process involved analyzing samples of the product(s) being priced as well as older technology items. Under this option, it may be necessary for us to obtain samples of new items as well as existing items if the relative cost of the items

cannot be determined without obtaining samples. For more complex items, it may be necessary to use a separate technology assessment contractor in addition to skilled CMS and contractor personnel such as biomedical engineers to conduct the technology assessment. To clarify, this option is not the same as using fees for comparable items, where existing fee schedule amounts for older items are used for newer items determined to be comparable to the older items. If new items are not comparable to older items with existing fee schedule amounts, the supplier cost of furnishing the new item(s) can be compared to the supplier cost of furnishing an older item(s) with established fee schedule amounts and the relative difference in the cost of the new item versus the older item(s) can be determined using a technology assessment.

Once the relative cost of the new item is determined, a pricing percentage would be established based on the results of the technology assessment to establish the fee schedule amount for the new DMEPOS item. For example, if it is determined that the cost of a new DMEPOS item is approximately twice the cost of existing DMEPOS item(s), the pricing percentage would equal 200. Thus, if the fee schedule amount for an existing DMEPOS item is \$500, then the fee schedule amount for the new DMEPOS item would be \$1,000 (200 percent of \$500 or \$500 multiplied by two). Another example is when it is determined that the cost of the new DMEPOS item is approximately 75 percent of the cost of the old DMEPOS item(s). For example, if the fee schedule amount for the old DMEPOS item is \$500, then the fee schedule amount for the new DMEPOS item would be \$375 (75 percent of \$500 or \$500 multiplied by 0.75). We believe using the relative cost of new items versus older items keeps all DMEPOS items (old and new) on a level playing field and priced in accordance with the historic reasonable charges for DMEPOS in general. We believe this method also helps foster innovation since new items that cost more would be priced based on these higher costs relative to older items with lower costs. We propose that technology assessments would be used whenever we believe it is necessary to determine the relative cost of a new DMEPOS item compared to DMEPOS items that CMS paid for during the fee schedule base period. CMS would use these technology assessments to gap-fill fees for the new DMEPOS item when supplier or commercial price lists are not available or verifiable or do not

appear to represent a reasonable relative difference in supplier costs of furnishing the new DMEPOS item relative to the supplier costs of furnishing DMEPOS items from the fee schedule base period. For example, if a code is added for a new type of manual hospital bed and supplier or commercial prices are 20 times higher than the fee schedule amounts for all other types of manual hospital beds, we would use a technology assessment of the supplier costs of furnishing different types of manual hospital beds to determine the relative supplier costs of furnishing the new type of manual hospital bed, which in turn would be used to establish the fee schedule amounts for the new type of manual hospital bed. The technology assessment is a tool for obtaining more information about the costs of the new item relative to the older items.

To summarize, we propose to add a provision to the regulations at § 414.236 that addresses the continuity of pricing when items are re-designated from one HCPCS code to another. For new items without a pricing history, we propose to add a provision to the regulations at §§ 414.112 and 414.238 to establish five main categories of components or attributes of DMEPOS items that would be evaluated to determine if a new item is comparable to older existing item(s) for gap-filling purposes. If it is determined that the new item is comparable to the older existing item(s), we are proposing to use the fee schedule amounts for the older existing item(s) to establish the fee schedule amounts for the new item. We also propose that if it is determined that there are no comparable items to use for gap-filling purposes, the fee schedule amounts for a new item would generally be based on supplier or commercial price lists, deflated to the fee schedule base period and updated by the covered item update factors. If supplier or commercial price lists are not available or verifiable or do not appear to represent a reasonable relative difference in supplier costs of furnishing the new DMEPOS item relative to the supplier costs of furnishing DMEPOS items from the fee schedule base period, we propose to use technology assessments that determine the relative costs of the newer DMEPOS items compared to older DMEPOS item(s) to establish the fee schedule amounts for the newer DMEPOS items.

3. Timing of Fee Schedule Calculations and Interim Pricing

In some cases, HCPCS codes for new DMEPOS items may take effect before the DMEPOS fee schedule amounts have been calculated and added to the national DMEPOS fee schedule files. In

these cases, the DME MACs and other contractors establish interim local fee schedule amounts in order to allow for payment of claims in accordance with fee schedule payment rules. We anticipate the need to continue the establishment of interim fees and in certain cases, an interim fee could be effective as long as 6 months to a year if complex technology assessments are needed in order to establish a fee schedule amount for the new item. Changes to the national DMEPOS fee schedule files can be made on a quarterly basis, and this can include corrections of errors made in calculating fee schedule amounts (see section 60.2 of chapter 23 of the Medicare Claims Processing Manual). Corrections to errors in fee schedule amounts are made on a quarterly basis due to limited resources and the need to test changes to the fee schedule files and claims processing edits and systems.

As explained in section V.B.4 of this proposed rule, the time during which temporary, local fee schedule amounts may be necessary for payment purposes could be affected by the process used to obtain public consultation and feedback from stakeholders on the pricing of new items.

4. Public Consultation and Stakeholder Input

Consistent with section 531(b) of BIPA, CMS obtains public consultation on preliminary coding and payment determinations for new DME items and services each year at public meetings held at CMS headquarters in Baltimore, Maryland. These meetings are also held to obtain public consultation on preliminary coding and payment determinations for other DMEPOS items in addition to DME. The public meetings for preliminary coding and payment determinations could be used to obtain public consultation on gap-filling issues such as the comparability of new items versus older items, the relative cost of new items versus older items, and additional information on the pricing of new DMEPOS items. In addition, manufacturers of new items often request meetings with CMS to provide information about their products, and CMS can reach out to manufacturers and other stakeholders for additional information that may be necessary in the future for pricing new DMEPOS items.

5. Pricing Data and Information Integrity

Our concerns about the integrity of the data and information submitted by manufacturers for the purpose of assisting CMS to establish new DMEPOS fee schedule amounts have led

CMS to review our process for establishing fee schedule amounts for new DMEPOS items. We have concerns with using supplier invoices and information for commercial pricing such as internet and manufacturer-submitted pricing. Our experience with reviewing manufacturer submitted prices and available information on the internet for new DMEPOS has caused CMS to have the following concerns about using invoices and information for commercial pricing:

- Internet prices may not be available or reliable, especially if the posted price is the manufacturer's suggested price or some other price that does not represent prices that are actually paid in the commercial markets.
- New products are often only available from one manufacturer that controls the market and price.
- Current invoices from suppliers may not represent the entire universe of prices and typically do not reflect volume discounts, manufacturer rebates, or other discounts that reduce the actual cost of the items.
- Prices from other payers may not reflect the unique costs and program requirements applicable to Medicare payment for DMEPOS and may be excessive if they represent the manufacturer suggested retail prices rather than negotiated lower rates.
- If the prices result in excessive payment amounts, it may be difficult to determine a realistic and equitable payment amount using the inherent reasonableness authority or lower the payment amounts by, for example, including the items in a competitive bidding program.
- Using excessive prices to calculate fee schedule amounts for new items would be unfair to manufacturers and suppliers of older, competitor products not priced using the same inflated commercial prices.

Numerous challenges exist including the significant number of sources of pricing information: Medicare Advantage (MA) plans, private insurers, the Veterans Benefits Administration, Tricare, Federal Employee Health Plans, Medicaid state agencies, internet prices, catalog prices, retail store prices, and other sources. Prices for a particular item or service can vary significantly depending on the source used. If the median price paid by one group of payers (for example, non-Medicare payers) is significantly higher than the median price paid by another group of payers (for example, MA plans), not using or factoring in the prices from the group of payers with the lower prices could result in grossly excessive fee schedule amounts that are then difficult

to adjust using the inherent reasonableness authority, which requires numerous time consuming and resource-intensive steps. These are just a few of the reasons why we believe it is always best to use established fee schedule amounts for older items, if possible, and compare those older items to the newer items, rather than using supplier invoices and information for commercial pricing such as internet and manufacturer-submitted pricing to establish the fee schedule amounts for new items. This is also why we believe we should use technology assessments to price newer items if the newer items are not comparable to older items and available supplier invoices and/or commercial pricing information is either not verifiable or appears to be unreasonable.

6. Adjustment of Fees Over Time

We have been consistent in applying the following guidelines once fee schedule amounts have been established using the gap-filling process and included in the DMEPOS fee schedule: (1) Fee schedule amounts are not changed by switching from one gap-filling method (such as using supplier price lists) to another gap-filling method (such as using fees for comparable items); and (2) fee schedule amounts are not changed as new items falling under the same HCPCS code. However, we have revised fee schedule amounts established using the gap-filling process when we determined that an error was made in the initial gap-filling of the fee schedule amounts or when adjustments were made to the fee schedule amounts based on the payments determined under the DMEPOS competitive bidding program. If fee schedule amounts were gap-filled using supplier price lists, and the prices subsequently decrease or increase, the gap-filled fee schedule amounts are not revised to reflect the changes in the prices.

However, we recognize that this gap-filling method of using supplier prices could result in excessive fee schedule amounts in cases where the market for the new category of items is not yet competitive due to a limited number of manufacturers and suppliers. We now believe that if supplier or commercial prices are used to establish fee schedule amounts for new items, and the prices decrease within 5 years (once the market for the new items is more established), that CMS should gap-fill those prices again in an effort to reflect supplier prices from a market that is more established, stable, and competitive than the market and prices for the item at the time CMS initially gap-filled the fee schedule amounts. For

example, most DME items furnished during the applicable 1986/87 fee schedule base period, such as wheelchairs, hospital beds, ventilators, and oxygen equipment, were covered by Medicare in 1986/87 and paid for on a reasonable charge basis for many years (20 years in many cases). Thus the fee schedule amounts calculated using average reasonable charges from the 1986/87 fee schedule base period(s) reflected prices from stable, competitive markets. In contrast, new items that are not comparable to older items are often made by one or a few manufacturers, so the market for a new item is not yet stable or competitive, especially as compared to the market for most DMEPOS items that have fee schedule amounts that were established based on reasonable charges during the fee schedule base period. During the various fee schedule base periods such as 1986/87 for DME, prosthetic devices, prosthetics and orthotics, most items had been on the market for many years, were made by multiple competing manufacturers, and were furnished by multiple competing suppliers in different localities throughout the nation. Therefore, the average reasonable charges from the fee schedule base period generally reflect supplier charges for furnishing items in a stable and competitive market.

We believe that if supplier or commercial prices used to gap-fill fee schedule amounts for a new item decrease within 5 years of the initial gap-filling exercise, that the new, lower prices likely represent prices from a more stable and competitive market. We also believe that supplier prices from a stable and competitive market better represent the prices in the market for DMEPOS items covered during the fee schedule base period and therefore are a better proxy for average reasonable charges from a fee schedule base period (as specified in the statute) as compared to supplier or commercial prices when an item is brand new to the market. We believe that gap-filling a second time once the market for the item has become more stable and competitive would result in fee schedule amounts that are more reflective of average reasonable charges for DMEPOS items from the fee schedule base period. We believe CMS should conduct gap-filling the second time within a relatively short period of time after the fees are initially established (5 years) and only in cases where the result of the second gap-filling is a decrease in the fee schedule amounts of less than 15 percent. Thus, if the supplier or commercial prices used to establish fee schedule amounts

for a new DMEPOS item decrease by any amount below 15 percent within 5 years of establishing the initial fee schedule amounts, and fee schedule amounts calculated using the new supplier or commercial prices would be no more than 15 percent lower than the initial fee schedule amounts, we believe gap-filling should be conducted a second time to reduce the fee schedule amounts by up to 14.99 percent as a result of using new, lower prices from a more stable and competitive market. We do not believe that a similar adjustment is necessary to account for increases in supplier or commercial prices within 5 years of establishing initial fee schedule amounts since the fee schedule calculation methodology already includes an annual covered item update to address increases in costs of furnishing items and services over time.

Thus we are proposing a one-time adjustment to gap-filled fee schedule amounts based on decreases in supplier or commercial prices. The statute requires CMS to establish fee schedule amounts for DMEPOS items and services based on average reasonable charges from a past period of time, generally when the market for most items was stable and competitive. In many cases, fee schedule amounts may be gap-filled using manufacturer prices or prices from other payers for new technology items that may only be made by one manufacturer with limited competition. In these situations, competition from other manufacturers or increases in the volume of items paid for by Medicare and other payers could bring down the market prices for the item within a relatively short period of time after the initial fee schedule amounts are established, creating a more stable and competitive market for the item, we believe that gap-filling using prices from a stable, competitive market is a better reflection of average reasonable charges for the item from the fee schedule base period. While the fee schedule covered item update as described in sections 1834(a)(14), 1834(h)(4), 1834(i)(1)(B), and 1842(s)(1)(B)(ii) of the Act allow for increases to the fees schedule amounts that can address increases in cost of furnishing items and services over time or track increases in supplier or commercial prices, there is no corresponding covered item update that results in a decrease in fee schedule amounts when the market for a new item becomes more mature and competitive following the initial gap-filling of the fee schedule amounts. We also do not believe that a situation in which prices increase within a short

period of time after the item comes on the market and fee schedule amounts are initially established for the item would be common. We therefore are not proposing similar one-time increases in fee schedule amounts established using supplier or commercial prices, however, we invite comments on this issue.

We do not believe gap-filling fee schedule amounts for new items should be conducted a second time in situations where the prices decrease by 15 percent or more within 5 years of the initial gap-filling of the fee schedule amounts. In cases where supplier or commercial prices used to establish original gap-filled fee schedule amounts increase or decrease by 15 percent or more after the initial fee schedule amounts are established, this would generally mean that the fee schedule amounts would be grossly excessive or deficient within the meaning of section 1842(b)(8)(A)(i)(I) of the Act. In such circumstances we believe that CMS could consider making an adjustment to the fee schedule amounts in accordance with regulations at § 405.502(g). We can also consider whether changes to the regulations at § 405.502(g) should be made in the future to specifically address situations where supplier or commercial prices change by 15 percent or more and how this information could potentially be used to adjust fee schedule amounts established using supplier or commercial prices.

C. Provisions of the Proposed Rule

1. Continuity of Pricing When HCPCS Codes Are Divided or Combined

We propose to add § 414.110 under subpart C for fee schedule amounts for PEN and medical supplies, including splints and casts and intraocular lenses inserted in a physician's office, and § 414.236 under subpart D for DME, prosthetic devices, prosthetics, orthotics, surgical dressings, and therapeutic shoes and inserts to address the continuity of pricing when HCPCS codes are divided or combined. If a DMEPOS item is assigned a new HCPCS code, it does not necessarily mean that Medicare payment on a fee schedule basis has never been made for the item and service described by the new code. For example, Medicare payment on a fee schedule basis may have been made for the item under a different code. We propose that if a new code is added, CMS or contractors would make every effort to determine whether the item and service has a fee schedule pricing history. If there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) would be associated with, or cross walked to the

new code(s), to ensure continuity of pricing. Since there are different kinds of coding changes, the way the proposed rule would be applied varies. For example, when the code for an item is divided into several codes for the components of that item, the total of the separate fee schedule amounts established for the components would not be higher than the fee schedule amount for the original item. However, when there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code would continue to apply to each of the items described by the new codes. When the codes for the components of a single item are combined in a single global code, the fee schedule amounts for the new code would be established by adding the fee schedule amounts used for the components (that is, use the total of the fee schedule amounts for the components as the fee schedule amount for the global code). However, when the codes for several different items are combined into a single code, the fee schedule amounts for the new code would be established using the average (arithmetic mean), weighted by allowed services, of the fee schedule amounts for the formerly separate codes.

2. Establishing Fee Schedule Amounts for New HCPCS Codes for Items and Services Without a Fee Schedule Pricing History

We are proposing to add § 414.112 under subpart C for fee schedule amounts for PEN and medical supplies, including splints and casts and intraocular lenses inserted in a physician's office, and § 414.238 under subpart D for DME, prosthetic devices, prosthetics, orthotics, surgical dressings, and therapeutic shoes and inserts to address the calculation of fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history. We propose that if a HCPCS code is new and describes items and services that do not have a fee schedule pricing history, the fee schedule amounts for the new code would be established whenever possible using fees for comparable items with existing fee schedule amounts. We propose that items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: Physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. We

propose that if there are no items with existing fee schedule amounts that are comparable to the items and services under the new code, the fee schedule amounts for the new code would be established using supplier or commercial price lists or technology assessments if supplier or commercial price lists are not available or verifiable or do not appear to represent a reasonable relative difference in supplier costs of furnishing the new DMEPOS item relative to the supplier costs of furnishing DMEPOS items from the fee schedule base period.

We propose that if items with existing fee schedule amounts that are comparable to the new item are not identified, the fee schedule amounts for the new item would be established using supplier or commercial price lists. However, if the supplier or commercial price lists are not available or verifiable or do not appear to represent a reasonable relative difference in supplier costs of furnishing the new DMEPOS item relative to the supplier costs of furnishing DMEPOS items from the fee schedule base period, we propose that the fee schedule amounts for the new item would be established using technology assessments. We propose that supplier or commercial price lists would include catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item, which could include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. We propose that if the only available price information is from a period other than the fee schedule base period, deflation factors would be applied against current pricing in order to approximate the base period price. We propose that the annual deflation factors would be specified in program instructions and would be based on the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period, as calculated using the following formula:
$$\frac{((\text{base CPI-U} - \text{current CPI-U}) \div \text{current CPI-U}) + 1}{\text{year difference}}$$

The deflated amounts would then be considered an approximation to average reasonable charges from the fee schedule base period and would be increased by the annual covered item update factors specified in statute for use in updating average reasonable charges from the fee schedule base period, such as the covered item update factors specified for DME at section

1834(a)(14) of the Act. We propose that, if within 5 years of establishing fee schedule amounts using supplier or commercial prices, the supplier or commercial prices decrease by less than 15 percent, a one-time adjustment to the fee schedule amounts would be made using the new prices. As a result of the market for the new item becoming more established over time, the new prices would be used to establish the new fee schedule amounts in the same way that the older prices were used, including application of the deflation formula. Again, supplier price lists can include catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include verifiable information from supplier invoices and non-Medicare payer data. We are not proposing a similar adjustment if supplier or commercial prices increase by less than 15 percent, but we invite comments on this issue.

We propose that fee schedule amounts for items and services described by new HCPCS codes without a fee schedule pricing history that are not comparable to items and services with existing fee schedule amounts may also be established using technology assessments. We propose that these technology assessments would be performed by biomedical engineers, certified orthotists and prosthetists, and CMS, and others knowledgeable about DMEPOS items and services, to determine the relative cost of the items and services described by the new codes to items and services with existing fee schedule amounts. We propose that a pricing percentage would be established based on the results of the technology assessment and would be used to establish the fee schedule amounts for the new code(s). For example, if it is determined that the cost of the item and services described by the new code(s) is approximately twice the cost of the items and services described by the code(s) with existing fee schedule amounts, the pricing percentage would be 200, and the current fee schedule amount for the old code(s) would be multiplied by two to establish the fee schedule amounts for the new code(s). Or, if it is determined that the cost of the items and services described by the new code(s) is approximately 75 percent of the cost of the items and services described by the code(s) with existing fee schedule amounts, the pricing percentage would be 75. The pricing percentages would be applied to the current fee schedule amounts for

HCPCS codes with existing fee schedule amounts to calculate the fee schedule amounts for new HCPCS codes without a fee schedule pricing history.

We propose that technology assessments would be used when we believe it is necessary to determine the relative cost of a new item compared to items that were available and had established fee schedule amounts using data from the fee schedule base period in order to gap-fill fees for the new item when supplier or commercial price lists are not available or verifiable or do not appear to represent a reasonable relative difference in supplier costs of furnishing the new DMEPOS item relative to the supplier costs of furnishing DMEPOS items from the fee schedule base period. Technology assessments are a tool for obtaining more information about the relative costs of the new item to the older items.

We are soliciting comments on these proposals.

VI. Standard Elements for a Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Order; Master List of DMEPOS Items Potentially Subject to Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements

A. Background

The Comprehensive Error Rate Testing (CERT) program measures improper payments in the Medicare Fee-For-Service (FFS) program. CERT is designed to comply with the Improper Payments Information Act of 2002 (IPIA) (Pub. L. 107–300), as amended by the Improper Payments Elimination and Recovery Act of 2010 (IPERA) (Pub. L. 111–204), as updated by the Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA) (Pub. L. 112–248). As stated in the CERT 2018 Medicare FFS Supplemental Improper Payment Data report, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) claims had an improper payment rate of 35.5 percent, accounting for approximately 8.2 percent of the overall Medicare FFS improper payment rate.³⁸

The Department of Health and Human Services Office of Inspector General (HHS–OIG) provides independent and objective oversight that promotes economy, efficiency, and effectiveness

in the programs and operations of the HHS. HHS–OIG’s mission is to protect the integrity of HHS programs and is carried out through a network of audits, investigations, and inspections.

The Government Accountability Office (GAO) audits the Centers for Medicare & Medicaid Services’ (CMS’) operations to determine whether federal funds are being spent efficiently and effectively, as well as to identify areas where Medicare and other CMS programs may be vulnerable to fraud and/or improper payments.

A number of HHS–OIG and GAO reports have focused on waste, fraud, and abuse within the DMEPOS sector, which has led to the enactment of legislation (as outlined in the background section of this proposed regulation) to safeguard beneficiaries and the Medicare Trust Funds. In an effort to reduce improper payments, CMS has issued regulations and sub-regulatory guidance to clarify the payment rules for Medicare DMEPOS suppliers rendering items and submitting claims for payment.

Currently, the scope of payment for medical supplies, appliances, and devices, including prosthetics and orthotics, are defined at 42 CFR 410.36(a) and the scope and certain conditions for payment of durable medical equipment (DME) are described at § 410.38. Medicare pays for DMEPOS items only if the beneficiary’s medical record contains sufficient documentation of the beneficiary’s medical condition to support the need for the type and quantity of items ordered. In addition, other conditions of payment must be satisfied for the claim to be paid. These conditions of payment vary by item, but are specified in statute and in our regulations. They are further detailed in our manuals and in local and national coverage determinations.

The purpose of this rule is to simplify and revise conditions of payment aimed at reducing unnecessary utilization and aberrant billing for items described in § 410.36(a) and § 410.38. To avoid differing conditions of payment for different items paid under the DMEPOS Fee Schedule, we propose the conditions of payment described in proposed § 410.38(d), would also be applied to items specified under § 410.36(a).

1. Face-to-Face and Prescription Requirements for Power Mobility Devices (PMDs)

Section 302(a)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), in part, added conditions of coverage specific to power mobility

devices (PMDs) in section 1834(a)(1)(E)(iv) of the Social Security Act (the Act), that specify payment may not be made for a covered item consisting of a motorized or power wheelchair unless a physician (as defined in section 1861(r)(1) of the Act), physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS) (as such non-physician practitioners are defined in section 1861(aa)(5) of the Act) has conducted a face-to-face examination of the individual and written a prescription for the item.

On April 5, 2006, we published a final rule in the **Federal Register** titled “Medicare Program; Conditions for Payment of Power Mobility Devices, including Power Wheelchairs and Power-Operated Vehicles” (71 FR 17021), hereinafter referred to as “April 2006 final rule,” to implement the requirements for a face-to-face examination and written prescription in accordance with the authorizing legislation. In § 410.38(c)(2)(ii), we required that prescriptions for PMDs must be in writing, signed and dated by the treating practitioner who performed the face-to-face examination, and received by the supplier within 45 days after the face-to-face examination. The April 2006 final rule mandated that the supplier receive supporting documentation, including pertinent parts of the beneficiary’s medical record to support the medical necessity for the PMD, within 45 days after the face-to-face examination. It provided that the PMD prescription must include a 7-element order composed of—(1) The beneficiary’s name; (2) the date of the face-to-face examination; (3) the diagnoses and conditions that the PMD is expected to modify; (4) a description of the item (for example, a narrative description of the specific type of PMD; (5) the length of need; (6) the physician or treating practitioner’s signature; and (7) the date the prescription is written.

2. Face-to-Face and Prescription Requirements for Specified DMEPOS

Section 6407 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) amended section 1834(a)(11)(B) of the Act, which already required a written order, to also require that a physician, PA, NP, or CNS have a face-to-face encounter with the beneficiary within a 6-month period preceding the written order for certain DMEPOS, or other reasonable timeframe as determined by the Secretary of the Department of Health and Human Services (the Secretary).

On November 16, 2012, we published a final rule with comment period in the

³⁸ 2018 Medicare Fee-for-Service Supplemental Improper Payment Data: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/CERT-Reports-Items/2018MedicareFFS-SupplementalImproperPaymentData.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending>. Accessed January 8, 2019.

Federal Register titled “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013” (77 FR 68892) hereinafter referred to as “November 2012 final rule,” that established a list of DME items subject to the face-to-face encounter and written order prior to delivery requirements as a condition of payment. CMS selected items for this list based on an item having met one of the following four criteria: (1) Items that required a written order prior to delivery per instructions in the Medicare Program Integrity Manual (at the time of rulemaking); (2) items that cost more than \$1,000 (at the time of rulemaking in 2012); (3) items CMS, based on experience and recommendations from the DME MACs, believed were particularly susceptible to fraud, waste, and abuse; and (4) items determined by CMS as vulnerable to fraud, waste and abuse based on reports of the OIG, GAO, or other oversight entities.

Section 504 of the Medicare Access and Children’s Health Insurance Program (CHIP) Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) amended section 1834(a)(11)(B)(ii) of the Act to eliminate the requirement that only physicians could document face-to-face encounters, including those conducted by NPs, PAs, or CNSs. In effect, this change in the law permits NPs, PAs, or CNSs to document their face-to-face encounter, without the co-signature of a physician. For the purpose of this proposed rule, we use the term “practitioner” as an all-inclusive term to capture physicians and non-physician practitioners (that is, NPs, PAs, and CNSs).

Section 1834(a)(11)(B)(ii) of the Act, as amended by section 504 of MACRA, mandates that the Secretary require for certain items of DMEPOS (as identified by the Secretary) a written order pursuant to a physician, a PA, an NP, or a CNS (as these three terms are defined in section 1861 of the Act) documenting that such a physician, PA, NP, or CNS has had a face-to-face encounter (including through use of telehealth under section 1834 (m) of the Act and other than with respect to encounters that are incident to services involved) with the individual involved during the 6-month period preceding such written order, or other reasonable timeframe as determined by the Secretary.

Our regulations at § 410.38(g)(4) require written orders for certain

specified covered items, as selected per the regulatory instruction in § 410.38(g)(2), to contain 5 elements: (1) The beneficiary’s name; (2) the item of DME ordered; (3) the signature of the prescribing practitioner; (4) the prescribing practitioner National Provider Identifier (NPI); and (5) the date of the order.

3. Subregulatory Requirements for Orders and Face-to-Face Encounters for Other DMEPOS

CMS through subregulatory guidance developed standards for orders for DMEPOS items not included on the list of specified covered items requiring a written order prior to delivery and a face-to-face encounter. In addition, certain items of DMEPOS require face-to-face encounters in item-specific coverage requirements, such as those in the MAC-developed local coverage determinations.

4. Prior Authorization

The Medicare Prior Authorization of PMDs Demonstration was initially implemented in 2012 in 7 states and subsequently extended in 2014 to 12 additional states (for 19 states in total) until its completion in August of 2018. For additional information about this demonstration, see the notice we published in the **Federal Register** on August 3, 2012 (77 FR 46439).

Based on early signs of the demonstration’s promising results, on December 30, 2015 we published a final rule in the **Federal Register** titled “Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies” (80 FR 81674), hereinafter referred to as the “December 2015 final rule,” that established a permanent prior authorization program nationally. The December 2015 final rule was based on the authority outlined in section 1834(a)(15) of the Act, which permits the Secretary to develop and periodically update a list of DMEPOS items that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization and to develop a prior authorization process for these items. Specifically, the December 2015 final rule established a new provision at § 414.234 that specified a process for the prior authorization of DMEPOS items. The provision interpreted “frequently subject to unnecessary utilization” to include items on the DMEPOS fee schedule with an average purchase fee of \$1,000 (adjusted annually for inflation using consumer price index for all urban consumers (CPI-U)) or greater, or an average rental fee schedule of \$100

(adjusted annually for inflation using CPI-U) or greater, that also met one of the following two criteria: (1) The item has been identified as having a high rate of fraud or unnecessary utilization in a report that is national in scope from 2007 or later, as published by the OIG or the GAO; or (2) the item was listed in the 2011 or later CERT program’s Annual Medicare FFS Improper Payment Rate DME and/or DMEPOS Service Specific Report(s). Section 414.234(b) lists DMEPOS items that met these criteria on a “Master List of Items Frequently Subject to Unnecessary Utilization.” Placement on the Master List makes an item eligible for CMS to require prior authorization as a condition of payment. CMS selects items from the Master List to require prior authorization as a condition of payment and publishes notice of such items in the **Federal Register**. Items on the Master List are updated annually, based on payment thresholds and changes in vulnerability reports, as well as other factors described in § 414.234.

We note that burden estimates associated with prior authorization are related to the time and effort necessary for the submitter to locate and obtain the supporting documentation for the prior authorization request and to forward the materials to the contractor for medical review. Prior authorization does not change documentation requirements specified in policy or who originates the documentation. The associated information collection (OMB Control number 0938–1293) was revised and OMB approved the revision on March 6, 2019.

5. Overview

Over time, the implementation of the aforementioned overlapping rules and guidance may have created unintended confusion for some providers and suppliers and contributed to unintended noncompliance. We continue to believe that practitioner involvement in the DMEPOS ordering process, through the face-to-face and written order requirements assists in limiting waste, fraud, and abuse. We believe practitioner involvement also helps to ensure that beneficiaries can access DMEPOS items to meet their specific needs. In addition, we maintain that the explicit identification of information to be included in a written order/prescription, for payment purposes, promotes uniformity among practitioners and precision in rendering intended items. It also supports our program integrity goals of limiting improper payments and fraudulent or abusive activities by having documentation of practitioner oversight

and standardized ordering requirements. Likewise, prior authorization supports ongoing efforts to safeguard beneficiaries' access to medically necessary items and services, while reducing improper Medicare billing and payments. This is important because documentation of practitioner involvement, including their orders for DMEPOS items and documented medical necessity (as assessed under prior authorization), are all used to support proper Medicare payment for DMEPOS items.

The purpose of this subsequent proposal is to streamline the existing requirements and reduce provider or supplier confusion, while maintaining the concepts of practitioner involvement, order requirements, and a prior authorization process. We believe streamlining our requirements would further our efforts to reduce waste, fraud, and abuse by promoting a better understanding of our conditions of payment, which may result in increased compliance.

B. Provisions of the Proposed Regulations

1. Technical Corrections to § 410.38(a) and (b)

We propose to make technical changes to § 410.38 by adding headings for paragraphs (a) and (b), and to update obsolete language under paragraph (a). For paragraphs (a) and (b), we propose the headings as "General scope" and "Institutions that may not qualify as the patient's home," respectively. Paragraph (a) addresses the general scope of the DME benefit, but includes outdated language related to the Medicare payment rules for DME, which are more appropriately addressed under §§ 414.210 and 414.408. In addition, the terms "iron lungs" and "oxygen tents" refer to obsolete DME technology that is no longer in use. We are therefore proposing to revise § 410.38(a) to remove language related to payment rules for DME and to replace the terms "iron lungs" and "oxygen tents" with "ventilators" and "oxygen equipment," respectively.

2. Definitions

We are proposing to update § 410.38(c) to include definitions related to certain requirements for the DMEPOS benefit.

We are proposing to add new definitions, redesignate existing definitions within the regulatory text, and amend existing definitions. We believe these changes would promote transparency and create uniform definitions applicable across the

DMEPOS benefit and consequently, increase understanding of DMEPOS payment requirements, and may result in increased compliance.

We propose at § 410.38(c) to include the following terms:

- **Physician** means a practitioner defined in section 1861(r)(1) of the Act. We are proposing this definition as paragraph (c)(1) and we note that it is same as our current definition of "physician" in § 410.38.

- **Treating practitioner** means both physicians, as defined in section 1861(r)(1) of the Act, and non-physician practitioners (that is, PAs, NPs, and CNSs) defined in section 1861(aa)(5) of the Act. This definition is consistent with the practitioners permitted to perform and document the face-to-face encounter pursuant to section 1834(a)(11)(B) of the Act. We are proposing this definition as paragraph (c)(2).

- **DMEPOS supplier** means an entity with a valid Medicare supplier number that furnishes durable medical equipment prosthetics orthotics and/or supplies including an entity that furnishes these items through the mail. We have a similar definition in our current regulation but § 410.38 required revisions to accommodate the proposed unified conditions of payment. We are proposing this definition as paragraph (c)(3).

- **Written order/prescription** means an order/prescription that is a written communication from a treating practitioner that documents the need for a beneficiary to be provided an item of DMEPOS. All DMEPOS items require a written order/prescription to be communicated to the supplier prior to claim submission. In the case of items appearing on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the written order/prescription must additionally be communicated to the supplier before the delivery of the item. As discussed further in this proposed rule, we would standardize the elements of written orders/prescriptions provided for DMEPOS. We are proposing this definition as paragraph (c)(4).

- **Face-to-face encounter** means an in-person or telehealth encounter between the treating practitioner and the beneficiary. The face-to-face encounter is used for the purpose of gathering subjective and objective information associated with diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered. As discussed further in this proposed rule, we would standardize the face-to-face and documentation requirements for certain

DMEPOS. We are proposing this definition as paragraph (c)(5).

- **Power Mobility Device (PMD)** means a covered item of DME that is in a class of wheelchairs that includes a power wheelchair (a four-wheeled motorized vehicle whose steering is operated by an electronic device or a joystick to control direction and turning) or a power-operated vehicle (a three or four-wheeled motorized scooter that is operated by a tiller) that a beneficiary uses in the home. Our proposal is the same as our current regulatory definition of this term. Section 410.38(c)(1) required reformatting to accommodate the proposed unified conditions of payment and therefore, we are proposing this definition as paragraph (c)(6).

- **Master List of DMEPOS Items Potentially Subject to Face-To-Face Encounter and Written Orders Prior to Delivery and/or Prior Authorization Requirements**, referred to as the "Master List" means items of DMEPOS that CMS has identified in accordance with sections 1834(a)(11)(B) and 1834(a)(15) of the Act. The criteria for this list are specified in proposed § 414.234(b). The Master List shall serve as a library of DMEPOS items from which items may be selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List and/or the Required Prior Authorization List. We are proposing this definition as paragraph (c)(7).

- **Required Face-to-Face Encounter and Written Order Prior to Delivery List** means a list of DMEPOS items selected from the Master List and subject to the requirements of a Face-to-Face Encounter and Written Order Prior to Delivery, and communicated to the public via a 60-day **Federal Register** notice. When selecting items from the Master List for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, CMS may consider factors such as operational limitations, item utilization, cost-benefit analysis (for example, comparing the cost of review versus the anticipated amount of improper payment identified), emerging trends (for example, billing patterns, medical review findings,) vulnerabilities identified in official agency reports, or other analysis. We are proposing this definition as paragraph (c)(8). We note that Required Face-to-Face Encounter and Written Order Prior to Delivery List is distinct from the "Required Prior Authorization List," as defined in existing § 414.234(c)(1)(i).

3. Master List

a. Creating the Master List

In the April 2006 final rule, we established face-to-face examination and written order prior to delivery requirements for PMDs.

In the November 2012 final rule (77 FR 68892), we created a list of Specified Covered Items always subject to face-to-face encounter and written order prior to delivery requirements based on separate inclusion criteria currently outlined in § 410.38.

In the December 2015 final rule (80 FR 81674), we created a “Master List of Items Frequently Subject to Unnecessary Utilization” based on inclusion criteria found at § 414.234 that would potentially be subject to prior authorization upon selection. We propose to create one list of items known as the “Master List of DMEPOS Items Potentially Subject to Face-To-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements,” or the “Master List,” and specify the criteria for this list in § 414.234.

Our proposal would harmonize the resultant three lists created by the former rules and develop one master list of items potentially subject to prior authorization and/or the face-to-face encounter and written order prior to delivery requirement. In determining DMEPOS appropriate for inclusion in the Master List, we believe there to be inherent similarities in those items posing vulnerabilities mitigated by additional practitioner oversight (face-to-face encounters and written orders prior to delivery) and those items posing vulnerabilities mitigated by prior authorization. Therefore, we believe it is appropriate for the Master List to include both those items that may potentially be subject to the face-to-face encounter and written order prior to delivery requirements as conditions of payment upon selection, and those items that may potentially be subject to prior authorization as a condition of payment upon selection. As such, we propose to have a single Master List of items potentially subject to face-to-face and written order prior to delivery and/or prior authorization requirements. (See Table 10: Proposed Master List Of DMEPOS Items Potentially Subject to a Face-To-Face Encounter and Written Order Prior To Delivery and/or Prior Authorization Requirements.) We note that prosthetic devices and orthotic and prosthetic items have the same requirements under section 1834(a)(11) of the Act as other items of DME have in statute. Section 1834(h)(3) of the Act requires that section 1834(a)(11) of the

Act apply to prosthetic devices, orthotics, and prosthetics in the same manner as it applies to items of DME. Therefore, we are proposing the items identified in § 410.36(a) would be subject to the requirements identified in proposed § 410.38.

While the regulatory requirements used to create the resultant three lists (outlined in the April 2006, November 2012, and December 2015 final rules) were inherently distinct and conformed to different legislative mandates, we nonetheless assessed the items captured by those individual lists to determine whether the items are included in the new proposed inclusion criteria and resultant Master List. We compared the proposed Master List to both those items of DME that require a face-to-face encounter and written order prior to delivery due to (i) the statutory requirements for all PMDs or (ii) the list of specified covered items of DME that we established in accordance with section 1834(a)(11)(B) of the Act. We found that 103 items currently captured as either a PMD or included in the list published in the November 2012 rule would not be included in the proposed Master List. We further identified there are 306 items potentially subject to a face-to-face encounter and a written order prior to delivery under the proposed Master List that do not require it under our current conditions of payment. The remainder of items on the proposed Master List are both currently subject to a face-to-face encounter and a written order prior to delivery requirements as a condition of payment, and potentially would be subject to these conditions of payment under our proposal. All 135 items on the current list potentially subject to prior authorization are also included in our proposed Master List. This proposal would outline the inclusion criteria that developed the proposed Master List of 413 items potentially subject to these conditions of payment.

While the Master List created by this proposed rule would increase the number of DMEPOS items potentially eligible to be selected and added to the Required Prior Authorization list (which requires a technical update to Paperwork Reduction Act Information Collection CMS–10524; OMB–0938–1293,) there is no newly identified burden, no change in the required documentation associated with prior authorization and no plans to exponentially increase the number of items subject to required prior authorization in the near future.

We propose at § 414.234(b)(1) that items that meet the following criteria would be added to the Master List:

- Any DMEPOS items included in the DMEPOS Fee Schedule that have an average purchase fee of \$500 (adjusted annually for inflation using CPI–U, and reduced by 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 (FY), year, cost reporting period, or other annual period)) or greater, or an average monthly rental fee schedule of \$50 (adjusted annually for inflation using CPI–U, and reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period)) or greater, or are identified as accounting for at least 1.5 percent of Medicare expenditures for all DMEPOS items over a recent 12-month period, that are:

- ++ Identified as having a high rate of potential fraud or unnecessary utilization in an OIG or GAO report that is national in scope and published in 2015 or later, or

- ++ Listed in the CERT 2018 or later Medicare FFS Supplemental Improper Payment Data report as having a high improper payment rate.

- The annual Master List updates shall include any items with at least 1,000 claims and 1 million dollars in payments during a recent 12-month period that are determined to have aberrant billing patterns and lack explanatory contributing factors (for example, new technology or coverage policies). Items with aberrant billing patterns would be identified as those items with payments during a 12-month timeframe that exceed payments made during the preceding 12-months, by the greater of:

- ++ Double the percent change of all DMEPOS claim payments for items that meet the above claim and payment criteria, from the preceding 12-month period, or

- ++ exceeding a 30 percent increase in payments for the item from the preceding 12-month period.

- Any item statutorily requiring a face-to-face encounter, a written order prior to delivery, or prior authorization.

The following hypothetical data patterns are not factual, but rather provided for exemplary purposes, to demonstrate how data would be assessed in coordination with our new criteria for identifying items, subject to aberrant billing patterns and having a lack of explanatory contributing factors, that would be appropriate for inclusion in the Master List:

Example 1: After removing any item for which there are less than 1,000 claims billed or less than \$1 million paid from CY 2018, there were \$6.2 billion in total payments for all DMEPOS items. There were \$5.6 billion in total payments for all DMEPOS items in the prior 12-month period (CY 2017). The percent change in payments between CY 2017 and CY 2018 is 10.7 percent. The doubled percent change is 21.4 percent.

—DMEPOS Item X had \$3.2 million in payments in CY 2018 and \$2.4 million in payments in CY 2017. This is a 33.3 percent change in payment for DMEPOS Item X. Therefore, Item X would be added to the Master List since it exceeds a 30 percent increase in payments, which is greater than double the percent change of all DMEPOS claim payments, for items that meet the claim and payment criteria (more than 1,000 claims billed or \$1 million paid), from the preceding 12-month period.

—DMEPOS Item Y had \$17.1 million in payments in CY 2018 and \$13.4 million in payments in CY 2017. This is a 27.6 percent change in payment for DMEPOS Item Y. Therefore, Item Y would not be added to the Master List since it is less than 30 percent.

Example 2: After removing any item for which there are less than 1,000 claims billed or less than \$1 million paid from CY 2018, there were \$6.5 billion in total payments for all DMEPOS items. There were \$5.5 billion in total payments for all DMEPOS items in the prior 12-month period (CY 2017). The percent change in payments between CY 2017 and CY 2018 is 18.2 percent. The doubled percent change is 36.4 percent.

—DMEPOS Item X had \$20.4 million in payments in CY 2018 and \$14.3 million in payments in CY 2017. This is a 42.7 percent change in payment for DMEPOS Item X. Therefore, Item X would be added to the Master List since it exceeds a 36.4 percent increase in payments which is more than double the percent change in payment in the preceding 12-month period, and is greater than 30 percent.

—DMEPOS Item Y had \$3.2 million in payments in CY 2018 and \$2.4 million in payments in CY 2017. This is a 33.3 percent change in payment for DMEPOS Item Y. Therefore, Item Y does not meet the inclusion criteria since it is less than 36.4 percent or double the percent change in payment in the preceding 12-month period.

The proposed criteria adheres to the statutory language in section 1834(a)(11)(B) of the Act, which allows

us to specify covered items for the face-to-face and written order prior to delivery requirements, and section 1834(a)(15) of the Act, which provides discretion for the Secretary to develop and periodically update a list of items that on the basis of prior payment experience, are frequently subject to unnecessary utilization.

We also note that under our proposal, any item that by statute requires a face-to-face encounter, a written order prior to delivery, or prior authorization would be added to the Master List and potentially subject to any of these requirements. For example, in accordance with section 1834(a)(1)(E)(iv) of the Act, payment may not be made for motorized or power wheelchairs unless there is a face-to-face encounter and a written order prior to delivery. Under our proposal, motorized and power wheelchairs would also potentially be subject to the prior authorization requirement. We think this is appropriate because any item statutorily subject to additional program integrity measures can reasonably be assumed to be “frequently subject to unnecessary utilization” (the standard for prior authorization in section 1834(a)(15)) and therefore should be included on the Master List.

In addition, we believe that proposing criteria based on (1) cost, (2) spending thresholds, and (3) data conveying possible overutilization and/or abuse allows us to more effectively focus our program integrity efforts. While the November 2012 and December 2015 final rules included higher cost thresholds (\$1,000 purchase/\$100 rental thresholds), we note that programmatic changes, including competitive bidding, had the overall impact of lowering the payment amount for certain items, which is the reason we are proposing to lower these cost thresholds. We are proposing the \$500 purchase/\$50 rental thresholds based on analysis of the current fee schedule cost of DMEPOS items when compared with known vulnerabilities. This threshold captures items of known vulnerability, as previously identified and included in the Master List of items potentially subject to prior authorization, while remaining cognizant of the overall impact to DMEPOS items. To select the cumulative threshold, we identified low cost items with a significant cumulative impact on the Trust Fund. We then found that approximately the top 10 items individually account for at least 1.5 percent of DMEPOS allowed costs. We accordingly are proposing 1.5 percent to capture the items with the highest allowed amounts, while not

creating an overly inclusive list. However, we recognize that item(s) may fail to meet the \$500 purchase, \$50 rental, or cumulative cost thresholds identified in this proposed rule; nonetheless, such items may demonstrate aberrant billing patterns inconsistent with predictable claim volumes.

We use the CERT Medicare FFS Supplemental Improper Payment Data to identify DMEPOS service-specific rates of improper payments; and the OIG and GAO reports to identify DMEPOS items as having a high rate of fraud or unnecessary utilization. Inclusion of an item in these reports are indications that the item is frequently subject to unnecessary utilization. We recognize that there are inherent delays from the time aberrant billing patterns are identified and the publication of CERT, OIG, and GAO reports. We previously captured reports dating as far back as 2007; however, we have learned that billing practices may be subject to shifts as a result of changed policies from CMS, new technologies and other emerging trends.

Our objective is to focus on more current data, and in this proposed rule, we propose to redefine the timeframe for identifying items in OIG and GAO reports to 2015 or later, in CERT Medicare FFS Supplemental Improper Payment Data reports to 2018 or later, and add a new Master List inclusion criteria to capture current aberrant billing patterns. We believe the Master List, as it appears in this proposed rule, is a good representation of those items that may pose risk to the Medicare Trust Funds. If this proposed rule is finalized as proposed, in future years, we would apply the new criteria on billing patterns occurring over a 12-month period to allow CMS to be nimble to industry change.

We propose the identification of aberrant billing patterns to be limited to those instances in which the total payment is at least 1 million dollars and at least 1,000 claims in a recent 12-month period prior to CMS updating the list annually. This avoids us targeting items with very low payments or very few claims, when considered overall.

b. Notice and Maintenance of the Master List

We propose at § 414.234(b)(2) that the Master List would be self-updating, at a minimum, annually. The current “self-updating” process remains unchanged and includes applying the criteria to items that appear on the DMEPOS fee-for-service payment schedule. That is, items on the DMEPOS Fee Schedule that meet the payment threshold (for

monthly rentals, purchases, or cumulative impacts) are added to the list when the item is also listed in a future CERT, OIG, or GAO report, and items not meeting the cost thresholds would be added based on findings of aberrant billing patterns (meeting the above inclusion criteria in section VI.B.3.a of this proposed rule) that are not otherwise explained. We believe the proposed inclusion criteria are capable of capturing more current vulnerabilities. However, we also believe that the current standard process in which items on the list expire after 10 years if they have not otherwise been removed is appropriate to achieve behavioral change (such as compliance with Medicare coverage instructions and the correction of behaviors previously resulting in improper payments) and protect the Medicare Trust Funds. To that end, we propose to keep this timeframe, and further clarify that if we identify any item currently on the Master List as being included in a subsequent OIG or GAO report, as having a high rate of fraud or unnecessary utilization, or as having a high improper payment rate in the CERT Medicare FFS Supplemental Improper Payment Data report, the item would be maintained on the Master List for 10 years from the date of the most recent report's publication.

All other list maintenance processes currently specified in § 414.234(b) would be maintained with two exceptions: (1) First, we propose to allow the Master List to be updated as needed and more frequently than annually (for example, to address emerging billing trends). (2) Second, we are also making technical changes to the language in § 414.234(b) to reflect the proposed new cost thresholds and report years discussed in this proposed rule. We would maintain our current process and publish any additions or deletions to the Master List, for any of the reasons and conditions discussed, in a **Federal Register** notice and on the CMS website.

4. Required Face-to-Face Encounter and Written Order Prior to Delivery List

a. Creating the Required Face-to-Face Encounter and Written Order Prior to Delivery List

Section 1834(a)(1)(E)(iv) of the Act prohibits payment for motorized or power wheelchairs unless a practitioner conducts a face-to-face examination and writes an order for the item. Section 1834(a)(11)(B) of the Act requires that a practitioner have a face-to-face encounter and written order communicated to the supplier prior to

delivery for other specified covered items of DMEPOS, as identified by the Secretary. Analysis of a 1-year snapshot of claims indicates that approximately 97 percent of beneficiaries receiving DMEPOS have had a recent face-to-face encounter (either before or after the DMEPOS date of service). This data was drawn without regard for the item's presence on the existing DME List of Specified Covered Items, which requires a face-to-face encounter and a written order prior to delivery. While we believe this information helps provide important context, we note that this rule requires that face-to-face encounters occur prior to the delivery of DMEPOS for those items selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List. We propose to revise § 410.38(d)(1) and § 410.38(d)(2) to limit the face-to-face encounter and written order prior to delivery conditions of payment to only those items selected from the Master List and included on the "Required Face-to-Face Encounter and Written Order Prior to Delivery List." In this way, we have a broader list of potential items that could be selected, but expect only a subset of items from the Master List to be subject to the Required Face-to-Face Encounter and Written Order Prior to Delivery List, based on those items identified to be of highest risk. Tailoring the lists in this way significantly reduces any potential provider impact—and could even decrease the scope of impacted items and providers.

Since the face-to-face encounter and written order are statutorily required for PMDs, they would be included on the Master List and the Required Face-to-Face Encounter and Written Order Prior to Delivery List in accordance with our statutory obligation, and would remain there. The Master List would include statutorily-identified items, as well as any other items posing potential vulnerability to the Trust Fund, as identified via the proposed Master List inclusion criteria.

We propose at § 410.38(c), in the definition of the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the factors that we may consider when determining which items may be appropriate to require a face-to-face encounter and written order prior to delivery. Specifically, we may consider: operational limitations, item utilization, cost-benefit analysis, emerging trends, vulnerabilities identified in official agency reports, or other analysis. We developed factors that we believe to be indicative of the need for the face-to-face encounter and written order prior to delivery

requirements, but this list is not exhaustive. We note that we have not proposed an all-inclusive list of factors to account for the fluidity of program operations and associated vulnerabilities, and believe this is critical to protect beneficiaries, the program, and industry. We solicit comments on both our underlying presumption that the list should not be exhaustive, as well as the factors we should consider when selecting an item from the Master List and including it on the Required Face-to-Face Encounter and Written Order Prior to Delivery List. We also note that this notice and comment rulemaking provides the forum for stakeholders to comment on the proposed Master List from which items may be selected in the future to be subject to the Face-to-Face Encounter and Written Order Prior to Delivery requirement.

As previously stated, we propose at § 410.38(c)(5) to define the term "face-to-face encounter" as an in-person or telehealth encounter between the treating practitioner and the beneficiary. We further propose at § 410.38(d)(2) that any telehealth encounter must meet the existing telehealth requirements of § 410.78 and § 414.65. Telehealth services currently are permitted to be used to satisfy the DME face-to-face encounter requirements. Proposed § 410.38(d)(2) emphasizes that telehealth services used to meet DMEPOS face-to-face encounter requirements must meet the requirements found at § 410.78 and § 414.65 to support payment of the DMEPOS claim.

Additionally, the face-to-face encounter must be used for the purpose of gathering subjective and objective information associated with diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered and must occur within the 6 months preceding the date of the order/prescription. We propose at § 410.38(d)(3) to clarify the documentation necessary to support the face-to-face encounter and associated claims for payment. This documentation includes the written order/prescription and documentation to support medical necessity, which may include the beneficiary's medical history, physical examination, diagnostic tests, findings, progress notes, and plans for treatment. We believe our proposed definition in § 410.38(c)(5) of a face-to-face encounter and required documentation in § 410.38(d)(3) are reflective of clinical practice and the information necessary to demonstrate medical necessity and the appropriateness of claim payment.

Section 1834(h)(5) of the Act states that for purposes of determining the reasonableness and medical necessity of orthotics and prosthetics, documentation created by orthotists and prosthetists shall be considered part of the individual's medical record to support documentation created by eligible professionals as described in section 1848(k)(3)(B) of the Act. Documentation from a face-to-face encounter conducted by a treating practitioner, as well as documentation created by an orthotist or prosthetist, becomes part of the medical records and if the notes corroborate, together they can be used to support medical necessity of an ordered DMEPOS item.

Our regulations currently require that the written order be communicated prior to delivery for certain specified covered items, within 6 months of the face-to-face encounter, and for PMDs, within 45 days of the face-to-face examination. We propose to revise § 410.38 to apply the 6-month timeframe to all items on the Required Face-to-Face Encounter and Written Order Prior to Delivery List (including PMDs, which previously required a 45-day timeframe) for uniformity purposes. Since the industry has become accustomed to the 6-month timeframe, we believe this timeframe is relevant, and changing it would create unnecessary confusion. Therefore, if finalized as proposed, a face-to-face encounter would be consistently required within 6 months of a written order prior to delivery for those items for which a face-to-face encounter is required.

The 6-month timing requirement does not supplant other policies that may require more frequent face-to-face encounters for specific items. For example, the National Coverage Determination 240.2 titled "Home Use of Oxygen" requires a face-to-face examination within a month of starting home oxygen therapy.

The Paperwork Reduction Act Record of Information Collection for medical review (CMS-10417; OMB-0938-0969) covers the burden for responding to documentation requests, generally. Medical review requests require the provider or supplier to submit all documentation necessary to demonstrate compliance with coverage and payment requirements, including the face-to-face encounter. We do not believe this proposed rule would create any new burdens for the medical review process, but we ask commenters for feedback on this assumption.

b. Notice and Application of the Required Face-to-Face Encounter and Written Order Prior to Delivery List

We propose at § 410.38(c)(8) that CMS would publish a 60-day **Federal Register** notice and post on the CMS' website any item on the Master List that is selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List. This is consistent with our current practices for items selected from the Master list of items frequently subject to unnecessary utilization. Any DMEPOS item included on this list would be subject to the face-to-face encounter and written order prior to delivery requirement as a national condition of payment, and claims for those items would be denied if the condition of payment is not met.

We propose at § 410.38(e) to allow the face-to-face encounter and written order prior to delivery requirements to be nationally suspended by CMS for any items at any time, without undertaking a separate rulemaking, except for those items whose inclusion on the Master List (and subsequently, the Required Face-to-Face Encounter and Written Order Prior to Delivery List) was required by statute. For example, we may need to suspend or cease the face-to-face encounter and written order prior to delivery requirements for a particular item(s) for which we determine the face-to-face encounter and written order prior to delivery requirements are unnecessary to meet our previously described objective of limiting waste, fraud, and abuse. If we suspend or cease the face-to-face encounter and the written order prior to delivery requirement for any item(s), we would provide stakeholder notification of the suspension on the CMS website.

5. Required Prior Authorization List

a. Creation and Application of the Required Prior Authorization List

In order to balance minimizing provider and supplier burden with our need to protect the Medicare Trust Funds, we propose to continue to limit prior authorization to a subset of items on the Master List as currently specified at § 414.234(a)(4). The subset of items requiring prior authorization are referred to as the Required Prior Authorization List.

OIG and GAO reports, as well as the CERT Medicare FFS Supplemental Improper Payment Data reports, provide national summary data and also often include regional data. Utilization trends within Medicare Contractor localities may show aberrant billing patterns or other identifiable vulnerabilities. At times, claims data analysis shows that

unnecessary utilization of the selected item(s) is concentrated among certain suppliers or in certain locations or regions. Similar to the requirements at current § 414.234(c)(1)(ii), we propose that we may decide to select and implement prior authorization of an item(s) nationally or, in collaboration with the DME MACs locally. We propose to revise § 414.234(c)(1)(ii) to state that all suppliers (either nationally or within a contractor jurisdiction) would initially be subject to prior authorization for items identified through a **Federal Register** notice and posted to CMS' website. However, CMS may later elect to exempt suppliers demonstrating compliance from such requirements through the prior authorization process. We believe this proposal meets our fiduciary obligation to protect the Medicare Trust Funds while remaining cognizant of contractor resource limitations and provider/supplier burden.

We specify at § 414.234 that we may consider factors such as geographic location, item utilization or cost, system capabilities, emerging trends, vulnerabilities identified in official agency reports, or other analysis in selecting items for national or local implementation. For example, items that are the focus of law enforcement investigations may require additional oversight and be appropriate for prior authorization. Likewise, when assessing cost we may prior authorize low dollar items for which the prior authorization decision is applied to duplicates of the same items rendered to the same beneficiary (for example, items dispensed in units or billed monthly for which the initial decision would remain appropriate), but would not prior authorize a single low cost item for which the cost of the review would outweigh the anticipated amount of improper payments identified.

We solicit comments on the proposed factors to be considered when selecting an item from the Master List and including it on the Required Prior Authorization List, such as whether the factors could be over-inclusive or under-inclusive. We also note that this notice and comment rulemaking provides the forum for stakeholders to comment on the proposed Master List from which items may be selected in the future to be placed on the Required Prior Authorization List.

We note that despite the proposed changes in the Master List inclusion criteria, the prior authorization program would continue to apply in all competitive bidding areas because CMS conditions of payment apply under the Medicare DMEPOS Competitive Bidding

Program. We recognize that there may be accessories for which stakeholders would like to request prior authorization that may not always appear on the Master List and would not be eligible to include on the Required Prior Authorization List. Any accessory included on a prior authorization request submitted for an item on the Required Prior Authorization List, may nonetheless receive a prior authorization decision for operational simplicity even if the accessory is not on the Required Prior Authorization List. The inclusion of such items is voluntary and does not create a condition of payment for items not present on the Required Prior Authorization List. An example of when this occurs is accessories for certain PMDs subject to prior authorization. If this proposed rule is finalized as proposed, the effective date of the final rule may precede shared systems changes that are required to support the addition of accessories that are not on the Master List and Required Prior Authorization List. Accordingly, there may be a delay in the adoption of this proposed operational change from the date of publication.

As previously stated in the November 2015 final rule, CMS established a prior authorization process for certain DMEPOS items. In 2017, CMS operationalized a prior authorization program, based on the regulatory process codified in 2015, which was initially established in four states for certain PMDs and subsequently expanded nationally (81 FR 93636). The DMEPOS items currently subject to the prior authorization requirement also meet the proposed Master List inclusion criteria, in this rule, and would continue to be eligible for prior authorization if the proposed criteria are finalized as proposed. To date, feedback related to the DMEPOS prior authorization process has been largely positive; however, the majority of comments have been from suppliers. We encourage all stakeholders, including those representing beneficiaries and Medicare consumer advocacy organizations, to submit their comments about prior authorization during the public comment period, as specified in the **ADDRESSES** section of this proposed rule.

We propose that the items currently subject to prior authorization would be grandfathered into the prior authorization program, if this rule is finalized as proposed, until the implementation of the first Required Prior Authorization List (which would be published subsequent to the rule). This proposal would avoid the

administrative and stakeholder burdens associated with the termination of the current prior authorization program and the implementation of a revised program created under this rule, if finalized as proposed. We would maintain the current process, as described in § 414.234, of publishing in the **Federal Register** and on the CMS website the Required Prior Authorization List at least 60 days prior to the effective date.

We propose to retain the documentation requirements for submitting prior authorization requests at § 414.234(d); however, we are proposing to add a reference to encompass the payment requirements proposed at § 410.38. In addition, we propose to retain the process for submitting prior authorization requests and receiving responses, but propose restructuring § 414.234(e) to conform to the formatting of the preceding paragraphs.

We propose to maintain the authority to suspend or cease the prior authorization requirement generally or for a particular item or items at any time without undertaking a separate rulemaking, as described in current § 414.234(f). For example, we may need to suspend or cease the prior authorization program due to new payment policies, which may render the prior authorization requirement obsolete or remove the item from Medicare coverage. If we suspend or cease the prior authorization requirement, we would publish a notice in the **Federal Register** and post notification of the suspension on the CMS website and include the date of suspension.

b. Notice of the Required Prior Authorization List

Section § 414.234 currently requires us to inform the public of items included on the Required Prior Authorization List in the **Federal Register** with 60-day notice before implementation. We are not proposing any changes to this section. In addition, all other prior authorization processes described in § 414.234 not mentioned in this proposed rule remain unchanged.

We believe that it is important that CMS have the authority to require prior authorization for an eligible item(s) (that is, on the Master List) locally to encourage immediate response to shifts in billing patterns, which may be related to potential fraud or abuse, or nationally, as the situation may so dictate. We would maintain our current process, as outlined in § 414.234, and publish a 60-day **Federal Register** notice and post on the CMS website when

items are placed on the Required Prior Authorization List.

6. Standardizing the Written Order/Prescription

We note that through subregulatory guidance and the implementation of several regulations, we have adopted different requirements for orders for different items of DMEPOS. To simplify order/prescription requirements and to reduce confusion, we propose at § 410.38(d)(1) to adopt one set of required written order/prescription elements for orders/prescriptions for all DMEPOS items.

We believe that the process to obtain DMEPOS items is sufficiently similar across the healthcare environment, and that a standardized order requirement is appropriate and would help promote compliance and reduce the confusion associated with complying with multiple, different order/prescription requirements for DMEPOS items. However, we note that the required timing for the order to be provided (from the treating practitioner to the supplier) would continue to vary for DMEPOS items. We propose at § 410.38(d) that for those items on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the written order/prescription must be communicated to the supplier prior to delivery of the item (per statutory requirement); for all other DMEPOS items, a written order/prescription must be communicated to the supplier prior to claim submission.

We believe the proposed requirements of the standardized DMEPOS orders/prescriptions are commonly included in orders/prescriptions rendered in clinical practice. We believe consistent requirements for all items would prove useful as electronic vendors develop programs in support of electronic records for provider and supplier use. We propose at § 410.38(d)(1)(i) that the standardized order/prescription require the elements listed here:

- Beneficiary Name or Medicare Beneficiary Identifier (MBI).
- General Description of the Item.
- Quantity To Be dispensed, if applicable.
- Date.
- Practitioner Name or National Provider Identifier.
- Practitioner Signature.

Traditionally, these required standardized order elements are written on a prescription/order; however, we recognize that these required elements may be found in the beneficiary's medical record. We propose at § 410.38(d)(1) that if the rule is finalized as proposed, DME MACs shall consider

the totality of the medical records when reviewing for compliance with standardized order/prescription elements.

While the above standardized elements are conditions of payment, we recognize that additional information might be helpful on the order/prescription for clinical practice and quality of care. Information may be added to the order/prescription or found in the beneficiary's medical records but are not conditions of payment. For example, route of administration—such

as whether oxygen is delivered via nasal cannula or face mask is not required as a condition of payment, but may be indicated for good clinical practice.

Current § 410.38(d), (e) and (f) contain written order and documentation requirements specific to equipment that is used for treatment of decubitus ulcers, seat-lifts, and transcutaneous electrical nerve stimulator units. We believe the requirements found at § 410.38(d), (e) and (f) are appropriate for inclusion in the standardized written order/prescription and medical record

documentation requirements outlined in this proposed rule. In addition, we believe item-specific coverage requirements may be included in national or local coverage documents, as appropriate. Therefore, we propose to delete the coverage requirements currently outlined in § 410.38(d), (e) and (f), and to replace sections § 410.38(d) and (e), with our proposed conditions of payment and process for suspending the face-to-face encounter and written order prior to delivery requirements, respectively.

TABLE 10—PROPOSED MASTER LIST OF DMEPOS ITEMS POTENTIALLY SUBJECT TO FACE-TO-FACE ENCOUNTER AND WRITTEN ORDER PRIOR TO DELIVERY AND/OR PRIOR AUTHORIZATION REQUIREMENTS

HCPSCS	Long description
A4253	Blood Glucose Test Or Reagent Strips For Home Blood Glucose Monitor, Per 50 Strips.
A4351	Intermittent Urinary Catheter; Straight Tip, With Or Without Coating (Teflon, Silicone, Silicone Elastomer, Or Hydrophilic, Etc.), Each.
A7025	High Frequency Chest Wall Oscillation System Vest, Replacement For Use With Patient Owned Equipment, Each.
E0170	Commode Chair With Integrated Seat Lift Mechanism, Electric, Any Type.
E0193	Powered Air Flotation Bed (Low Air Loss Therapy).
E0194	Air Fluidized Bed.
E0250	Hospital Bed, Fixed Height, With Any Type Side Rails, With Mattress.
E0251	Hospital Bed, Fixed Height, With Any Type Side Rails, Without Mattress.
E0255	Hospital Bed, Variable Height, Hi-Lo, With Any Type Side Rails, With Mattress.
E0256	Hospital Bed, Variable Height, Hi-Lo, With Any Type Side Rails, Without Mattress.
E0260	Hospital Bed, Semi-Electric (Head And Foot Adjustment), With Any Type Side Rails, With Mattress.
E0261	Hospital Bed, Semi-Electric (Head And Foot Adjustment), With Any Type Side Rails, Without Mattress.
E0265	Hospital Bed, Total Electric (Head, Foot And Height Adjustments), With Any Type Side Rails, With Mattress.
E0266	Hospital Bed, Total Electric (Head, Foot And Height Adjustments), With Any Type Side Rails, Without Mattress.
E0277	Powered Pressure-Reducing Air Mattress.
E0290	Hospital Bed, Fixed Height, Without Side Rails, With Mattress.
E0292	Hospital Bed, Variable Height, Hi-Lo, Without Side Rails, With Mattress.
E0293	Hospital Bed, Variable Height, Hi-Lo, Without Side Rails, Without Mattress.
E0294	Hospital Bed, Semi-Electric (Head And Foot Adjustment), Without Side Rails, With Mattress.
E0295	Hospital Bed, Semi-Electric (Head And Foot Adjustment), Without Side Rails, Without Mattress.
E0296	Hospital Bed, Total Electric (Head, Foot And Height Adjustments), Without Side Rails, With Mattress.
E0297	Hospital Bed, Total Electric (Head, Foot And Height Adjustments), Without Side Rails, Without Mattress.
E0300	Pediatric Crib, Hospital Grade, Fully Enclosed, With Or Without Top Enclosure.
E0301	Hospital Bed, Heavy Duty, Extra Wide, With Weight Capacity Greater Than 350 Pounds, But Less Than Or Equal To 600 Pounds, With Any Type Side Rails, Without Mattress.
E0302	Hospital Bed, Extra Heavy Duty, Extra Wide, With Weight Capacity Greater Than 600 Pounds, With Any Type Side Rails, Without Mattress.
E0303	Hospital Bed, Heavy Duty, Extra Wide, With Weight Capacity Greater Than 350 Pounds, But Less Than Or Equal To 600 Pounds, With Any Type Side Rails, With Mattress.
E0304	Hospital Bed, Extra Heavy Duty, Extra Wide, With Weight Capacity Greater Than 600 Pounds, With Any Type Side Rails, With Mattress.
E0316	Safety Enclosure Frame/Canopy For Use With Hospital Bed, Any Type.
E0371	Nonpowered Advanced Pressure Reducing Overlay For Mattress, Standard Mattress Length And Width.
E0372	Powered Air Overlay For Mattress, Standard Mattress Length And Width.
E0373	Nonpowered Advanced Pressure Reducing Mattress.
E0424	Stationary Compressed Gaseous Oxygen System, Rental; Includes Container, Contents, Regulator, Flowmeter, Humidifier, Nebulizer, Cannula Or Mask, And Tubing.
E0431	Portable Gaseous Oxygen System, Rental; Includes Portable Container, Regulator, Flowmeter, Humidifier, Cannula Or Mask, And Tubing.
E0433	Portable Liquid Oxygen System, Rental; Home Liquefier Used To Fill Portable Liquid Oxygen Containers, Includes Portable Containers, Regulator, Flowmeter, Humidifier, Cannula Or Mask And Tubing, With Or Without Supply Reservoir And Contents Gauge.
E0434	Portable Liquid Oxygen System, Rental; Includes Portable Container, Supply Reservoir, Humidifier, Flowmeter, Refill Adaptor, Contents Gauge, Cannula Or Mask, And Tubing.
E0439	Stationary Liquid Oxygen System, Rental; Includes Container, Contents, Regulator, Flowmeter, Humidifier, Nebulizer, Cannula Or Mask, & Tubing.
E0462	Rocking Bed With Or Without Side Rails.
E0465	Home Ventilator, Any Type, Used With Invasive Interface, (For Example, Tracheostomy Tube).
E0466	Home Ventilator, Any Type, Used With Non-Invasive Interface, (For Example, Mask, Chest Shell).
E0470	Respiratory Assist Device, Bi-Level Pressure Capability, Without Backup Rate Feature, Used With Noninvasive Interface, (For Example, Nasal Or Facial Mask (Intermittent Assist Device With Continuous Positive Airway Pressure Device)).
E0471	Respiratory Assist Device, Bi-Level Pressure Capability, With Back-Up Rate Feature, Used With Noninvasive Interface, (For Example, Nasal Or Facial Mask (Intermittent Assist Device With Continuous Positive Airway Pressure Device)).

TABLE 10—PROPOSED MASTER LIST OF DMEPOS ITEMS POTENTIALLY SUBJECT TO FACE-TO-FACE ENCOUNTER AND WRITTEN ORDER PRIOR TO DELIVERY AND/OR PRIOR AUTHORIZATION REQUIREMENTS—Continued

HCPCS	Long description
E0472	Respiratory Assist Device, Bi-Level Pressure Capability, With Backup Rate Feature, Used With Invasive Interface, (For Example, Tracheostomy Tube (Intermittent Assist Device With Continuous Positive Airway Pressure Device)).
E0483	High Frequency Chest Wall Oscillation Air-Pulse Generator System, (Includes Hoses And Vest), Each.
E0550	Humidifier, Durable For Extensive Supplemental Humidification During lppb Treatments Or Oxygen Delivery.
E0575	Nebulizer, Ultrasonic, Large Volume.
E0600	Respiratory Suction Pump, Home Model, Portable Or Stationary, Electric.
E0601	Continuous Positive Airway Pressure (Cpap) Device.
E0617	External Defibrillator With Integrated Electrocardiogram Analysis.
E0620	Skin Piercing Device For Collection Of Capillary Blood, Laser, Each.
E0630	Patient Lift, Hydraulic Or Mechanical, Includes Any Seat, Sling, Strap(s) Or Pad(s).
E0635	Patient Lift, Electric With Seat Or Sling.
E0636	Multipositional Patient Support System, With Integrated Lift, Patient Accessible Controls.
E0639	Patient Lift, Moveable From Room To Room With Disassembly And Reassembly, Includes All Components/Accessories.
E0640	Patient Lift, Fixed System, Includes All Components/Accessories.
E0747	Osteogenesis Stimulator, Electrical, Non-Invasive, Other Than Spinal Applications.
E0748	Osteogenesis Stimulator, Electrical, Non-Invasive, Spinal Applications.
E0760	Ostogenesis Stimulator, Low Intensity Ultrasound, Non-Invasive.
E0781	Ambulatory Infusion Pump, Single Or Multiple Channels, Electric Or Battery Operated, With Administrative Equipment, Worn By Patient.
E0784	External Ambulatory Infusion Pump, Insulin.
E0791	Parenteral Infusion Pump, Stationary, Single Or Multi-Channel.
E0912	Trapeze Bar, Heavy Duty, For Patient Weight Capacity Greater Than 250 Pounds, Free Standing, Complete With Grab Bar.
E0983	Manual Wheelchair Accessory, Power Add-On To Convert Manual Wheelchair To Motorized Wheelchair, Joystick Control.
E0986	Manual Wheelchair Accessory, Push-Rim Activated Power Assist System.
E0988	Manual Wheelchair Accessory, Lever-Activated, Wheel Drive, Pair.
E1002	Wheelchair Accessory, Power Seating System, Tilt Only.
E1003	Wheelchair Accessory, Power Seating System, Recline Only, Without Shear Reduction.
E1004	Wheelchair Accessory, Power Seating System, Recline Only, With Mechanical Shear Reduction.
E1005	Wheelchair Accessory, Power Seating System, Recline Only, With Power Shear Reduction.
E1006	Wheelchair Accessory, Power Seating System, Combination Tilt And Recline, Without Shear Reduction.
E1007	Wheelchair Accessory, Power Seating System, Combination Tilt And Recline, With Mechanical Shear Reduction.
E1008	Wheelchair Accessory, Power Seating System, Combination Tilt And Recline, With Power Shear Reduction.
E1010	Wheelchair Accessory, Addition To Power Seating System, Power Leg Elevation System, Including Leg Rest, Pair.
E1012	Wheelchair Accessory, Addition To Power Seating System, Center Mount Power Elevating Leg Rest/Platform, Complete System, Any Type, Each.
E1030	Wheelchair Accessory, Ventilator Tray, Gimbaled.
E1035	Multi-Positional Patient Transfer System, With Integrated Seat, Operated By Care Giver, Patient Weight Capacity Up To And Including 300 Pounds.
E1036	Multi-Positional Patient Transfer System, Extra-Wide, With Integrated Seat, Operated By Caregiver, Patient Weight Capacity Greater Than 300 Pounds.
E1037	Transport Chair, Pediatric Size.
E1161	Manual Adult Size Wheelchair, Includes Tilt In Space.
E1232	Wheelchair, Pediatric Size, Tilt-In-Space, Folding, Adjustable, With Seating System.
E1233	Wheelchair, Pediatric Size, Tilt-In-Space, Rigid, Adjustable, Without Seating System.
E1234	Wheelchair, Pediatric Size, Tilt-In-Space, Folding, Adjustable, Without Seating System.
E1235	Wheelchair, Pediatric Size, Rigid, Adjustable, With Seating System.
E1236	Wheelchair, Pediatric Size, Folding, Adjustable, With Seating System.
E1237	Wheelchair, Pediatric Size, Rigid, Adjustable, Without Seating System.
E1238	Wheelchair, Pediatric Size, Folding, Adjustable, Without Seating System.
E1390	Oxygen Concentrator, Single Delivery Port, Capable Of Delivering 85 Percent Or Greater Oxygen Concentration At The Prescribed Flow Rate.
E1391	Oxygen Concentrator, Dual Delivery Port, Capable Of Delivering 85 Percent Or Greater Oxygen Concentration At The Prescribed Flow Rate, Each.
E1392	Portable Oxygen Concentrator, Rental.
E1405	Oxygen And Water Vapor Enriching System With Heated Delivery.
E1406	Oxygen And Water Vapor Enriching System Without Heated Delivery.
E2000	Gastric Suction Pump, Home Model, Portable Or Stationary, Electric.
E2100	Blood Glucose Monitor With Integrated Voice Synthesizer.
E2204	Manual Wheelchair Accessory, Nonstandard Seat Frame Depth, 22 To 25 Inches.
E2227	Manual Wheelchair Accessory, Gear Reduction Drive Wheel, Each.
E2228	Manual Wheelchair Accessory, Wheel Braking System And Lock, Complete, Each.
E2310	Power Wheelchair Accessory, Electronic Connection Between Wheelchair Controller And One Power Seating System Motor, Including All Related Electronics, Indicator Feature, Mechanical Function Selection Switch, And Fixed Mounting Hardware.
E2311	Power Wheelchair Accessory, Electronic Connection Between Wheelchair Controller And Two Or More Power Seating System Motors, Including All Related Electronics, Indicator Feature, Mechanical Function Selection Switch, And Fixed Mounting Hardware.
E2312	Power Wheelchair Accessory, Hand Or Chin Control Interface, Mini-Proportional Remote Joystick, Proportional, Including Fixed Mounting Hardware.
E2321	Power Wheelchair Accessory, Hand Control Interface, Remote Joystick, Nonproportional, Including All Related Electronics, Mechanical Stop Switch, And Fixed Mounting Hardware.

TABLE 10—PROPOSED MASTER LIST OF DMEPOS ITEMS POTENTIALLY SUBJECT TO FACE-TO-FACE ENCOUNTER AND WRITTEN ORDER PRIOR TO DELIVERY AND/OR PRIOR AUTHORIZATION REQUIREMENTS—Continued

HCPCS	Long description
E2322	Power Wheelchair Accessory, Hand Control Interface, Multiple Mechanical Switches, Nonproportional, Including All Related Electronics, Mechanical Stop Switch, And Fixed Mounting Hardware.
E2325	Power Wheelchair Accessory, Sip And Puff Interface, Nonproportional, Including All Related Electronics, Mechanical Stop Switch, And Manual Swingaway Mounting Hardware.
E2327	Power Wheelchair Accessory, Head Control Interface, Mechanical, Proportional, Including All Related Electronics, Mechanical Direction Change Switch, And Fixed Mounting Hardware.
E2328	Power Wheelchair Accessory, Head Control Or Extremity Control Interface, Electronic, Proportional, Including All Related Electronics And Fixed Mounting Hardware.
E2329	Power Wheelchair Accessory, Head Control Interface, Contact Switch Mechanism, Nonproportional, Including All Related Electronics, Mechanical Stop Switch, Mechanical Direction Change Switch, Head Array, And Fixed Mounting Hardware.
E2330	Power Wheelchair Accessory, Head Control Interface, Proximity Switch Mechanism, Nonproportional, Including All Related Electronics, Mechanical Stop Switch, Mechanical Direction Change Switch, Head Array, And Fixed Mounting Hardware.
E2351	Power Wheelchair Accessory, Electronic Interface To Operate Speech Generating Device Using Power Wheelchair Control Interface.
E2368	Power Wheelchair Component, Drive Wheel Motor, Replacement Only.
E2369	Power Wheelchair Component, Drive Wheel Gear Box, Replacement Only.
E2370	Power Wheelchair Component, Integrated Drive Wheel Motor And Gear Box Combination, Replacement Only.
E2373	Power Wheelchair Accessory, Hand Or Chin Control Interface, Compact Remote Joystick, Proportional, Including Fixed Mounting Hardware.
E2374	Power Wheelchair Accessory, Hand Or Chin Control Interface, Standard Remote Joystick (Not Including Controller), Proportional, Including All Related Electronics And Fixed Mounting Hardware, Replacement Only.
E2375	Power Wheelchair Accessory, Non-Expandable Controller, Including All Related Electronics And Mounting Hardware, Replacement Only.
E2376	Power Wheelchair Accessory, Expandable Controller, Including All Related Electronics And Mounting Hardware, Replacement Only.
E2377	Power Wheelchair Accessory, Expandable Controller, Including All Related Electronics And Mounting Hardware, Upgrade Provided At Initial Issue.
E2378	Power Wheelchair Component, Actuator, Replacement Only.
E2402	Negative Pressure Wound Therapy Electrical Pump, Stationary Or Portable.
E2614	Positioning Wheelchair Back Cushion, Posterior, Width 22 Inches Or Greater, Any Height, Including Any Type Mounting Hardware.
E2616	Positioning Wheelchair Back Cushion, Posterior-Lateral, Width 22 Inches Or Greater, Any Height, Including Any Type Mounting Hardware.
E2620	Positioning Wheelchair Back Cushion, Planar Back With Lateral Supports, Width Less Than 22 Inches, Any Height, Including Any Type Mounting Hardware.
E2621	Positioning Wheelchair Back Cushion, Planar Back With Lateral Supports, Width 22 Inches Or Greater, Any Height, Including Any Type Mounting Hardware.
E2626	Wheelchair Accessory, Shoulder Elbow, Mobile Arm Support Attached To Wheelchair, Balanced, Adjustable.
E2627	Wheelchair Accessory, Shoulder Elbow, Mobile Arm Support Attached To Wheelchair, Balanced, Adjustable Rancho Type.
E2628	Wheelchair Accessory, Shoulder Elbow, Mobile Arm Support Attached To Wheelchair, Balanced, Reclining.
E2629	Wheelchair Accessory, Shoulder Elbow, Mobile Arm Support Attached To Wheelchair, Balanced, Friction Arm Support (Friction Dampening To Proximal And Distal Joints).
E2630	Wheelchair Accessory, Shoulder Elbow, Mobile Arm Support, Monosuspension Arm And Hand Support, Overhead Elbow Forearm Hand Sling Support, Yoke Type Suspension Support.
K0002	Standard Hemi (Low Seat) Wheelchair.
K0003	Lightweight Wheelchair.
K0004	High Strength, Lightweight Wheelchair.
K0005	Ultralightweight Wheelchair.
K0006	Heavy Duty Wheelchair.
K0007	Extra Heavy Duty Wheelchair.
K0009	Other Manual Wheelchair/Base.
K0455	Infusion Pump Used For Uninterrupted Parenteral Administration Of Medication, (For example, Epoprostenol Or Treprostinol).
K0606	Automatic External Defibrillator, With Integrated Electrocardiogram Analysis, Garment Type.
K0609	Replacement Electrodes For Use With Automated External Defibrillator, Garment Type Only, Each.
K0730	Controlled Dose Inhalation Drug Delivery System.
K0738	Portable Gaseous Oxygen System, Rental; Home Compressor Used To Fill Portable Oxygen Cylinders; Includes Portable Containers, Regulator, Flowmeter, Humidifier, Cannula Or Mask, And Tubing.
K0800	Power Operated Vehicle, Group 1 Standard, Patient Weight Capacity Up To And Including 300 Pounds.
K0801	Power Operated Vehicle, Group 1 Heavy Duty, Patient Weight Capacity, 301 To 450 Pounds.
K0802	Power Operated Vehicle, Group 1 Very Heavy Duty, Patient Weight Capacity 451 To 600 Pounds.
K0806	Power Operated Vehicle, Group 2 Standard, Patient Weight Capacity Up To And Including 300 Pounds.
K0807	Power Operated Vehicle, Group 2 Heavy Duty, Patient Weight Capacity 301 To 450 Pounds.
K0808	Power Operated Vehicle, Group 2 Very Heavy Duty, Patient Weight Capacity 451 To 600 Pounds.
K0813	Power Wheelchair, Group 1 Standard, Portable, Sling/Solid Seat And Back, Patient Weight Capacity Up To And Including 300 Pounds.
K0814	Power Wheelchair, Group 1 Standard, Portable, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds.
K0815	Power Wheelchair, Group 1 Standard, Sling/Solid Seat And Back, Patient Weight Capacity Up To And Including 300 Pounds.
K0816	Power Wheelchair, Group 1 Standard, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds.
K0820	Power Wheelchair, Group 2 Standard, Portable, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds.
K0821	Power Wheelchair, Group 2 Standard, Portable, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds.

TABLE 10—PROPOSED MASTER LIST OF DMEPOS ITEMS POTENTIALLY SUBJECT TO FACE-TO-FACE ENCOUNTER AND WRITTEN ORDER PRIOR TO DELIVERY AND/OR PRIOR AUTHORIZATION REQUIREMENTS—Continued

HCPSCS	Long description
K0822	Power Wheelchair, Group 2 Standard, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds.
K0823	Power Wheelchair, Group 2 Standard, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds.
K0824	Power Wheelchair, Group 2 Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds.
K0825	Power Wheelchair, Group 2 Heavy Duty, Captains Chair, Patient Weight Capacity 301 To 450 Pounds.
K0826	Power Wheelchair, Group 2 Very Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds.
K0827	Power Wheelchair, Group 2 Very Heavy Duty, Captains Chair, Patient Weight Capacity 451 To 600 Pounds.
K0828	Power Wheelchair, Group 2 Extra Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 601 Pounds Or More.
K0829	Power Wheelchair, Group 2 Extra Heavy Duty, Captains Chair, Patient Weight Capacity 601 Pounds Or More.
K0835	Power Wheelchair, Group 2 Standard, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds.
K0836	Power Wheelchair, Group 2 Standard, Single Power Option, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds.
K0837	Power Wheelchair, Group 2 Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds.
K0838	Power Wheelchair, Group 2 Heavy Duty, Single Power Option, Captains Chair, Patient Weight Capacity 301 To 450 Pounds.
K0839	Power Wheelchair, Group 2 Very Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds.
K0840	Power Wheelchair, Group 2 Extra Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 601 Pounds Or More.
K0841	Power Wheelchair, Group 2 Standard, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds.
K0842	Power Wheelchair, Group 2 Standard, Multiple Power Option, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds.
K0843	Power Wheelchair, Group 2 Heavy Duty, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds.
K0848	Power Wheelchair, Group 3 Standard, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds.
K0849	Power Wheelchair, Group 3 Standard, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds.
K0850	Power Wheelchair, Group 3 Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds.
K0851	Power Wheelchair, Group 3 Heavy Duty, Captains Chair, Patient Weight Capacity 301 To 450 Pounds.
K0852	Power Wheelchair, Group 3 Very Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds.
K0853	Power Wheelchair, Group 3 Very Heavy Duty, Captains Chair, Patient Weight Capacity, 451 To 600 Pounds.
K0854	Power Wheelchair, Group 3 Extra Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 601 Pounds Or More.
K0855	Power Wheelchair, Group 3 Extra Heavy Duty, Captains Chair, Patient Weight Capacity 601 Pounds Or More.
K0856	Power Wheelchair, Group 3 Standard, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds.
K0857	Power Wheelchair, Group 3 Standard, Single Power Option, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds.
K0858	Power Wheelchair, Group 3 Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds.
K0859	Power Wheelchair, Group 3 Heavy Duty, Single Power Option, Captains Chair, Patient Weight Capacity 301 To 450 Pounds.
K0860	Power Wheelchair, Group 3 Very Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds.
K0861	Power Wheelchair, Group 3 Standard, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds.
K0862	Power Wheelchair, Group 3 Heavy Duty, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds.
K0863	Power Wheelchair, Group 3 Very Heavy Duty, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds.
K0864	Power Wheelchair, Group 3 Extra Heavy Duty, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 601 Pounds Or More.
L0631	Lumbar-Sacral Orthosis, Sagittal Control, With Rigid Anterior And Posterior Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise.
L0635	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, Lumbar Flexion, Rigid Posterior Frame/Panel(S), Lateral Articulating Design To Flex The Lumbar Spine, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panel(S), Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Anterior Panel, Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment.
L0636	Lumbar Sacral Orthosis, Sagittal-Coronal Control, Lumbar Flexion, Rigid Posterior Frame/Panels, Lateral Articulating Design To Flex The Lumbar Spine, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Anterior Panel, Pendulous Abdomen Design, Custom Fabricated.
L0637	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Anterior And Posterior Frame/Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise.

TABLE 10—PROPOSED MASTER LIST OF DMEPOS ITEMS POTENTIALLY SUBJECT TO FACE-TO-FACE ENCOUNTER AND WRITTEN ORDER PRIOR TO DELIVERY AND/OR PRIOR AUTHORIZATION REQUIREMENTS—Continued

HPCPS	Long description
L0638	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Anterior And Posterior Frame/Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Custom Fabricated.
L0639	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, Rigid Shell(S)/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Anterior Extends From Symphysis Pubis To Xyphoid, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Overall Strength Is Provided By Overlapping Rigid Material And Stabilizing Closures, Includes Straps, Closures, May Include Soft Interface, Pendulous Abdomen Design, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise.
L0640	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, Rigid Shell(S)/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Anterior Extends From Symphysis Pubis To Xyphoid, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Overall Strength Is Provided By Overlapping Rigid Material And Stabilizing Closures, Includes Straps, Closures, May Include Soft Interface, Pendulous Abdomen Design, Custom Fabricated.
L0648	Lumbar-Sacral Orthosis, Sagittal Control, With Rigid Anterior And Posterior Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Off-The-Shelf.
L0650	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Anterior And Posterior Frame/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panel(S), Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Off-The-Shelf.
L0651	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, Rigid Shell(S)/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Anterior Extends From Symphysis Pubis To Xyphoid, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Overall Strength Is Provided By Overlapping Rigid Material And Stabilizing Closures, Includes Straps, Closures, May Include Soft Interface, Pendulous Abdomen Design, Prefabricated, Off-The-Shelf.
L1680	Hip Orthosis, Abduction Control Of Hip Joints, Dynamic, Pelvic Control, Adjustable Hip Motion Control, Thigh Cuffs (Rancho Hip Action Type), Custom Fabricated.
L1685	Hip Orthosis, Abduction Control Of Hip Joint, Postoperative Hip Abduction Type, Custom Fabricated.
L1686	Hip Orthosis, Abduction Control Of Hip Joint, Postoperative Hip Abduction Type, Prefabricated, Includes Fitting And Adjustment.
L1690	Combination, Bilateral, Lumbo-Sacral, Hip, Femur Orthosis Providing Adduction And Internal Rotation Control, Prefabricated, Includes Fitting And Adjustment.
L1700	Legg Perthes Orthosis, (Toronto Type), Custom-Fabricated.
L1710	Legg Perthes Orthosis, (Newington Type), Custom Fabricated.
L1720	Legg Perthes Orthosis, Trilateral, (Tachdijan Type), Custom-Fabricated.
L1730	Legg Perthes Orthosis, (Scottish Rite Type), Custom-Fabricated.
L1755	Legg Perthes Orthosis, (Patten Bottom Type), Custom-Fabricated.
L1832	Knee Orthosis, Adjustable Knee Joints (Unicentric Or Polycentric), Positional Orthosis, Rigid Support, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise.
L1833	Knee Orthosis, Adjustable Knee Joints (Unicentric Or Polycentric), Positional Orthosis, Rigid Support, Prefabricated, Off-The-Shelf.
L1834	Knee Orthosis, Without Knee Joint, Rigid, Custom-Fabricated.
L1840	Knee Orthosis, Derotation, Medial-Lateral, Anterior Cruciate Ligament, Custom Fabricated.
L1843	Knee Orthosis, Single Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise.
L1844	Knee Orthosis, Single Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Custom Fabricated.
L1845	Knee Orthosis, Double Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise.
L1846	Knee Orthosis, Double Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Custom Fabricated.
L1847	Knee Orthosis, Double Upright With Adjustable Joint, With Inflatable Air Support Chamber(S), Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise.
L1848	Knee Orthosis, Double Upright With Adjustable Joint, With Inflatable Air Support Chamber(S), Prefabricated, Off-The-Shelf.
L1851	Knee Orthosis (Ko), Single Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Prefabricated, Off-The-Shelf.
L1852	Knee Orthosis (Ko), Double Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Prefabricated, Off-The-Shelf.
L1860	Knee Orthosis, Modification Of Supracondylar Prosthetic Socket, Custom-Fabricated (Sk).
L1907	Ankle Orthosis, Supramalleolar With Straps, With Or Without Interface/Pads, Custom Fabricated.
L1932	Afo, Rigid Anterior Tibial Section, Total Carbon Fiber Or Equal Material, Prefabricated, Includes Fitting And Adjustment.
L1940	Ankle Foot Orthosis, Plastic Or Other Material, Custom-Fabricated.
L1945	Ankle Foot Orthosis, Plastic, Rigid Anterior Tibial Section (Floor Reaction), Custom-Fabricated.
L1950	Ankle Foot Orthosis, Spiral, (Institute Of Rehabilitative Medicine Type), Plastic, Custom-Fabricated.
L1951	Ankle Foot Orthosis, Spiral, (Institute Of Rehabilitative Medicine Type), Plastic Or Other Material, Prefabricated, Includes Fitting And Adjustment.
L1960	Ankle Foot Orthosis, Posterior Solid Ankle, Plastic, Custom-Fabricated.
L1970	Ankle Foot Orthosis, Plastic With Ankle Joint, Custom-Fabricated.

TABLE 10—PROPOSED MASTER LIST OF DMEPOS ITEMS POTENTIALLY SUBJECT TO FACE-TO-FACE ENCOUNTER AND WRITTEN ORDER PRIOR TO DELIVERY AND/OR PRIOR AUTHORIZATION REQUIREMENTS—Continued

HCPCS	Long description
L2000	Knee Ankle Foot Orthosis, Single Upright, Free Knee, Free Ankle, Solid Stirrup, Thigh And Calf Bands/Cuffs (Single Bar Ak Orthosis), Custom-Fabricated.
L2005	Knee Ankle Foot Orthosis, Any Material, Single Or Double Upright, Stance Control, Automatic Lock And Swing Phase Release, Any Type Activation, Includes Ankle Joint, Any Type, Custom Fabricated.
L2010	Knee Ankle Foot Orthosis, Single Upright, Free Ankle, Solid Stirrup, Thigh And Calf Bands/Cuffs (Single Bar Ak Orthosis), Without Knee Joint, Custom-Fabricated.
L2020	Knee Ankle Foot Orthosis, Double Upright, Free Ankle, Solid Stirrup, Thigh And Calf Bands/Cuffs (Double Bar Ak Orthosis), Custom-Fabricated.
L2030	Knee Ankle Foot Orthosis, Double Upright, Free Ankle, Solid Stirrup, Thigh And Calf Bands/Cuffs, (Double Bar Ak Orthosis), Without Knee Joint, Custom Fabricated.
L2034	Knee Ankle Foot Orthosis, Full Plastic, Single Upright, With Or Without Free Motion Knee, Medial Lateral Rotation Control, With Or Without Free Motion Ankle, Custom Fabricated.
L2036	Knee Ankle Foot Orthosis, Full Plastic, Double Upright, With Or Without Free Motion Knee, With Or Without Free Motion Ankle, Custom Fabricated.
L2037	Knee Ankle Foot Orthosis, Full Plastic, Single Upright, With Or Without Free Motion Knee, With Or Without Free Motion Ankle, Custom Fabricated.
L2038	Knee Ankle Foot Orthosis, Full Plastic, With Or Without Free Motion Knee, Multi-Axis Ankle, Custom Fabricated.
L2050	Hip Knee Ankle Foot Orthosis, Torsion Control, Bilateral Torsion Cables, Hip Joint, Pelvic Band/Belt, Custom-Fabricated.
L2060	Hip Knee Ankle Foot Orthosis, Torsion Control, Bilateral Torsion Cables, Ball Bearing Hip Joint, Pelvic Band/Belt, Custom-Fabricated.
L2106	Ankle Foot Orthosis, Fracture Orthosis, Tibial Fracture Cast Orthosis, Thermoplastic Type Casting Material, Custom-Fabricated.
L2108	Ankle Foot Orthosis, Fracture Orthosis, Tibial Fracture Cast Orthosis, Custom-Fabricated.
L2114	Ankle Foot Orthosis, Fracture Orthosis, Tibial Fracture Orthosis, Semi-Rigid, Prefabricated, Includes Fitting And Adjustment.
L2116	Ankle Foot Orthosis, Fracture Orthosis, Tibial Fracture Orthosis, Rigid, Prefabricated, Includes Fitting And Adjustment.
L2126	Knee Ankle Foot Orthosis, Fracture Orthosis, Femoral Fracture Cast Orthosis, Thermoplastic Type Casting Material, Custom-Fabricated.
L2128	Knee Ankle Foot Orthosis, Fracture Orthosis, Femoral Fracture Cast Orthosis, Custom-Fabricated.
L2132	Kafo, Fracture Orthosis, Femoral Fracture Cast Orthosis, Soft, Prefabricated, Includes Fitting And Adjustment.
L2134	Kafo, Fracture Orthosis, Femoral Fracture Cast Orthosis, Semi-Rigid, Prefabricated, Includes Fitting And Adjustment.
L2136	Kafo, Fracture Orthosis, Femoral Fracture Cast Orthosis, Rigid, Prefabricated, Includes Fitting And Adjustment.
L2350	Addition To Lower Extremity, Prosthetic Type, (Bk) Socket, Molded To Patient Model, (Used For Ptb Afo Orthoses).
L2510	Addition To Lower Extremity, Thigh/Weight Bearing, Quadri-Lateral Brim, Molded To Patient Model.
L2525	Addition To Lower Extremity, Thigh/Weight Bearing, Ischial Containment/Narrow M-L Brim Molded To Patient Model.
L2526	Addition To Lower Extremity, Thigh/Weight Bearing, Ischial Containment/Narrow M-L Brim, Custom Fitted.
L2570	Addition To Lower Extremity, Pelvic Control, Hip Joint, Clevis Type Two Position Joint, Each.
L2627	Addition To Lower Extremity, Pelvic Control, Plastic, Molded To Patient Model, Reciprocating Hip Joint And Cables.
L2628	Addition To Lower Extremity, Pelvic Control, Metal Frame, Reciprocating Hip Joint And Cables.
L3330	Lift, Elevation, Metal Extension (Skate).
L3671	Shoulder Orthosis, Shoulder Joint Design, Without Joints, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment.
L3674	Shoulder Orthosis, Abduction Positioning (Airplane Design), Thoracic Component And Support Bar, With Or Without Nontorsion Joint/Turnbuckle, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment.
L3720	Elbow Orthosis, Double Upright With Forearm/Arm Cuffs, Free Motion, Custom-Fabricated.
L3730	Elbow Orthosis, Double Upright With Forearm/Arm Cuffs, Extension/Flexion Assist, Custom-Fabricated.
L3740	Elbow Orthosis, Double Upright With Forearm/Arm Cuffs, Adjustable Position Lock With Active Control, Custom-Fabricated.
L3761	Elbow Orthosis (Eo), With Adjustable Position Locking Joint(S), Prefabricated, Off-The-Shelf.
L3763	Elbow Wrist Hand Orthosis, Rigid, Without Joints, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment.
L3764	Elbow Wrist Hand Orthosis, Includes One Or More Nontorsion Joints, Elastic Bands, Turnbuckles, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment.
L3765	Elbow Wrist Hand Finger Orthosis, Rigid, Without Joints, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment.
L3766	Elbow Wrist Hand Finger Orthosis, Includes One Or More Nontorsion Joints, Elastic Bands, Turnbuckles, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment.
L3900	Wrist Hand Finger Orthosis, Dynamic Flexor Hinge, Reciprocal Wrist Extension/Flexion, Finger Flexion/Extension, Wrist Or Finger Driven, Custom-Fabricated.
L3901	Wrist Hand Finger Orthosis, Dynamic Flexor Hinge, Reciprocal Wrist Extension/Flexion, Finger Flexion/Extension, Cable Driven, Custom-Fabricated.
L3904	Wrist Hand Finger Orthosis, External Powered, Electric, Custom-Fabricated.
L3905	Wrist Hand Orthosis, Includes One Or More Nontorsion Joints, Elastic Bands, Turnbuckles, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment.
L3960	Shoulder Elbow Wrist Hand Orthosis, Abduction Positioning, Airplane Design, Prefabricated, Includes Fitting And Adjustment.
L3961	Shoulder Elbow Wrist Hand Orthosis, Shoulder Cap Design, Without Joints, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment.
L3962	Shoulder Elbow Wrist Hand Orthosis, Abduction Positioning, Erbs Palsey Design, Prefabricated, Includes Fitting And Adjustment.
L3967	Shoulder Elbow Wrist Hand Orthosis, Abduction Positioning (Airplane Design), Thoracic Component And Support Bar, Without Joints, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment.
L3971	Shoulder Elbow Wrist Hand Orthosis, Shoulder Cap Design, Includes One Or More Nontorsion Joints, Elastic Bands, Turnbuckles, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment.

TABLE 10—PROPOSED MASTER LIST OF DMEPOS ITEMS POTENTIALLY SUBJECT TO FACE-TO-FACE ENCOUNTER AND WRITTEN ORDER PRIOR TO DELIVERY AND/OR PRIOR AUTHORIZATION REQUIREMENTS—Continued

HCPCS	Long description
L3973	Shoulder Elbow Wrist Hand Orthosis, Abduction Positioning (Airplane Design), Thoracic Component And Support Bar, Includes One Or More Nontorsion Joints, Elastic Bands, Turnbuckles, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment.
L3975	Shoulder Elbow Wrist Hand Finger Orthosis, Shoulder Cap Design, Without Joints, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment.
L3976	Shoulder Elbow Wrist Hand Finger Orthosis, Abduction Positioning (Airplane Design), Thoracic Component And Support Bar, Without Joints, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment.
L3977	Shoulder Elbow Wrist Hand Finger Orthosis, Shoulder Cap Design, Includes One Or More Nontorsion Joints, Elastic Bands, Turnbuckles, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment.
L3978	Shoulder Elbow Wrist Hand Finger Orthosis, Abduction Positioning (Airplane Design), Thoracic Component And Support Bar, Includes One Or More Nontorsion Joints, Elastic Bands, Turnbuckles, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment.
L3981	Upper Extremity Fracture Orthosis, Humeral, Prefabricated, Includes Shoulder Cap Design, With Or Without Joints, Forearm Section, May Include Soft Interface, Straps, Includes Fitting And Adjustments.
L4010	Replace Trilateral Socket Brim.
L4020	Replace Quadrilateral Socket Brim, Molded To Patient Model.
L4030	Replace Quadrilateral Socket Brim, Custom Fitted.
L4130	Replace Pretibial Shell.
L4631	Ankle Foot Orthosis, Walking Boot Type, Varus/Valgus Correction, Rocker Bottom, Anterior Tibial Shell, Soft Interface, Custom Arch Support, Plastic Or Other Material, Includes Straps And Closures, Custom Fabricated.
L5000	Partial Foot, Shoe Insert With Longitudinal Arch, Toe Filler.
L5010	Partial Foot, Molded Socket, Ankle Height, With Toe Filler.
L5020	Partial Foot, Molded Socket, Tibial Tubercle Height, With Toe Filler.
L5050	Ankle, Symes, Molded Socket, Sach Foot.
L5060	Ankle, Symes, Metal Frame, Molded Leather Socket, Articulated Ankle/Foot.
L5100	Below Knee, Molded Socket, Shin, Sach Foot.
L5105	Below Knee, Plastic Socket, Joints And Thigh Lacer, Sach Foot.
L5150	Knee Disarticulation (Or Through Knee), Molded Socket, External Knee Joints, Shin, Sach Foot.
L5160	Knee Disarticulation (Or Through Knee), Molded Socket, Bent Knee Configuration, External Knee Joints, Shin, Sach Foot.
L5200	Above Knee, Molded Socket, Single Axis Constant Friction Knee, Shin, Sach Foot.
L5210	Above Knee, Short Prosthesis, No Knee Joint (Stubbies), With Foot Blocks, No Ankle Joints, Each.
L5220	Above Knee, Short Prosthesis, No Knee Joint (Stubbies), With Articulated Ankle/Foot, Dynamically Aligned, Each.
L5230	Above Knee, For Proximal Femoral Focal Deficiency, Constant Friction Knee, Shin, Sach Foot.
L5250	Hip Disarticulation, Canadian Type; Molded Socket, Hip Joint, Single Axis Constant Friction Knee, Shin, Sach Foot.
L5270	Hip Disarticulation, Tilt Table Type; Molded Socket, Locking Hip Joint, Single Axis Constant Friction Knee, Shin, Sach Foot.
L5280	Hemipelvectomy, Canadian Type; Molded Socket, Hip Joint, Single Axis Constant Friction Knee, Shin, Sach Foot.
L5301	Below Knee, Molded Socket, Shin, Sach Foot, Endoskeletal System.
L5312	Knee Disarticulation (Or Through Knee), Molded Socket, Single Axis Knee, Pylon, Sach Foot, Endoskeletal System.
L5321	Above Knee, Molded Socket, Open End, Sach Foot, Endoskeletal System, Single Axis Knee.
L5331	Hip Disarticulation, Canadian Type, Molded Socket, Endoskeletal System, Hip Joint, Single Axis Knee, Sach Foot.
L5341	Hemipelvectomy, Canadian Type, Molded Socket, Endoskeletal System, Hip Joint, Single Axis Knee, Sach Foot.
L5400	Immediate Post Surgical Or Early Fitting, Application Of Initial Rigid Dressing, Including Fitting, Alignment, Suspension, And One Cast Change, Below Knee.
L5420	Immediate Post Surgical Or Early Fitting, Application Of Initial Rigid Dressing, Including Fitting, Alignment And Suspension And One Cast Change Ak Or Knee Disarticulation.
L5430	Immediate Post Surgical Or Early Fitting, Application Of Initial Rigid Dressing, Incl. Fitting, Alignment And Suspension, Ak Or Knee Disarticulation, Each Additional Cast Change And Realignment.
L5460	Immediate Post Surgical Or Early Fitting, Application Of Non-Weight Bearing Rigid Dressing, Above Knee.
L5500	Initial, Below Knee Ptb Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Plaster Socket, Direct Formed.
L5505	Initial, Above Knee—Knee Disarticulation, Ischial Level Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Plaster Socket, Direct Formed.
L5510	Preparatory, Below Knee Ptb Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Plaster Socket, Molded To Model.
L5520	Preparatory, Below Knee Ptb Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Direct Formed.
L5530	Preparatory, Below Knee Ptb Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Molded To Model.
L5535	Preparatory, Below Knee Ptb Type Socket, Non-Alignable System, No Cover, Sach Foot, Prefabricated, Adjustable Open End Socket.
L5540	Preparatory, Below Knee Ptb Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Laminated Socket, Molded To Model.
L5560	Preparatory, Above Knee—Knee Disarticulation, Ischial Level Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Plaster Socket, Molded To Model.
L5570	Preparatory, Above Knee—Knee Disarticulation, Ischial Level Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Direct Formed.
L5580	Preparatory, Above Knee—Knee Disarticulation Ischial Level Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Molded To Model.
L5585	Preparatory, Above Knee—Knee Disarticulation, Ischial Level Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Prefabricated Adjustable Open End Socket.
L5590	Preparatory, Above Knee—Knee Disarticulation Ischial Level Socket, Non-Alignable System, Pylon No Cover, Sach Foot, Laminated Socket, Molded To Model.

TABLE 10—PROPOSED MASTER LIST OF DMEPOS ITEMS POTENTIALLY SUBJECT TO FACE-TO-FACE ENCOUNTER AND WRITTEN ORDER PRIOR TO DELIVERY AND/OR PRIOR AUTHORIZATION REQUIREMENTS—Continued

HCPSCS	Long description
L5595	Preparatory, Hip Disarticulation-Hemipelvectomy, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Molded To Patient Model.
L5600	Preparatory, Hip Disarticulation-Hemipelvectomy, Pylon, No Cover, Sach Foot, Laminated Socket, Molded To Patient Model.
L5610	Addition To Lower Extremity, Endoskeletal System, Above Knee, Hydracadence System.
L5611	Addition To Lower Extremity, Endoskeletal System, Above Knee—Knee Disarticulation, 4 Bar Linkage, With Friction Swing Phase Control.
L5613	Addition To Lower Extremity, Endoskeletal System, Above Knee-Knee Disarticulation, 4 Bar Linkage, With Hydraulic Swing Phase Control.
L5614	Addition To Lower Extremity, Exoskeletal System, Above Knee-Knee Disarticulation, 4 Bar Linkage, With Pneumatic Swing Phase Control.
L5616	Addition To Lower Extremity, Endoskeletal System, Above Knee, Universal Multiplex System, Friction Swing Phase Control.
L5617	Addition To Lower Extremity, Quick Change Self-Aligning Unit, Above Knee Or Below Knee, Each.
L5626	Addition To Lower Extremity, Test Socket, Hip Disarticulation.
L5628	Addition To Lower Extremity, Test Socket, Hemipelvectomy.
L5638	Addition To Lower Extremity, Below Knee, Leather Socket.
L5639	Addition To Lower Extremity, Below Knee, Wood Socket.
L5640	Addition To Lower Extremity, Knee Disarticulation, Leather Socket.
L5642	Addition To Lower Extremity, Above Knee, Leather Socket.
L5643	Addition To Lower Extremity, Hip Disarticulation, Flexible Inner Socket, External Frame.
L5644	Addition To Lower Extremity, Above Knee, Wood Socket.
L5645	Addition To Lower Extremity, Below Knee, Flexible Inner Socket, External Frame.
L5646	Addition To Lower Extremity, Below Knee, Air, Fluid, Gel Or Equal, Cushion Socket.
L5647	Addition To Lower Extremity, Below Knee Suction Socket.
L5648	Addition To Lower Extremity, Above Knee, Air, Fluid, Gel Or Equal, Cushion Socket.
L5649	Addition To Lower Extremity, Ischial Containment/Narrow M-L Socket.
L5650	Additions To Lower Extremity, Total Contact, Above Knee Or Knee Disarticulation Socket.
L5651	Addition To Lower Extremity, Above Knee, Flexible Inner Socket, External Frame.
L5653	Addition To Lower Extremity, Knee Disarticulation, Expandable Wall Socket.
L5661	Addition To Lower Extremity, Socket Insert, Multi-Durometer Symes.
L5665	Addition To Lower Extremity, Socket Insert, Multi-Durometer, Below Knee.
L5671	Addition To Lower Extremity, Below Knee/Above Knee Suspension Locking Mechanism (Shuttle, Lanyard Or Equal), Excludes Socket Insert.
L5673	Addition To Lower Extremity, Below Knee/Above Knee, Custom Fabricated From Existing Mold Or Prefabricated, Socket Insert, Silicone Gel, Elastomeric Or Equal, For Use With Locking Mechanism.
L5677	Additions To Lower Extremity, Below Knee, Knee Joints, Polycentric, Pair.
L5679	Addition To Lower Extremity, Below Knee/Above Knee, Custom Fabricated From Existing Mold Or Prefabricated, Socket Insert, Silicone Gel, Elastomeric Or Equal, Not For Use With Locking Mechanism.
L5681	Addition To Lower Extremity, Below Knee/Above Knee, Custom Fabricated Socket Insert For Congenital Or Atypical Traumatic Amputee, Silicone Gel, Elastomeric Or Equal, For Use With Or Without Locking Mechanism, Initial Only (For Other Than Initial, Use Code L5673 Or L5679).
L5682	Addition To Lower Extremity, Below Knee, Thigh Lacer, Gluteal/Ischial, Molded.
L5683	Addition To Lower Extremity, Below Knee/Above Knee, Custom Fabricated Socket Insert For Other Than Congenital Or Atypical Traumatic Amputee, Silicone Gel, Elastomeric Or Equal, For Use With Or Without Locking Mechanism, Initial Only (For Other Than Initial, Use Code L5673 Or L5679).
L5700	Replacement, Socket, Below Knee, Molded To Patient Model.
L5701	Replacement, Socket, Above Knee/Knee Disarticulation, Including Attachment Plate, Molded To Patient Model.
L5702	Replacement, Socket, Hip Disarticulation, Including Hip Joint, Molded To Patient Model.
L5703	Ankle, Symes, Molded To Patient Model, Socket Without Solid Ankle Cushion Heel (Sach) Foot, Replacement Only.
L5704	Custom Shaped Protective Cover, Below Knee.
L5705	Custom Shaped Protective Cover, Above Knee.
L5706	Custom Shaped Protective Cover, Knee Disarticulation.
L5707	Custom Shaped Protective Cover, Hip Disarticulation.
L5711	Additions Exoskeletal Knee-Shin System, Single Axis, Manual Lock, Ultra-Light Material.
L5716	Addition, Exoskeletal Knee-Shin System, Polycentric, Mechanical Stance Phase Lock.
L5718	Addition, Exoskeletal Knee-Shin System, Polycentric, Friction Swing And Stance Phase Control.
L5722	Addition, Exoskeletal Knee-Shin System, Single Axis, Pneumatic Swing, Friction Stance Phase Control.
L5724	Addition, Exoskeletal Knee-Shin System, Single Axis, Fluid Swing Phase Control.
L5726	Addition, Exoskeletal Knee-Shin System, Single Axis, External Joints Fluid Swing Phase Control.
L5728	Addition, Exoskeletal Knee-Shin System, Single Axis, Fluid Swing And Stance Phase Control.
L5780	Addition, Exoskeletal Knee-Shin System, Single Axis, Pneumatic/Hydra Pneumatic Swing Phase Control.
L5781	Addition To Lower Limb Prosthesis, Vacuum Pump, Residual Limb Volume Management And Moisture Evacuation System.
L5782	Addition To Lower Limb Prosthesis, Vacuum Pump, Residual Limb Volume Management And Moisture Evacuation System, Heavy Duty.
L5785	Addition, Exoskeletal System, Below Knee, Ultra-Light Material (Titanium, Carbon Fiber Or Equal).
L5790	Addition, Exoskeletal System, Above Knee, Ultra-Light Material (Titanium, Carbon Fiber Or Equal).
L5795	Addition, Exoskeletal System, Hip Disarticulation, Ultra-Light Material (Titanium, Carbon Fiber Or Equal).
L5810	Addition, Endoskeletal Knee-Shin System, Single Axis, Manual Lock.
L5811	Addition, Endoskeletal Knee-Shin System, Single Axis, Manual Lock, Ultra-Light Material.
L5812	Addition, Endoskeletal Knee-Shin System, Single Axis, Friction Swing And Stance Phase Control (Safety Knee).
L5814	Addition, Endoskeletal Knee-Shin System, Polycentric, Hydraulic Swing Phase Control, Mechanical Stance Phase Lock.
L5816	Addition, Endoskeletal Knee-Shin System, Polycentric, Mechanical Stance Phase Lock.

TABLE 10—PROPOSED MASTER LIST OF DMEPOS ITEMS POTENTIALLY SUBJECT TO FACE-TO-FACE ENCOUNTER AND WRITTEN ORDER PRIOR TO DELIVERY AND/OR PRIOR AUTHORIZATION REQUIREMENTS—Continued

HCPSCS	Long description
L5818	Addition, Endoskeletal Knee-Shin System, Polycentric, Friction Swing, And Stance Phase Control.
L5822	Addition, Endoskeletal Knee-Shin System, Single Axis, Pneumatic Swing, Friction Stance Phase Control.
L5824	Addition, Endoskeletal Knee-Shin System, Single Axis, Fluid Swing Phase Control.
L5826	Addition, Endoskeletal Knee-Shin System, Single Axis, Hydraulic Swing Phase Control, With Miniature High Activity Frame.
L5828	Addition, Endoskeletal Knee-Shin System, Single Axis, Fluid Swing And Stance Phase Control.
L5830	Addition, Endoskeletal Knee-Shin System, Single Axis, Pneumatic/Swing Phase Control.
L5840	Addition, Endoskeletal Knee/Shin System, 4-Bar Linkage Or Multiaxial, Pneumatic Swing Phase Control.
L5845	Addition, Endoskeletal, Knee-Shin System, Stance Flexion Feature, Adjustable.
L5848	Addition To Endoskeletal Knee-Shin System, Fluid Stance Extension, Dampening Feature, With Or Without Adjustability.
L5856	Addition To Lower Extremity Prosthesis, Endoskeletal Knee-Shin System, Microprocessor Control Feature, Swing And Stance Phase, Includes Electronic Sensor(S), Any Type.
L5857	Addition To Lower Extremity Prosthesis, Endoskeletal Knee-Shin System, Microprocessor Control Feature, Swing Phase Only, Includes Electronic Sensor(S), Any Type.
L5858	Addition To Lower Extremity Prosthesis, Endoskeletal Knee Shin System, Microprocessor Control Feature, Stance Phase Only, Includes Electronic Sensor(S), Any Type.
L5859	Addition To Lower Extremity Prosthesis, Endoskeletal Knee-Shin System, Powered And Programmable Flexion/Extension Assist Control, Includes Any Type Motor(S).
L5920	Addition, Endoskeletal System, Above Knee Or Hip Disarticulation, Alignable System.
L5930	Addition, Endoskeletal System, High Activity Knee Control Frame.
L5940	Addition, Endoskeletal System, Below Knee, Ultra-Light Material (Titanium, Carbon Fiber Or Equal).
L5950	Addition, Endoskeletal System, Above Knee, Ultra-Light Material (Titanium, Carbon Fiber Or Equal).
L5960	Addition, Endoskeletal System, Hip Disarticulation, Ultra-Light Material (Titanium, Carbon Fiber Or Equal).
L5961	Addition, Endoskeletal System, Polycentric Hip Joint, Pneumatic Or Hydraulic Control, Rotation Control, With Or Without Flexion And/Or Extension Control.
L5962	Addition, Endoskeletal System, Below Knee, Flexible Protective Outer Surface Covering System.
L5964	Addition, Endoskeletal System, Above Knee, Flexible Protective Outer Surface Covering System.
L5966	Addition, Endoskeletal System, Hip Disarticulation, Flexible Protective Outer Surface Covering System.
L5968	Addition To Lower Limb Prosthesis, Multiaxial Ankle With Swing Phase Active Dorsiflexion Feature.
L5973	Endoskeletal Ankle Foot System, Microprocessor Controlled Feature, Dorsiflexion And/Or Plantar Flexion Control, Includes Power Source.
L5976	All Lower Extremity Prostheses, Energy Storing Foot (Seattle Carbon Copy li Or Equal).
L5979	All Lower Extremity Prosthesis, Multi-Axial Ankle, Dynamic Response Foot, One Piece System.
L5980	All Lower Extremity Prostheses, Flex Foot System.
L5981	All Lower Extremity Prostheses, Flex-Walk System Or Equal.
L5982	All Exoskeletal Lower Extremity Prostheses, Axial Rotation Unit.
L5984	All Endoskeletal Lower Extremity Prosthesis, Axial Rotation Unit, With Or Without Adjustability.
L5986	All Lower Extremity Prostheses, Multi-Axial Rotation Unit (Mcp Or Equal).
L5987	All Lower Extremity Prosthesis, Shank Foot System With Vertical Loading Pylon.
L5988	Addition To Lower Limb Prosthesis, Vertical Shock Reducing Pylon Feature.
L5990	Addition To Lower Extremity Prosthesis, User Adjustable Heel Height.
L8035	Custom Breast Prosthesis, Post Mastectomy, Molded To Patient Model.
V2531	Contact Lens, Scleral, Gas Permeable, Per Lens (For Contact Lens Modification, See 92325).

VII. DMEPOS Competitive Bidding Program (CBP) Amendments

A. Background

Medicare pays for certain DMEPOS items and services furnished within competitive bidding areas based on the payment rules that are set forth in section 1847 of the Social Security Act (the Act) and 42 CFR part 414, subpart F. We propose to revise the existing DMEPOS Competitive Bidding Program (CBP) regulations in § 414.422(d) on change of ownership (CHOW) in recognition of the fact that CHOWs may occur on shorter timeframes than our regulations previously contemplated. We also propose to revise § 414.423(f) for the submission of a hearing request in notices of breach of contract.

B. Proposed Amendments

In § 414.422(d) we propose to revise the following amendments:

- We propose to add the acronym “CHOW” after the title of the paragraph and use the acronym throughout the section where we previously wrote out in full text “change of ownership”.
- We propose to remove the notification requirement at paragraph (d)(1) because we no longer believe it is necessary for CMS to be notified 60 days in advance when a contract supplier is negotiating a CHOW. In past rounds of the CBP, there have been situations in which contract suppliers have undergone CHOWs within the 60-day timeframe and they were unable to meet the 60-day notice requirement due to circumstances that were not fully within their control. We now recognize that the 60-day notice requirement is a bit onerous and as such we are proposing

to remove paragraph (d)(1) in its entirety. We are also proposing changes to the rest of paragraph (d).

- We propose to remove the distinction of a “new entity” from paragraph (d)(2)(ii) in its entirety, and retain the successor entity requirements in paragraph (d)(2)(i) with changes, as we are aligning the CHOW requirements for all entities, regardless of whether a “new” entity is formed as a result of the CHOW. We also propose to revise the requirement to submit the documentation described in § 414.414(b) through (d) from 30 days prior to the anticipated effective date of the CHOW to instead require submission prior to the effective date of the CHOW. We further propose to change the requirement on submission of a signed novation agreement 30 days before the CHOW to instead require that the novation agreement be submitted by

the successor entity no later than 10 days after the effective date of the CHOW. We want to allow flexibility for the timing of submission of documents since it may not always be possible for the successor entity to submit the applicable documentation 30 days before the anticipated effective date of the CHOW. Through our education and outreach efforts, we will encourage the successor entity to work with CMS to submit draft documentation as far in advance as possible for CMS to review to ensure that the novation agreement is acceptable to CMS. We believe shortening the timeframe for submission from 30 days to 10 days would expedite CMS's determination on whether to allow transfer of the contract to the successor entity. We also propose that the successor entity must submit a novation agreement that states that it assumes all obligations under the contract.

- We propose to remove the phrase "new qualified" before "entity" and replace it with the term "successor" in paragraph (d)(3) as this is applicable to all successor entities. We also propose to add the term "may" to make it clear that the transfer of the entire contract to a successor entity is at CMS' discretion upon CMS' review of all required documentation. The revision would align with existing language in paragraph (d)(4), which specifies that CMS may transfer the portion of the contract if certain conditions are met.

- We propose to revise paragraph (d)(4) by removing the "e.g." parenthetical after "distinct company" to retain only the example of a subsidiary, and noting it as "for example" as we realized that it is the clearest example. In addition, some of the other examples were not accurate (for example, a sole proprietor) and this could lead to confusion. We also propose to remove the reference to "new qualified" before "entity" and replace it with the term "successor," as the resulting entity in a transfer of a portion of the contract may not result in a "new" entity but would always result in a "successor" entity. In addition, we propose to remove the phrase "new qualified owner who" in paragraph (d)(4)(i) and replace it with "successor entity that" to align with the language used throughout § 414.422(d). We also propose to remove the acronym "i.e." and replace it with "that is."

In § 414.423(f)(2), we currently require that a request for a hearing be "received by" the Competitive Bidding Implementation Contractor (CBIC) within 30 days from the date of the notice of breach of contract. We propose to revise paragraph (f)(2) to specify that

the request for a hearing must be "submitted to" the CBIC rather than "received by" the CBIC. Previously, the CBIC was only able to receive a written request via mail or fax for a hearing from a contract supplier, however, now contract suppliers have a secure online method to submit hearing requests. Now that hearing requests can be submitted online, it will be apparent to all parties when the request for a hearing is submitted, as the date on which the request was received by the CBIC was not apparent to suppliers in the past. Furthermore, this revision aligns with language used throughout § 414.423.

We solicit public comments on these amendments and request that when commenting on this section, commenters reference "DMEPOS CBP Proposed Amendments."

VIII. Requests for Information

A. Data Collection

1. Technical Expert Panel on Improving the Reporting of Composite Rate Costs Under the ESRD PPS

a. Background

A Technical Expert Panel (TEP) was held on December 6, 2018 to discuss options for improving data collection to refine the ESRD PPS case-mix adjustment model. CMS contracted with a data contractor to convene this TEP and conduct research and analysis to refine the case-mix adjustment model. This TEP represented the first step in acquiring stakeholder and expert input to inform these refinements. The final TEP report and other materials can be found at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources.html.

The TEP was comprised of 16 expert stakeholders, including ESRD facilities, representatives of professional associations, independent academic clinical researchers, and patient advocates. In addition, a select number of observers attended, including representatives of governmental agencies and independent policy advisory groups. The TEP was organized into seven sessions, including an overview of the ESRD PPS and the cost components of dialysis treatment, four topical sessions corresponding to potential data collection strategies, and a final summary session.

b. Summary of the Data Contractor's Presentation to the TEP

i. Components of Dialysis Treatment Costs and Limitations of Current Data Collection

The data contractor's pre-TEP analysis of CY 2016 cost report data showed that composite rate costs comprise nearly 90 percent of average total treatment costs, with capital, direct patient care labor, and administrative costs representing approximately 88 percent of total average composite rate cost per treatment. Nevertheless, under current reporting practices, there are no data on the patient- and treatment-level variation in the cost of composite rate items and services. These findings underscore the importance of identifying variation in these costs to inform the development of a refined case-mix adjustment model.

ii. Data Collection Options

The data contractor presented the participants in the TEP with several options for optimizing data collection on composite rate items and services, and each option was specifically formulated to minimize reporting burden for ESRD facilities where possible. Feedback on these options and input on alternative approaches, as provided by the participants, would be used to further develop practical approaches for more accurate data collection.

Among the options presented for optimizing the collection of composite rate cost data were (1) improving the accuracy of charges and/or itemizing the use of composite rate services on claims; (2) reporting duration of each dialysis treatment session on claims (3) identifying and allocating costs to discrete categories of patients or patient characteristics that are associated with high cost of treatment; and (4) improving the reporting of facility-level costs. Each of these options is described in the following sections. The TEP participants' responses to these approaches are summarized in the Key Findings section at the end of this section. We note that our summary of the key findings is based on a review of the individual comments and is not meant to represent a consensus view shared by all TEP participants, but rather to consolidate related suggestions made by one or more participant.

iii. Improving the Accuracy of Charges

The data contractor presented two approaches for directly collecting data on the utilization of composite rate items and services. The first was to require more accurate reporting of

charges for each dialysis session. Recent analysis of charge data revealed little variation in charges for any given revenue center code associated with a dialysis treatment, indicating that facilities are using standardized charges. The second approach was to require itemized reporting of all or a limited number of high cost composite rate items and services. Beginning in 2015,³⁹ ESRD facilities were required to report selected composite rate services that were included on the Consolidated Billing List (CBL), however, the data contractor's analysis of reporting on use of these items showed that compliance has been minimal. Participants noted that these two options would be burdensome for ESRD facilities.

iv. Collection of Data on Duration of Dialysis Treatment

A singular option that would provide sufficient data to develop a refined case-mix adjustment model is the collection of dialysis treatment duration for each session. If dialysis session time were reported for each dialysis treatment, cost report and treatment-level data could be integrated to infer differences in composite rate costs across patients. In this paradigm, patient-level differences in composite rate costs could be attributed to two discrete categories: Differences due to dialysis treatment duration (measured in units of time) and differences unrelated to treatment duration. Treatment duration would not be used to directly adjust payment, rather, it would be used to apportion composite rate costs that are currently only observable at the facility level to the patient or treatment level for use in the case-mix adjustment. Data on the duration of dialysis session would allow for a proportionately higher proportion of composite rate costs to be allocated to patients with longer dialysis treatment times.

The data contractor provided examples of ways that longer duration of dialysis time might be associated with increased treatment costs, including utility costs, accelerated depreciation on equipment, and lower daily census counts, which, among other things, would result in increased per-treatment capital costs. Additional labor hours for a patient with longer treatments on average could increase per-treatment labor costs, and patients with increased use of dialysate and water treatment supplies or equipment

likely have higher average per-treatment supply costs.

The data contractor proposed two approaches to collect treatment duration data: (1) Use existing data from Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) on delivered dialysis minutes during the monthly session when a laboratory specimen is drawn to measure blood urea nitrogen (BUN) or (2) have ESRD facilities report treatment duration on Medicare claims. For the latter, treatment duration data could be reported by using a new HCPCS or revenue center code to indicate units of treatment time for each dialysis treatment or by updating the definition of the existing revenue center code for dialysis treatments so that the units correspond to treatment time instead of the number of treatments. ESRD facilities already report to CMS a single monthly treatment time in CROWNWeb for in-facility treatments, indicating that facilities currently collect treatment duration.⁴⁰ Moreover, many ESRD facilities' electronic health records (EHR) systems automatically collect this information for every dialysis treatment, minimizing additional burden of reporting this metric on claims.

v. Capturing Variation in Costs Associated With Complex Patients

Participants on the TEP also discussed the variation in composite rate costs that is independent of treatment duration and associated with severity of illness or disability in the dialysis patient population. In preparation for the TEP, the data contractor interviewed a number of ESRD facilities to identify sources of composite rate cost variation associated with the provision of care to more complex patients. Patient level-factors identified during the course of these interviews and during the TEP included seven points: (1) Maintenance of isolation rooms and use of dedicated nurses to attend patients with active hepatitis B infection; (2) treatment and care for incident dialysis patients (first 120 days); (3) treatment and care for catheterized patients; (4) pre- and post-dialysis session care for non-ambulatory patients; (5) treatment and care for pediatric patients; (6) treatment of patients exhibiting behavioral problems related to mental illness/drug

dependency; and (7) treatment and care for home dialysis patients.

During the TEP, participants identified additional factors associated with higher treatment costs. These included hemodynamic instability, dual eligibility for Medicare and Medicaid, depression or mental illness, poor functional status, no primary caregiver, and institutionalized status or incarcerated or residence in a skilled nursing facility.

A common thread among these factors is that they all require more intense use of labor, especially direct patient care staff and highly specialized nursing or social work care or other intervention, such as would be provided by staff to assist in transfer for non-ambulatory patients.

The data contractor described alternative approaches for collecting sufficient data on these composite rate costs to inform a refined case-mix adjustment model. The first would entail reporting such items and services as line items on the claim. The second would involve grouping patients into a set of "high-risk" or "high-cost" patient types, in a hierarchical fashion and apportioning costs to each patient grouping based on known use of services.

vi. Facility-Level Costs

The TEP also included discussion of facility-level costs, identifying drivers of these costs, and the ESRD facility characteristics that may result in cost differences across facility types and potential revisions to the cost reports to better capture these costs. Participants on the TEP indicated that drivers of facility-level costs include: (1) Facility size (treatment volume and treatment capacity), which affects economies of scale; (2) geographic location, which affects both input prices and wages; (3) hospital versus freestanding status; (4) ownership type; and (5) whether the facility offers specialized services, such as pediatric or home dialysis treatment. These facility characteristics can affect both capital and labor costs, as well as the costs for drugs, laboratory tests and supplies.

c. Key Findings

Based on a review of the individual participant responses to each of the data collection options, CMS has summarized key conclusions in the following sections. The sections are arranged in the order of the topical sessions, as they were presented earlier.

³⁹ Department of Health and Human Services. Centers for Medicare and Medicaid Services. Change Request 8978. December 2, 2014 (pp 3–4). <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R200BP.pdf>.

⁴⁰ Centers for Medicare & Medicaid Services (CMS) End-Stage Renal Disease Quality Incentive Program (ESRD QIP) Payment Year (PY) 2021 Measure Technical Specifications. Page 23. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/PY-2021-Technical-Specifications-.pdf>.

i. Components of Dialysis Treatment Costs and Limitations of Current Data Collection

During this session, the participants agreed that capital, labor, and administrative costs make up the majority of composite rate costs. They stated that the level of complexity of dialysis patients has been increasing over time, and noted some costs at the margins (for example, information technology costs) that are not reflected in cost reports. Participants were averse to reporting individualized charges to reflect treatment-level variation in the items and services provided, unless this reporting was somehow linked to payment.

ii. Duration of Dialysis Treatment

To record time on dialysis, participants preferred that the data be collected on Medicare claims. They did not support using existing CROWNWeb data on treatment duration, as there were too many questions about its completeness and timeliness. They agreed that if duration of dialysis treatment time is collected on claims that it should be reported in actual minutes dialyzed and not, for example, in 15-minute increments. The participants cautioned that reporting time on dialysis on the claims would place additional burden on facilities, but for facilities with EHRs, the burden associated with the collection of dialysis treatment time is expected to be small and temporary because the information is already collected. Collecting time on dialysis could be difficult to accomplish for ESRD facilities that do not use EHRs. Some participants maintained that certain factors related to patient complexity—such as comorbidities and mental health status—that are associated with treatment costs are unrelated to treatment duration.

iii. Identifying Costs Associated With Complex Patients

The participants expressed support for improving consistency in cost reporting across facilities. They recommended clarifying cost report instructions to ensure comparable reporting across facilities. They agreed that labor is the major source of patient-level cost variation, but expressed concern that allocating labor costs to the patient level or even the patient type would pose significant challenges. The participants noted that certain high-cost items and services used to treat complex patients, such as isolation rooms or lifts, could be easily itemized on claims and reported in cost reports. They proposed alternative approaches for quantifying

resource use associated with complex patients, such as classifying resource use by intensity of care provided or tracking staff time across patients.

iv. Facility-Level Costs

The participants stated that there are differences in cost at the facility level associated with the characteristics presented in the Facility-level Drivers of Cost session. They noted EHR practices are also associated with variation in facility-level cost. In addition, they emphasized that treatment volume relative to capacity has a significant financial impact on dialysis facilities; however, these costs currently are not reflected in cost reports. They also suggested that it might be beneficial to reflect missed treatments through a capacity utilization measure on the cost report and this could distinguish between more costly missed treatments and less costly planned absences, as the latter can be adjusted so that the facility chair is filled. The participants also indicated that rural facilities have costs not incurred by non-rural facilities, even among facilities with similar treatment volume, and do not believe the low volume payment adjustment and rural adjuster to be redundant.

d. Summary

This TEP focused on data collection on composite rate costs to inform the development of a more refined case-mix adjustment model for the ESRD PPS. Currently two equations are used to calculate the base rate for payment: (1) One at the facility level and, (2) one at the patient or treatment level—because items in the composite rate are not collected at the patient level.⁴¹

While formerly separately billable items and services are itemized at the treatment level on claims and also reflected in cost reports, composite rate services, which comprise the bulk of the total costs for dialysis treatment are not itemized and can only be estimated at the facility level from cost reports. Charges for these services, as reported on claims, show little variation across facilities and cannot be used for estimating patient- or treatment-level variation in cost. Solutions for optimizing data collection on individual use of composite rate services were proposed by the data contractor and discussed by the participants. CMS' current goal, as emphasized throughout the TEP, is to explore options to improve the identification of per-treatment composite rate costs, and we

invite comment on all of the options proposed during this TEP and discussed as part of this comment solicitation. We agree with the participants on the TEP that the benefits of improving the ESRD PPS case-mix adjustment model must be weighed against any additional ESRD facility burden that could result from changes to claims and cost reporting.

e. Solicitation for Input and Comment: Improving Data Collection on Composite Rate Costs

CMS seeks input on options for improving the reporting of composite rate costs for the ESRD PPS. We believe improved reporting of both patient level costs, as reported on claims, and facility level costs, as reported on cost reports, is needed in order to obtain sufficient, high quality data to inform a refined case mix adjusted model for the ESRD PPS. We are seeking comments on, or elaborations of, the options presented and discussed during the TEP, described previously in section VIII.A.1.b.ii of this proposed rule, as well as novel approaches for improving the reporting of patient-level and facility-level costs that are not described here. CMS will consider new input from stakeholders as we develop methodologies for implementing select changes to claims and cost reports that serve to elucidate composite rate costs. CMS has not endorsed any particular method or option at this time.

i. Input Sought on Identifying Components of Composite Rate Costs

During the TEP, the data contractor identified six cost components comprising composite rate costs for the ESRD PPS. These include: (1) Capital, (2) administrative, (3) labor, (4) drug, (5) laboratory and, (6) supply costs. Options were presented to improve the precision and accuracy of reporting costs for each component. Data on costs of some components, including capital, administrative and labor, are found chiefly in facility cost reports and reflect spending at the facility level. These facility-level costs, in combination with treatment counts can be used to estimate patient or treatment level composite rate costs. Data on other cost components, including drugs, laboratory tests and supplies, can be found both on the cost reports and on claims, however composite rate laboratory and supply costs are not specified on the cost report. Basic treatment charges are seen to vary little across patients or across facilities. Cost report data were questioned by the participants with regard to their accuracy and reliability.

Therefore, CMS seeks further input on ways to improve (1) the accuracy of

⁴¹ Medicare Claims Processing Manual, Chapter 8—Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims. (Rev. 4202, 01–18–19). Page 7/143.

charges and (2) the precision and reliability with which cost composite rate costs are identified and reported in cost reports.

Commenters are invited to submit their responses to the following questions and requests:

- Do the six cost components include all aspects of dialysis treatment costs covered by Medicare?

- ++ If not, please describe any further component costs within each component?

- ++ Within each component, are there significant costs that are not currently captured in cost reports?

- The data contractor found that most composite rate costs are embedded in the capital, administrative and labor components. Given the relatively small contribution of drugs, laboratory tests, and supplies to composite rate costs, is there a justification for any further consideration of composite rate costs from capital, labor and administrative components?

- Why is there such limited variation in reported charges? Would it be useful to focus on improving reporting of these charges instead of collecting new information on cost reports or claims? Why is there such limited reporting of costs for items and services included in the CBL? Are there subsets of composite rate items and services that could be successfully reported on claims?

ii. Input Sought on Collection of Duration of Treatment Data

During the TEP, the data contractor proposed a paradigm by which to consider select changes to cost reporting that would reveal patient-level variation in costs, differentiating costs by those which can be attributed to dialysis treatment duration and those unrelated to treatment duration. Capturing data on these two types of differences was the thrust of the discussion during much of the TEP. CMS seeks further input on these two elements of cost differential.

Dialysis session duration data could be used to refine calculations of per-treatment costs by increasing specificity in the allocation of composite rate costs. Applying this change only to current data collection practices would suffice to account for treatment level differences in costs due to length of treatment. Duration data would allow for the distribution of composite rate component costs in such a way that a higher proportion of a facility's composite rate costs could be attributed to patients with longer dialysis treatment times. This would improve the precision with which costs for the use of such composite rate items and

services as capital equipment use, water treatment and dialysate are allocated.

We invite comments on the option of collecting duration of treatments data, including responses to the following questions:

- Which of the six composite rate cost components (capital, administrative, labor, drug, laboratory, and supply costs) are most likely to vary with treatment duration?

- Should new information for these cost components be collected on cost reports, for use in better inferring the composite rate costs associated with treatment duration? If yes, please describe the additional information that would be needed and how this information could be used.

- Describe any challenges that would be encountered by ESRD facilities in reporting treatment duration, using a line item corresponding to units of time as a new revenue center code on the claim.

- Describe any alternatives to the use of dialysis treatment duration that could be used as a proxy for intensity of resource utilization and which can be reported at the patient/treatment level.

- Do facilities record the total time the patient spends in the facility before and after the actual dialysis treatment time, as well as the duration of the actual dialysis treatment? If so, please describe any obstacles to reporting this information on the claim.

iii. Input Sought on Collection of Data To Identify Sources of Variation in Treatment Costs Associated With Complex Patients

The data contractor presented a list of conditions, identified during pre-TEP interviews with ESRD facilities, associated with higher cost treatment for dialysis patients. During the TEP, the participants added to this list. The combined list of these conditions is described in section VIII.A.1.b.v of this proposed rule.

The data contractor also presented alternative approaches for collecting sufficient data on these composite rate costs so as to inform a refined case-mix model. One approach would entail reporting such items and services as line items on the claim. The second would involve grouping patients into a set of "high risk" or "high cost" patient types, in a hierarchical fashion, and apportioning costs to each patient grouping based on known use of services. There was no consensus among participants with regard to the best way to capture these costs.

CMS solicits comments and suggestions about how to best capture these costs. Some questions to consider

include the following: First, to the extent labor is the dominant source of variation in cost in providing dialysis services to complex patients, please describe the amount and type of labor required to care for patients with the conditions described above or any other conditions which complicate the provision of basic dialysis treatment. Second, please describe other dimensions of dialysis care and treatment for which composite rate costs vary independent of treatment duration. Third, are there discrete, high-cost composite rate items and services that vary at the patient level that could be feasibly itemized on claims? Fourth, how could a set of mutually exclusive, exhaustive patient groups be constructed to incorporate patients with common patterns of resource use? Fifth, what challenges might be faced in implementing the proposed reporting solutions (a) on claims and (b) on cost reports? Sixth, are pediatric and home dialysis costs accurately apportioned across cost components in cost reports? If not, please describe.

iv. Input Sought on Collection of Facility-Level Data

During the TEP the data contractor presented a framework for considering facility-level drivers of cost, which meet two criteria: (i) They are independent of patient-level factors, and (ii) they affect the cost of dialysis treatment. The TEP debated each criterion for facility-level cost drivers, including facility size and realized treatment capacity. Geographic location affects wages and prices of goods and services. While some commenters have suggested that rural ESRD facilities incur higher costs, the data contractor's analysis of 2016 cost report data for the December 2018 TEP indicates that overall composite rate costs for rural facilities may be lower than for urban facilities. Further analysis by cost component suggests that with the exception of drug costs, urban facilities incur higher costs for each composite rate cost component. Ownership and other organizational factors, such as whether the facility administers a home dialysis program or serves the pediatric population also have a bearing on cost.

CMS seeks input from stakeholders regarding the further identification of facility-level drivers of cost, especially those that affect the cost of composite rate services. Please consider the following questions: First, what facility level factors should be added or further specified in the cost report to better reflect actual facility costs for the provision of composite rate items and services? Second, what are costs

incurred by pediatric dialysis units that do not vary at the patient-level? Third, what types of costs do facilities providing home dialysis services incur that do not vary at the patient-level? Fourth, how do variations in drivers of facility costs affect composite rate costs at the facility level? Fifth, to what extent are these composite rate costs outside the facility's control? Sixth, what are the challenges or barriers to reporting missed treatments on claims and/or cost reports?

v. Other Input Needed

We also seek to gather responses to the following questions that arose during the TEP. Answers to these questions from the stakeholder community will help us to develop and refine reporting options for composite rate costs.

Beginning January 1, 2015, ESRD facilities have been required to itemize on claims the use of composite rate drugs listed on the CBL.⁴² As presented at the TEP, the data contractor's analysis of 2016 claims data revealed that approximately 40 percent of facilities were not reporting these items. We are requesting that commenters identify any obstacles that might be preventing ESRD facilities from reporting the use of these composite rate drugs. Also, are there any drugs listed in the most recent CBL that are particularly challenging to report? If there are, please describe those challenges.

The participants mentioned that Medicare Advantage and other secondary payers will sometimes reject claims that include billing for certain items and services, such as oral medications. We are requesting comments on the specific billing practices that lead to such claims being rejected, along with the specific items and services that are rejected by payers.

The participants expressed reservations about the reliability of cost report data and also about the comparability of cost reports between freestanding and hospital-based ESRD facilities.

We are also soliciting comments regarding suggested specific changes to the cost reports or cost report instructions that would be most useful to improve the consistency of reporting across facilities.

We solicit public comments for the request for information regarding data collection and request that when commenting on this section,

commenters reference "RFI—Data Collection."

B. Wage Index Comment Solicitation

As discussed in section II.B.5.b of this proposed rule, historically, we have calculated the ESRD PPS wage index values using unadjusted wage index values from another provider setting. Stakeholders have frequently commented on certain aspects of the ESRD PPS wage index values and their impact on payments. We are soliciting comments on concerns stakeholders may have regarding the wage index used to adjust the labor-related portion of the ESRD PPS base rate and suggestions for possible updates and improvements to the geographic wage index payment adjustment under the ESRD PPS.

We solicit public comments for the request for information regarding the wage index and request that when commenting on this section, commenters reference "RFI—Wage Index."

C. Comment Solicitation on Sources of Market-Based Data Measuring Sales of Diabetic Testing Strips to Medicare Beneficiaries (Section 50414 of the Bipartisan Budget Act of 2018)

1. Background

Section 1847(a)(2)(A) of the Act mandates competitive bidding programs for "covered items" and supplies used in conjunction with DME such as blood glucose monitors used by beneficiaries with diabetes. The supplies used with these blood glucose monitors (such as blood glucose test strips and lancets) are referred to under the DMEPOS CBP as diabetic supplies or diabetic testing supplies. In the April 10, 2007 final rule published in the **Federal Register** titled "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues" (72 FR 17992), which implemented the DMEPOS CBP, we established regulations to implement competitions on a regional or national level for certain items such as diabetic testing supplies that are furnished on a mail order basis. We explained our rationale for establishing a national DMEPOS CBP for items furnished on a mail order basis in the May 1, 2006 proposed rule published in the **Federal Register** titled "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues" (71 FR 25669) and in the April 2007 final rule (72 FR 18018).

On January 16, 2009, we published an interim final rule in the **Federal**

Register titled "Medicare Program; Changes to the Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) by Certain Provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)" that implemented certain changes to the DMEPOS CBP (74 FR 2873). Specifically, the rule implemented section 154 of MIPPA (Pub. L. 110–275), which delayed implementation of Round One of the program, required CMS to conduct a second Round One competition in 2009, and mandated certain changes for both the Round One Rebids and subsequent rounds of the program. In the January 2009 interim final rule, we indicated that we would be considering alternatives for competition of diabetic testing supplies in future notice and comment rulemaking.

On July 13, 2010 we published a proposed rule in the **Federal Register** titled "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011" (75 FR 40211), in which we discussed alternatives for competition of diabetic testing supplies and proposed the implementation of a revised national mail order CBP for diabetic testing supplies. Under the proposed mail order DMEPOS CBP, we would award contracts to suppliers to furnish these items across the nation to beneficiaries who elect to have replacement diabetic testing supplies delivered to their residence. Suppliers wishing to furnish these items through the mail to Medicare beneficiaries would be required to submit bids to participate in the national mail order CBP for diabetic testing supplies.

Section 154(d) of MIPPA modified section 1847(b)(10) of the Act to prohibit CMS from awarding a contract to a supplier of diabetes test strips if the supplier's bid does not cover at least 50 percent, by volume, of all types of diabetes test strips on the market. With respect to any competition for diabetic testing strips after the first round of competition, a supplier must demonstrate that its bid to furnish diabetic testing strips covers the types of diabetic testing strip products that, in the aggregate and taking into account volume for the different products, cover at least 50 percent of all such types of products on the market. CMS and the CBIC refer to this rule as the "50 percent rule."⁴³ Section 1847(a)(10)(A) of the

⁴² Department of Health and Human Services. Centers for Medicare and Medicaid Services. Change Request 8978. December 2, 2014 (pp 3–4). <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R200BP.pdf>.

⁴³ [https://www.dmecompetitivebid.com/Palmetto/Cbic.nsf/files/R2_Fact_Sheet_Mail-Order_Diabetic_Supplies.pdf/\\$File/R2_Fact_Sheet_Mail-Order_Diabetic_Supplies.pdf](https://www.dmecompetitivebid.com/Palmetto/Cbic.nsf/files/R2_Fact_Sheet_Mail-Order_Diabetic_Supplies.pdf/$File/R2_Fact_Sheet_Mail-Order_Diabetic_Supplies.pdf).

Act also specified that the volume for the different products may be determined in accordance with data (which may include market based data) recognized by the Secretary.

Section 1847(b)(10)(B) of the Act mandated that the Office of Inspector General (OIG) conduct a study before 2011 to determine the types of diabetic testing strips by volume that could be used by CMS for the purpose of evaluating bidders in the national mail order CBP for diabetic testing supplies. Under the DMEPOS CBP, bidding suppliers are required to provide information on the products they plan to furnish if awarded a contract. We proposed in the July 2010 proposed rule (75 FR 40211) to use information submitted by bidding suppliers and information on the market share (volume) of the various diabetic testing strip products to educate suppliers on meeting the requirements of this special 50 percent rule. We noted that it may be necessary to obtain additional information from suppliers such as invoices or purchase orders to verify that the requirements in the statute have been met (75 FR 40214). We proposed that suppliers be required to demonstrate that their bids cover the minimum 50-percent threshold provided in the statute, but we invited comments on whether a higher threshold should be used (75 FR 40214). We proposed the 50 percent threshold in part because we believed that all suppliers have an inherent incentive to furnish a wide variety of types of diabetic testing products to generate a wider customer referral base (75 FR 40214). The 50 percent threshold would ensure that beneficiaries have access to mail order delivery of the top-selling diabetic test strip products (75 FR 40214). In addition, we proposed an “anti-switching provision” that we said would obviate the need to establish a threshold of greater than 50 percent for the purpose of implementing this special rule because the contract suppliers would not be able to carry a limited variety of products and switch beneficiaries to those products (75 FR 40214). For purposes of implementing the special rule in section 1847(b)(10)(A) of the Act, we proposed to define “diabetic testing strip product” as a specific brand and model of test strip, as we said that was the best way to distinguish among different products (75 FR 40214). Therefore, we planned to use market based data for specific brands and models of diabetic test strips to determine the relative market share or volume of the various products on the market that are

available to Medicare beneficiaries (75 FR 40214). We said we would apply this rule to non-mail order competitions and/or local competitions conducted for diabetic testing strips after Round One of the DMEPOS CBP (75 FR 40214).

In the November 29, 2010 final rule with comment period published in the **Federal Register** titled “Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011” (75 FR 73567), we established requirements for the national mail order CBP for diabetic testing supplies. We finalized the proposed special 50 percent rule mandated by section 1847(b)(10)(A) of the Act (75 FR 73611). We finalized our proposal to require each bidder in the national mail order CBP for diabetic testing supplies to demonstrate that its bid covers types of diabetic testing strip products that, in the aggregate and taking into account volume for the different products, cover 50 percent (or such higher percentage as the Secretary may specify) of all such types of products (75 FR 73611). We said that the 50 percent threshold would ensure that beneficiaries have access to mail order delivery of the top selling diabetic test strip products from every contract supplier, and we adopted the 50 percent rule because we believed this was reflective of what suppliers were currently doing and ensured appropriate access for beneficiaries (75 FR 73611). We also said that the OIG was conducting a study to generate volume data for various diabetic testing strip products furnished on a mail order basis (75 FR 73572). We said that we would use this data as guidance to implement this special rule for mail order contract suppliers and ensure that their bids cover at least 50 percent of the volume of testing strip products currently furnished to beneficiaries via mail order (75 FR 73572). The OIG was required to complete their study before 2011 and we said we would make their data available to the public (75 FR 73572).

The OIG released its study in 2010, and the OIG has since determined the market shares of the types of diabetes test strips before each round of competitive bidding.⁴⁴ The data from this series of reports informs CMS about the types of diabetes test strips that suppliers provide to Medicare beneficiaries via mail order.

2. Current Issues

The Bipartisan Budget Act of 2018 (BBA) was enacted on February 9, 2018, and section 50414 of the BBA amended

section 1847(b)(10)(A) of the Act to establish additional rules for the competition for diabetic testing strips. Section 1847(b)(10)(A) of the Act now requires that for bids to furnish diabetic testing strips on or after January 1, 2019, the volume for such products be determined by the Secretary through the use of multiple sources of data (from mail order and non-mail order Medicare markets), including market-based data measuring sales of diabetic testing strip products that are not exclusively sold by a single retailer from such markets.

The OIG reports to CMS the Medicare Part B market share of mail order diabetic test strips before each round of the Medicare national mail order CBP, and pursuant to section 1847(b)(10)(A) of the Act, the OIG will now report on the non-mail order diabetic test strip Medicare Part B market. On January 19, 2019, the OIG released a report that documented the Medicare Part B market share of mail order diabetic test strips for the 3-month period of April through June 2018.⁴⁵ On March 19, 2019, the OIG released another report that documented the Medicare Part B market share of non-mail-order diabetic test strip for the same 3-month period.⁴⁶ These data briefs represent OIG’s third round of diabetic test strip Medicare market share reports since 2010, but this is the first series of reports that includes non-mail-order diabetic test strip data.⁴⁷

Because section 1847(b)(10)(A) of the Act now requires the use of “multiple sources of data,” we are requesting public comments on other potential sources of data (sources other than the OIG), that fulfill the data requirements set forth in section 1847(b)(10)(A) of the Act. We are requesting comments on other potential sources of data because the word “multiple” in the phrase “multiple sources of data” could mean that we should use more than one source of data, and that the OIG is one source of data. We are therefore requesting comments from the public on other potential sources of data regarding the mail order and non-mail order Medicare markets for diabetic testing strips through this request for information. In particular, we are seeking data that:

- Has a sufficient sample size, and is unbiased and credible;
- Separately provides the market shares of the mail-order Medicare Part B market, and the non-mail order Medicare Part B market (does not combine the two markets into one); and

⁴⁵ <https://oig.hhs.gov/oei/reports/oei-04-18-00440.pdf>.

⁴⁶ <https://oig.hhs.gov/oei/reports/oei-04-18-00441.pdf>.

⁴⁴ <https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000311.asp>.

- Includes market-based data measuring sales of diabetic testing strip products that are not exclusively sold by a single retailer from such markets.

IX. Collection of Information Requirements

A. Legislative 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 requirement 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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

Using the following format describe the information collection requirements that are in each section.

B. Requirements in Regulation Text

In sections II.B.1, II.B.2 and II.B.3 of this proposed rule, we are proposing changes to regulatory text for the ESRD PPS in CY 2020. However, the changes that are being proposed do not impose any new information collection requirements.

C. Additional Information Collection Requirements

This proposed rule does not impose any new information collection requirements in the regulation text, as specified above. However, there are changes in some currently approved information collections. The following is a discussion of these information collections.

1. ESRD QIP—Wage Estimates

To derive wages estimates, we used data from the U.S. Bureau of Labor Statistics' May 2018 National Occupational Employment and Wage Estimates. In the CY 2016 ESRD PPS

final rule (80 FR 69069), we stated that it was reasonable to assume that Medical Records and Health Information Technicians, who are responsible for organizing and managing health information data, are the individuals tasked with submitting measure data to CROWNWeb and NHSN, as well as compiling and submitting patient records for purpose of the data validation studies, rather than a Registered Nurse, whose duties are centered on providing and coordinating care for patients. The mean hourly wage of a Medical Records and Health Information Technician is \$21.16 per hour.⁴⁸ Fringe benefit and overhead are calculated at 100 percent. Therefore, using these assumptions, we estimate an hourly labor cost of \$42.32 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP. We have adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. These are necessarily rough adjustments, 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, there is no practical alternative and we believe that these are reasonable estimation methods.

We used this updated wage estimate, along with updated facility and patient counts as well as a refined estimate of the time spent completing data entry for reporting data, to re-estimate the total information collection burden in the ESRD QIP for PY 2022 that we discussed in the CY 2019 ESRD QIP final rule (83 FR 57050 through 57052) and to estimate the total information collection burden in the ESRD QIP for PY 2023. We provide the re-estimated information collection burden associated with the PY 2022 ESRD QIP and the newly estimated information collection burden associated with the PY 2023 ESRD QIP in sections IV.C.2 and IV.C.3 of this proposed rule.

2. Estimated Burden Associated With the Data Validation Requirements for PY 2022 and PY 2023

In the CY 2019 ESRD PPS final rule, we finalized a policy to adopt the CROWNWeb data validation methodology that we previously adopted for the PY 2016 ESRD QIP as the methodology we would use to validate CROWNWeb data for all payment years, beginning with PY 2021

(83 FR 57001 through 57002). Under this methodology, 300 facilities would be selected each year to submit to CMS not more than 10 records, and we would reimburse these facilities for the costs associated with copying and mailing the requested records. The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. We estimated that the aggregate cost of the CROWNWeb data validation each year will be approximately \$30,885 (750 hours × \$41.18), or an annual total of approximately \$103 (\$30,885/300 facilities) per facility in the sample. In this proposed rule, we are updating these estimates using a newly available wage estimate of a Medical Records and Health Information Technician and have made no other changes to our methodology for calculating the annual burden associated with the CROWNWeb validation study. We estimate that it would take each facility approximately 2.5 hours to comply with this requirement. If 300 facilities are asked to submit records, we estimate that the total combined annual burden for these facilities would be 750 hours (300 facilities × 2.5 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff would submit these data, we estimate that the aggregate cost of the CROWNWeb data validation each year would be approximately \$31,740 (750 hours × \$42.32), or an annual total of approximately \$105.80 (\$31,740/300 facilities) per facility in the sample. The increase in our burden estimate is due to an updated wage estimate for Medical Records and Health Information Technicians or similar staff and is not the result of any policies proposed in this proposed rule. The burden associated with these requirements is captured in an information collection request (OMB control number 0938–1289).

In section IV.B.7 of this proposed rule, we propose to continue in PY 2023 and subsequent payment years the NHSN data validation study using the methodology finalized in the CY 2019 ESRD PPS final rule for PY 2022 (83 FR 57001 through 57002) and to adopt the NHSN validation study as a permanent feature of the ESRD QIP. Under this methodology, we would select 300 facilities for participation in the PY 2023 validation study. A CMS contractor would send these facilities requests for 20 patients' records for each of the first 2 quarters of CY 2021 (for a total of 40 patient records per facility).

⁴⁸ <https://www.bls.gov/oes/current/oes292071.htm>.

The burden associated with these data validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. Using the newly available wage estimate of a Medical Records and Health Information Technician, we estimate that it would take each facility approximately 10 hours to comply with this requirement. If 300 facilities are asked to submit records, we estimate that the total combined annual burden for these facilities would be 3,000 hours (300 facilities \times 10 hours). Since we anticipate that Medical Records and Health Information Technicians or similar staff would submit these data, we estimate that the aggregate cost of the NHSN data validation each year would be approximately \$126,960 (3,000 hours \times \$42.32), or a total of approximately \$423.20 (\$126,960/300 facilities) per facility in the sample. The increase in our burden estimate is due to an updated wage estimate for Medical Records and Health Information Technicians or similar staff and is not the result of any policies proposed in this proposed rule. The burden associated with these requirements is captured in an information collection request (OMB control number 0938–1340).

3. CROWNWeb Reporting Requirements for PY 2022 and PY 2023

To determine the burden associated with the CROWNWeb reporting requirements, we look at the total number of patients nationally, the number of data elements per patient-year that the facility would be required to submit to CROWNWeb for each measure, the amount of time required for data entry, the estimated wage plus benefits applicable to the individuals within facilities who are most likely to be entering data into CROWNWeb, and the number of facilities submitting data to CROWNWeb. In the CY 2019 ESRD PPS final rule, we estimated that the burden associated CROWNWeb reporting requirements for the PY 2022 ESRD QIP was approximately \$202 million. We are not proposing any changes that would affect the burden associated with CROWNWeb reporting requirements for PY 2022 or PY 2023. However, we have re-calculated the burden estimate for PY 2022 using updated estimates of the total number of dialysis facilities, the total number of patients nationally, and wages for Medical Records and Health Information Technicians or similar staff as well as a refined estimate of the number of hours needed to complete data entry for CROWNWeb reporting. In the CY 2019 ESRD PPS final rule, we

estimated that the amount of time required to submit measure data to CROWNWeb was 2.5 minutes per element and used a rounded estimate of 0.042 hours in our calculations. In this proposed rule, we did not use a rounded estimate of the time needed to complete data entry for CROWNWeb reporting. As a result of these changes in the methodology, we estimate that the PY 2022 burden is \$205 million (or 4.8 million hours), and the net incremental burden from PY 2022 to PY 2023 is \$0 (or 0 hours).

X. 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 preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

XI. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal

governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimate that this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that to the best of our ability presents the costs and benefits of the rulemaking.

We solicit comments on the regulatory impact analysis provided.

2. Statement of Need

a. ESRD PPS

This rule proposes a number of routine updates and several policy changes to the ESRD PPS in CY 2020. The proposed routine updates include the CY 2020 wage index values, the wage index budget-neutrality adjustment factor, and outlier payment threshold amounts. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2020 for renal dialysis services furnished to ESRD patients.

b. AKI

This rule also proposes routine updates to the payment for renal dialysis services furnished by ESRD facilities to individuals with AKI. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2020 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

c. ESRD QIP

This rule proposes to implement requirements for the ESRD QIP, including proposals to modify the scoring methodology for the NHSN Dialysis Event reporting measure beginning with the PY 2022 ESRD QIP; a proposal to convert the STR clinical measure to a reporting measure; and a proposal to convert the NHSN validation study into a permanent feature of the program using the

methodology finalized for the PY 2022 NHSN validation study. In addition, we are proposing to establish CY 2021 and CY 2019 as the performance period and baseline period, respectively, for the PY 2023 ESRD QIP for all measures. For future ESRD QIP payment years, we propose to adopt automatically a performance and baseline period for each year that is 1 year advanced from those specified for the previous payment year.

d. DMEPOS

i. Establishing Payment Amounts for New DMEPOS Items and Services (Gap-Filling)

This rule proposes to establish a gap-filling methodology.

ii. Adjusting Payment Amounts for DMEPOS Items and Services Gap-Filled Using Supplier or Commercial Prices

This rule proposes a method for making a one-time adjustment to the gap-filled fee schedule amounts in cases where prices decrease by less than 15 percent within 5 years of establishing the initial fee schedule amounts.

e. Conditions of Payment To Be Applied to Certain DMEPOS Items

This proposed rule would streamline the requirements for ordering DMEPOS items. It would also develop one Master List of DMEPOS items potentially subject to a face-to-face encounter, written orders prior to delivery and/or prior authorization requirements under the authority provided under sections 1834(a)(1)(E)(iv), 1834(a)(11)(B), and 1834(a)(15) of the Act.

3. Overall Impact

a. ESRD PPS

We estimate that the proposed revisions to the ESRD PPS would result in an increase of approximately \$210 million in payments to ESRD facilities in CY 2020, which includes the amount associated with updates to the outlier thresholds, payment rate update, updates to the wage index, and the proposal to change the basis of payment for the TDAPA for calcimimetics from ASP+6 percent to ASP+0 percent. These figures do not reflect estimated increases or decreases in expenditures based on our proposals to refine the TDAPA eligibility criteria, condition the TDAPA on ASP data availability, and provide a transitional add-on payment adjustment for new and innovative renal dialysis equipment and supplies. The fiscal impact of these proposals cannot be determined due to the uniqueness of the new renal dialysis drugs and biological products and new renal

dialysis equipment and supplies and their costs.

b. AKI

We are estimating approximately \$42 million that would now be paid to ESRD facilities for dialysis treatments provided to AKI beneficiaries.

c. ESRD QIP

For PY 2022, we have re-estimated the costs associated with information collection requirements under the Program with updated estimates of the total number of dialysis facilities, the total number of patients nationally, wages for Medical Records and Health Information Technicians or similar staff, and a refined estimate of the number of hours needed to complete data entry for CROWNWeb reporting. We have made no other changes to our methodology for calculating the annual burden associated with the information collection requirements for with the CROWNWeb validation study, the NHSN validation study, and CROWNWeb reporting. None of the policies proposed in this proposed rule would affect our estimates of the annual burden associated with the Program's information collection requirements.

We also re-estimated the payment reductions under the ESRD QIP to correct an error in the way the weights were redistributed when estimating the PY 2022 payment reductions for the CY 2019 ESRD PPS final rule (83 FR 57060) and in accordance with the proposed policy changes described earlier, including the proposed changes to the scoring methodology for the NHSN Dialysis Event reporting measure and the proposed conversion of the STRR measure from a clinical measure to a reporting measure. We also updated the payment reduction estimates using newly available data for the PPPW clinical measure and the Ultrafiltration reporting measure and more recent data for the other measures in the ESRD QIP measure set. We estimate that these updates would result in an overall impact of \$219 million as a result of the policies we have previously finalized and the policies we have proposed in this proposed rule, which includes an estimated \$205 million in information collection burden and an additional \$14 million in estimated payment reductions across all facilities, for PY 2022.

For PY 2023, we estimate that the proposed revisions to the ESRD QIP would result in an overall impact of \$219 million as a result of the policies we have previously finalized and the policies we have proposed in this proposed rule, which includes a \$14

million in estimated payment reductions across all facilities.

d. DMEPOS

i. Establishing Payment Amounts for New DMEPOS Items and Services

This rule proposes to establish a gap-filling methodology for new items and services. The fiscal impact of establishing payment amounts of new items based on the proposed gap-filling methodology cannot be determined due to the uniqueness of new items and their costs.

ii. Adjusting Payment Amounts for DMEPOS Items and Services Gap-Filled Using Supplier or Commercial Prices

While these adjustments would decrease fee schedule amounts that have been established using supplier or commercial prices by less than 15 percent, the savings are considered a small offset to the potential increase in costs of establishing fee schedule amounts based on supplier invoices or prices from commercial payers. The fiscal impact for this provision is therefore considered negligible.

e. Conditions of Payment To Be Applied to Certain DMEPOS Items

This rule proposes to streamline the requirements for ordering DMEPOS items, and to identify the process for subjecting certain DMEPOS items to a face-to-face encounter and written order prior to delivery and/or prior authorization as a condition of payment. The fiscal impact of these requirements cannot be estimated as this rule only identifies all items that are potentially subject to the face-to-face encounter and written order prior to delivery requirements and/or prior authorization.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We

welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the Bureau of Labor Statistics (BLS) (https://www.bls.gov/oes/2018/may/naics4_621100.htm) for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is \$110.00 per hour, including overhead and fringe benefits. Assuming an average reading speed, we estimate that it would take approximately 6.25 hours for the staff to review half of this proposed rule. For each ESRD facility that reviews the rule, the estimated cost

is \$687.50 (6.25 hours × \$110.00). Therefore, we estimate that the total cost of reviewing this regulation rounds to \$107,250. (\$687.50 × 156 reviewers).

For manufacturers of DMEPOS products, DMEPOS suppliers, and other DMEPOS industry representatives, we calculate a different cost of reviewing this rule. Assuming an average reading speed, we estimate that it would take approximately 1 hour for the staff to review this proposed rule. For each entity that reviews this proposed rule, the estimated cost is \$110.00. Therefore, we estimate that the total cost of reviewing this proposed rule is \$71,500 (\$110.00 × 650 reviewers).

B. Detailed Economic Analysis

1. CY 2020 End-Stage Renal Disease Prospective Payment System

a. Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different

categories of ESRD facilities, it is necessary to compare estimated payments in CY 2019 to estimated payments in CY 2020. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of payments in CY 2019 and CY 2020 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this proposed rule, we used CY 2018 data from the Part A and Part B Common Working Files as of February 15, 2019, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2018 claims to 2019 and 2020 using various updates. The updates to the ESRD PPS base rate are described in section II.B.5.d of this proposed rule. Table 11 shows the impact of the estimated CY 2020 ESRD payments compared to estimated payments to ESRD facilities in CY 2019.

TABLE 11—IMPACT OF PROPOSED CHANGES IN PAYMENT TO ESRD FACILITIES FOR CY 2020 PROPOSED RULE

Facility type	Number of facilities	Number of treatments (in millions)	Effect of 2020 changes in outlier policy (%)	Effect of 2020 changes in wage index (%)	Effect of 2020 changes in payment rate update (%)	Effect of 2020 changes in TDAPA (%)	Effect of total 2020 proposed changes (%)
	(A)	(B)	(C)	(D)	(E)	(F)	(G)
All Facilities	7,386	44.6	0.3	0.0	1.7	−0.4	1.6
Type:							
Freestanding	6,995	42.7	0.3	0.0	1.7	−0.4	1.5
Hospital based	391	1.9	0.6	0.0	1.7	−0.3	1.9
Ownership Type:							
Large dialysis organization	5,603	34.5	0.3	0.0	1.7	−0.4	1.5
Regional chain	927	5.7	0.3	0.1	1.7	−0.5	1.6
Independent	512	2.9	0.3	−0.1	1.7	−0.4	1.5
Hospital based ¹	305	1.5	0.6	0.0	1.7	−0.3	1.9
Unknown	39	0.0	0.5	0.0	1.7	−0.5	1.7
Geographic Location:							
Rural	1,285	6.5	0.3	0.3	1.7	−0.4	1.8
Urban	6,101	38.2	0.3	0.0	1.7	−0.4	1.5
Census Region:							
East North Central	1,188	6.1	0.3	−0.1	1.7	−0.4	1.5
East South Central	587	3.3	0.3	0.1	1.7	−0.5	1.5
Middle Atlantic	806	5.4	0.3	−0.2	1.7	−0.4	1.4
Mountain	409	2.3	0.2	0.1	1.7	−0.3	1.7
New England	198	1.4	0.3	−0.4	1.7	−0.4	1.2
Pacific ²	870	6.4	0.3	0.0	1.7	−0.3	1.7
Puerto Rico and Virgin Islands	47	0.3	0.1	0.3	1.7	−0.3	1.7
South Atlantic	1,699	10.5	0.3	−0.1	1.7	−0.5	1.4
West North Central	508	2.2	0.4	0.4	1.7	−0.4	2.1
West South Central	1,074	6.6	0.3	0.1	1.7	−0.5	1.6
Facility Size:							
Less than 4,000 treatments	1,206	2.5	0.3	0.1	1.7	−0.4	1.7
4,000 to 9,999 treatments	2,644	11.9	0.3	0.1	1.7	−0.4	1.6
10,000 or more treatments	3,159	29.8	0.3	0.0	1.7	−0.5	1.5
Unknown	377	0.5	0.4	0.0	1.7	−0.4	1.7
Percentage of Pediatric Patients:							
Less than 2%	7,288	44.3	0.3	0.0	1.7	−0.4	1.6
Between 2% and 19%	38	0.2	0.3	0.0	1.7	−0.4	1.6
Between 20% and 49%	14	0.0	0.2	−0.1	1.7	−0.1	1.8
More than 50%	46	0.0	0.2	−0.1	1.7	0.0	1.8

¹ Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

² Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis

treatments (in millions). The overall effect of the proposed changes to the outlier payment policy described in section II.B.5.c of this proposed rule is

shown in column C. For CY 2020, the impact on all ESRD facilities as a result of the changes to the outlier payment policy would be a 0.3 percent increase

in estimated payments. Nearly all ESRD facilities are anticipated to experience a positive effect in their estimated CY 2020 payments as a result of the proposed outlier policy changes.

Column D shows the effect of the proposed CY 2020 wage indices and the wage index floor of 0.50. The categories of types of facilities in the impact table show changes in estimated payments ranging from a 0.4 percent decrease to a 0.4 percent increase due to these proposed updates in the wage indices.

Column E shows the effect of the proposed CY 2020 ESRD PPS payment rate update. The proposed ESRD PPS payment rate update is 1.7 percent, which reflects the proposed ESRDB market basket percentage increase factor for CY 2020 of 2.1 percent and the proposed MFP adjustment of 0.4 percent.

Column F reflects the change in the payment of the TDAPA from ASP+6 percent to ASP+0 percent.

Column G reflects the overall impact, that is, the effects of the proposed outlier policy changes, the proposed wage index floor, payment rate update, and proposed TDAPA payment changes. We expect that overall ESRD facilities would experience a 1.6 percent increase in estimated payments in CY 2020. The categories of types of facilities in the impact table show impacts ranging from an increase of 1.2 percent to 2.1 percent in their CY 2020 estimated payments.

b. Effects on Other Providers

Under the ESRD PPS, Medicare pays ESRD facilities a single bundled payment for renal dialysis services, which may have been separately paid to other providers (for example, laboratories, durable medical equipment suppliers, and pharmacies) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2020, we estimate that the proposed ESRD PPS would have zero impact on these other providers.

c. Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2020 would be approximately \$11.1 billion. This estimate takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 1.7 percent in CY 2020.

d. Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 1.6 percent overall increase in the proposed CY 2020 ESRD PPS payment amounts, we estimate that there would be an increase in beneficiary co-insurance payments of 1.6 percent in CY 2020, which translates to approximately \$50 million.

e. Alternatives Considered

i. Eligibility Criteria for the TDAPA

In section II.B.1 of this proposed rule, we proposed revisions to the drug designation process regulation for new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category. In an effort to support innovation in the renal dialysis space, while simultaneously considering the cost to Medicare, for the refinement of the TDAPA eligibility we considered limiting it to only the Type 1 NDA classification code, section 351(a) biological products and section 351(k) biosimilar or interchangeable biological products. However, we wanted to support other innovative changes of drugs and biological products in the renal dialysis space and acknowledge that innovation may occur incrementally.

ii. New and Innovative Renal Dialysis Equipment and Supplies Under the ESRD PPS

In section II.B.3 of this proposed rule, we proposed to provide a transitional add-on payment adjustment to support the use of new and innovative renal

dialysis equipment and supplies by ESRD facilities. With regard to pricing mechanisms for equipment and supplies, we considered alternatives such as those used in the DMEPOS program and consultation with the Pricing, Data, and Analysis Contractor. However, methodologies such as reasonable charges and use of fee schedules was lacking for many items and did not address the upcoming new and innovative renal dialysis equipment and supplies that we expect to be forthcoming with the KidneyX program.

2. Proposed Payment for Renal Dialysis Services Furnished to Individuals With AKI

a. Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is necessary to compare estimated payments in CY 2019 to estimated payments in CY 2020. To estimate the impact among various types of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is imperative that the estimates of payments in CY 2019 and CY 2020 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this proposed rule, we used CY 2018 data from the Part A and Part B Common Working Files as of February 15, 2019, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the 2018 claims to 2019 and 2020 using various updates. The updates to the AKI payment amount are described in section III.B of this proposed rule. Table 12 shows the impact of the estimated CY 2020 payments for renal dialysis services furnished to individuals with AKI compared to estimated payments for renal dialysis services furnished to individuals with AKI in CY 2019.

TABLE 12—IMPACT OF PROPOSED CHANGES IN PAYMENT FOR RENAL DIALYSIS SERVICES FURNISHED TO INDIVIDUALS WITH AKI FOR CY 2020 PROPOSED RULE

Facility type	Number of facilities	Number of treatments (in thousands)	Effect of 2020 changes in wage index (%)	Effect of 2020 changes in payment rate update (%)	Effect of total 2020 proposed changes (%)
	(A)	(B)	(C)	(D)	(E)
All Facilities	4,372	172.7	−0.1	1.7	1.7
Type:					
Freestanding	4,257	168.8	−0.1	1.7	1.7
Hospital based	115	3.9	0.1	1.7	1.8
Ownership Type:					
Large dialysis organization	3,600	135.0	−0.0	1.7	1.7

TABLE 12—IMPACT OF PROPOSED CHANGES IN PAYMENT FOR RENAL DIALYSIS SERVICES FURNISHED TO INDIVIDUALS WITH AKI FOR CY 2020 PROPOSED RULE—Continued

Facility type	Number of facilities	Number of treatments (in thousands)	Effect of 2020 changes in wage index (%)	Effect of 2020 changes in payment rate update (%)	Effect of total 2020 proposed changes (%)
(A)	(B)	(C)	(D)	(E)	
Regional chain	526	25.5	−0.1	1.7	1.6
Independent	171	9.9	−0.1	1.7	1.6
Hospital based ¹	68	2.2	0.1	1.7	1.8
Unknown	7	0.1	0.3	1.7	2.0
Geographic Location:					
Rural	772	30.5	0.3	1.7	2.0
Urban	3,600	142.2	−0.1	1.7	1.6
Census Region:					
East North Central	790	33.0	−0.0	1.7	1.7
East South Central	372	16.2	0.2	1.7	1.9
Middle Atlantic	452	20.0	−0.3	1.7	1.4
Mountain	267	11.0	0.0	1.7	1.7
New England	138	5.0	−0.4	1.7	1.3
Pacific ²	513	21.5	−0.1	1.7	1.6
Puerto Rico and Virgin Islands	2	0.0	0.4	1.7	2.1
South Atlantic	1,008	41.3	−0.1	1.7	1.6
West North Central	278	8.3	0.4	1.7	2.1
West South Central	552	16.4	0.0	1.7	1.8
Facility Size:					
Less than 4,000 treatments	493	15.9	−0.1	1.7	1.6
4,000 to 9,999 treatments	1,646	61.4	0.0	1.7	1.7
10,000 or more treatments	2,108	92.0	−0.1	1.7	1.6
Unknown	125	3.4	0.1	1.7	1.8
Percentage of Pediatric Patients:					
Less than 2%	4,371	172.7	−0.1	1.7	1.7
Between 2% and 19%	0	0.0	0.0	0.0	0.0
Between 20% and 49%	0	0.0	0.0	0.0	0.0
More than 50%	1	0.0	−1.6	1.7	0.1

¹ Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

² Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of AKI dialysis treatments (in thousands).

Column C shows the effect of the proposed CY 2020 wage indices and the wage index floor of 0.50. The categories of types of facilities in the impact table show changes in estimated payments of a 0.1 percent decrease due to these proposed updates in the wage indices.

Column D shows the effect of the proposed CY 2020 ESRD PPS payment rate update. The proposed ESRD PPS payment rate update is 1.7 percent, which reflects the proposed ESRDB market basket percentage increase factor for CY 2020 of 2.1 percent and the MFP adjustment of 0.4 percent.

Column E reflects the overall impact, that is, the effects of the proposed wage index floor and payment rate update. We expect that overall ESRD facilities would experience a 1.7 percent increase in estimated payments in CY 2020. The categories of types of facilities in the impact table show impacts ranging from

an increase of 0.0 percent to 2.1 percent in their CY 2020 estimated payments.

b. Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we are proposing to update the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers and suppliers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The decision about where the renal dialysis services are furnished is made by the patient and his or her physician. Therefore, this proposal will have zero impact on other Medicare providers.

c. Effects on the Medicare Program

We estimate approximately \$42 million would be paid to ESRD facilities in CY 2020 as a result of AKI patients receiving renal dialysis services in the ESRD facility at the lower ESRD PPS base rate versus receiving those services only in the hospital outpatient setting and paid under the outpatient

prospective payment system, where services were required to be administered prior to the TPEA.

d. Effects on Medicare Beneficiaries

Currently, beneficiaries have a 20 percent co-insurance obligation when they receive AKI dialysis in the hospital outpatient setting. When these services are furnished in an ESRD facility, the patients would continue to be responsible for a 20 percent co-insurance. Because the AKI dialysis payment rate paid to ESRD facilities is lower than the outpatient hospital PPS's payment amount, we would expect beneficiaries to pay less co-insurance when AKI dialysis is furnished by ESRD facilities.

e. Alternatives Considered

As we discussed in the CY 2017 ESRD PPS proposed rule (81 FR 42870), we considered adjusting the AKI payment rate by including the ESRD PPS case-mix adjustments, and other adjustments at section 1881(b)(14)(D) of the Act, as well as not paying separately for AKI specific drugs and laboratory tests. We

ultimately determined that treatment for AKI is substantially different from treatment for ESRD and the case-mix adjustments applied to ESRD patients may not be applicable to AKI patients and as such, including those policies and adjustment would be inappropriate. We continue to monitor utilization and trends of items and services furnished to individuals with AKI for purposes of refining the payment rate in the future. This monitoring would assist us in developing knowledgeable, data-driven proposals.

3. ESRD QIP

a. Effects of the PY 2022 ESRD QIP on ESRD Facilities

The ESRD QIP is intended to prevent possible reductions in the quality of ESRD dialysis facility services provided to beneficiaries. We are proposing in this proposed rule to convert the STrR clinical measure to a reporting measure, and also to change the way the NHSN Dialysis Event reporting measure is scored. The general methodology that we are using to determine a facility's TPS is described in our regulations at § 413.178(d).⁴⁹

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2022 ESRD QIP would apply to the ESRD PPS payments made to the facility for services furnished in CY 2022, as codified in our regulations at § 413.177.

For the PY 2022 ESRD QIP, we estimate that, of the 7,099 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 21.9 percent or 1,506 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2022. The total payment reductions for all the 1,506 facilities expected to receive a payment reduction is approximately \$13,905,923.02. Facilities that do not receive a TPS do not receive a payment reduction.

Table 13 shows the overall estimated distribution of payment reductions resulting from the PY 2022 ESRD QIP.

TABLE 13—ESTIMATED DISTRIBUTION OF PY 2022 ESRD QIP PAYMENT REDUCTIONS

Payment reduction (%)	Number of facilities	Percent of facilities *
0.0	5,370	78.10
0.5	1,116	16.23
1.0	325	4.73
1.5	56	0.81
2.0	9	0.13

* 223 facilities not scored due to insufficient data.

To estimate whether a facility would receive a payment reduction for PY 2022, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from CROWNWeb and Medicare claims. Payment reduction estimates are calculated using the most recent data available (specified in Table 14) in accordance with the policies proposed in this proposed rule. Measures used for the simulation are shown in Table 14. We also note that we are proposing in section IV.B.3.b of this proposed rule to convert the STrR measure from a clinical measure to a reporting measure.

TABLE 14—DATA USED TO ESTIMATE PY 2022 ESRD QIP PAYMENT REDUCTIONS

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2016–Dec 2016	Jan 2017–Dec 2017.
SRR	Jan 2016–Dec 2016	Jan 2017–Dec 2017.
STrR	Jan 2016–Dec 2016	Jan 2017–Dec 2017.
SHR	Jan 2016–Dec 2016	Jan 2017–Dec 2017.
PPPW	Jan 2016–Dec 2016	Jan 2017–Dec 2017.
Kt/V Dialysis Adequacy Comprehensive	Jan 2016–Dec 2016	Jan 2017–Dec 2017.
VAT:		
Standardized Fistula Ratio	Jan 2016–Dec 2016	Jan 2017–Dec 2017.
%Catheter	Jan 2016–Dec 2016	Jan 2017–Dec 2017.
Hypercalcemia	Jan 2016–Dec 2016	Jan 2017–Dec 2017.

For all measures except SHR and STrR, clinical measure topic areas with less than 11 cases for a facility were not included in that facility's TPS. For SHR and STrR, facilities were required to have at least 5 at risk patients and 10 at risk patients, respectively, in order to be included in the facility's TPS. Each facility's TPS was compared to an estimated minimum TPS and an estimated payment reduction table that were consistent with the proposals outlined in section IV.B of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2017 and CY 2018. Facilities were required to have at least one

measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2022 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2017 and December 2017 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility: Total ESRD payment in January 2017 through December 2017 times the estimated payment reduction percentage.

Table 15 shows the estimated impact of the finalized ESRD QIP payment

reductions to all ESRD facilities for PY 2022. The table details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and by facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2022 ESRD QIP, the actual impact of the PY 2022 ESRD QIP may vary significantly from the values provided here.

⁴⁹ We are proposing to redesignate paragraph (d) as paragraph (e) in this proposed rule.

TABLE 15—IMPACT OF PROPOSED ESRD QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2022

	Number of facilities	Number of treatments 2017 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
All Facilities	7,099	45.1	6,876	1,506	−0.14
Facility Type:					
Freestanding	6,681	43.0	6,510	1,407	−0.13
Hospital-based	418	2.2	366	99	−0.22
Ownership Type:					
Large Dialysis	5,400	34.9	5,290	1,068	−0.12
Regional Chain	881	5.7	848	192	−0.14
Independent	485	2.9	454	165	−0.26
Hospital-based (non-chain)	327	1.7	284	81	−0.24
Unknown	6	0.0	0	0	—
Facility Size:					
Large Entities	6,281	40.6	6,138	1,260	−0.12
Small Entities ¹	812	4.6	738	246	−0.25
Unknown	6	0.0	0	0	—
Rural Status:					
(1) Yes	1,271	6.5	1,231	119	−0.05
(2) No	5,828	38.6	5,645	1,387	−0.16
Census Region:					
Northeast	968	7.0	930	205	−0.15
Midwest	1,642	8.6	1,584	347	−0.14
South	3,193	20.5	3,099	763	−0.15
West	1,237	8.6	1,205	166	−0.08
U.S. Territories ²	59	0.4	58	25	−0.30
Census Division:					
Unknown	8	0.1	7	4	−0.42
East North Central	1,145	6.3	1,107	286	−0.17
East South Central	572	3.3	562	116	−0.13
Middle Atlantic	777	5.5	745	184	−0.16
Mountain	400	2.3	390	39	−0.06
New England	191	1.5	185	21	−0.07
Pacific	837	6.4	815	127	−0.09
South Atlantic	1,622	10.6	1,571	405	−0.16
West North Central	497	2.3	477	61	−0.08
West South Central	999	6.6	966	242	−0.16
U.S. Territories ²	51	0.3	51	21	−0.28
Facility Size (# of total treatments):					
Less than 4,000 treatments	1,246	2.1	1,060	193	−0.14
4,000–9,999 treatments	2,666	11.9	2,656	439	−0.10
Over 10,000 treatments	3,147	31.0	3,144	866	−0.17
Unknown	40	0.2	16	8	−0.37

¹ Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.

² Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

b. Effects of the PY 2023 ESRD QIP on ESRD Facilities

For the PY 2023 ESRD QIP, we estimate that, of the 7,099 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 21.9 percent or 1,506 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2023. The total payment reductions for all the 1,506 facilities expected to receive a payment reduction is approximately \$13,905,923.02. Facilities that do not receive a TPS do not receive a payment reduction.

Table 16 shows the overall estimated distribution of payment reductions resulting from the PY 2023 ESRD QIP.

TABLE 16—ESTIMATED DISTRIBUTION OF PY 2023 ESRD QIP PAYMENT REDUCTIONS

Payment reduction (%)	Number of facilities	Percent of facilities *
0.0	5,370	78.10
0.5	1,116	16.23
1.0	325	4.73
1.5	56	0.81
2.0	9	0.13

* 223 facilities not scored due to insufficient data.

To estimate whether a facility would receive a payment reduction in PY 2023, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from CROWNWeb and Medicare claims. Payment reduction estimates are calculated using the most recent data available (specified in Table 16) in accordance with the policies proposed in this proposed rule. Measures used for the simulation are shown in Table 17. We also note that we are proposing in section IV.B.3.b of this proposed rule to convert the STRr measure from a clinical measure to a reporting measure.

TABLE 17—DATA USED TO ESTIMATE PY 2023 ESRD QIP PAYMENT REDUCTIONS

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2016–Dec 2016	Jan 2017–Dec 2017.
SRR	Jan 2016–Dec 2016	Jan 2017–Dec 2017.
STrR	Jan 2016–Dec 2016	Jan 2017–Dec 2017.
SHR	Jan 2016–Dec 2016	Jan 2017–Dec 2017.
PPPW	Jan 2016–Dec 2016	Jan 2017–Dec 2017.
Kt/V Dialysis Adequacy Comprehensive	Jan 2016–Dec 2016	Jan 2017–Dec 2017.
VAT:		
Standardized Fistula Ratio	Jan 2016–Dec 2016	Jan 2017–Dec 2017.
%Catheter	Jan 2016–Dec 2016	Jan 2017–Dec 2017.
Hypercalcemia	Jan 2016–Dec 2016	Jan 2017–Dec 2017.

For all measures except SHR and STrR, clinical measure topic areas with less than 11 cases for a facility were not included in that facility's TPS. For SHR and STrR, facilities were required to have at least 5 at-risk patients and 10 at-risk patients, respectively, in order to be included in the facility's TPS. Each facility's TPS was compared to an estimated minimum TPS and an estimated payment reduction table that were consistent with the proposals outlined in section IV.B and IV.C of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2017 and CY 2018. Facilities were required to have at

least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2023 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2017 and December 2017 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility: Total ESRD payment in January 2017 through December 2017 times the estimated Payment reduction percentage.

Table 18 shows the estimated impact of the finalized ESRD QIP payment

reductions to all ESRD facilities for PY 2023. The table details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and by facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are proposing to use for the PY 2023 ESRD QIP, the actual impact of the PY 2023 ESRD QIP may vary significantly from the values provided here.

TABLE 18—IMPACT OF PROPOSED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2023

	Number of facilities	Number of treatments 2017 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
All Facilities	7,099	45.1	6,876	1,506	–0.14
Facility Type:					
Freestanding	6,681	43.0	6,510	1,407	–0.13
Hospital-based	418	2.2	366	99	–0.22
Ownership Type:					
Large Dialysis	5,400	34.9	5,290	1,068	–0.12
Regional Chain	881	5.7	848	192	–0.14
Independent	485	2.9	454	165	–0.26
Hospital-based (non-chain)	327	1.7	284	81	–0.24
Unknown	6	0.0	0	0
Facility Size:					
Large Entities	6,281	40.6	6,138	1,260	–0.12
Small Entities ¹	812	4.6	738	246	–0.25
Unknown	6	0.0	0	0
Rural Status:					
(1) Yes	1,271	6.5	1,231	119	–0.05
(2) No	5,828	38.6	5,645	1,387	–0.16
Census Region:					
Northeast	968	7.0	930	205	–0.15
Midwest	1,642	8.6	1,584	347	–0.14
South	3,193	20.5	3,099	763	–0.15
West	1,237	8.6	1,205	166	–0.08
U.S. Territories ²	59	0.4	58	25	–0.30
Census Division:					
Unknown	8	0.1	7	4	–0.42
East North Central	1,145	6.3	1,107	286	–0.17
East South Central	572	3.3	562	116	–0.13
Middle Atlantic	777	5.5	745	184	–0.16
Mountain	400	2.3	390	39	–0.06

TABLE 18—IMPACT OF PROPOSED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2023—Continued

	Number of facilities	Number of treatments 2017 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
New England	191	1.5	185	21	−0.07
Pacific	837	6.4	815	127	−0.09
South Atlantic	1,622	10.6	1,571	405	−0.16
West North Central	497	2.3	477	61	−0.08
West South Central	999	6.6	966	242	−0.16
U.S. Territories ²	51	0.3	51	21	−0.28
Facility Size (# of total treatments):					
Less than 4,000 treatments	1,246	2.1	1,060	193	−0.14
4,000–9,999 treatments	2,666	11.9	2,656	439	−0.10
Over 10,000 treatments	3,147	31.0	3,144	866	−0.17
Unknown	40	0.2	16	8	−0.37

¹ Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.

² Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

c. Effects on Other Providers

The ESRD QIP is applicable to dialysis facilities. We are aware that several of our measures impact other providers. For example, with the introduction of the SRR clinical measure in PY 2017 and the SHR clinical measure in PY 2020, we anticipate that hospitals may experience financial savings as dialysis facilities work to reduce the number of unplanned readmissions and hospitalizations. We are exploring various methods to assess the impact these measures have on hospitals and other facilities, such as through the impacts of the Hospital Readmission Reduction Program and the Hospital-Acquired Conditions Reduction Program, and we intend to continue examining the interactions between our quality programs to the greatest extent feasible.

d. Effects on the Medicare Program

For PY 2023, we estimate that the ESRD QIP would contribute approximately \$13,905,923.02 in Medicare savings. For comparison, Table 19 shows the payment reductions that we estimate will be applied by the ESRD QIP from PY 2018 through PY 2023. We note that Table 19 contains a lower estimated payment reduction for PY 2022 than we included in Table 49 of the CY 2019 ESRD PPS final rule (83 FR 57061).

TABLE 19—ESTIMATED PAYMENT REDUCTIONS PAYMENT YEARS 2018 THROUGH 2023

Payment year	Estimated payment reductions
PY 2023	\$13,905,923.02.
PY 2022	13,905,923.02.
PY 2021	32,196,724 (83 FR 57062).

TABLE 19—ESTIMATED PAYMENT REDUCTIONS PAYMENT YEARS 2018 THROUGH 2023—Continued

Payment year	Estimated payment reductions
PY 2020	31,581,441 (81 FR 77960).
PY 2019	15,470,309 (80 FR 69074).
PY 2018	11,576,214 (79 FR 66257).

e. Effects on Medicare Beneficiaries

The ESRD QIP is applicable to dialysis facilities. Since the Program's inception, there is evidence on improved performance on ESRD QIP measures. As we stated in the CY 2018 ESRD PPS final rule, one objective measure we can examine to demonstrate the improved quality of care over time is the improvement of performance standards (82 FR 50795). As the ESRD QIP has refined its measure set and as facilities have gained experience with the measures included in the Program, performance standards have generally continued to rise. We view this as evidence that facility performance (and therefore the quality of care provided to Medicare beneficiaries) is objectively improving. We are in the process of monitoring and evaluating trends in the quality and cost of care for patients under the ESRD QIP, incorporating both existing measures and new measures as they are implemented in the Program. We will provide additional information about the impact of the ESRD QIP on beneficiaries as we learn more. However, in future years we are interested in examining these impacts through the analysis of available data from our existing measures.

f. Alternatives Considered

In response to the concern raised by commenters about the validity of the modified STrR measure, we considered

aligning the STrR measure's specifications with those used for the measure prior to the PY 2021 ESRD QIP. However, that version of the STrR clinical measure was not endorsed by the NQF due to the concern expressed by the Renal Standing Committee about variability in hospital coding practices.

4. DMEPOS

a. Establishing Payment Amounts for New DMEPOS Items and Services (Gap-Filling)

(1) Effects on Other Providers

We believe that establishing payment amounts for new DMEPOS items and services would have a positive economic impact on suppliers by making the pricing of new items more easily understood and encourage innovation. The cost of this proposal cannot be estimated as these new items are not identified.

(2) Effects on the Medicare Program

This proposal has an indeterminable cost to the Medicare program associated with it due to the unpredictable nature of future new items.

(3) Effects on Medicare Beneficiaries

This proposal has an indeterminable cost to the Medicare beneficiary due to the unpredictable nature of future new items. Likewise, this proposal has an indeterminable cost to the dual-eligible beneficiary who is enrolled in the Medicare and the Medicaid programs for the same reason as indicated above.

(4) Alternatives Considered

One alternative we considered was to continue the process for establishing payment amounts for new items on a sub-regulatory basis. This would have

no economic impact on the Medicare program or its beneficiaries.

b. Adjusting Payment Amounts for DMEPOS Items and Services Gap-Filled Using Supplier or Commercial Prices

(1) Effects on Other Providers

We believe that adjusting payment amounts for new DMEPOS items and services when initially set based on supplier or commercial prices would have a negative economic impact on suppliers by lowering fees. The savings of this proposal cannot be estimated as these new items are not identified.

(2) Effects on the Medicare Program

We believe that adjusting payment amounts for new DMEPOS items and services when initially set based on supplier or commercial prices would have a positive economic impact on the Medicare Program by lowering fees and achieving savings. The savings of this proposal cannot be estimated as these new items are not identified.

(3) Effects on Medicare Beneficiaries

We believe that adjusting payment amounts for new DMEPOS items and services when initially set based on supplier or commercial prices would have a positive economic impact on Medicare beneficiaries by lowering fees, therefore resulting in lower coinsurance for such items. The savings of this proposal cannot be estimated as these new items are not identified.

(4) Alternatives Considered

An alternative we considered was to continue not adjusting payment amounts for new items based on revised supplier and commercial price lists. This would have created, in some cases, what we consider to be unreasonable fee schedule amounts and a cost to the program and beneficiaries.

5. Conditions of Payment To Be Applied to Certain DMEPOS Items

This rule proposes to streamline the requirements for ordering DMEPOS items, and to identify the process for subjecting certain DMEPOS items to a face-to-face encounter and written order prior to delivery and/or prior authorization as a condition of payment. The fiscal impact of these requirements cannot be estimated as this rule only identifies all items that are potentially subject to the face-to-face encounter and written order prior to delivery requirements and/or prior authorization.

C. Accounting Statement

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars_

a004_a-4), in Table 20, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this proposed rule.

TABLE 20—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS/SAVINGS

ESRD PPS and AKI	
Category	Transfers
Annualized Monetized Transfers. From Whom to Whom	\$160 million. Federal government to ESRD providers.
Increased Beneficiary Co-insurance Payments. From Whom to Whom	\$50 million. Beneficiaries to ESRD providers.
ESRD QIP for PY 2022	
Annualized Monetized Transfers. From Whom to Whom	—\$14 million. Federal government to ESRD providers.
ESRD QIP for PY 2023	
Annualized Monetized Transfers. From Whom to Whom	—\$14 million. Federal government to ESRD providers.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

D. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (September 19, 1980, Pub. L. 96-354) (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, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Approximately 11 percent of ESRD dialysis facilities are considered small entities according to the Small Business Administration's (SBA) size standards, which classifies small businesses as those dialysis facilities having total revenues of less than \$38.5 million in any 1 year. Individuals and states are not included in the definitions of a small entity. For more information on SBA's size standards, see the Small Business Administration's website at <http://www.sba.gov/content/small-business-size-standards> (Kidney Dialysis Centers are listed as 621492 with a size standard of \$38.5 million).

We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or

included in this estimated RFA analysis. Individuals and states are not included in the definition of a small entity.

For purposes of the RFA, we estimate that approximately 11 percent of ESRD facilities are small entities as that term is used in the RFA (which includes small businesses, nonprofit organizations, and small governmental jurisdictions). This amount is based on the number of ESRD facilities shown in the ownership category in Table 11. Using the definitions in this ownership category, we consider 512 facilities that are independent and 305 facilities that are shown as hospital-based to be small entities. The ESRD facilities that are owned and operated by Large Dialysis Organizations (LDOs) and regional chains would have total revenues of more than \$38.5 million in any year when the total revenues for all locations are combined for each business (individual LDO or regional chain), and are not, therefore, included as small entities.

For the ESRD PPS updates proposed in this rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of dialysis facility) is estimated to receive a 1.9 percent increase in payments for CY 2020. An independent facility (as defined by ownership type) is also estimated to receive a 1.5 percent increase in payments for CY 2020.

For AKI dialysis, we are unable to estimate whether patients would go to ESRD facilities, however, we have estimated there is a potential for \$42 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

For the ESRD QIP, we estimate that of the 1,506 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2023 ESRD QIP, 246 are ESRD small entity facilities. We present these findings in Table 16 ("Estimated Distribution of PY 2023 ESRD QIP Payment Reductions") and Table 18 ("Impact of Proposed QIP Payment Reductions to ESRD Facilities for PY 2023"). We estimate that the payment reductions would average approximately \$9,233.68 per facility across the 1,506 facilities receiving a payment reduction, and \$8,850.82 for each small entity facility. We also estimate that there are 812 small entity facilities in total, and that the aggregate ESRD PPS payments to these facilities would decrease 0.25 percent in CY 2023.

The DMEPOS provisions in this proposed rule, Establishing Payment Amounts for New DMEPOS Items and Services and Gap-Filling and Adjusting Payment Amounts for DMEPOS Items

and Services Gap-Filled Using Supplier or Commercial Prices in section V of this proposed rule, are not considered to have a significant impact on a number of small suppliers. We note that the fiscal impact of the Conditions of Payment to be applied to Certain DMEPOS Items in section VI of this proposed rule cannot be estimated as this rule only identifies all items that are potentially subject to the face-to-face encounter and written order prior to delivery requirements and/or prior authorization.

Therefore, the Secretary has determined that these proposed rules would not have a significant economic impact on a substantial number of small entities. The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically "significant" only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs.

We solicit comment on the RFA analysis provided.

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. Any such regulatory impact 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 fewer than 100 beds. We do not believe this proposed rule would have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 126 rural hospital-based dialysis facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 126 rural hospital-based dialysis facilities will experience an estimated 2.2 percent increase in payments.

Therefore, the Secretary has determined that these proposed rules would not have a significant impact on the operations of a substantial number of small rural hospitals.

E. 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. In 2019, that threshold is approximately \$154 million. These proposed rules do not include any mandates that would impose spending costs on state, local, or Tribal governments in the aggregate, or by the private sector, of \$154 million. Moreover, HHS interprets UMRA as applying only to unfunded mandates. We do not interpret Medicare payment rules as being unfunded mandates, but simply as conditions for the receipt of payments from the federal government for providing services that meet federal standards. This interpretation applies whether the facilities or providers are private, state, local, or tribal.

F. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have reviewed these proposed rules under the threshold criteria of Executive Order 13132, Federalism, and have determined that it would not have substantial direct effects on the rights, roles, and responsibilities of states, local or Tribal governments.

G. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. It has been determined that this is a transfer rule, which imposes no more than de minimis costs. As a result, this rule is not considered a regulatory or deregulatory action under Executive Order 13771.

H. Congressional Review Act

These proposed rules are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

XII. Files Available to the Public via the Internet

The Addenda for the annual ESRD PPS proposed and final rulemakings will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the internet and is posted on the CMS website at <http://www.cms.gov/ESRDPayment/PAY/list.asp>. In addition to the Addenda, limited data set files are available for purchase at <http://www.cms.gov/>

Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile.html. Readers who experience any problems accessing the Addenda or LDS files, should contact ESRDPayment@cms.hhs.gov.

List of Subjects

42 CFR Part 405

Federal health insurance for the aged and disabled, Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 413

Health facilities, Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologicals, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as follows:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

- 1. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

- 2. Section 410.36 is amended by revising paragraph (b) to read as follows:

§ 410.36 Medical supplies, appliances, and devices: Scope.

* * * * *

(b) The conditions of payment described in § 410.38(d) also apply to medical supplies, appliances, and devices.

- 3. Section 410.38 is amended—
- a. By revising section heading;
- b. By revising paragraph (a);
- c. In paragraph (b), by adding a paragraph heading;
- d. By revising paragraphs (c), (d), and (e); and
- e. By removing paragraphs (f) and (g).

The revisions and addition read as follows:

§ 410.38 Durable medical equipment, prosthetics, orthotics and supplies (DMEPOS): Scope and conditions.

(a) *General scope.* Medicare Part B pays for durable medical equipment, including ventilators, oxygen equipment, hospital beds, and wheelchairs, if the equipment is used in the patient's home or in an institution that is used as a home.

(b) *Institutions that may not qualify as the patient's home.* * * *

(c) *Definitions.* As used in this section:

(1) *Physician* has the same meaning as in section 1861(r)(1) of the Act.

(2) *Treating practitioner* means physician as defined in section 1861(r)(1) of the Act, or physician assistant, nurse practitioner, or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act.

(3) *DMEPOS supplier* means an entity with a valid Medicare supplier number, including an entity that furnishes items through the mail.

(4) *Written Order/Prescription* is a written communication from a treating practitioner that documents the need for a beneficiary to be provided an item of DMEPOS.

(5) *Face-to-face encounter* is an in-person or telehealth encounter between the treating practitioner and the beneficiary.

(6) *Power mobility device (PMD)* means a covered item of durable medical equipment that is in a class of wheelchairs that includes a power wheelchair (a four-wheeled motorized vehicle whose steering is operated by an electronic device or a joystick to control direction and turning) or a power-operated vehicle (a three or four-wheeled motorized scooter that is operated by a tiller) that a beneficiary uses in the home.

(7) *Master List of DMEPOS items Potentially Subject to Face-to-Face Encounter and Written Orders Prior to Delivery and/or Prior Authorization Requirements, also referred to as "Master List"* are items of DMEPOS that CMS has identified in accordance with sections 1834(a)(11)(B) and 1834(a)(15) of the Act. The criteria for this list are specified in § 414.234. The Master List shall serve as a library of DMEPOS items from which items may be selected for inclusion on Required Face-to-Face Encounter and Written Order Prior to Delivery List and/or the Required Prior Authorization List.

(8) *Required Face-to-Face Encounter and Written Order Prior to Delivery List* is a list of DMEPOS items selected from the Master List and subject to the requirements of a Face-to-Face

Encounter and Written Order Prior to Delivery. The list of items would be communicated to the public via a 60-day **Federal Register** document and posted to the CMS website. When selecting items from the Master List, CMS may consider factors such as operational limitations, item utilization, cost-benefit analysis, emerging trends, vulnerabilities identified in official agency reports, or other analysis.

(d) *Conditions of payment.* The requirements described in this paragraph (d) are conditions of payment applicable to DMEPOS items.

(1) *Written Order/Prescription.* All DMEPOS items require a written order/prescription for Medicare payment. Medicare Contractors shall consider the totality of the medical records when reviewing for compliance with standardized written order/prescription elements.

(i) *Elements.* A written order/prescription must include the following elements:

(A) Beneficiary Name or Medicare Beneficiary Identifier (MBI).

(B) General Description of the item.

(C) Quantity to be dispensed, if applicable.

(D) Date.

(E) Practitioner Name or National Provider Identifier (NPI).

(F) Practitioner Signature.

(ii) *Timing of the Written Order/Prescription.* (A) For PMDs and other DMEPOS items selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the written order/prescription must be communicated to the supplier prior to delivery.

(B) For all other DMEPOS, the written order/prescription must be communicated to the supplier prior to claim submission.

(2) *Items requiring a Face-to-Face Encounter.* For PMDs and other DMEPOS items selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the treating practitioner must document and communicate to the DMEPOS supplier that the treating practitioner has had a face-to-face encounter with the beneficiary within the 6 months preceding the date of the written order/prescription.

(i) The encounter must be used for the purpose of gathering subjective and objective information associated with diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered.

(ii) If it is a telehealth encounter, the requirements of §§ 410.78 and 414.65 must be met.

(3) *Documentation:* A supplier must maintain the written order/prescription and the supporting documentation provided by the treating practitioner and make them available to CMS and its agents upon request.

(i) Upon request by CMS or its agents, a supplier must submit additional documentation to CMS or its agents to support and/or substantiate the medical necessity for the DMEPOS item.

(ii) The face-to-face encounter must be documented in the pertinent portion of the medical record (for example, history, physical examination, diagnostic tests, summary of findings, progress notes, treatment plans or other sources of information that may be appropriate). The supporting documentation must include subjective and objective beneficiary specific information used for diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered.

(e) *Suspension of face-to-face encounter and written order prior to delivery requirements.* CMS may suspend face-to-face encounter and written order prior to delivery requirements generally or for a particular item or items at any time and without undertaking rulemaking, except those items for which inclusion on the Master List was statutorily imposed.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 4. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww; and sec. 124 of Public Law 106–113, 113 Stat. 1501A–332; sec. 3201 of Public Law 112–96, 126 Stat. 156; sec. 632 of Public Law 112–240, 126 Stat. 2354; sec. 217 of Public Law 113–93, 129 Stat. 1040; and sec. 204 of Public Law 113–295, 128 Stat. 4010; and sec. 808 of Public Law 114–27, 129 Stat. 362.

■ 5. Section 413.178 is amended—

■ a. In paragraph (a)(4) by removing the reference “paragraphs (d)(1)(i) through (v)” and adding in its place the reference “paragraphs (e)(1)(i) through (v)”;

■ b. In paragraph (a)(13) by removing the reference to “paragraph (d)(1)(vi)” and adding in its place the reference “paragraph (e)(1)(vi)”;

■ c. By redesignating paragraphs (d) through (f) as paragraphs (e) through (g), respectively;

■ d. By adding a new paragraph (d);

■ e. In newly redesignated paragraph (e)(2)(i) by removing the reference “paragraph (d)(1)” and adding in its place the reference “paragraph (e)(1)”; and

■ f. In newly redesignated paragraph (f)(2) by removing the cross-reference to “paragraph (e)(1)” and adding in its place “paragraph (f)(1)”.

The addition reads as follows:

§ 413.178 ESRD quality incentive program.

* * * * *

(d) *Data submission requirement.* (1) Except as provided in paragraph (d)(3) and (4) of this section, and for a payment year, facilities must submit to CMS data on each measure specified by CMS under paragraph (c) of this section. Facilities must submit these data in the form, manner, and at a time specified by CMS.

(2) For purposes of paragraph (d)(1) of this section, the baseline period that applies to the 2023 payment year is calendar year 2019 for purposes of calculating the achievement threshold, benchmark and minimum total performance score, and calendar year 2020 for purposes of calculating the improvement threshold, and the performance period that applies to the 2023 payment year is calendar year 2021. Beginning with the 2024 payment year, the performance period and corresponding baseline periods are each advanced 1 year for each successive payment year.

(3) A facility may request and CMS may grant exceptions to the reporting requirements under paragraph (d)(1) of this section for one or more calendar days, when there are certain extraordinary circumstances beyond the control of the facility.

(4) A facility may request an exception within 90 days of the date that the extraordinary circumstances occurred by submitting the Extraordinary Circumstances Exception request form, which is available on the QualityNet website (<https://www.qualitynet.org/>), to CMS via email to the ESRD QIP mailbox at ESRDQIP@cms.hhs.gov. Facilities must provide the following information on the form:

- (i) Facility CCN.
- (ii) Facility name.
- (iii) CEO name and contact information.
- (iv) Additional contact name and contact information.
- (v) Reason for requesting an exception.
- (vi) Dates affected.

(vii) Date the facility will start submitting data again, with justification for this date.

(viii) Evidence of the impact of the extraordinary circumstances, including but not limited to photographs, newspaper, and other media articles.

(5) CMS will not consider an exception request unless the facility requesting such exception has complied fully with the requirements in paragraph (d) of this section.

(6) CMS may grant exceptions to facilities without a request if it determines that one or more of the following has occurred:

(i) An extraordinary circumstance affects an entire region or locale.

(ii) An unresolved issue with a CMS data system affected the ability of a facility to submit data in accordance with paragraph (d)(1) of this section and CMS was unable to provide the facility with an alternative method of data submission.

(7) A facility that has been granted an exception to the data submission requirements under paragraph (d)(6) of this section may notify CMS that it will continue to submit data under paragraph (d)(1) of this section by sending an email signed by the CEO or another designated contact to the ESRD QIP mailbox at ESRDQIP@cms.hhs.gov. Upon receipt of an email under this clause, CMS will notify the facility in writing that CMS is withdrawing the exception it previously granted to the facility.

* * * * *

■ 6. Section 413.230 is amended by revising paragraphs (b) and (c) and adding paragraph (d) and (e) to read as follows:

§ 413.230 Determining the per treatment payment amount.

* * * * *

(b) Any outlier payment under § 413.237;

(c) Any training adjustment add-on under § 413.235(c);

(d) Any transitional drug add-on payment adjustment under § 413.234(c); and

(e) Any transitional add-on payment adjustment for new and innovative equipment and supplies under § 413.236(d).

■ 7. Section 413.234 is amended—

■ a. In paragraph (a) by revising the definitions of “ESRD PPS functional category” and “Oral only drug;”

■ b. By revising paragraph (b)(1)(ii), as amended November 14, 2018, at 83 FR 57070, and effective January 1, 2020;

■ c. By revising paragraph (c) introductory text, as amended November 14, 2018, at 83 FR 57070, and effective January 1, 2020; and

■ d. By adding paragraph (e).

The revisions and addition read as follows:

§ 413.234 Drug designation process.

(a) * * *

ESRD PPS functional category. A distinct grouping of drugs or biological products, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD.

* * * * *

Oral-only drug. A drug or biological product with no injectable equivalent or other form of administration other than an oral form.

(b) * * *

(1) * * *

(ii) Except as provided in paragraph (e) of this section, the new renal dialysis drug or biological product is paid for using the transitional drug add-on payment adjustment described in paragraph (c)(1) of this section.

* * * * *

(c) *Transitional drug add-on payment adjustment.* A new renal dialysis drug or biological product is paid for using a transitional drug add-on payment adjustment, which is based on 100 percent of average sales price (ASP). If ASP is not available then the transitional drug add-on payment adjustment is based on 100 percent of wholesale acquisition cost (WAC) and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

Notwithstanding the provisions in paragraphs (c)(1) and (2) of this section, if CMS does not receive a full calendar quarter of ASP data for a new renal dialysis drug or biological product within 30 days of the last day of the 3rd calendar quarter after we begin applying the transitional drug add-on payment adjustment for the product, CMS will no longer apply the transitional drug add-on payment adjustment for that product beginning no later than 2-calendar quarters after we determine a full calendar quarter of ASP data is not available. If CMS stops receiving the latest full calendar quarter of ASP data for a new renal dialysis drug or biological product during the applicable time period specified in paragraph (c)(1) or (2) of this section, CMS will no longer apply the transitional drug add-on payment adjustment for the product beginning no later than 2-calendar quarters after CMS determines that the latest full calendar quarter of ASP data is not available.

* * * * *

(e) *Exclusion criteria for the transitional drug add-on payment*

adjustment. A new renal dialysis drug used to treat or manage a condition for which there is an ESRD PPS functional category is not eligible for payment using the transitional drug add-on payment adjustment described in paragraph (c)(1) of this section if the drug is approved by FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or the new drug application (NDA) for the drug is classified by FDA as Type 3, 5, 7, or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the parent NDA is a Type 3, 5, 7 or 8 as described in paragraphs (e)(1) through (7) of this section, respectively:

(1) *Type 3 NDA—New Dosage Form.*

(i) A *Type 3 NDA* is for a new dosage form of an active ingredient that has been approved or marketed in the United States (U.S.) by the same or another applicant but in a different dosage form. The indication for the drug product does not need to be the same as that of the already marketed drug product. Once a new dosage form has been approved for an active ingredient, subsequent applications for the same dosage form and active ingredient should be classified as a *Type 5 NDA*, as described in paragraph (e)(2) of this section.

(ii) [Reserved]

(2) *Type 5 NDA—New Formulation or Other Differences.* (i) A *Type 5 NDA* is for a product, other than a new dosage form, that differs from a product already approved or marketed in the U.S. because of one of the following:

(A) The product involves changes in inactive ingredients that require either bioequivalence studies or clinical studies for approval and is submitted as an original NDA rather than as a supplement by the applicant of the approved product;

(B) The product is a duplicate of a drug product by another applicant (same active ingredient, same dosage form, same or different indication, or same combination), and

(1) Requires bioequivalence testing (including bioequivalence studies with clinical endpoints), but is not eligible for submission as a section 505(j) of the FD&C Act application; or

(2) Requires safety or effectiveness testing because of novel inactive ingredients; or

(3) Requires full safety or effectiveness testing because it is:

(i) Subject to exclusivity held by another applicant, or

(ii) A product of biotechnology and its safety and/or effectiveness are not assessable through bioequivalence testing, or

(iii) A crude natural product, or

(iv) Ineligible for submission under section 505(j) of the FD&C Act because it differs in bioavailability (for example, products with different release patterns); or

(4) The applicant has a right of reference to the application.

(C) The product contains an active ingredient or active moiety that has been previously approved or marketed in the U.S. only as part of a combination. This applies to active ingredients previously approved or marketed as part of a physical or chemical combination, or as part of a mixture derived from recombinant deoxyribonucleic acid technology or natural sources.

(D) The product is a combination product that differs from a previously marketed combination by the removal of one or more active ingredients or by substitution of a new ester or salt or other noncovalent derivative of an active ingredient for one or more of the active ingredients. In the latter case, the NDA would be classified as a combination of a *Type 2 NDA* as described in paragraph (e)(5)(i) of this section, with a *Type 5 NDA* as described in this paragraph (e)(2).

(E) The product contains a different strength of one or more active ingredients in a previously approved or marketed combination. A *Type 5 NDA*, as described in this paragraph (e)(2), would generally be submitted by an applicant other than the holder of the approved application for the approved product. A similar change in an approved product by the applicant of the approved product would usually be submitted as a supplemental application.

(F) The product differs in bioavailability (for example, superbioavailable or different controlled-release pattern) and, therefore, is ineligible for submission as an abbreviated new drug application (ANDA) under section 505(j) of the FD&C Act.

(G) The product involves a new plastic container that requires safety studies beyond limited confirmatory testing (see 21 CFR 310.509, *Parenteral drug products in plastic containers*).

(ii) [Reserved]

(3) *Type 7 NDA—Previously Marketed But Without an Approved NDA.* (i) A *Type 7 NDA* is for a drug product that contains an active moiety that has not been previously approved in an application, but has been marketed in the U.S. This classification applies only to the first NDA approved for a drug product containing this (these) active

moiety(ies). *Type 7 NDAs* include, but are not limited to:

(A) The first post-1962 application for an active moiety marketed prior to 1938.

(B) The first application for an active moiety first marketed between 1938 and 1962 that is identical, related or similar (IRS) to a drug covered by a Drug Efficacy Study Implementation notice. The regulation at 21 CFR 310.6(b)(1) states that an identical, related, or similar drug includes other brands, potencies, dosage forms, salts, and esters of the same drug moiety as well as any of drug moiety related in chemical structure or known pharmacological properties.

(C) The first application for an IRS drug product first marketed after 1962.

(D) The first application for an active moiety that was first marketed without an NDA after 1962.

(ii) [Reserved]

(4) *Type 8 NDA—Prescription to Over-the-Counter (OTC).* (i) A *Type 8 NDA* is for a drug product intended for OTC marketing that contains an active ingredient that has been approved previously or marketed in the U.S. only for dispensing by prescription (OTC switch). A *Type 8 NDA* may provide for a different dosing regimen, different strength, different dosage form, or different indication from the product approved previously for prescription sale.

(ii) If the proposed OTC switch will apply to all indications, uses, and strengths of an approved prescription dosage form (leaving no prescription-only products of that particular dosage form on the market), the application holder should submit the change as a supplement to the approved application. If the applicant intends to switch only some indications, uses, or strengths of the dosage form to OTC status (while continuing to market other indications, uses, or strengths of the dosage form for prescription-only sale), the applicant should submit a new NDA for the OTC products, which would be classified as a *Type 8 NDA*.

(5) *Combination of Type 3 NDA.* Type 3 NDA, as described in paragraph (e)(1) of this section, in combination with a Type 2 NDA, as described in paragraph (e)(5)(i) of this section, or in combination with a Type 4 NDA, as described in paragraph (e)(5)(ii) of this section;

(i) *Type 2 NDA—New Active Ingredient.* (A) A *Type 2 NDA* is for a drug product that contains a new active ingredient, but not a new molecular entity (NME). A new active ingredient includes those products whose active moiety has been previously approved or marketed in the U.S., but whose

particular ester, salt, or noncovalent derivative of the unmodified parent molecule has not been approved by FDA or marketed in the U.S., either alone, or as part of a combination product. Similarly, if any ester, salt, or noncovalent derivative has been marketed first, the unmodified parent molecule would also be considered a new active ingredient, but not an NME. The indication for the drug product does not need to be the same as that of the already marketed product containing the same active moiety.

(B) If the active ingredient is a single enantiomer and a racemic mixture containing that enantiomer has been previously approved by FDA or marketed in the U.S., or if the active ingredient is a racemic mixture containing an enantiomer that has been previously approved by FDA or marketed in the U.S., the NDA will be classified as a *Type 2 NDA*.

(ii) *Type 4 NDA—New Combination*. (A) A *Type 4 NDA* is for a new drug-drug combination of two or more active ingredients. An application for a new drug-drug combination product may have more than one classification code if at least one component of the combination is an NME or a new active ingredient. The new product may be a physical or chemical (for example, covalent ester or noncovalent derivative) combination of two or more active moieties.

(B) A new *physical combination* may be two or more active ingredients combined into a single dosage form, or two or more drugs packaged together with combined labeling. When at least one of the active moieties is classified as an NME, the NDA is classified as a combination of a *Type 1 NDA*, as described in paragraph (e)(5)(ii)(B)(1) of this section, with a *Type 4 NDA*, as described in paragraph (e)(5)(ii) of this section. When none of the active moieties is an NME, but at least one is a new active ingredient, the NDA is classified as a combination of a *Type 2 NDA*, as described in paragraph (e)(5)(i) of this section, with a *Type 4 NDA*, as described in paragraph (e)(5)(ii) of this section.

(1) *Type 1 NDA—New Molecular Entity*. (i) A *Type 1 NDA* is for a drug product that contains an NME. An NME is an active ingredient that contains no active moiety that has been previously approved by FDA in an application submitted under section 505 of the FD&C Act or has been previously marketed as a drug in the U.S. A pure enantiomer or a racemic mixture is an NME only when neither has been previously approved or marketed.

(ii) An NDA for a drug product containing an active moiety that has been marketed as a drug in the U.S., but never approved in an application submitted under section 505 of the FD&C Act, would be considered a *Type 7 NDA* as described in paragraph (e)(3) of this section, not a *Type 1 NDA*.

(iii) An NDA for a drug-drug combination product containing an active moiety that is an NME in combination with another active moiety that had already been approved by FDA would be classified as a new combination containing an NME (that is, *Type 1,4 NDA*, as described in paragraph (e)(5)(ii) of this section). For example, a drug-drug combination can include a fixed-combination drug product or a co-packaged drug product with two or more active moieties.

(iv) An active moiety in a radiopharmaceutical (or radioactive drug product) which has not been approved by the FDA or marketed in the U.S. is classified as an NME.

(v) In addition, if a change in isotopic form results in an active moiety that has never been approved by the FDA or marketed in the U.S., the active ingredient is classified as an NME.

(C) An NDA for an active ingredient that is a *chemical combination* of two or more previously approved or marketed active moieties that are linked by an ester bond is classified as a combination of a *Type 2 NDA* as described in paragraph (e)(5)(i) of this section, with a *Type 4 NDA* as described in paragraph (e)(5)(ii) of this section, if the active moieties have not been previously marketed or approved as a physical combination. If the physical combination has been previously marketed or approved, however, such a product would no longer be considered a *new combination* and the NDA would thus be classified as a *Type 2 NDA*, as described in paragraph (e)(5)(i) of this section.

(6) *Combination of Type 5 NDA*. *Type 5 NDA*, as described in paragraph (e)(2) of this section, in combination with a *Type 2 NDA*, as described in paragraph (e)(5)(i) of this section.

(7) *Type 9 NDA when the parent NDA is a Type 3, Type 5, Type 7, or a Type 8*. A *Type 9 NDA*, as described in paragraph (e)(7)(i) of this section when the parent NDA is a *Type 3 NDA* as described in paragraph (e)(1) of this section or a *Type 5 NDA* as described in paragraph (e)(2) of this section or *Type 7 NDA* as described in paragraph (e)(3) of this section or a *Type 8 NDA* as described in paragraph (e)(4) of this section.

(i) *Type 9 NDA—New Indication or Claim, Drug Not to be Marketed under*

Type 9 NDA after Approval. (A) A *Type 9 NDA* is for a new indication or claim for a drug product that is currently being reviewed under a different NDA (the “parent NDA”), and the applicant does not intend to market this drug product under the *Type 9 NDA* after approval. Generally, a *Type 9 NDA* is submitted as a separate NDA so as to be in compliance with the guidance for industry on *Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees*.

(B) When the *Type 9 NDA* is submitted, it will be given the same NDA classification as the pending NDA. When one application is approved, the other will be reclassified as *Type 9* regardless of whether it was the first or second NDA actually submitted. After the approval of a *Type 9 NDA*, FDA will “administratively close” the *Type 9 NDA* and thereafter only accept submissions to the “parent” NDA.

(ii) [Reserved]

■ 8. Section 413.236 is added to read as follows:

§ 413.236 Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies.

(a) *Basis*. This section establishes a payment adjustment to support ESRD facilities in the uptake of new and innovative renal dialysis equipment and supplies under the ESRD prospective payment system under the authority of section 1881(b)(14)(D)(iv) of the Social Security Act.

(b) *Eligibility criteria*. For dates of service occurring on or after January 1, 2020, CMS provides for a transitional add-on payment adjustment for new and innovative equipment and supplies (as specified in paragraph (d) of this section) that is added to the per treatment base rate established in § 413.220, adjusted for wages as described in § 413.231, and adjusted for facility-level and patient-level characteristics as described in §§ 413.232 and 413.235 to an ESRD facility for furnishing a covered equipment or supply only if the item:

(1) Has been designated by CMS as a renal dialysis service under § 413.171;

(2) Is new, meaning it is granted marketing authorization by the Food and Drug Administration (FDA) on or after January 1, 2020;

(3) Is commercially available;

(4) Has a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures;

(5) Is innovative, meaning it meets the criteria specified in § 412.87(b)(1) of this chapter and related guidance; and

(6) Is not a capital-related asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired).

(c) *Announcement of determinations and deadline for consideration of new renal dialysis equipment or supply applications.* CMS will consider whether a new renal dialysis supply or equipment meets the eligibility criteria specified in paragraph (b) of this section and announce the results in the **Federal Register** as part of its annual updates and changes to the ESRD prospective payment system. CMS will only consider a complete application received by CMS by February 1 prior to the particular calendar year.

(d) *Transitional add-on payment adjustment for new and innovative equipment and supplies.* A new and innovative renal dialysis equipment or supply will be paid for using a transitional add-on payment adjustment for new and innovative equipment and supplies based on 65 percent of the MAC-determined price, as specified in paragraph (e) of this section.

(1) The transitional add-on payment adjustment for new and innovative equipment and supplies is paid for 2-calendar years.

(2) Following payment of the transitional add-on payment adjustment for new and innovative equipment and supplies, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will be an eligible outlier service as provided in § 413.237.

(e) *Pricing of new and innovative renal dialysis equipment and supplies.*

(1) The Medicare Administrative Contractors (MACs) on behalf of CMS will establish prices for new and innovative renal dialysis equipment and supplies that meet the eligibility criteria specified in paragraph (b) of this section using verifiable information from the following sources of information, if available:

(i) The invoice amount, facility charges for the item, discounts, allowances, and rebates;

(ii) The price established for the item by other MACs and the sources of information used to establish that price;

(iii) Payment amounts determined by other payers and the information used to establish those payment amounts; and

(iv) Charges and payment amounts required for other equipment and supplies that may be comparable or otherwise relevant.

(2) [Reserved]

■ 9. Section 413.237 is amended by—

■ a. Revising paragraphs (a)(1)(i) through (iv);

■ b. Redesignating paragraph (a)(1)(v) as paragraph (a)(1)(vi);

■ c. Adding new paragraph (a)(1)(v); and

■ d. Revising newly redesignated paragraph (a)(1)(vi).

The revisions and addition read as follows:

§ 413.237 Outliers.

(a) * * *

(1) * * *

(i) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;

(ii) Renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;

(iii) Renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;

(iv) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including renal dialysis oral-only drugs effective January 1, 2025; and

(v) Renal dialysis equipment and supplies that receive the transitional add-on payment adjustment as specified in § 413.236 after the payment period has ended.

(vi) As of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 10. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(1).

■ 11. Section 414.110 is added to subpart C to read as follows:

§ 414.110 Continuity of pricing when HCPCS codes are divided or combined.

(a) *General rule.* If a new HCPCS code is added, CMS or contractors make every effort to determine whether the item and service has a fee schedule pricing history. If there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing.

(b) *Mapping fee schedule amounts based on different kinds of coding changes.* When the code for an item is divided into several codes for the components of that item, the total of the separate fee schedule amounts established for the components must not be higher than the fee schedule amount for the original item. When there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes. When the codes for the components of a single item are combined in a single global code, the fee schedule amounts for the new code are established by totaling the fee schedule amounts used for the components (that is, use the total of the fee schedule amounts for the components as the fee schedule amount for the global code). When the codes for several different items are combined into a single code, the fee schedule amounts for the new code are established using the average (arithmetic mean), weighted by allowed services, of the fee schedule amounts for the formerly separate codes.

■ 12. Section 414.112 is added to subpart C to read as follows:

§ 414.112 Establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history.

(a) *General rule.* If a HCPCS code is new and describes items and services that do not have a fee schedule pricing history (classified and paid for previously under a different code), the fee schedule amounts for the new code are established based on the process described in paragraphs (b) through (d) of this section.

(b) *Comparability.* Fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: Physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. If there are no items with existing fee schedule amounts that are comparable to the items and services under the new code, the fee schedule amounts for the new code are established in accordance with paragraph (c) or (d) of this section.

(c) *Use of supplier or commercial price lists.* (1) Fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS codes that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price.

(i) The annual deflation factors are specified in program instructions and are based on the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period, as calculated using the following formula:

$$\frac{(\text{base CPI-U minus current CPI-U})}{\text{divided by current CPI-U plus one}}$$

(ii) The deflated amounts are then increased by the update factors specified in § 414.102(c).

(2) If within 5 years of establishing fee schedule amounts using supplier or commercial prices, the supplier or commercial prices decrease by less than 15 percent, a one-time adjustment to the fee schedule amounts is made using the new prices. The new supplier or commercial prices would be used to establish the new fee schedule amounts in the same way that the older prices were used, including application of the deflation formula in paragraph (c)(1) of this section.

(d) *Use of technology assessments.* (1) Fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS codes that are not comparable to items and services with existing fee schedule amounts may be established using technology assessments, performed by biomedical engineers, certified orthotists and prosthetists, and others knowledgeable about the cost of DMEPOS items and services, to determine the relative cost of the items and services described by the new codes to items and services with existing fee schedule amounts to determine a pricing percentage as described in paragraph (d)(2) of this section for the

purpose of establishing the fee schedule amounts for the new code.

(2) A pricing percentage is established based on the results of the technology assessment and is used to establish the fee schedule amounts for the new code(s). The pricing percentages are applied to the fee schedule amounts for HCPCS codes with existing fee schedule amounts to calculate the fee schedule amounts for new HCPCS codes without a fee schedule pricing history. Technology assessments would be used whenever it is necessary to determine the relative cost of a new item compared to items from the fee schedule base period in order to establish fee schedule amounts for the new item when supplier or commercial price lists are not available or verifiable or do not appear to represent a reasonable relative difference in supplier costs of furnishing the new DMEPOS item relative to the supplier costs of furnishing DMEPOS items from the fee schedule base period.

■ 13. Section 414.234 is amended—

■ a. In paragraph (a) by adding in alphabetical order a definition for “Required Prior Authorization List”;

■ b. By revising the heading of paragraph (b) and revising paragraphs (b)(1) and (2), (b)(3)(i) through (iii), and (b)(4) and (6);

■ c. By revising paragraphs (c)(1)(i) and (ii), (d)(1) introductory text and (d)(1)(i), and (e)(3) and (4); and

■ d. By adding paragraph (e)(5).

The revisions and addition read as follows:

§ 414.234 Prior authorization for items frequently subject to unnecessary utilization.

(a) * * *

Required Prior Authorization List is a list of DMEPOS items selected from the Master List and subject to the requirements of prior authorization as a condition of payment.

* * * * *

(b) *Master List of Items Potentially Subject to Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements.* (1) Master List Inclusion Criteria are as follows:

(i) Any DMEPOS items included in the DMEPOS Fee Schedule that have an average purchase fee of \$500 (adjusted annually for inflation using consumer price index for all urban consumers (CPI-U), and reduced by 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 FY, year, cost reporting period, or other

annual period)) or greater, or an average monthly rental fee schedule of \$50 (adjusted annually for inflation using consumer price index for all urban consumers (CPI-U), and reduced by 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 FY, year, cost reporting period, or other annual period)) or greater, or are identified as accounting for at least 1.5 percent of Medicare expenditures for all DMEPOS items over a 12-month period that are:

(A) Identified as having a high rate of potential fraud or unnecessary utilization in an Office of Inspector General (OIG) or Government Accountability Office (GAO) report that is national in scope and published in 2015 or later, or

(B) Listed in the 2018 or later Comprehensive Error Rate Testing (CERT) Medicare Fee-for-Service (FFS) Supplemental Improper Payment Data report as having a high improper payment rate, or

(ii) The annual Master List updates shall include any items with at least 1,000 claims and 1 million dollars in payments during a recent 12-month period that are determined to have aberrant billing patterns and lack explanatory contributing factors (for example, new technology or coverage policies). Items with aberrant billing patterns would be identified as those items with payments during a 12-month timeframe that exceed payments made during the preceding 12-months, by the greater of:

(A) Double the percent change of all DMEPOS claim payments for items that meet the above claim and payment criteria, from the preceding 12-month period, or

(B) Exceeding a 30 percent increase in payment, or

(iii) Any item statutorily requiring a face-to-face encounter, a written order prior to delivery, or prior authorization.

(2) The Master List is self-updating at a minimum annually, and is published in the **Federal Register**.

(3) * * *

(i) OIG reports published after 2020.

(ii) GAO reports published after 2020.

(iii) Listed in the CERT Medicare FFS Supplemental Improper Payment Data report(s) published after 2020 as having a high improper payment rate.

(4) Items are removed from the Master List after 10 years from the date the item was added to the Master List, unless the item was identified in an OIG report, GAO report, or having been identified in the CERT Medicare FFS Supplemental

Improper Payment Data report as having a high improper payment rate, within the 5-year period preceding the anticipated date of expiration.

* * * * *

(6) An item is removed from the list if the cost drops below the payment threshold criteria set forth in paragraph (b)(1)(i) of this section.

* * * * *

(c) * * *

(1) * * *

(i) The Required Prior Authorization List specified in paragraph (c)(1) of this section is selected from the Master List. CMS may consider factors such as geographic location, item utilization or cost, system capabilities, emerging trends, vulnerabilities identified in official agency reports, or other analysis and may implement prior authorization nationally or locally.

(ii) CMS may elect to limit the prior authorization requirement to a particular region of the country if claims data analysis shows that unnecessary utilization of the selected item(s) is concentrated in a particular region. CMS may elect to exempt suppliers from prior authorization upon demonstration of compliance with Medicare coverage, coding, and payment rules through such prior authorization process.

* * * * *

(d) * * *

(1) Include all relevant documentation necessary to show that the item meets applicable Medicare coverage, coding, and payment rules, including those outlined in § 410.38 and all of the following:

(i) Written order/prescription.

* * * * *

(e) * * *

(3) If applicable Medicare coverage, coding, and payment rules are not met, CMS or its contractor issues a non-affirmation decision to the requester.

(4) If the requester receives a non-affirmation decision, the requester may resubmit a prior authorization request before the item is furnished to the beneficiary and before the claim is submitted for processing.

(5) A prior authorization request for an expedited review must include documentation that shows that processing a prior authorization request using a standard timeline for review could seriously jeopardize the life or health of the beneficiary or the beneficiary's ability to regain maximum function. If CMS or its contractor agrees that processing a prior authorization request using a standard timeline for review could seriously jeopardize the life or health of the beneficiary or the beneficiary's ability to regain maximum

function, then CMS or its contractor expedites the review of the prior authorization request and communicates the decision following the receipt of all applicable Medicare required documentation.

* * * * *

■ 14. Section 414.236 is added to subpart D to read as follows:

§ 414.236 Continuity of pricing when HCPCS codes are divided or combined.

(a) *General rule.* If a new HCPCS code is added, CMS or contractors make every effort to determine whether the item and service has a fee schedule pricing history. If there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing.

(b) *Mapping fee schedule amounts based on different kinds of coding changes.* When the code for an item is divided into several codes for the components of that item, the total of the separate fee schedule amounts established for the components must not be higher than the fee schedule amount for the original item. When there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes. When the codes for the components of a single item are combined in a single global code, the fee schedule amounts for the new code are established by totaling the fee schedule amounts used for the components (that is, use the total of the fee schedule amounts for the components as the fee schedule amount for the global code). When the codes for several different items are combined into a single code, the fee schedule amounts for the new code are established using the average (arithmetic mean), weighted by allowed services, of the fee schedule amounts for the formerly separate codes.

■ 15. Section 414.238 is added to subpart D to read as follows:

§ 414.238 Establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history.

(a) *General rule.* If a HCPCS code is new and describes items and services that do not have a fee schedule pricing history (classified and paid for previously under a different code), the fee schedule amounts for the new code are established based on the process

described in paragraphs (b) through (d) of this section.

(b) *Comparability.* Fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: Physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. If there are no items with existing fee schedule amounts that are comparable to the items and services under the new code, the fee schedule amounts for the new code are established in accordance with paragraph (c) or (d) of this section.

(c) *Use of supplier or commercial price lists.* (1) Fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS codes that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price.

(i) The annual deflation factors are specified in program instructions and are based on the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period, as calculated using the following formula:

$$\frac{((\text{base CPI-U minus current CPI-U}) \text{ divided by current CPI-U}) \text{ plus one}}$$

(ii) The deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Act for DME, section 1834(h)(4) of the Act for prosthetic devices, prosthetics, orthotics, and therapeutic shoes and inserts, and section 1834(i)(1)(B) of the Act for surgical dressings.

(2) If within 5 years of establishing fee schedule amounts using supplier or commercial prices, the prices decrease by less than 15 percent, a one-time adjustment to the fee schedule amounts

is made using the new prices. The new prices would be used to establish the new fee schedule amounts in the same way that the older prices were used, including application of the deflation formula in paragraph (c)(1) of this section.

(d) *Use of technology assessments.* (1) Fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS codes that are not comparable to items and services with existing fee schedule amounts may be established using technology assessments, performed by biomedical engineers, certified orthotists and prosthetists, and others knowledgeable about the cost of DMEPOS items and services, to determine the relative cost of the items and services described by the new codes to items and services with existing fee schedule amounts to determine a pricing percentage as described in paragraph (d)(2) of this section for the purpose of establishing the fee schedule amounts for the new code.

(2) A pricing percentage is established based on the results of the technology assessment and is used to establish the fee schedule amounts for the new code(s). The pricing percentages are applied to the fee schedule amounts for HCPCS codes with existing fee schedule amounts to calculate the fee schedule amounts for new HCPCS codes without a fee schedule pricing history. Technology assessments would be used whenever it is necessary to determine the relative cost of a new item compared to items from the fee schedule base period in order to establish fee schedule amounts for the new item when supplier or commercial price lists are not available or verifiable or do not appear to represent a reasonable relative difference in supplier costs of furnishing the new DMEPOS item relative to the supplier costs of furnishing DMEPOS items from the fee schedule base period.

■ 16. Section 414.422 is amended by revising paragraph (d) to read as follows:

§ 414.422 Terms of contracts.

* * * * *

(d) *Change of ownership (CHOW).* (1) CMS may transfer a contract to a successor entity that merges with, or acquires, a contract supplier if the successor entity—

(i) Meets all requirements applicable to contract suppliers for the applicable competitive bidding program;

(ii) Submits to CMS the documentation described under § 414.414(b) through (d) if documentation has not previously been submitted by the successor entity or if the documentation is no longer sufficient for CMS to make a financial determination. A successor entity is not required to duplicate previously submitted information if the previously submitted information is not needed to make a financial determination. This documentation must be submitted prior to the effective date of the CHOW; and

(iii) Submits to CMS a signed novation agreement acceptable to CMS stating that it assumes all obligations under the contract. This documentation must be submitted no later than 10 days after the effective date of the CHOW.

(2) Except as specified in paragraph (d)(3) of this section, CMS may transfer the entire contract, including all product categories and competitive bidding areas, to a successor entity.

(3) For contracts issued in the Round 2 Recompete and subsequent rounds in the case of a CHOW where a contract supplier sells a distinct company (for example, a subsidiary) that furnishes a specific product category or services a specific CBA, CMS may transfer the portion of the contract performed by that company to a successor entity, if the following conditions are met:

(i) Every CBA, product category, and location of the company being sold must be transferred to the successor entity

that meets all competitive bidding requirements; that is, financial, accreditation, and licensure;

(ii) All CBAs and product categories in the original contract that are not explicitly transferred by CMS remain unchanged in that original contract for the duration of the contract period unless transferred by CMS pursuant to a subsequent CHOW;

(iii) All requirements of paragraph (d)(1) of this section are met;

(iv) The sale of the distinct company includes all of the contract supplier's assets associated with the CBA and/or product category(s); and

(v) CMS determines that transfer of part of the original contract will not result in disruption of service or harm to beneficiaries.

* * * * *

■ 17. Section 414.423 is amended by revising paragraph (f)(2) to read as follows:

§ 414.423 Appeals process for breach of a DMEPOS competitive bidding program contract actions.

* * * * *

(f) * * *

(2) A supplier that wishes to appeal the breach of contract action(s) specified in the notice of breach of contract must submit a written request to the CBIC. The request for a hearing must be submitted to the CBIC within 30 days from the date of the notice of breach of contract.

* * * * *

Dated: June 21, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 24, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–16369 Filed 7–29–19; 4:15 pm]

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42 CFR Part 412

Medicare Program; FY 2020 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates for Fiscal Year Beginning October 1, 2019 (FY 2020); Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS-1712-F]

RIN 0938-AT69

Medicare Program; FY 2020 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates for Fiscal Year Beginning October 1, 2019 (FY 2020)

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

ACTION: Final rule.

SUMMARY: This final rule updates the prospective payment rates, the outlier threshold, and the wage index for Medicare inpatient hospital services provided by Inpatient Psychiatric Facilities (IPFs), which include psychiatric hospitals and excluded psychiatric units of an inpatient prospective payment system hospital or critical access hospital. Additionally, this final rule revises and rebases the IPF market basket to reflect a 2016 base year and removes the IPF Prospective Payment System (PPS) 1-year lag of the wage index data. Finally, this final rule implements updates to the Inpatient Psychiatric Facilities Quality Reporting Program. These changes will be effective for IPF discharges beginning during the fiscal year (FY) from October 1, 2019 through September 30, 2020 (FY 2020).

DATES: These regulations are effective on October 1, 2019.

FOR FURTHER INFORMATION CONTACT: The IPF Payment Policy mailbox at IPFPaymentPolicy@cms.hhs.gov for general information.

Mollie Knight, (410) 786-7948 or Hudson Osgood, (410) 786-7897, for information regarding the market basket rebasing, update, or the labor related share.

Theresa Bean, (410) 786-2287 or James Hardesty, (410) 786-2629, for information regarding the regulatory impact analysis.

James Poyer, (410) 786-2261 or Jeffrey Buck, (410) 786-0407, for information regarding the inpatient psychiatric facility quality reporting program.

SUPPLEMENTARY INFORMATION:

Availability of Certain Tables Exclusively Through the Internet on the CMS Website

Addendum A to this final rule summarizes the FY 2020 IPF PPS

payment rates, outlier threshold, cost of living adjustment factors for Alaska and Hawaii, national and upper limit cost-to-charge ratios, and adjustment factors. In addition, the B Addenda to this final rule show the complete listing of ICD-10 Clinical Modification (CM) and Procedure Coding System codes underlying the Code First table (Addendum B-1), the FY 2020 IPF PPS comorbidity adjustment (Addenda B-2 and B-3), and electroconvulsive therapy (ECT) procedure codes (Addendum B-4). The A and B addenda are available online at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html>.

Tables setting forth the FY 2020 Wage Index for Urban Areas Based on Core-Based Statistical Area (CBSA) Labor Market Areas and the FY 2020 Wage Index Based on CBSA Labor Market Areas for Rural Areas are available exclusively through the internet, on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/IPFPPS/WageIndex.html>. In addition, Addendum C to this final rule is a provider-level file of the effects of the change to the wage index methodology, and is available at the same CMS website address.

I. Executive Summary

A. Purpose

This final rule updates the prospective payment rates, the outlier threshold, and the wage index for Medicare inpatient hospital services provided by Inpatient Psychiatric Facilities (IPFs) for discharges occurring during the Fiscal Year (FY) beginning October 1, 2019 through September 30, 2020. Additionally, this final rule rebases and revises the IPF market basket to reflect a 2016 base year and uses the concurrent hospital wage data as the basis of the IPF wage index rather than using the prior year's Inpatient Prospective Payment System (IPPS) hospital wage data. Finally, this final rule updates the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program.

B. Summary of the Major Provisions

1. Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS)

In this final rule we:

- *Rebase and revise the IPF market basket to reflect a 2016 base year:* Since the IPF PPS inception, the market basket used to update IPF PPS payments has been periodically rebased and revised to reflect more recent data on IPF cost

structures. We last rebased and revised the market basket applicable to IPFs in the FY 2016 IPF PPS rule (80 FR 46656 through 46679), when we adopted a 2012-based IPF-specific market basket.

- *Adjust the 2016-based IPF market basket update (2.9 percent) by a reduction for economy-wide productivity (0.4 percentage point) as required by section 1886(s)(2)(A)(i) of the Social Security Act (the Act).* We further reduced the 2016-based IPF market basket update by 0.75 percentage point as required by section 1886(s)(2)(A)(ii) of the Act, resulting in an IPF payment rate update of 1.75 percent for FY 2020.

- *Made technical rate setting changes:* The IPF PPS payment rates are adjusted annually for inflation, as well as statutory and other policy factors. We updated:

- ++ The IPF PPS federal per diem base rate from \$782.78 to \$798.55.

- ++ The IPF PPS federal per diem base rate for providers who failed to report quality data to \$782.85.

- ++ The Electroconvulsive therapy (ECT) payment per treatment from \$337.00 to \$343.79.

- ++ The ECT payment per treatment for providers who failed to report quality data to \$337.03.

- ++ The labor-related share from 74.8 percent to 76.9 percent.

- ++ The core-based statistical area (CBSA) rural and urban wage indices for FY 2020, using the FY 2020 pre-floor, pre-reclassified IPPS hospital wage index data and OMB designations from OMB Bulletin 17-01.

- ++ The wage index budget-neutrality factor to 1.0026.

- ++ The fixed dollar loss threshold amount from \$12,865 to \$14,960 to maintain estimated outlier payments at 2 percent of total estimated aggregate IPF PPS payments.

- *Eliminate the 1-year lag in the wage index data:* We aligned the IPF wage index data with the concurrent IPPS wage index data by removing the 1-year lag of the pre-floor, pre-reclassified IPPS hospital wage index upon which the IPF wage index is based.

2. Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

We updated the IPFQR Program by adding a new measure for the program.

C. Summary of Impacts

Provision description	Total transfers & cost reductions
FY 2020 IPF PPS payment update	The overall economic impact of this final rule is an estimated \$65 million in increased payments to IPFs during FY 2020.
Updated quality reporting program (IPFQR) Program requirements.	\$0.

II. Background

A. Overview of the Legislative Requirements of the IPF PPS

Section 124 of the Medicare, Medicaid, and State Children's Health Insurance Program Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) required the establishment and implementation of an IPF PPS. Specifically, section 124 of the BBRA mandated that the Secretary of the Department of Health and Human Services (the Secretary) develop a per diem PPS for inpatient hospital services furnished in psychiatric hospitals and excluded psychiatric units including an adequate patient classification system that reflects the differences in patient resource use and costs among psychiatric hospitals and excluded psychiatric units. “Excluded psychiatric unit” means a psychiatric unit in an IPPS hospital that is excluded from the IPPS, or a psychiatric unit in a Critical Access Hospital (CAH) that is excluded from the CAH payment system. These excluded psychiatric units would be paid under the IPF PPS.

Section 405(g)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) extended the IPF PPS to psychiatric distinct part units of CAHs.

Sections 3401(f) and 10322 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) as amended by section 10319(e) of that Act and by section 1105(d) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (hereafter referred to jointly as “the Affordable Care Act”) added subsection (s) to section 1886 of the Act.

Section 1886(s)(1) of the Act titled “Reference to Establishment and Implementation of System,” refers to section 124 of the BBRA, which relates to the establishment of the IPF PPS.

Section 1886(s)(2)(A)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the IPF PPS for the rate year (RY) beginning in 2012 (that is, a RY that coincides with a FY) and each subsequent RY. As noted in our FY 2019 IPF PPS final rule with comment period, published in the **Federal Register** on August 6, 2018 (83 FR 38576 through 38620), for the RY beginning in 2018,

the productivity adjustment currently in place is equal to 0.8 percentage point.

Section 1886(s)(2)(A)(ii) of the Act requires the application of an “other adjustment” that reduces any update to an IPF PPS base rate by a percentage point amount specified in section 1886(s)(3) of the Act for the RY beginning in 2010 through the RY beginning in 2019. As noted in the FY 2019 IPF PPS final rule, for the RY beginning in 2018, section 1886(s)(3)(E) of the Act requires that the other adjustment reduction currently in place be equal to 0.75 percentage point.

Sections 1886(s)(4)(A)–(D) of the Act require that for RY 2014 and each subsequent RY, IPFs that fail to report required quality data with respect to such a RY will have their annual update to a standard federal rate for discharges reduced by 2.0 percentage points. This may result in an annual update being less than 0.0 for a RY, and may result in payment rates for the upcoming RY being less than such payment rates for the preceding RY. Any reduction for failure to report required quality data will apply only to the RY involved, and the Secretary will not take into account such reduction in computing the payment amount for a subsequent RY. (See section II.C of this final rule for an explanation of the IPF PPS RY.) More information about the specifics of the current IPFQR Program is available in the FY 2019 IPF PPS and Quality Reporting Updates for Fiscal Year Beginning October 1, 2018 final rule (83 FR 38589 through 38608).

To implement and periodically update these provisions, we have published various proposed and final rules and notices in the **Federal Register**. For more information regarding these documents, see the Center for Medicare & Medicaid (CMS) website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacIPPS/index.html?redirect=/InpatientPsychFacIPPS/>.

B. Overview of the IPF PPS

The November 2004 IPF PPS final rule (69 FR 66922) established the IPF PPS, as required by section 124 of the BBRA and codified at 42 CFR part 412, subpart N. The November 2004 IPF PPS final rule set forth the federal per diem base rate for the implementation year

(the 18-month period from January 1, 2005 through June 30, 2006), and provided payment for the inpatient operating and capital costs to IPFs for covered psychiatric services they furnish (that is, routine, ancillary, and capital costs, but not costs of approved educational activities, bad debts, and other services or items that are outside the scope of the IPF PPS). Covered psychiatric services include services for which benefits are provided under the fee-for-service Part A (Hospital Insurance Program) of the Medicare program.

The IPF PPS established the federal per diem base rate for each patient day in an IPF derived from the national average daily routine operating, ancillary, and capital costs in IPFs in FY 2002. The average per diem cost was updated to the midpoint of the first year under the IPF PPS, standardized to account for the overall positive effects of the IPF PPS payment adjustments, and adjusted for budget-neutrality.

The federal per diem payment under the IPF PPS is comprised of the federal per diem base rate described previously and certain patient- and facility-level payment adjustments for characteristics that were found in the regression analysis to be associated with statistically significant per diem cost differences, with statistical significance defined as *p* less than 0.05.

The patient-level adjustments include age, Diagnosis-Related Group (DRG) assignment, and comorbidities; additionally, there are adjustments to reflect higher per diem costs at the beginning of a patient's IPF stay and lower costs for later days of the stay. Facility-level adjustments include adjustments for the IPF's wage index, rural location, teaching status, a cost-of-living adjustment for IPFs located in Alaska and Hawaii, and an adjustment for the presence of a qualifying emergency department (ED).

The IPF PPS provides additional payment policies for outlier cases, interrupted stays, and a per treatment payment for patients who undergo electroconvulsive therapy (ECT). During the IPF PPS mandatory 3-year transition period, stop-loss payments were also provided; however, since the transition ended as of January 1, 2008, these payments are no longer available.

A complete discussion of the regression analysis that established the IPF PPS adjustment factors can be found in the November 2004 IPF PPS final rule (69 FR 66933 through 66936).

C. Annual Requirements for Updating the IPF PPS

Section 124 of the BBRA did not specify an annual rate update strategy for the IPF PPS and was broadly written to give the Secretary discretion in establishing an update methodology.

Therefore, in the November 2004 IPF PPS final rule, we implemented the IPF PPS using the following update strategy:

- Calculate the final federal per diem base rate to be budget-neutral for the 18-month period of January 1, 2005 through June 30, 2006.

- Use a July 1 through June 30 annual update cycle.

- Allow the IPF PPS first update to be effective for discharges on or after July 1, 2006 through June 30, 2007.

In RY 2012, we proposed and finalized switching the IPF PPS payment rate update from a RY that begins on July 1 and ends on June 30, to one that coincides with the federal FY that begins October 1 and ends on September 30. In order to transition from one timeframe to another, the RY 2012 IPF PPS covered a 15-month period from July 1, 2011 through September 30, 2012. Therefore, the IPF RY has been equivalent to the October 1 through September 30 federal FY since RY 2013. For further discussion of the 15-month market basket update for RY 2012 and changing the payment rate update period to coincide with a FY period, we refer readers to the RY 2012 IPF PPS proposed rule (76 FR 4998) and the RY 2012 IPF PPS final rule (76 FR 26432).

In November 2004, we implemented the IPF PPS in a final rule that published on November 15, 2004 in the **Federal Register** (69 FR 66922). In developing the IPF PPS, and to ensure that the IPF PPS is able to account adequately for each IPF's case-mix, we performed an extensive regression analysis of the relationship between the per diem costs and certain patient and facility characteristics to determine those characteristics associated with statistically significant cost differences on a per diem basis. That regression analysis is described in detail in our November 28, 2003 IPF proposed rule (68 FR 66923; 66928 through 66933) and our November 15, 2004 IPF final rule (69 FR 66933 through 66960). For characteristics with statistically significant cost differences, we used the regression coefficients of those variables

to determine the size of the corresponding payment adjustments.

In that final rule, we explained the reasons for delaying an update to the adjustment factors, derived from the regression analysis, including waiting until we have IPF PPS data that yields as much information as possible regarding the patient-level characteristics of the population that each IPF serves. We indicated that we did not intend to update the regression analysis and the patient-level and facility-level adjustments until we complete that analysis. Until that analysis is complete, we stated our intention to publish a notice in the **Federal Register** each spring to update the IPF PPS (69 FR 66966).

On May 6, 2011, we published a final rule in the **Federal Register** titled, "Inpatient Psychiatric Facilities Prospective Payment System—Update for Rate Year Beginning July 1, 2011 (RY 2012)" (76 FR 26432), which changed the payment rate update period to a RY that coincides with a FY update. Therefore, final rules are now published in the **Federal Register** in the summer to be effective on October 1. When proposing changes in IPF payment policy, a proposed rule would be issued in the spring, and the final rule in the summer to be effective on October 1. For a detailed list of updates to the IPF PPS, we refer readers to our regulations at 412.428.

The most recent IPF PPS annual update was published in a final rule on August 6, 2018 in the **Federal Register** titled, "Medicare Program; FY 2019 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates" (83 FR 38576), which updated the IPF PPS payment rates for FY 2019. That final rule updated the IPF PPS federal per diem base rates that were published in the FY 2018 IPF PPS Rate Update final rule (82 FR 36771) in accordance with our established policies.

III. Provisions of the FY 2020 IPF PPS Final Rule and Responses to Comments

On April 23, 2019 we published the FY 2020 IPF PPS proposed rule (84 FR 16948). We received 24 comments on the FY 2020 IPF PPS proposed rule, with some commenters addressing multiple issues. We received 4 comments on payment policy issues, 19 comments on quality issues, and 6 comments that were outside of the scope of the proposed rule.

A. Rebasing and Revising of the Market Basket for the IPF PPS

1. Background

Originally, the input price index used to develop the IPF PPS was the Excluded Hospital with Capital market basket. This market basket was based on 1997 Medicare cost reports for Medicare-participating inpatient rehabilitation facilities (IRFs), IPFs, long-term care hospitals (LTCHs), cancer hospitals, and children's hospitals. Although "market basket" technically describes the mix of goods and services used in providing health care at a given point in time, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies) derived from that market basket. Accordingly, the term "market basket," as used in this document, refers to an input price index.

Since the IPF PPS inception, the market basket used to update IPF PPS payments has been rebased and revised to reflect more recent data on IPF cost structures. We last rebased and revised the market basket applicable to the IPF PPS in the FY 2016 IPF PPS final rule (80 FR 46656 through 46679), where we adopted a 2012-based IPF market basket. The 2012-based IPF market basket used Medicare cost report data for both Medicare-participating freestanding psychiatric hospitals and hospital-based psychiatric units. References to the historical market baskets used to update IPF PPS payments are listed in the FY 2016 IPF PPS final rule (80 FR 46656). For the FY 2020 IPF PPS proposed rule, we proposed to rebase and revise the IPF market basket to reflect a 2016 base year.

2. Overview of the 2016-Based IPF Market Basket

The proposed 2016-based IPF market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time relative to a base period are not measured.

The index itself is constructed in three steps. First, a base period is selected (for the proposed IPF market basket, the base period is 2016) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories. Each category is calculated as a proportion of total costs. These proportions are called cost or expenditure weights. Second, each expenditure category is matched to

an appropriate price or wage variable, referred to as a price proxy. In nearly every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As noted, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish IPF services. The effects on total expenditures resulting from changes in the mix of goods and services purchased after the base period are not measured. For example, an IPF hiring more nurses after the base period to accommodate the needs of patients will increase the volume of goods and services purchased by the IPF, but would not be factored into the price change measured by a fixed-weight IPF market basket. Only when the index is rebased will changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect recent changes in the mix of goods and services that IPFs purchase to furnish inpatient care between base periods.

3. Creating an IPF-Specific Market Basket

As discussed in the FY 2016 final rule (80 FR 46656 through 46679), the 2012-based IPF market basket reflects the Medicare cost reports for both freestanding and hospital-based facilities. Previous market baskets, such as the 2008-based rehabilitation, psychiatric, and long-term care (RPL) market basket, were calculated using Medicare cost report data for freestanding facilities only. We used only freestanding facilities due to concerns regarding our ability to incorporate Medicare cost report data for hospital-based providers. After research on the available Medicare cost report data, we concluded that Medicare cost report data for both freestanding IPFs and hospital-based IPFs can be

used to calculate the major market basket cost weights for a stand-alone IPF market basket. In the FY 2016 IPF PPS final rule (80 FR 46656 through 46679), we finalized a detailed methodology to derive market basket cost weights using Medicare cost report data for both freestanding IPFs and hospital-based IPFs.

For the FY 2020 proposed rule, we proposed to rebase and revise the 2012-based IPF market basket to a 2016 base year reflecting both freestanding IPFs and hospital-based IPFs. In section III.A.3.a., “Development of Cost Categories and Weights,” we provide a detailed description of our proposed methodology used to develop the 2016-based IPF market basket.

a. Development of Cost Categories and Weights

i. Medicare Cost Reports

We proposed a 2016-based IPF market basket that consists of seven major cost categories and a residual derived from the 2016 Medicare cost reports (CMS Form 2552–10 effective for cost reports beginning on or after May 1, 2010) for freestanding and hospital-based IPFs. CMS Form 2552–10 was also used to derive the major cost categories in the 2012-based IPF market basket. The seven cost categories are Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional Liability Insurance (PLI), Home Office Contract Labor, and Capital. The 2012-based IPF market basket did not have a Home Office Contract Labor cost category. The residual “All Other” category reflects all remaining costs not captured in the seven cost categories. The 2016 cost reports include providers whose cost reporting period beginning date is on or between October 1, 2015 and September 30, 2016. We proposed to select 2016 as the base year because we believe that the Medicare cost reports for this year represent the most recent, complete set of Medicare cost report data available at the time of rulemaking.

Similar to the Medicare cost report data used to develop the 2012-based IPF market basket, the Medicare cost report data for 2016 show large differences between some providers’ Medicare length of stay (LOS) and total facility LOS. Our goal has always been to measure cost weights that are reflective of case mix and practice patterns associated with providing services to Medicare beneficiaries. Therefore, we proposed to limit our selection of Medicare cost reports used in the 2016-based IPF market basket to those facilities that had a Medicare LOS

within a comparable range of their total facility average LOS. The Medicare average LOS for freestanding IPFs is calculated from data reported on line 14 of Worksheet S–3, part I. The Medicare average LOS for hospital-based IPFs is calculated from data reported on line 16 of Worksheet S–3, part I. To derive the proposed 2016-based IPF market basket, for those IPFs with an average facility LOS of greater than or equal to 15 days, we proposed to include IPFs where the Medicare LOS is within 50 percent (higher or lower) of the average facility LOS. For those IPFs whose average facility LOS is less than 15 days, we proposed to include IPFs where the Medicare LOS is within 95 percent (higher or lower) of the facility LOS. We proposed to apply this LOS edit to the data for IPFs to exclude providers that serve a population whose LOS would indicate that the patients served are not consistent with a LOS of a typical Medicare patient. This is the same LOS edit applied to the 2012-based IPF market basket.

Applying these trims to the approximate 1,600 total cost reports (freestanding and hospital-based) resulted in roughly 1,500 IPF Medicare cost reports with an average Medicare LOS of 12 days, average facility LOS of 9 days, and Medicare utilization (as measured by Medicare inpatient IPF days as a percentage of total facility days) of 26 percent. Providers excluded from the proposed 2016-based IPF market basket (about 130 Medicare cost reports) had an average Medicare LOS of 25 days, average facility LOS of 55 days, and a Medicare utilization of 4 percent. Of those excluded, about 70 percent of these were freestanding providers; on the other hand, freestanding providers represent about 30 percent of all IPFs. We note that seventy percent of those excluded from the 2012-based IPF market basket using this LOS edit were also freestanding providers.

Using the post-LOS set of 2016 Medicare cost reports, we calculated costs for the seven major cost categories (Wages and Salaries, Employee Benefits, Contract Labor, Professional Liability Insurance, Pharmaceuticals, Home Office Contract Labor, and Capital). For comparison, the 2012-based IPF market basket utilized the Bureau of Economic Analysis Benchmark Input-Output data to derive the Home Office Contract Labor cost weight rather than the Medicare cost report data. A more detailed discussion of this methodological change is provided.

Similar to the 2012-based IPF market basket major cost weights, the proposed 2016-based IPF market basket cost weights reflect Medicare allowable costs

(routine, ancillary, and capital costs) that are eligible for inclusion under the IPF PPS payments. We proposed to define Medicare allowable costs for freestanding IPFs as Worksheet B, part I, column 26, lines 30 through 35, 50 through 76 (excluding 52 and 75), 90 through 91, and 93. For hospital-based IPFs, we proposed that total Medicare allowable costs be equal to total costs for the IPF inpatient unit after the allocation of overhead costs (Worksheet B, part I, column 26, line 40) and a portion of total ancillary costs (Worksheet B, part I, column 26, lines 50 through 76 (excluding 52 and 75), 90 through 91, and 93). We proposed to calculate the portion of ancillary costs attributable to the hospital-based IPF for a given ancillary cost center by multiplying total facility ancillary costs for the specific cost center (as reported on Worksheet B, part I, column 26) by the ratio of IPF Medicare ancillary costs for the cost center (as reported on Worksheet D-3, column 3 for IPF subproviders) to total Medicare ancillary costs for the cost center (equal to the sum of Worksheet D-3, column 3 for all Inpatient Prospective Payment System (IPPS), Skilled Nursing Facility (SNF), IRF, and IPF). This is the same methodology used for the 2012-based IPF market basket.

We provide a description of the proposed methodologies used to derive costs for the seven major cost categories.

Wages and Salaries Costs

For freestanding IPFs, we proposed that Wages and Salaries costs be derived as the sum of routine inpatient salaries, ancillary salaries, and a proportion of overhead (or general service cost centers in the MCR) salaries as reported on Worksheet A, column 1. Since overhead salary costs are attributable to the entire IPF, we only include the proportion attributable to the Medicare allowable cost centers. We proposed to estimate the proportion of overhead salaries that are attributed to Medicare allowable costs centers by multiplying the ratio of Medicare allowable salaries (Worksheet A, column 1, lines 50 through 76 (excluding 52 and 75), 90 through 91, and 93) to total salaries (Worksheet A, column 1, line 200) times total overhead salaries (Worksheet A, column 1, lines 4 through 18). This is the same methodology used in the 2012-based IPF market basket.

We proposed that Wages and Salaries costs for hospital-based IPFs are derived by summing inpatient routine salary costs, ancillary salaries, overhead salary costs attributable to the IPF inpatient unit, and a portion of overhead salary

costs attributable to the ancillary departments.

We proposed to calculate hospital-based inpatient routine salary costs using Worksheet A, column 1, line 40.

We proposed to calculate hospital-based ancillary salary costs for a specific cost center (Worksheet A, column 1, lines 50 through 76 (excluding 52 and 75), 90 through 91, and 93) using salary costs from Worksheet A, column 1 multiplied by the ratio of IPF Medicare ancillary costs for the cost center (as reported on Worksheet D-3, column 3 for IPF subproviders) to total Medicare ancillary costs for the cost center (equal to the sum of Worksheet D-3, column 3 for IPPS, SNF, IRF, and IPF).

We proposed to calculate the hospital-based overhead salaries attributable to the IPF inpatient unit by first calculating total noncapital overhead costs (Worksheet B, part I, columns 4–18, line 40 less Worksheet B, part II, columns 4–18) for each ancillary department. We then multiplied total noncapital overhead costs by the ratio of total facility overhead salaries (as reported on Worksheet A, column 1, lines 4–18) to total facility noncapital overhead costs (as reported on Worksheet A, column 1 and 2, lines 4–18).

We proposed to calculate the hospital-based portion of overhead salaries attributable to each ancillary department by first calculating total noncapital overhead costs attributable to each specific ancillary department (Worksheet B, part I, columns 4–18 less Worksheet B, part II, columns 4–18). We then identified the portion of these noncapital overhead costs attributable to Wages and Salaries by multiplying these costs by the ratio of total facility overhead salaries (as reported on Worksheet A, column 1, lines 4–18) to total overhead costs (as reported on Worksheet A, column 1 & 2, lines 4–18). Finally, we identified the portion of these overhead salaries for each ancillary department that is attributable to the hospital-based IPF by multiplying by the ratio of IPF Medicare ancillary costs for the cost center (as reported on Worksheet D-3, column 3 for hospital-based IPFs) to total Medicare ancillary costs for the cost center (equal to the sum of Worksheet D-3, column 3 for all IPPS, SNF, IRF, and IPF).

This is the same Wages and Salaries Costs methodology used to derive the 2012-based IPF market basket.

Employee Benefits Costs

Effective with the implementation of CMS Form 2552-10, we began collecting Employee Benefits and

Contract Labor data on Worksheet S-3, part V.

For 2016 Medicare cost report data, the majority of providers did not report data on Worksheet S-3, part V. One (1) percent of freestanding IPFs and roughly 40 percent of hospital-based IPFs reported data on Worksheet S-3, part V. Again, we continue to encourage all providers to report these data on the Medicare cost report.

For freestanding IPFs, we proposed Employee Benefits costs were equal to the data reported on Worksheet S-3, part V, column 2, line 2. We note that while not required to do so, freestanding IPFs also may report Employee Benefits data on Worksheet S-3, part II, which is applicable to only IPPS providers. For those freestanding IPFs that reported Worksheet S-3, part II data, but not Worksheet S-3, part V, we proposed to use the sum of Worksheet S-3, part II lines 17, 18, 20, and 22 to derive Employee Benefits costs. This proposed method allowed us to obtain data from more than 20 freestanding IPFs (roughly 5 percent of all freestanding IPFs) than if we were to only use Worksheet S-3, part V data as done for the 2012-based IPF market basket.

For hospital-based IPFs, we proposed to calculate total benefit costs as the sum of inpatient unit benefit costs, a portion of ancillary benefits, and a portion of overhead benefits attributable to the routine inpatient unit and a portion of overhead benefits attributable to the ancillary departments.

We proposed hospital-based inpatient unit benefit costs be equal to Worksheet S-3 part V, column 2, line 3.

We proposed the hospital-based portion of ancillary benefit costs be equal to hospital-based ancillary salaries times the ratio of total facility benefits to total facility salaries.

We proposed that the hospital-based portion of overhead benefits attributable to the routine inpatient unit and ancillary departments be calculated by multiplying ancillary salaries for the hospital-based IPF and overhead salaries attributable to the hospital-based IPF (determined in the derivation of hospital-based IPF Wages and Salaries costs as described) by the ratio of total facility benefits to total facility salaries. Total facility benefits is equal to the sum of Worksheet S-3, part II, column 4, lines 17–25 and total facility salaries is equal to Worksheet S-3, part II, column 4, line 1.

Contract Labor Costs

Contract Labor costs are primarily associated with direct patient care services. Contract Labor costs are exclusive of Home Office Contract Labor

costs. Contract labor costs for other services such as accounting, billing, and legal are calculated separately using other government data sources as described in section III.A.3.a.iii of this final rule. To derive contract labor costs using Worksheet S-3, part V data, for freestanding IPFs, we proposed Contract Labor costs be equal to Worksheet S-3, part V, column 1, line 2. As we noted for Employee Benefits, freestanding IPFs also may report Contract Labor data on Worksheet S-3, part II, which is applicable to only IPPS providers. For those freestanding IPFs that reported Worksheet S-3, part II data, but not Worksheet S-3, part V, we proposed to use the sum of Worksheet S-3, part II lines 11 and 13 to derive Contract Labor costs. For the 2012-based IPF market basket, we only used data from Worksheet S-3, part V, column 1, line 2 to derive the Contract Labor costs for freestanding IPFs.

For hospital-based IPFs, we proposed that Contract Labor costs be equal to Worksheet S-3, part V, column 1, line 3. Reporting of this data continues to be somewhat limited; therefore, we continue to encourage all providers to report these data on the Medicare cost report.

Pharmaceuticals Costs

For freestanding IPFs, we proposed to calculate pharmaceuticals costs using non-salary costs reported on Worksheet A, column 7 less Worksheet A, column 1 for the pharmacy cost center (line 15) and drugs charged to patients cost center (line 73).

For hospital-based IPFs, we proposed to calculate pharmaceuticals costs as the sum of a portion of the non-salary pharmacy costs and a portion of the non-salary drugs charged to patient costs reported for the total facility.

We proposed that hospital-based non-salary pharmacy costs attributable to the hospital-based IPF are calculated by multiplying total pharmacy costs attributable to the hospital-based IPF (as reported on Worksheet B, part I, column 15, line 40) by the ratio of total non-salary pharmacy costs (Worksheet A, column 2, line 15) to total pharmacy costs (sum of Worksheet A, column 1 and 2 for line 15) for the total facility.

We proposed that hospital-based non-salary drugs charged to patient costs attributable to the hospital-based IPF are calculated by multiplying total non-salary drugs charged to patient costs (Worksheet B, part I, column 0, line 73 plus Worksheet B, part I, column 15, line 73 less Worksheet A, column 1, line 73) for the total facility by the ratio of Medicare drugs charged to patient ancillary costs for the IPF unit (as

reported on Worksheet D-3 for IPF subproviders, column 3, line 73) to total Medicare drugs charged to patients ancillary costs for the total facility (equal to the sum of Worksheet D-3, column 3, line 73, for all IPPS, SNF, IRF, and IPF).

This is the same Pharmaceuticals Costs methodology used to derive the 2012-based IPF market basket.

Professional Liability Insurance (PLI) Costs

For freestanding IPFs, we proposed that PLI costs (often referred to as malpractice costs) are equal to premiums, paid losses and self-insurance costs reported on Worksheet S-2, part I, columns 1 through 3, line 118.

For hospital-based IPFs, we proposed to assume that the PLI weight for the total facility is similar to the hospital-based IPF unit since the only data reported on this worksheet is for the entire facility. Therefore, hospital-based IPF PLI costs were equal to total facility PLI (as reported on Worksheet S-2, part I, columns 1 through 3, line 118) divided by total facility costs (as reported on Worksheet A, columns 1 and 2, line 200) times hospital-based IPF Medicare allowable total costs. Our assumption is that the same proportion of expenses are used among each unit of the hospital.

This is the same methodology used to derive the 2012-based IPF market basket.

Home Office/Related Organization Contract Labor Costs

For the 2016-based IPF market basket, we proposed to determine the home office/related organization contract labor costs using Medicare cost report data. This is a different methodology compared to the 2012-based IPF market basket. We believe this proposed methodology is an improvement as it is based on the data directly submitted by providers on the Medicare cost report. It is also consistent with the methodology we adopted when we rebased and revised the 2014-based IPPS market basket (52 FR 38159).

For hospital-based IPFs, we proposed to calculate the home office contract labor cost weight using data reported on Worksheet S-3, part II, column 4, lines 14, 1401, 1402, 2550, and 2551 and total facility costs (Worksheet B, part 1, column 26, line 202). We proposed to use total facility costs as the denominator for calculating the home office contract labor cost weight as these expenses reported on Worksheet S-3, part II reflect the entire hospital facility. Our assumption is that the same

proportion of expenses are used among each unit of the hospital. Similar to the other market basket costs weights, we proposed to trim the Home Office Contract Labor cost weight to remove outliers. Since not all hospital-based IPFs will have home office contract labor costs, we proposed to trim the top one percent of the Home Office Contract Labor cost weight. This is the same trimming methodology used to calculate the Home Office Contract Labor cost weight in the 2016-based IPPS market basket. Using this proposed methodology, we calculate a Home Office Contract Labor cost weight for hospital-based IPFs of 3.7 percent. We discuss the trimming methodology for the other major cost categories in the "Final Major Cost Category Computation" in section ii. of this final rule.

Freestanding IPFs are not required to complete Worksheet S-3, part II. Therefore, to estimate the Home Office Contract Labor cost weight, we proposed the following methodology:

(1) Using hospital-based IPFs with a home office and also passing the one percent trim as described, we calculate the ratio of the Home Office Contract Labor cost weight to the Medicare allowable nonsalary, noncapital cost weight (Medicare allowable nonsalary, noncapital costs as a percent of total Medicare allowable costs).

(2) We identify freestanding IPFs that report a home office on Worksheet S-2, part I, line 140—roughly 85 percent. We proposed to calculate a Home Office Contract Labor cost weight for these freestanding IPFs by multiplying the ratio calculated in Step (1) by the Medicare allowable nonsalary, noncapital cost weight for those freestanding IPFs with a home office.

(3) We then calculated the freestanding IPF cost weight by multiplying the Home Office Contract Labor cost weight in step (2) by the total Medicare allowable costs for IPFs with a home office as a percent of total Medicare allowable costs for all freestanding IPFs.

To calculate the Home Office Contract Labor cost weight, we proposed to weight together the freestanding Home Office Contract Labor cost weight (3.0 percent) and the hospital-based Home Office Contract Labor cost weight (3.7 percent) using total Medicare allowable costs. The resulting overall cost weight for Home Office was 3.5 percent (3.0 percent \times 37 percent + 3.7 percent \times 63 percent).

For the 2012-based IPF market basket, we calculated the Home Office Contract Labor cost weight using the Bureau of Economic Analysis Input-Output

expense data for North American Industry Classification System (NAICS) code 55, Management of Companies and Enterprises using the methodology described in section III.A.3.a.iii (Derivation of the Detailed Operating Cost Weights) of this final rule.

Capital Costs

For freestanding IPFs, we proposed capital costs to be equal to Medicare allowable capital costs as reported on Worksheet B, part II, column 26, lines 30 through 35, 50 through 76 (excluding 52 and 75), 90 through 91, and 93. This is the same methodology used for the 2012-based IPF market basket.

For hospital-based IPFs, we proposed capital costs to be equal to IPF inpatient capital costs (as reported on Worksheet B, part II, column 26, line 40) and a portion of IPF ancillary capital costs. We calculated the portion of ancillary capital costs attributable to the hospital-based IPF for a given cost center by multiplying total facility ancillary capital costs for the specific ancillary cost center (as reported on Worksheet B,

part II, column 26) by the ratio of IPF Medicare ancillary costs for the cost center (as reported on Worksheet D–3, column 3 for IPF subproviders) to total Medicare ancillary costs for the cost center (equal to the sum of Worksheet D–3, column 3 for all IPPS, SNF, IRF, and IPF). This is the same methodology used for the 2012-based IPF market basket.

ii. Final Major Cost Category Computation

After we derived costs for the seven major cost categories for each provider using the Medicare cost report data as described, we proposed to trim the data for outliers. The proposed trimming methodology for the Home Office Contract Labor cost weight is slightly different than the proposed trimming methodology for the other six cost categories. For the Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional Liability Insurance, and Capital cost weights, we first divided the costs for each of these six categories by total Medicare

allowable costs calculated for the provider to obtain cost weights for the universe of IPF providers. Next, we applied a mutually exclusive top and bottom 5 percent trim for each cost weight to remove outliers. After the outliers have been removed, we summed the costs for each category across all remaining providers. We then divided this by the sum of total Medicare allowable costs across all remaining providers to obtain a cost weight for the proposed 2016-based IPF market basket for the given category.

Finally, we calculated the residual “All Other” cost weight that reflects all remaining costs that are not captured in the seven cost categories listed. We did not receive any comments on the derivation of the major cost weights. In this final rule, we are finalizing our methodology for deriving the major cost weights as we proposed.

Table 1 presents the major cost categories and weights calculated from the Medicare cost reports for the 2016-based IPF market basket as well as for the 2012-based IPF market basket.

TABLE 1—MAJOR COST CATEGORIES AS DERIVED FROM MEDICARE COST REPORTS

Major cost categories	Final 2016-based IPF market basket (percent)	2012-based IPF market basket (percent)
Wages and Salaries	51.2	51.0
Employee Benefits	13.5	13.1
Contract Labor	1.3	1.3
Professional Liability Insurance (Malpractice)	0.9	1.1
Pharmaceuticals	4.7	4.8
Home Office/Related Organization Contract Labor	3.5	n/a
Capital	7.1	7.0
“All Other” Residual	17.9	21.6

Note: Total may not sum to 100 due to rounding.

As we did for the 2012-based IPF market basket, we proposed to allocate the Contract Labor cost weight to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions under the assumption that contract labor costs are comprised of both wages and salaries and employee benefits. The Contract Labor allocation proportion for Wages

and Salaries is equal to the Wages and Salaries cost weight as a percent of the sum of the Wages and Salaries cost weight and the Employee Benefits cost weight. For the proposed rule, this rounded percentage was 79 percent; therefore, we proposed to allocate 79 percent of the Contract Labor cost weight to the Wages and Salaries cost weight and 21 percent to the Employee

Benefits cost weight. The 2012-based IPF market basket percentage was 80 percent. We did not receive any comments on the allocation of the Contract Labor cost weight.

Table 2 shows the Wages and Salaries and Employee Benefit cost weights after Contract Labor cost weight allocation for both the 2016-based IPF market basket and 2012-based IPF market basket.

TABLE 2—WAGES AND SALARIES AND EMPLOYEE BENEFITS COST WEIGHTS AFTER CONTRACT LABOR ALLOCATION

Major cost categories	Final 2016-based IPF market basket	2012-Based IPF market basket
Wages and Salaries	52.2	52.1
Employee Benefits	13.8	13.4

iii. Derivation of the Detailed Operating Cost Weights

To further divide the “All Other” residual cost weight estimated from the 2016 Medicare Cost Report data into more detailed cost categories, we proposed to use the 2012 Benchmark Input-Output (I-O) “Use Tables/Before Redefinitions/Purchaser Value” for NAICS 622000 Hospitals, published by the Bureau of Economic Analysis (BEA). These data, publicly available at http://www.bea.gov/industry/io_annual.htm, are the most recent data available at the time of rulemaking. For the 2012-based IPF market basket, we used the 2007 Benchmark I-O data.

The BEA Benchmark I-O data are scheduled for publication every five years. The 2012 Benchmark I-O data are derived from the 2012 Economic Census and are the building blocks for BEA’s economic accounts. They represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.¹ BEA also produces Annual I-O estimates; however, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data becomes available. Instead of using the less detailed Annual I-O data, we proposed to inflate the 2012 Benchmark I-O data forward to 2016 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories obtained from the 2012 Benchmark I-O data. We then proposed to calculate the cost shares that each cost category represents of the inflated 2016 data. These resulting 2016 cost shares were applied to the “All Other” residual cost weight to obtain the proposed detailed cost weights for the 2016-based IPF market basket. For example, the cost for Food: Direct Purchases represents 5.0 percent of the sum of the “All Other” 2016 Benchmark I-O Hospital Expenditures inflated to 2016. Therefore, the Food: Direct Purchases cost weight represents 5.0 percent of the 2016-based IPF market basket’s “All Other” cost category (17.9 percent), yielding a “final” Food: Direct Purchases cost weight of 0.9 percent in the proposed 2016-based IPF market basket ($0.05 \times 17.9 \text{ percent} = 0.9 \text{ percent}$).

Using this methodology, we proposed to derive seventeen detailed IPF market basket cost category weights from the proposed 2016-based IPF market basket residual cost weight (17.9 percent).

These categories were: (1) Electricity, (2) Fuel, Oil, and Gasoline, (3) Food: Direct Purchases, (4) Food: Contract Services, (5) Chemicals, (6) Medical Instruments, (7) Rubber & Plastics, (8) Paper and Printing Products, (9) Miscellaneous Products, (10) Professional Fees: Labor-related, (11) Administrative and Facilities Support Services, (12) Installation, Maintenance, and Repair, (13) All Other Labor-related Services, (14) Professional Fees: Nonlabor-related, (15) Financial Services, (16) Telephone Services, and (17) All Other Nonlabor-related Services. We note that for the 2012-based IPF market basket, we had a Water and Sewerage cost weight. For the proposed 2016-based IPF market basket, we proposed to include Water and Sewerage in the Electricity cost weight due to the small amount of costs in this category.

We did not receive any comments on the derivation of the detailed operating cost weights. In this final rule, we are finalizing our methodology for deriving the detailed operating cost weights as we proposed.

iv. Derivation of the Detailed Capital Cost Weights

As described in section III.A.3.a.i. of this final rule, we proposed a Capital-Related cost weight of 7.1 percent as obtained from the 2016 Medicare cost reports for freestanding and hospital-based IPF providers. We proposed to further separate this total Capital-Related cost weight into more detailed cost categories. Using 2016 Medicare cost reports, we were able to group Capital-Related costs into the following categories: Depreciation, Interest, Lease, and Other Capital-Related costs. For each of these categories, we proposed to determine separately for hospital-based IPFs and freestanding IPFs what proportion of total capital-related costs the category represent.

For freestanding IPFs, we proposed to derive the proportions for Depreciation, Interest, Lease, and Other Capital-related costs using the data reported by the IPF on Worksheet A-7, which is the same methodology used for the 2012-based IPF market basket.

For hospital-based IPFs, data for these four categories were not reported separately for the subprovider; therefore, we proposed to derive these proportions using data reported on Worksheet A-7 for the total facility. We are assuming the cost shares for the overall hospital are representative for the hospital-based subprovider IPF unit. For example, if depreciation costs make up 60 percent of total capital costs for the entire facility, we believe it was reasonable to assume that the hospital-

based IPF will also have a 60 percent proportion because it is a subprovider unit contained within the total facility. This is the same methodology used for the 2012-based IPF market basket.

In order to combine each detailed capital cost weight for freestanding and hospital-based IPFs into a single capital cost weight for the 2016-based IPF market basket, we proposed to weight together the shares for each of the categories (Depreciation, Interest, Lease, and Other Capital-related costs) based on the share of total capital costs each provider type represents of the total capital costs for all IPFs for 2016. Applying this methodology results in proportions of total capital-related costs for Depreciation, Interest, Lease and Other Capital-related costs that are representative of the universe of IPF providers. This is the same methodology used for the 2012-based IPF market basket.

Next, we proposed to allocate lease costs across each of the remaining detailed capital-related cost categories as done in the 2012-based IPF market basket. This resulted in three primary capital-related cost categories in the 2016-based IPF market basket: Depreciation, Interest, and Other Capital-Related costs. As done in the 2012-based IPF market basket, lease costs are unique in that they are not broken out as a separate cost category in the 2016-based IPF market basket, but rather we proposed to proportionally distribute these costs among the cost categories of Depreciation, Interest, and Other Capital-Related, reflecting the assumption that the underlying cost structure of leases is similar to that of capital-related costs in general. As done under the 2012-based IPF market basket, we proposed to assume that 10 percent of the lease costs as a proportion of total capital-related costs represents overhead and assign those costs to the Other Capital-Related cost category accordingly. We proposed to distribute the remaining lease costs proportionally across the three cost categories (Depreciation, Interest, and Other Capital-Related) based on the proportion that these categories comprise of the sum of the Depreciation, Interest, and Other Capital-related cost categories (excluding lease expenses). This is the same methodology used for the 2012-based IPF market basket. The allocation of these lease expenses are shown in Table 3.

Finally, we proposed to further divide the Depreciation and Interest cost categories. We proposed to separate Depreciation into the following two categories: (1) Building and Fixed Equipment; and (2) Movable Equipment;

¹ http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.

and proposed to separate Interest into the following two categories: (1) Government/Nonprofit; and (2) For-profit.

To disaggregate the Depreciation cost weight, we determined the percent of total Depreciation costs for IPFs that is attributable to Building and Fixed Equipment, which we hereafter refer to as the “fixed percentage.” For the 2016-based IPF market basket, we proposed to use slightly different methods to obtain the fixed percentages for hospital-based IPFs compared to freestanding IPFs.

For freestanding IPFs, we proposed to use depreciation data from Worksheet A–7 of the 2016 Medicare cost reports. However, for hospital-based IPFs, we determined that the fixed percentage for the entire facility may not be representative of the IPF subprovider unit due to the entire facility likely employing more sophisticated movable assets that are not utilized by the hospital-based IPF. Therefore, for hospital-based IPFs, we proposed to calculate a fixed percentage using: (1)

Building and fixture capital costs allocated to the subprovider unit as reported on Worksheet B, part I line 40; and (2) building and fixture capital costs for the top five ancillary cost centers utilized by hospital-based IPFs. We proposed to then weight these two fixed percentages (inpatient and ancillary) using the proportion that each capital cost type represents of total capital costs in the proposed 2016-based IPF market basket. We then proposed to weight the fixed percentages for hospital-based and freestanding IPFs together using the proportion of total capital costs each provider type represents. For both freestanding and hospital-based IPFs, this is the same methodology used for the 2012-based IPF market basket.

To disaggregate the Interest cost weight, we determined the percent of total interest costs for IPFs that were attributable to government and nonprofit facilities, the “nonprofit percentage.” For the 2016-based IPF market basket, we proposed to use

interest costs data from Worksheet A–7 for both freestanding and hospital-based IPFs. We then determined the percent of total interest costs that are attributed to government and nonprofit IPFs separately for hospital-based and freestanding IPFs and weight the nonprofit percentages for hospital-based and freestanding IPFs together using the proportion of total capital costs each provider type represents. This is the same methodology used for the 2012-based IPF market basket.

We did not receive public comments on the derivation of the detailed capital cost weights. In this final rule, we are finalizing our methodology for deriving the detailed capital cost weights as we proposed. Table 3 provides the detailed capital cost share composition of the 2016-based IPF market basket. These detailed capital cost share composition percentages are applied to the total Capital-Related cost weight of 7.1 percent determined in section III.A.3.a.i. of this final rule.

TABLE 3—CAPITAL COST SHARE COMPOSITION FOR THE FINAL 2016-BASED IPF MARKET BASKET

	Capital cost share composition before lease expense allocation (percent)	Capital cost share composition after lease expense allocation (percent)
Depreciation	60	74
Building and Fixed Equipment	43	52
Movable Equipment	18	22
Interest	13	16
Government/Nonprofit	10	12
For Profit	3	4
Lease	20	n/a
Other	7	10

Note: Detail may not add to total due to rounding.

v. 2016-Based IPF Market Basket Cost Categories and Weights

Table 4 shows the cost categories and weights for the final 2016-based IPF

market basket and the 2012-based IPF market basket.

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Table 4: Final 2016-based IPF Market Basket Cost Weights Compared to 2012-based IPF Market Basket Cost Weights

<u>Cost Category</u>	<u>Final 2016-based IPF Market Basket Cost Weight</u>	<u>2012-based IPF Market Basket Cost Weight</u>
Total	100.0	100.0
Compensation	66.0	65.5
Wages and Salaries	52.2	52.1
Employee Benefits	13.8	13.4
Utilities	1.1	1.7
Electricity	0.8	0.8
Fuel, Oil, and Gasoline	0.3	0.9
Water & Sewerage	n/a	0.1
Professional Liability Insurance	0.9	1.1
Malpractice	0.9	1.1
All Other Products and Services	24.9	24.6
All Other Products	10.7	11.5
Pharmaceuticals	4.7	4.8
Food: Direct Purchases	0.9	1.4
Food: Contract Services	1.0	0.9
Chemicals	0.3	0.6
Medical Instruments	2.3	1.9
Rubber & Plastics	0.3	0.5
Paper and Printing Products	0.5	0.9
Miscellaneous Products	0.7	0.6
All Other Services	14.2	13.1
Labor-Related Services	7.7	6.6
Professional Fees: Labor-related	4.4	2.9
Administrative and Facilities Support Services	0.6	0.7
Installation, Maintenance, and Repair	1.3	1.6
All Other: Labor-related Services	1.4	1.5
Nonlabor-Related Services	6.5	6.5
Professional Fees: Nonlabor-related	4.5	2.6
Financial services	0.8	2.3
Telephone Services	0.3	0.6
All Other: Nonlabor-related Services	1.0	1.1
Capital-Related Costs	7.1	7.0

Depreciation	5.3	5.2
Fixed Assets	3.7	3.7
Movable Equipment	1.5	1.5
Interest Costs	1.2	1.2
Government/Nonprofit	0.9	1.0
For Profit	0.3	0.2
Other Capital-Related Costs	0.7	0.6

Note: Totals may not sum due to rounding.

b. Selection of Price Proxies

After developing the cost weights for the proposed 2016-based IPF market basket, we selected the most appropriate wage and price proxies currently available to represent the rate of price change for each expenditure category. For the majority of the cost weights, we based the price proxies on Bureau of Labor Statistics (BLS) data and grouped them into one of the following BLS categories:

- **Employment Cost Indexes.** Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the NAICS and the occupational ECIs are based on the Standard Occupational Classification System (SOC).

- **Producer Price Indexes.** Producer Price Indexes (PPIs) measure price changes for goods sold in other than retail markets. PPIs are used when the purchases of goods or services are made at the wholesale level.

- **Consumer Price Indexes.** Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by consumers. CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the wholesale level, or if no appropriate PPIs are available.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance:

- **Reliability.** Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation from the true population parameter that occurs by chance because only a sample was surveyed rather than the entire population.)

- **Timeliness.** Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly and, therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.

- **Availability.** Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.

- **Relevance.** Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs that we selected meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

Table 12 lists all price proxies that we proposed to use for the 2016-based IPF market basket. A detailed explanation of the price proxies we proposed for each cost category weight is provided.

i. Price Proxies for the Operating Portion of the 2016-Based IPF Market Basket

Wages and Salaries

There is not a published wage proxy that we believe represents the occupational distribution of workers in IPFs. To measure wage price growth in the proposed 2016-based IPF market basket, we proposed to apply a proxy blend based on six occupational subcategories within the Wages and Salaries category, which would reflect the IPF occupational mix, as done for the 2012-based IPF market basket.

We proposed to use the National Industry-Specific Occupational Employment and Wage estimates for NAICS 622200, Psychiatric & Substance Abuse Hospitals, published by the Bureau of Labor Statistics Office of Occupational Employment Statistics (OES), as the data source for the wage cost shares in the wage proxy blend. We proposed to use May 2016 OES data. Detailed information on the methodology for the national industry-specific occupational employment and wage estimates survey can be found at http://www.bls.gov/oes/current/oes_tec.htm. For the 2012-based IPF market basket, we used May 2012 OES data.

Based on the OES data, there are six wage subcategories: Management; NonHealth Professional and Technical; Health Professional and Technical; Health Service; NonHealth Service; and Clerical. Table 5 lists the 2016 occupational assignments for the six wage subcategories; these are the same occupational groups used in the 2012-based IPF market basket.

Table 5: 2016 Occupational Assignments for IPF Wage Blend

2016 Occupational Groupings	
Group 1	Management
11-0000	Management Occupations
Group 2	NonHealth Professional & Technical
13-0000	Business and Financial Operations Occupations
15-0000	Computer and Mathematical Occupations
19-0000	Life, Physical, and Social Science Occupations
23-0000	Legal Occupations
25-0000	Education, Training, and Library Occupations
27-0000	Arts, Design, Entertainment, Sports, and Media Occupations
Group 3	Health Professional & Technical
29-1021	Dentists, General
29-1031	Dietitians and Nutritionists
29-1051	Pharmacists
29-1062	Family and General Practitioners
29-1063	Internists, General
29-1066	Psychiatrists
29-1069	Physicians and Surgeons, All Other
29-1071	Physician Assistants
29-1122	Occupational Therapists
29-1123	Physical Therapists
29-1125	Recreational Therapists
29-1126	Respiratory Therapists
29-1127	Speech-Language Pathologists
29-1129	Therapists, All Other
29-1141	Registered Nurses
29-1171	Nurse Practitioners
29-1199	Health Diagnosing and Treating Practitioners, All Other
Group 4	Health Service
21-0000	Community and Social Services Occupations
29-2011	Medical and Clinical Laboratory Technologists
29-2012	Medical and Clinical Laboratory Technicians
29-2021	Dental Hygienists
29-2034	Radiologic Technologists
29-2041	Emergency Medical Technicians and Paramedics
29-2051	Dietetic Technicians
29-2052	Pharmacy Technicians
29-2053	Psychiatric Technicians
29-2061	Licensed Practical and Licensed Vocational Nurses

29-2071	Medical Records and Health Information Technicians
29-2099	Health Technologists and Technicians, All Other
29-9011	Occupational Health and Safety Specialists
29-9099	Healthcare Practitioner and Technical Workers, All Other
31-0000	Healthcare Support Occupations
Group 5	NonHealth Service
33-0000	Protective Service Occupations
35-0000	Food Preparation and Serving Related Occupations
37-0000	Building and Grounds Cleaning and Maintenance Occupations
39-0000	Personal Care and Service Occupations
41-0000	Sales and Related Occupations
47-0000	Construction and Extraction Occupations
49-0000	Installation, Maintenance, and Repair Occupations
51-0000	Production Occupations
53-0000	Transportation and Material Moving Occupations
Group 6	Clerical
43-0000	Office and Administrative Support Occupations

Total expenditures by occupation (that is, occupational assignment) were calculated by taking the OES number of employees multiplied by the OES annual average salary. These expenditures were aggregated based on the six groups in Table 5. We next calculated the proportion of each group's expenditures relative to the total

expenditures of all six groups. These proportions, listed in Table 6, represent the weights used in the wage proxy blend. We then proposed to use the published wage proxies in Table 6 for each of the six groups (that is, wage subcategories) as we believe these six price proxies are the most technically appropriate indices available to measure

the price growth of the Wages and Salaries cost category. These are the same price proxies used in the 2012-based IPF market basket. We did not receive any public comments on the 2016-based IPF wage price proxy. In this final rule, we are finalizing the 2016-based IPF wage price proxy as proposed.

Table 6: 2016-Based IPF Market Basket Wage Proxy Blend

Wage Subcategory	2016-based Wage Blend Weight	2012-based Wage Blend Weight	Price Proxy	BLS Series ID
Health Service	36.3%	36.2%	ECI for Wages and Salaries for All Civilian workers in Healthcare and Social Assistance	CIU1026200000000I
Health Professional and Technical	34.9%	33.5%	ECI for Wages and Salaries for All Civilian workers in Hospitals	CIU1026220000000I
NonHealth Service	8.9%	9.2%	ECI for Wages and Salaries for Private Industry workers in Service Occupations	CIU2020000300000I
NonHealth Professional and Technical	7.0%	7.3%	ECI for Wages and Salaries for Private Industry workers in Professional, Scientific, and Technical Services	CIU2025400000000I
Management	6.8%	7.1%	ECI for Wages and Salaries for Private Industry workers in Management, Business, and Financial	CIU2020000110000I
Clerical	6.1%	6.7%	ECI for Wages and Salaries for Private Industry workers in Office and Administrative Support	CIU2020000220000I
Total	100.0	100.0		

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A comparison of the yearly changes from FY 2017 to FY 2020 for the 2016-

based IPF wage blend and the 2012-based IPF wage blend is shown in Table 7. The average annual growth rate is the

same for both price proxies over 2017–2020.

TABLE 7—FISCAL YEAR GROWTH IN THE 2016-BASED IPF WAGE PROXY BLEND AND 2012-BASED IPF WAGE PROXY BLEND

	2017	2018	2019	2020	Average 2017–2020
2016-based IPF Final Wage Proxy Blend	2.4	2.6	3.0	3.2	2.8
2012-based IPF Wage Proxy Blend	2.4	2.6	3.0	3.2	2.8

**SOURCE: IHS Global Inc., 2nd Quarter 2019 forecast with historical data through 1st Quarter 2019.

Benefits

To measure benefits price growth in the 2016-based IPF market basket, we proposed to apply a benefits proxy blend based on the same six subcategories and the same six blend weights for the wage proxy blend. These subcategories and blend weights are listed in Table 8.

The benefit ECIs, listed in Table 8, are not publically available. Therefore, an

“ECIs for Total Benefits” is calculated using publically available “ECIs for Total Compensation” for each subcategory and the relative importance of wages within that subcategory’s total compensation. This is the same benefits ECI methodology that we implemented in our 2012-based IPF market basket as well as used in the IPPS, SNF, HHA, RPL, LTCH, and ESRD market baskets. We believe that the six price proxies

listed in Table 8 are the most technically appropriate indices to measure the price growth of the Benefits cost category in the proposed 2016-based IPF market basket. We did not receive any public comments on the 2016-based IPF benefit price proxy. In this final rule, we are finalizing the 2016-based IPF benefit price proxy as proposed.

TABLE 8—FINAL 2016-BASED IPF MARKET BASKET BENEFITS PROXY BLEND

Wage subcategory	2016-based benefit blend weight (percent)	2012-based benefit blend weight (percent)	Price proxy
Health Service	36.3	36.2	ECI for Total Benefits for All Civilian workers in Healthcare and Social Assistance.
Health Professional and Technical ..	34.9	33.5	ECI for Total Benefits for All Civilian workers in Hospitals.
NonHealth Service	8.9	9.2	ECI for Total Benefits for Private Industry workers in Service Occupations.
NonHealth Professional and Technical.	7.0	7.3	ECI for Total Benefits for Private Industry workers in Professional, Scientific, and Technical Services.
Management	6.8	7.1	ECI for Total Benefits for Private Industry workers in Management, Business, and Financial.
Clerical	6.1	6.7	ECI for Total Benefits for Private Industry workers in Office and Administrative Support.
Total	100.0	100.0	

A comparison of the yearly changes from FY 2017 to FY 2020 for the 2016-based IPF benefit proxy blend and the

2012-based IPF benefit proxy is shown in Table 9. The average annual growth

rate is the same for both price proxies over 2017–2020.

TABLE 9—FISCAL YEAR GROWTH IN THE 2016-BASED IPF BENEFIT PROXY BLEND AND 2012-BASED IPF BENEFIT PROXY BLEND

	2017	2018	2019	2020	Average 2017–2020
2016-based IPF Final Benefit Proxy Blend	1.9	2.1	2.5	3.0	2.4
2012-based IPF Benefit Proxy Blend	1.9	2.1	2.5	3.0	2.4

SOURCE: IHS Global Inc., 2nd Quarter 2019 forecast with historical data through 1st Quarter 2019.

Electricity

We proposed to continue to use the PPI Commodity Index for Commercial Electric Power (BLS series code WPU0542) to measure the price growth of this cost category. This is the same price proxy used in the 2012-based IPF market basket.

Fuel, Oil, and Gasoline

Similar to the 2012-based IPF market basket, for the 2016-based IPF market basket, we proposed to use a blend of the PPI for Petroleum Refineries and the PPI Commodity for Natural Gas. Our analysis of the BEA's 2012 Benchmark I–O data (use table before redefinitions, purchaser's value for NAICS 622000 [Hospitals]) shows that Petroleum Refineries expenses accounts for approximately 90 percent and Natural Gas accounts for approximately 10 percent of Hospitals (NAICS 622000) total Fuel, Oil, and Gasoline expenses. Therefore, we proposed to use a blend of 90 percent of the PPI for Petroleum Refineries (BLS series code PCU324110324110) and 10 percent of the PPI Commodity Index for Natural Gas (BLS series code WPU0531) as the price proxy for this cost category. The 2012-based IPF market basket used a 70/30 blend of these price proxies,

reflecting the 2007 I–O data. We believe that these two price proxies continue to be the most technically appropriate indices available to measure the price growth of the Fuel, Oil, and Gasoline cost category in the proposed 2016-based IPF market basket.

Professional Liability Insurance

We proposed to continue to use the CMS Hospital Professional Liability Index to measure changes in professional liability insurance (PLI) premiums. To generate this index, we collect commercial insurance premiums for a fixed level of coverage while holding non-price factors constant (such as a change in the level of coverage). This is the same proxy used in the 2012-based IPF market basket.

Pharmaceuticals

We proposed to continue to use the PPI for Pharmaceuticals for Human Use, Prescription (BLS series code WPU07003) to measure the price growth of this cost category. This is the same proxy used in the 2012-based IPF market basket.

Food: Direct Purchases

We proposed to continue to use the PPI for Processed Foods and Feeds (BLS series code WPU02) to measure the

price growth of this cost category. This is the same proxy used in the 2012-based IPF market basket.

Food: Contract Purchases

We proposed to continue to use the CPI for Food Away From Home (BLS series code CUUR0000SEFV) to measure the price growth of this cost category. This is the same proxy used in the 2012-based IPF market basket.

Chemicals

Similar to the 2012-based IPF market basket, we proposed to use a four part blended PPI as the proxy for the chemical cost category in the proposed 2016-based IPF market basket. The proposed blend is composed of the PPI for Industrial Gas Manufacturing Primary Products (BLS series code PCU325120325120P), the PPI for Other Basic Inorganic Chemical Manufacturing (BLS series code PCU32518–32518–), the PPI for Other Basic Organic Chemical Manufacturing (BLS series code PCU32519–32519–), and the PPI for Other Miscellaneous Chemical Product Manufacturing (BLS series code PCU325998325998).

We note that the four part blended PPI used in the 2012-based IPF market basket is composed of the PPI for Industrial Gas Manufacturing (BLS

series code PCU325120325120P), the PPI for Other Basic Inorganic Chemical Manufacturing (BLS series code PCU32518–32518–), the PPI for Other Basic Organic Chemical Manufacturing (BLS series code PCU32519–32519–), and the PPI for Soap and Cleaning

Compound Manufacturing (BLS series code PCU32561–32561–).

We proposed to derive the weights for the PPIs using the 2012 Benchmark I–O data. The 2012-based IPF market basket used the 2007 Benchmark I–O data to derive the weights for the four PPIs.

Table 10 shows the weights for each of the four PPIs used to create proposed blended Chemical proxy for the 2016-based IPF market basket compared to the 2012-based IPF market basket blended Chemical proxy.

TABLE 10—BLENDED CHEMICAL PPI WEIGHTS

Name	Final 2016-based IPF weights (percent)	2012-based IPF weights (percent)	NAICS
PPI for Industrial Gas Manufacturing	19	32	325120
PPI for Other Basic Inorganic Chemical Manufacturing	13	17	325180
PPI for Other Basic Organic Chemical Manufacturing	60	45	325190
PPI for Soap and Cleaning Compound Manufacturing	n/a	6	325610
PPI for Other Miscellaneous Chemical Product Manufacturing	8	n/a	325998

Medical Instruments

We proposed to continue to use a blend of two PPIs for the Medical Instruments cost category. The 2012 Benchmark I–O data shows an approximate 57/43 split between Surgical and Medical Instruments and Medical and Surgical Appliances and Supplies for this cost category. Therefore, we proposed a blend composed of 57 percent of the commodity-based PPI for Surgical and Medical Instruments (BLS series code WPU1562) and 43 percent of the commodity-based PPI for Medical and Surgical Appliances and Supplies (BLS series code WPU1563). The 2012-based IPF market basket used a 50/50 blend of these PPIs based on the 2007 Benchmark I–O data.

Rubber and Plastics

We proposed to continue to use the PPI for Rubber and Plastic Products (BLS series code WPU07) to measure price growth of this cost category. This is the same proxy used in the 2012-based IPF market basket.

Paper and Printing Products

We proposed to continue to use the PPI for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category. This is the same proxy used in the 2012-based IPF market basket.

Miscellaneous Products

We proposed to continue to use the PPI for Finished Goods Less Food and Energy (BLS series code WPUFD4131) to measure the price growth of this cost category. This is the same proxy used in the 2012-based IPF market basket.

Professional Fees: Labor-Related

We proposed to continue to use the ECI for Total Compensation for Private Industry workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same proxy used in the 2012-based IPF market basket.

Administrative and Facilities Support Services

We proposed to continue to use the ECI for Total Compensation for Private Industry workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this category. This is the same proxy used in the 2012-based IPF market basket.

Installation, Maintenance, and Repair

We proposed to continue to use the ECI for Total Compensation for Civilian workers in Installation, Maintenance, and Repair (BLS series code CIU1010000430000I) to measure the price growth of this cost category. This is the same proxy used in the 2012-based IPF market basket.

All Other: Labor-Related Services

We proposed to continue to use the ECI for Total Compensation for Private Industry workers in Service Occupations (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This is the same proxy used in the 2012-based IPF market basket.

Professional Fees: Nonlabor-Related

We proposed to continue to use the ECI for Total Compensation for Private Industry workers in Professional and Related (BLS series code CIU2010000120000I) to measure the

price growth of this category. This is the same proxy used in the 2012-based IPF market basket.

Financial Services

We proposed to continue to use the ECI for Total Compensation for Private Industry workers in Financial Activities (BLS series code CIU201520A000000I) to measure the price growth of this cost category. This is the same proxy used in the 2012-based IPF market basket.

Telephone Services

We proposed to continue to use the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This is the same proxy used in the 2012-based IPF market basket.

All Other: Nonlabor-Related Services

We proposed to continue to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. This is the same proxy used in the 2012-based IPF market basket. We did not receive any public comments on the 2016-based IPF price proxies. In this final rule, we are finalizing the 2016-based IPF price proxies as proposed.

ii. Price Proxies for the Capital Portion of the Proposed 2016-Based IPF Market Basket

Capital Price Proxies Prior to Vintage Weighting

We proposed to continue to use the same price proxies for the capital-related cost categories as were applied in the 2012-based IPF market basket, which are provided and described in Table 12. Specifically, we proposed to proxy:

- *Depreciation*: Building and Fixed Equipment cost category by BEA's

Chained Price Index for Nonresidential Construction for Hospitals and Special Care Facilities (BEA Table 5.4.4. Price Indexes for Private Fixed Investment in Structures by Type).

- *Depreciation:* Movable Equipment cost category by the PPI for Machinery and Equipment (BLS series code WPU11).
- Nonprofit Interest cost category by the average yield on domestic municipal bonds (Bond Buyer 20-bond index).
- For-profit Interest cost category by the average yield on Moody's Aaa bonds (Federal Reserve).
- Other Capital-Related cost category by the CPI-U for Rent of Primary Residence (BLS series code CUUS0000SEHA).

We believe these are the most appropriate proxies for IPF capital-related costs that meet our selection criteria of relevance, timeliness, availability, and reliability. We also proposed to continue to vintage weight the capital price proxies for Depreciation and Interest in order to capture the long-term consumption of capital. This vintage weighting method is similar to the method used for the 2012-based IPF market basket and is described in the section labeled Vintage Weights for Price Proxies.

Vintage Weights for Price Proxies

Because capital is acquired and paid for over time, capital-related expenses in any given year are determined by both past and present purchases of physical and financial capital. The vintage-weighted capital-related portion of the proposed 2016-based IPF market basket is intended to capture the long-term consumption of capital, using vintage weights for depreciation (physical capital) and interest (financial capital). These vintage weights reflect the proportion of capital-related purchases attributable to each year of the expected life of building and fixed equipment, movable equipment, and interest. We proposed to use vintage weights to compute vintage-weighted price changes associated with depreciation and interest expenses.

Capital-related costs are inherently complicated and are determined by complex capital-related purchasing decisions, over time, based on such factors as interest rates and debt financing. In addition, capital is depreciated over time instead of being consumed in the same period it is purchased. By accounting for the vintage nature of capital, we are able to provide an accurate and stable annual measure of price changes. Annual non-vintage price changes for capital are unstable due to the volatility of interest

rate changes and, therefore, do not reflect the actual annual price changes for IPF capital-related costs. The capital-related component of the proposed 2016-based IPF market basket reflects the underlying stability of the capital-related acquisition process.

The methodology used to calculate the vintage weights for the 2016-based IPF market basket is the same as that used for the 2012-based IPF market basket with the only difference being the inclusion of more recent data. To calculate the vintage weights for depreciation and interest expenses, we first needed a time series of capital-related purchases for building and fixed equipment and movable equipment. We found no single source that provides an appropriate time series of capital-related purchases by hospitals for all of the listed components of capital purchases. The early Medicare cost reports did not have sufficient capital-related data to meet this need. Data we obtained from the American Hospital Association (AHA) do not include annual capital-related purchases. However, the AHA provided a consistent database of total expenses back to 1963. Consequently, we proposed to use data from the AHA Panel Survey and the AHA Annual Survey to obtain a time series of total expenses for hospitals. We then proposed to use data from the AHA Panel Survey supplemented with the ratio of depreciation to total hospital expenses obtained from the Medicare cost reports to derive a trend of annual depreciation expenses for 1963 through 2016. We proposed to separate these depreciation expenses into annual amounts of building and fixed equipment depreciation and movable equipment depreciation as previously determined. From these annual depreciation amounts we derived annual end-of-year book values for building and fixed equipment and movable equipment using the expected life for each type of asset category. While data are not available that are specific to IPFs, we believe this information for all hospitals serves as a reasonable alternative for the pattern of depreciation for IPFs.

To continue to calculate the vintage weights for depreciation and interest expenses, we also needed the expected lives for Building and Fixed Equipment, Movable Equipment, and Interest for the proposed 2016-based IPF market basket. We proposed to calculate the expected lives using Medicare cost report data from freestanding and hospital-based IPFs. The expected life of any asset can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation

amount. This calculation yields the estimated expected life of an asset if the rates of depreciation were to continue at current year levels, assuming straight-line depreciation. We proposed to determine the expected life of building and fixed equipment separately for hospital-based IPFs and freestanding IPFs and weight these expected lives using the percent of total capital costs each provider type represents. We proposed to apply a similar method for movable equipment. Using these proposed methods, we determined the average expected life of building and fixed equipment to be equal to 22 years, and the average expected life of movable equipment to be equal to 11 years. For the expected life of interest, we believe vintage weights for interest should represent the average expected life of building and fixed equipment because, based on previous research described in the FY 1997 IPPS final rule (61 FR 46198), the expected life of hospital debt instruments and the expected life of buildings and fixed equipment are similar. We note that for the 2012-based IPF market basket the expected life of building and fixed equipment is 23 years and the expected life of movable equipment is 11 years.

Multiplying these expected lives by the annual depreciation amounts results in annual year-end asset costs for building and fixed equipment and movable equipment. We then calculated a time series, beginning in 1964, of annual capital purchases by subtracting the previous year's asset costs from the current year's asset costs.

For the building and fixed equipment and movable equipment vintage weights, we proposed to use the real annual capital-related purchase amounts for each asset type to capture the actual amount of the physical acquisition, net of the effect of price inflation. These real annual capital-related purchase amounts are produced by deflating the nominal annual purchase amount by the associated price proxy as provided. For the interest vintage weights, we proposed to use the total nominal annual capital-related purchase amounts to capture the value of the debt instrument (including, but not limited to, mortgages and bonds). Using these capital-related purchase time series specific to each asset type, we proposed to calculate the vintage weights for building and fixed equipment, for movable equipment, and for interest.

The vintage weights for each asset type are deemed to represent the average purchase pattern of the asset over its expected life (in the case of building and fixed equipment and

interest, 22 years, and in the case of movable equipment, 11 years). For each asset type, we used the time series of annual capital-related purchase amounts available from 2016 back to 1964. These data allow us to derive thirty-two 22-year periods of capital-related purchases for building and fixed equipment and interest, and forty-two 11-year periods of capital-related purchases for movable equipment. For each 22-year period for building and fixed equipment and interest, or 11-year

period for movable equipment, we calculated annual vintage weights by dividing the capital-related purchase amount in any given year by the total amount of purchases over the entire 22-year or 11-year period. This calculation is done for each year in the 22-year or 11-year period and for each of the periods for which we have data. We then calculated the average vintage weight for a given year of the expected life by taking the average of these vintage weights across the multiple

periods of data. We did not receive any public comments on the methodology used to derive the vintage weights. In this final rule, we are finalizing the 2016-based IPF market basket vintage weights as proposed. Table 11 presents the vintage weights for the capital-related portion of the 2016-based IPF market basket and the 2012-based IPF market basket.

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Table 11: Final 2016-based IPF Market Basket and 2012-based IPF Market Basket Vintage Weights for Capital-Related Price Proxies

Year	Building and Fixed Equipment		Movable Equipment		Interest	
	2016-based 22 years	2012-based 23 years	2016-based 11 years	2012-based 11 years	2016-based 22 years	2012-based 23 years
1	0.035	0.029	0.071	0.069	0.021	0.017
2	0.036	0.031	0.075	0.073	0.023	0.019
3	0.038	0.034	0.080	0.077	0.025	0.022
4	0.038	0.036	0.085	0.083	0.026	0.024
5	0.040	0.037	0.087	0.087	0.029	0.026
6	0.042	0.039	0.091	0.091	0.031	0.028
7	0.042	0.040	0.095	0.096	0.033	0.030
8	0.041	0.041	0.099	0.100	0.033	0.032
9	0.042	0.042	0.102	0.103	0.036	0.035
10	0.043	0.044	0.105	0.107	0.038	0.038
11	0.046	0.045	0.110	0.114	0.042	0.040
12	0.047	0.045	--	--	0.045	0.042
13	0.048	0.045	--	--	0.048	0.044
14	0.049	0.046	--	--	0.052	0.046
15	0.050	0.046	--	--	0.055	0.048
16	0.050	0.048	--	--	0.057	0.053
17	0.051	0.049	--	--	0.060	0.057
18	0.053	0.050	--	--	0.065	0.060
19	0.053	0.051	--	--	0.068	0.063
20	0.053	0.051	--	--	0.069	0.066
21	0.052	0.051	--	--	0.070	0.067
22	0.052	0.050	--	--	0.072	0.069
23	--	0.052	--	--	--	0.073
Total	1.000	1.000	1.000	1.000	1.000	1.000

Note: Numbers may not add to total due to rounding.

The process of creating vintage-weighted price proxies requires applying the vintage weights to the price proxy index where the last applied vintage weight in Table 11 is applied to

the most recent data point. We have provided on the CMS website an example of how the vintage weighting price proxies are calculated, using example vintage weights and example

price indices. The example can be found at the following link: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/>

MarketBasketResearch.html in the zip file titled “Weight Calculations as described in the IPPS FY 2010 Proposed Rule.”

iii. Summary of Price Proxies of the Final 2016-Based IPF Market Basket

Table 12 shows both the operating and capital price proxies for the 2016-based IPF market basket.

Table 12: Price Proxies for the Final 2016-based IPF Market Basket

Cost Description	Price Proxies	Weight (percent)
Total		100.0
Compensation		66.0
Wages and Salaries	Blended Wages and Salaries Price Proxy	52.2
Employee Benefits	Blended Benefits Price Proxy	13.8
Utilities		1.1
Electricity	PPI for Commercial Electric Power	0.8
Fuel, Oil, and Gasoline	Blend of the PPI for Petroleum Refineries and PPI for Natural Gas	0.3
Professional Liability Insurance		0.9
Malpractice	CMS Hospital Professional Liability Insurance Premium Index	0.9
All Other Products and Services		24.9
All Other Products		10.7
Pharmaceuticals	PPI for Pharmaceuticals for human use, prescription	4.7
Food: Direct Purchases	PPI for Processed Foods and Feeds	0.9
Food: Contract Services	CPI-U for Food Away From Home	1.0
Chemicals	Blend of Chemical PPIs	0.3
Medical Instruments	Blend of the PPI for Surgical and medical instruments and PPI for Medical and surgical appliances and supplies	2.3
Rubber & Plastics	PPI for Rubber and Plastic Products	0.3
Paper and Printing Products	PPI for Converted Paper and Paperboard Products	0.5
Miscellaneous Products	PPI for Finished Goods Less Food and Energy	0.7
All Other Services		14.2
Labor-Related Services		7.7
Professional Fees: Labor-related	ECI for Total compensation for Private industry workers in Professional and related	4.4
Administrative and Facilities Support Services	ECI for Total compensation for Private industry workers in Office and administrative support	0.6
Installation, Maintenance, and Repair	ECI for Total compensation for Civilian workers in Installation, maintenance, and repair	1.3
All Other: Labor-related Services	ECI for Total compensation for Private industry workers in Service occupations	1.4
Nonlabor-Related Services		6.5
Professional Fees: Nonlabor-related	ECI for Total compensation for Private industry workers in Professional and related	4.5
Financial services	ECI for Total compensation for Private industry workers in Financial activities	0.8
Telephone Services	CPI-U for Telephone Services	0.3
All Other: Nonlabor-related Services	CPI-U for All Items Less Food and Energy	1.0
Capital-Related Costs		7.1
Depreciation		5.3
Fixed Assets	BEA chained price index for nonresidential construction for hospitals and special care facilities - vintage weighted (22 years)	3.7
Movable Equipment	PPI for machinery and equipment - vintage weighted (11 years)	1.5

Interest Costs		1.2
Government/Nonprofit	Average yield on domestic municipal bonds (Bond Buyer 20 bonds) - vintage weighted (22 years)	0.9
For Profit	Average yield on Moody's Aaa bonds - vintage weighted (22 years)	0.3
Other Capital-Related Costs	CPI-U for Rent of primary residence	0.7

Note: Totals may not sum to 100.0 percent due to rounding

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Comment: One commenter supported the proposal to rebase and revise the IPF market basket to reflect a 2016 base year from a 2012 base year—as this ensures the most recent cost data is utilized.

Response: We appreciate the commenter's support.

Final Decision: After careful consideration of public comments, we are finalizing the 2016-based IPF market basket as proposed.

4. FY 2020 Market Basket Update

For FY 2020 (that is, beginning October 1, 2019 and ending September 30, 2020), we proposed to use an estimate of the 2016-based IPF market

basket increase factor to update the IPF PPS base payment rate. Consistent with historical practice, we estimate the market basket update for the IPF PPS based on IHS Global Inc.'s (IGI) forecast. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets and multifactor productivity (MFP). In the FY 2020 IPF proposed rule, we proposed a FY 2020 IPF market basket increase of 3.1 percent based on IGI's fourth quarter 2018 forecast with historical data through third quarter 2018. In the FY 2020 proposed rule, we also proposed that if more recent data are subsequently available (for example,

a more recent estimate of the market basket and MFP adjustment) we would use such data, to determine the FY 2020 update in the final rule.

Table 13 compares the final 2016-based IPF market basket and the 2012-based IPF market basket percent changes using the most recent estimate based on IGI's second quarter 2019 forecast with historical data through the first quarter of 2019. The projected 2016-based IPF market basket increase factor for FY 2020 is 2.9 percent. For comparison, the current 2012-based IPF market basket is also projected to increase by 2.9 percent in FY 2020 based on IGI's second quarter 2019 forecast.

TABLE 13—FINAL 2016-BASED IPF MARKET BASKET AND 2012-BASED IPF MARKET BASKET PERCENT CHANGES, FY 2015 THROUGH FY 2022

Fiscal year (FY)	Final 2016- based IPF market basket index percent change	2012-based IPF market basket index percent change
Historical data:		
FY 2015	1.9	1.8
FY 2016	1.9	1.9
FY 2017	2.4	2.5
FY 2018	2.6	2.6
Average 2015–2018	2.2	2.2
Forecast:		
FY 2019	2.6	2.7
FY 2020	2.9	2.9
FY 2021	3.1	3.2
FY 2022	3.1	3.1
Average 2019–2022	2.9	3.0

Note: These market basket percent changes do not include any further adjustments as may be statutorily required. Source: IHS Global Inc. 2nd quarter 2019 forecast.

5. Productivity Adjustment

Section 1886(s)(2)(A)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the IPF PPS for the RY beginning in 2012 (that is, a RY that coincides with a FY) and each subsequent RY. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-

year period ending with the applicable FY, year, cost reporting period, or other annual period) (the “MFP adjustment”). The BLS publishes the official measure of private non-farm business MFP. We refer readers to the BLS website at <http://www.bls.gov/mfp> for the BLS historical published MFP data.

MFP is derived by subtracting the contribution of labor and capital inputs growth from output growth. The projections of the components of MFP are currently produced by IGI, a nationally recognized economic

forecasting firm with which CMS contracts to forecast the components of the market baskets and MFP. For more information on the productivity adjustment, we refer reader to the discussion in the FY 2016 IPF PPS final rule (80 FR 46675).

For the FY 2020 final rule, using IGI's second quarter 2019 forecast, the MFP adjustment for FY 2020 (the 10-year moving average of MFP for the period ending FY 2020) is projected to be 0.4 percent. Thus, in accordance with section 1886(s)(2)(A)(i) of the Act, we

base the FY 2020 market basket update, which is used to determine the applicable percentage increase for the IPF payments, on the most recent estimate of the 2016-based IPF market basket (currently estimated to be 2.9 percent based on IGI's second quarter 2019 forecast). We then reduce this percentage increase of 2.9 percent by the current estimate of the MFP adjustment for FY 2020 of 0.4 percentage point (the 10-year moving average of MFP for the period ending FY 2020 based on IGI's second quarter 2019 forecast) yielding a productivity-adjusted IPF market basket update of 2.5 percent. In addition, for FY 2020 the 2016-based IPF PPS market basket update is further reduced by 0.75 percentage point as required by sections 1886(s)(2)(A)(ii) and 1886(s)(3)(E) of the Act. This results in a FY 2020 IPF PPS payment rate update of 1.75 percent ($2.9 - 0.4 - 0.75 = 1.75$ percent).

6. Labor-Related Share for FY 2020

Due to variations in geographic wage levels and other labor-related costs, we believe that payment rates under the IPF PPS should continue to be adjusted by a geographic wage index, which would apply to the labor-related portion of the Federal per diem base rate (hereafter referred to as the labor-related share). The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. We proposed to continue to classify a cost category as labor-related if the costs are labor intensive and vary with the local labor market.

We proposed to include in the labor-related share the sum of the relative importance of the following cost categories: Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair, All Other: Labor-related Services, and a portion of the Capital-Related cost weight from the proposed 2016-based IPF market basket. These are the same categories as the 2012-based IPF market basket.

Similar to the 2012-based IPF market basket, the 2016-based IPF market basket includes two cost categories for nonmedical Professional fees (including but not limited to, expenses for legal, accounting, and engineering services). These are Professional Fees: Labor-related and Professional Fees: Nonlabor-related. For the 2016-based IPF market basket, we proposed to estimate the labor-related percentage of non-medical professional fees (and assign these expenses to the Professional Fees: Labor-related services cost category) based on the same method that was

used to determine the labor-related percentage of professional fees in the 2012-based IPF market basket.

As done in the 2012-based IPF market basket, we proposed to determine the proportion of legal, accounting and auditing, engineering, and management consulting services that meet our definition of labor-related services based on a survey of hospitals conducted by CMS in 2008. We notified the public of our intent to conduct this survey on December 9, 2005 (70 FR 73250) and did not receive any public comments in response to the notice (71 FR 8588). A discussion of the composition of the survey and post-stratification can be found in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43850 through 43856). Based on the weighted results of the survey, we determined that hospitals purchase, on average, the following portions of contracted professional services outside of their local labor market:

- 34 percent of accounting and auditing services.
- 30 percent of engineering services.
- 33 percent of legal services.
- 42 percent of management consulting services.

We proposed to apply each of these percentages to the respective 2012 Benchmark I–O cost category underlying the professional fees cost category to determine the Professional Fees: Nonlabor-related costs. The Professional Fees: Labor-related costs were determined to be the difference between the total costs for each Benchmark I–O category and the Professional Fees: Nonlabor-related costs. This is the same methodology that we used to separate the 2012-based IPF market basket professional fees category into Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories.

In the 2016-based IPF market basket, nonmedical professional fees that were subject to allocation based on these survey results represent 3.6 percent of total costs (and are limited to those fees related to Accounting & Auditing, Legal, Engineering, and Management Consulting services). Based on our survey results, we proposed to apportion 2.3 percentage points of the 3.6 percentage point figure into the Professional Fees: Labor-related share cost category and designate the remaining 1.3 percentage point into the Professional Fees: Nonlabor-related cost category.

In addition to the professional services listed, for the 2016-based IPF market basket, we proposed to allocate a proportion of the Home Office Contract Labor cost weight, calculated

using the Medicare cost reports, into the Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories. We proposed to classify these expenses as labor-related and nonlabor-related as many facilities are not located in the same geographic area as their home office and, therefore, do not meet our definition for the labor-related share that requires the services to be purchased in the local labor market.

Similar to the 2012-based IPF market basket, we proposed for the 2016-based IPF market basket to use the Medicare cost reports for both freestanding IPF providers and hospital-based IPF providers to determine the home office labor-related percentages. The Medicare cost report requires a hospital to report information regarding their home office provider. Using information on the Medicare cost report, we then compare the location of the IPF with the location of the IPF's home office. We proposed to classify an IPF with a home office located in their respective labor market if the IPF and its home office are located in the same Metropolitan Statistical Area (MSA). We then determined the proportion of the Home Office Contract Labor cost weight that should be allocated to the labor-related share based on the percent of total Medicare allowable costs for those IPFs that had home offices located in their respective local labor markets of total Medicare allowable costs for IPFs with a home office. We determined an IPF's and its home office's MSA using their ZIP code information from the Medicare cost report. Using this methodology, we determined that 46 percent of IPFs' Medicare allowable costs were for home offices located in their respective local labor markets. Therefore, we proposed to allocate 46 percent of the Home Office Contract Labor cost weight (1.6 percentage points = 3.5 percent times 46 percent) to the Professional Fees: Labor-related cost weight and 54 percent of the Home Office Contract Labor cost weight to the Professional Fees: Nonlabor-related cost weight (1.9 percentage points = 3.5 percent times 54 percent). For the 2012-based IPF market basket, we used a similar methodology but we relied on provider counts rather than total Medicare allowable costs to determine the labor-related percentage.

In summary, based on the two allocations mentioned earlier, we apportioned percentage points of the professional fees and home office/related organization contract labor cost weights into the Professional Fees: Labor-Related cost category. This amount was added to the portion of professional fees that we already

identified as labor-related using the I-O data such as contracted advertising and marketing costs (approximately 0.5 percentage point of total costs) resulting in a Professional Fees: Labor-Related cost weight of 4.4 percent.

As stated, we proposed to include in the labor-related share the sum of the relative importance of Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair, All Other: Labor-related Services, and a portion of the Capital-Related cost weight from the proposed 2016-based IPF market basket. The relative importance reflects the different rates of price change for these cost categories between the base year (2016) and FY 2020. Based on IHS Global Inc. 4th quarter 2018 forecast of the proposed 2016-based IPF market basket, we proposed a total labor-related share for FY 2020 of 76.8 percent (the sum of 73.7 percent for the operating cost and 3.1 percent for the labor-related share of Capital).

Comment: One commenter opposed the increase in the labor-related share from 74.8 percent to 76.8 percent stating it would negatively impact any facility with a wage index below 1.0. The growing disparity in wage indices places facilities in low wage areas at a significant disadvantage, and this proposal will further increase that disparity. They encouraged CMS to maintain the FY 2019 labor-related share in FY 2020.

Response: For FY 2020, we proposed the FY 2020 labor-related share to be equal to the sum of the relative importance of shares of the following proposed 2016-based IPF market basket cost categories: Wages and Salaries,

Employee Benefits, Professional Fees: Labor-Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair, All Other: Labor-related Services, and a portion of the Capital-Related cost weight. The FY 2019 labor-related share reflected the sum of the relative importance shares of the same categories using the 2012-based IPF market basket.

The increase in the labor-related share from FY 2019 to FY 2020 is mostly a result of the rebasing and revising of the IPF market basket to reflect more recent data. Of the 2.0-percentage point difference between the FY 2020 labor-related share using the proposed 2016-based IPF market basket and the labor share used in FY 2019, 1.9 percentage point is from rebasing the market basket. The detailed factors contributing to the difference are: 0.6 percentage point is due to an increase in the Compensation and Capital cost weights as a result of incorporating the 2016 MCR data, 0.3 percentage point is due to revising the starting point of the calculation of the relative importance from 2012 to 2016, 0.3 percentage point is due to the use of MCR data to calculate the Home Office Contract Labor cost weight (a portion of which is included in the Professional Fees: Labor-related services cost weight), and the remaining 0.7 percentage point is due to the incorporation of the 2012 Benchmark I-O data, primarily stemming from an increase in the Professional Fees: Labor-related cost weight.

We appreciate the commenter's concern over the increase in the labor-related share; however, we believe it is technically appropriate to use the 2016-based IPF market basket to determine the labor-related share for FY 2020 as it is based on more recent data regarding

price pressures and cost structure of IPFs. Our policy to use the most recent market basket to determine the labor-related share is a policy we have regularly adopted for the IPF PPS as well as for other PPSs including but not limited to the IPPS, the Inpatient Rehabilitation Facility PPS, and the Long-term care hospital PPS.

Final Decision: After careful consideration of comments, in this final rule, we are finalizing the 2016-based IPF market basket labor-related share cost weights as proposed.

Based on IHS Global Inc. 2nd quarter 2019 forecast of the 2016-based IPF market basket, the sum of the FY 2020 relative importance for Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Facilities Support Services, Installation Maintenance & Repair Services, and All Other: Labor-related Services is 73.8 percent. The portion of Capital costs that is influenced by the local labor market is estimated to be 46 percent, which is the same percentage applied to the 2012-based IPF market basket. Since the relative importance for Capital is 6.8 percent of the 2016-based IPF market basket in FY 2020, we took 46 percent of 6.8 percent to determine the proposed labor-related share of Capital for FY 2020 of 3.1 percent. Therefore, we are finalizing a total labor-related share for FY 2020 of 76.9 percent (the sum of 73.8 percent for the operating cost and 3.1 percent for the labor-related share of Capital).

Table 14 shows the FY 2020 labor-related share using the final 2016-based IPF market basket relative importance and the FY 2019 labor-related share using the 2012-based IPF market basket.

Table 14: FY 2020 IPF Labor-Related Share and FY 2019 IPF Labor-Related Share

	FY 2020 Labor-related Share based on Final 2016-based IPF Market Basket¹	FY 2019 Final Labor-related Share based on 2012-based IPF Market Basket²
Wages and Salaries	52.5	52.0
Employee Benefits	13.6	13.2
Professional Fees: Labor-related ³	4.3	2.8
Administrative and Facilities Support Services	0.6	0.7
Installation, Maintenance and Repair	1.3	1.6
All Other: Labor-related Services	1.5	1.5
Subtotal	73.8	71.8
Labor-related portion of capital (46%)	3.1	3.0
Total LRS	76.9	74.8

¹ IHS Global Inc. 2nd quarter 2019 forecast.² Based on IHS Global Inc. 2nd quarter 2018 forecast as published in the Federal Register (83 FR 38579).³ Includes all contract advertising and marketing costs and a portion of accounting, architectural, engineering, legal, management consulting, and home office contract labor costs.*B. Updates to the IPF PPS Rates for FY Beginning October 1, 2019*

The IPF PPS is based on a standardized federal per diem base rate calculated from the IPF average per diem costs and adjusted for budget-neutrality in the implementation year. The federal per diem base rate is used as the standard payment per day under the IPF PPS and is adjusted by the patient-level and facility-level adjustments that are applicable to the IPF stay. A detailed explanation of how we calculated the average per diem cost appears in the November 2004 IPF PPS final rule (69 FR 66926).

1. Determining the Standardized Budget-Neutral Federal Per Diem Base Rate

Section 124(a)(1) of the BBRA required that we implement the IPF PPS in a budget-neutral manner. In other words, the amount of total payments under the IPF PPS, including any payment adjustments, must be projected to be equal to the amount of total payments that would have been made if the IPF PPS were not implemented. Therefore, we calculated the budget-neutrality factor by setting the total estimated IPF PPS payments to be equal to the total estimated payments that would have been made under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248)

methodology had the IPF PPS not been implemented. A step-by-step description of the methodology used to estimate payments under the TEFRA payment system appears in the November 2004 IPF PPS Final rule (69 FR 66926).

Under the IPF PPS methodology, we calculated the final federal per diem base rate to be budget-neutral during the IPF PPS implementation period (that is, the 18-month period from January 1, 2005 through June 30, 2006) using a July 1 update cycle. We updated the average cost per day to the midpoint of the IPF PPS implementation period (October 1, 2005), and this amount was used in the payment model to establish the budget-neutrality adjustment.

Next, we standardized the IPF PPS federal per diem base rate to account for the overall positive effects of the IPF PPS payment adjustment factors by dividing total estimated payments under the TEFRA payment system by estimated payments under the IPF PPS. Additional information concerning this standardization can be found in the November 2004 IPF PPS final rule (69 FR 66932) and the RY 2006 IPF PPS final rule (71 FR 27045). We then reduced the standardized federal per diem base rate to account for the outlier policy, the stop loss provision, and anticipated behavioral changes. A complete discussion of how we

calculated each component of the budget-neutrality adjustment appears in the November 2004 IPF PPS final rule (69 FR 66932 through 66933) and in the RY 2007 IPF PPS final rule (71 FR 27044 through 27046). The final standardized budget-neutral federal per diem base rate established for cost reporting periods beginning on or after January 1, 2005 was calculated to be \$575.95.

The federal per diem base rate has been updated in accordance with applicable statutory requirements and § 412.428 through publication of annual notices or proposed and final rules. A detailed discussion on the standardized budget-neutral federal per diem base rate and the electroconvulsive therapy (ECT) payment per treatment appears in the FY 2014 IPF PPS update notice (78 FR 46738 through 46740). These documents are available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/index.html>.

IPFs must include a valid procedure code for ECT services provided to IPF beneficiaries in order to bill for ECT services, as described in our Medicare Claims Processing Manual, Chapter 3, Section 190.7.3 (available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf>.) There were no changes to the ECT procedure codes

used on IPF claims as a result of the proposed update to the ICD-10-PCS code set for FY 2020. Addendum B-4 to this final rule shows the ECT procedure codes for FY 2020 and is available on our website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html>.

2. Update of the Federal Per Diem Base Rate and Electroconvulsive Therapy Payment Per Treatment

The current (FY 2019) federal per diem base rate is \$782.78 and the ECT payment per treatment is \$337.00. For the FY 2020 federal per diem base rate, we applied the payment rate update of 1.75 percent (that is, the 2016-based IPF market basket increase for FY 2020 of 2.9 percent less the productivity adjustment of 0.4 percentage point, and further reduced by the 0.75 percentage point required under section 1886(s)(3)(E) of the Act), and the wage index budget-neutrality factor of 1.0026 (as discussed in section III.D.1.f of this final rule) to the FY 2019 federal per diem base rate of \$782.78, yielding a federal per diem base rate of \$798.55 for FY 2020. Similarly, we applied the 1.75 percent payment rate update and the 1.0026 wage index budget-neutrality factor to the FY 2019 ECT payment per treatment of \$337.00, yielding an ECT payment per treatment of \$343.79 for FY 2020.

Section 1886(s)(4)(A)(i) of the Act requires that for RY 2014 and each subsequent RY, in the case of an IPF that fails to report required quality data with respect to such rate year, the Secretary will reduce any annual update to a standard federal rate for discharges during the RY by 2.0 percentage points. Therefore, we are applying a 2.0 percentage point reduction to the federal per diem base rate and the ECT payment per treatment as follows:

- For IPFs that fail requirements under the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program, we applied a –0.25 percent payment rate update (that is, the IPF market basket increase for FY 2020 of 2.9 percent less the productivity adjustment of 0.4 percentage point, further reduced by the 0.75 percentage point for an update of 1.75 percent, and further reduced by 2 percentage points in accordance with section 1886(s)(4)(A)(ii) of the Act, which results in a negative update percentage) and the wage index budget-neutrality factor of 1.0026 to the FY 2019 federal per diem base rate of \$782.78, yielding a federal per diem base rate of \$782.85 for FY 2020.

- For IPFs that fail to meet requirements under the IPFQR Program, we applied the –0.25 percent annual payment rate update and the 1.0026 wage index budget-neutrality factor to the FY 2019 ECT payment per treatment of \$337.00, yielding an ECT payment per treatment of \$337.03 for FY 2020.

C. Updates to the IPF PPS Patient-Level Adjustment Factors

1. Overview of the IPF PPS Adjustment Factors

The IPF PPS payment adjustments were derived from a regression analysis of 100 percent of the FY 2002 Medicare Provider and Analysis Review (MedPAR) data file, which contained 483,038 cases. For a more detailed description of the data file used for the regression analysis, see the November 2004 IPF PPS final rule (69 FR 66935 through 66936). We are finalizing our proposal to continue to use the existing regression-derived adjustment factors established in 2005 for FY 2020. However, we have used more recent claims data to simulate payments to finalize the outlier fixed dollar loss threshold amount and to assess the impact of the IPF PPS updates.

2. IPF PPS Patient-Level Adjustments

The IPF PPS includes payment adjustments for the following patient-level characteristics: Medicare Severity Diagnosis Related Groups (MS-DRGs) assignment of the patient's principal diagnosis, selected comorbidities, patient age, and the variable per diem adjustments.

a. Update to MS-DRG Assignment

We believe it is important to maintain for IPFs the same diagnostic coding and Diagnosis Related Group (DRG) classification used under the Inpatient Prospective Payment System (IPPS) for providing psychiatric care. For this reason, when the IPF PPS was implemented for cost reporting periods beginning on or after January 1, 2005, we adopted the same diagnostic code set (ICD-9-CM) and DRG patient classification system (MS-DRGs) that were utilized at the time under the IPPS. In the RY 2009 IPF PPS notice (73 FR 25709), we discussed CMS' effort to better recognize resource use and the severity of illness among patients. CMS adopted the new MS-DRGs for the IPPS in the FY 2008 IPPS final rule with comment period (72 FR 47130). In the RY 2009 IPF PPS notice (73 FR 25716), we provided a crosswalk to reflect changes that were made under the IPF PPS to adopt the new MS-DRGs. For a detailed description of the mapping

changes from the original DRG adjustment categories to the current MS-DRG adjustment categories, we refer readers to the RY 2009 IPF PPS notice (73 FR 25714).

The IPF PPS includes payment adjustments for designated psychiatric DRGs assigned to the claim based on the patient's principal diagnosis. The DRG adjustment factors were expressed relative to the most frequently reported psychiatric DRG in FY 2002, that is, DRG 430 (psychoses). The coefficient values and adjustment factors were derived from the regression analysis discussed in detail in the November 28, 2003 IPF proposed rule (68 FR 66923; 66928 through 66933) and the November 15, 2004 IPF final rule (69 FR 66933 through 66960). Mapping the DRGs to the MS-DRGs resulted in the current 17 IPF MS-DRGs, instead of the original 15 DRGs, for which the IPF PPS provides an adjustment. For FY 2020, we did not propose any changes to the IPF MS-DRG adjustment factors but are finalizing our proposal to maintain the existing IPF MS-DRG adjustment factors.

In the FY 2015 IPF PPS final rule published August 6, 2014 in the **Federal Register** titled, "Inpatient Psychiatric Facilities Prospective Payment System—Update for FY Beginning October 1, 2014 (FY 2015)" (79 FR 45945 through 45947), we finalized conversions of the ICD-9-CM-based MS-DRGs to ICD-10-CM/PCS-based MS-DRGs, which were implemented on October 1, 2015. Further information on the ICD-10-CM/PCS MS-DRG conversion project can be found on the CMS ICD-10-CM website at <https://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html>.

For FY 2020, we are finalizing our proposal to continue to make the existing payment adjustment for psychiatric diagnoses that group to one of the existing 17 IPF MS-DRGs listed in Addendum A. Addendum A is available on our website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html>. Psychiatric principal diagnoses that do not group to one of the 17 designated MS-DRGs will still receive the federal per diem base rate and all other applicable adjustments, but the payment will not include an MS-DRG adjustment.

The diagnoses for each IPF MS-DRG will be updated as of October 1, 2019, using the final IPPS FY 2020 ICD-10-CM/PCS code sets. The FY 2020 IPPS final rule includes tables of the final changes to the ICD-10-CM/PCS code sets which underlie the FY 2020 IPF

MS-DRGs. Both the FY 2020 IPPS final rule and the tables of proposed changes to the ICD-10-CM/PCS code sets which underlie the FY 2020 MS-DRGs are available on the IPPS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>.

Code First

As discussed in the ICD-10-CM Official Guidelines for Coding and Reporting, certain conditions have both an underlying etiology and multiple body system manifestations due to the underlying etiology. For such conditions, the ICD-10-CM has a coding convention that requires the underlying condition be sequenced first followed by the manifestation. Wherever such a combination exists, there is a “use additional code” note at the etiology code, and a “code first” note at the manifestation code. These instructional notes indicate the proper sequencing order of the codes (etiology followed by manifestation). In accordance with the ICD-10-CM Official Guidelines for Coding and Reporting, when a primary (psychiatric) diagnosis code has a “code first” note, the provider would follow the instructions in the ICD-10-CM text. The submitted claim goes through the CMS processing system, which will identify the primary diagnosis code as non-psychiatric and search the secondary codes for a psychiatric code to assign a DRG code for adjustment. The system will continue to search the secondary codes for those that are appropriate for comorbidity adjustment.

For more information on the code first policy, see our November 2004 IPF PPS final rule (69 FR 66945) and see sections I.A.13 and I.B.7 of the FY 2019 ICD-10-CM Coding Guidelines, available at <https://www.cdc.gov/nchs/icd/data/10cmguidelines-FY2019-final.pdf>. In the FY 2015 IPF PPS final rule, we provided a code first table for reference that highlights the same or similar manifestation codes where the code first instructions apply in ICD-10-CM that were present in ICD-9-CM (79 FR 46009). In FY 2018 and FY 2019, there were no changes to the final ICD-10-CM/PCS codes in the IPF Code First table. For FY 2020, there continue to be no changes to the ICD-10-CM/PCS codes in the proposed IPF Code First table. The final FY 2020 Code First table is shown in Addendum B-1 on our website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html>.

b. Payment for Comorbid Conditions

The intent of the comorbidity adjustments is to recognize the increased costs associated with comorbid conditions by providing additional payments for certain existing medical or psychiatric conditions that are expensive to treat. In our RY 2012 IPF PPS final rule (76 FR 26451 through 26452), we explained that the IPF PPS includes 17 comorbidity categories and identified the new, revised, and deleted ICD-9-CM diagnosis codes that generate a comorbid condition payment adjustment under the IPF PPS for RY 2012 (76 FR 26451).

Comorbidities are specific patient conditions that are secondary to the patient's principal diagnosis and that require treatment during the stay. Diagnoses that relate to an earlier episode of care and have no bearing on the current hospital stay are excluded and must not be reported on IPF claims. Comorbid conditions must exist at the time of admission or develop subsequently, and affect the treatment received, length of stay (LOS), or both treatment and LOS.

For each claim, an IPF may receive only one comorbidity adjustment within a comorbidity category, but it may receive an adjustment for more than one comorbidity category. Current billing instructions for discharge claims, on or after October 1, 2015, require IPFs to enter the complete ICD-10-CM codes for up to 24 additional diagnoses if they co-exist at the time of admission, or develop subsequently and impact the treatment provided.

The comorbidity adjustments were determined based on the regression analysis using the diagnoses reported by IPFs in FY 2002. The principal diagnoses were used to establish the DRG adjustments and were not accounted for in establishing the comorbidity category adjustments, except where ICD-9-CM code first instructions applied. In a code first situation, the submitted claim goes through the CMS processing system, which will identify the principal diagnosis code as non-psychiatric and search the secondary codes for a psychiatric code to assign an MS-DRG code for adjustment. The system will continue to search the secondary codes for those that are appropriate for comorbidity adjustment.

As noted previously, it is our policy to maintain the same diagnostic coding set for IPFs that is used under the IPPS for providing the same psychiatric care. The 17 comorbidity categories formerly defined using ICD-9-CM codes were converted to ICD-10-CM/PCS in our FY

2015 IPF PPS final rule (79 FR 45947 through 45955). The goal for converting the comorbidity categories is referred to as replication, meaning that the payment adjustment for a given patient encounter is the same after ICD-10-CM implementation as it would be if the same record had been coded in ICD-9-CM and submitted prior to ICD-10-CM/PCS implementation on October 1, 2015. All conversion efforts were made with the intent of achieving this goal. For FY 2020, we are finalizing our proposal to continue to use the same comorbidity adjustment factors in effect in FY 2019, which are found in Addendum A, available on our website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html>.

We have updated the ICD-10-CM/PCS codes which are associated with the existing IPF PPS comorbidity categories, based upon the final FY 2020 update to the ICD-10-CM/PCS code set. The final FY 2020 ICD-10-CM/PCS updates include 4 ICD-10-CM diagnosis codes added to the Poisoning comorbidity category and 88 ICD-10-PCS codes added to the Oncology Procedures comorbidity category. In addition, 3 ICD-10-PCS codes were deleted from the Oncology Procedures comorbidity category. These updates are detailed in Addenda B-2 and B-3 of this final rule, which are available on our website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html>.

In accordance with the policy established in the FY 2015 IPF PPS final rule (79 FR 45949 through 45952), we reviewed all new FY 2020 ICD-10-CM codes to remove codes that were site “unspecified” in terms of laterality from the FY 2020 ICD-10-CM/PCS codes in instances where more specific codes are available. As we stated in the FY 2015 IPF PPS final rule, we believe that specific diagnosis codes that narrowly identify anatomical sites where disease, injury, or a condition exists should be used when coding patients' diagnoses whenever these codes are available. We finalized that we would remove site “unspecified” codes from the IPF PPS ICD-10-CM/PCS codes in instances when laterality codes (site specified codes) are available, as the clinician should be able to identify a more specific diagnosis based on clinical assessment at the medical encounter. None of the proposed additions to the FY 2020 ICD-10-CM/PCS codes were site “unspecified” by laterality, therefore we are not removing any of the new codes.

c. Patient Age Adjustments

As explained in the November 2004 IPF PPS final rule (69 FR 66922), we analyzed the impact of age on per diem cost by examining the age variable (range of ages) for payment adjustments. In general, we found that the cost per day increases with age. The older age groups are more costly than the under 45 age group, the differences in per diem cost increase for each successive age group, and the differences are statistically significant. For FY 2020, we are finalizing our proposal to continue to use the patient age adjustments currently in effect in FY 2019, as shown in Addendum A of this rule (see <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacIPPS/tools.html>).

d. Variable Per Diem Adjustments

We explained in the November 2004 IPF PPS final rule (69 FR 66946) that the regression analysis indicated that per diem cost declines as the length of stay (LOS) increases. The variable per diem adjustments to the federal per diem base rate account for ancillary and administrative costs that occur disproportionately in the first days after admission to an IPF. As discussed in the November 2004 IPF PPS final rule, we used a regression analysis to estimate the average differences in per diem cost among stays of different lengths (69 FR 66947 to 66950). As a result of this analysis, we established variable per diem adjustments that begin on day 1 and decline gradually until day 21 of a patient's stay. For day 22 and thereafter, the variable per diem adjustment remains the same each day for the remainder of the stay. However, the adjustment applied to day 1 depends upon whether the IPF has a qualifying ED. If an IPF has a qualifying ED, it receives a 1.31 adjustment factor for day 1 of each stay. If an IPF does not have a qualifying ED, it receives a 1.19 adjustment factor for day 1 of the stay. The ED adjustment is explained in more detail in section III.D.4 of this rule.

For FY 2020, we are finalizing our proposal to continue to use the variable per diem adjustment factors currently in effect, as shown in Addendum A of this rule (available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacIPPS/tools.html>). A complete discussion of the variable per diem adjustments appears in the November 2004 IPF PPS final rule (69 FR 66946).

D. Updates to the IPF PPS Facility-Level Adjustments

The IPF PPS includes facility-level adjustments for the wage index, IPFs located in rural areas, teaching IPFs, cost of living adjustments for IPFs located in Alaska and Hawaii, and IPFs with a qualifying ED.

1. Wage Index Adjustment

a. Background

As discussed in the RY 2007 IPF PPS final rule (71 FR 27061), RY 2009 IPF PPS (73 FR 25719) and the RY 2010 IPF PPS notices (74 FR 20373), in order to provide an adjustment for geographic wage levels, the labor-related portion of an IPF's payment is adjusted using an appropriate wage index. Currently, an IPF's geographic wage index value is determined based on the actual location of the IPF in an urban or rural area, as defined in § 412.64(b)(1)(ii)(A) and (C).

b. Change to the IPF Wage Index Methodology

Due to the variation in costs and because of the differences in geographic wage levels, in the November 15, 2004 IPF PPS final rule, we required that payment rates under the IPF PPS be adjusted by a geographic wage index. We proposed and finalized a policy to use the unadjusted, pre-floor, pre-reclassified IPPS hospital wage index to account for geographic differences in IPF labor costs. We implemented use of the pre-floor, pre-reclassified IPPS hospital wage data to compute the IPF wage index since there was not an IPF-specific wage index available. We believe that IPFs generally compete in the same labor market as IPPS hospitals so the pre-floor, pre-reclassified IPPS hospital wage data should be reflective of labor costs of IPFs. We believe this pre-floor, pre-reclassified IPPS hospital wage index to be the best available data to use as proxy for an IPF specific wage index. As discussed in the rate year (RY) 2007 IPF PPS final rule (71 FR 27061 through 27067), under the IPF PPS, the wage index is calculated using the IPPS wage index for the labor market area in which the IPF is located, without taking into account geographic reclassifications, floors, and other adjustments made to the wage index under the IPPS. For a complete description of these IPPS wage index adjustments, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41362 through 41390). Our wage index policy was put into regulation at 412.424(a)(2), and requires us to use the best Medicare data available to estimate costs per day, including an appropriate

wage index to adjust for wage differences.

When the IPF PPS was implemented in the November 15, 2004 IPF PPS final rule, with an effective date of January 1, 2005, the pre-floor, pre-reclassified IPPS hospital wage index that was available at the time was the FY 2005 pre-floor, pre-reclassified IPPS hospital wage index. Historically, the IPF wage index for a given RY has used the pre-floor, pre-reclassified IPPS hospital wage index from the prior fiscal year as its basis. This has been due in part to the pre-floor, pre-reclassified IPPS hospital wage index data that were available during the IPF rulemaking cycle, where an annual IPF notice or IPF final rule was usually published in early May. This publication timeframe was relatively early compared to other Medicare payment rules because the IPF PPS follows an RY, which was defined in the implementation of the IPF PPS as the 12-month period from July 1 to June 30 (69 FR 66927). Therefore the best available data at the time the IPF PPS was implemented was the pre-floor, pre-reclassified IPPS hospital wage index from the prior fiscal year (for example, the RY 2006 IPF wage index was based on the FY 2005 pre-floor, pre-reclassified IPPS hospital wage index).

In the RY 2012 IPF PPS final rule, we changed the reporting year timeframe for IPFs from a RY to the FY, which begins October 1 and ends September 30 (76 FR 26434 through 26435). In that FY 2012 IPF PPS final rule, we continued our established policy of using the pre-floor, pre-reclassified IPPS hospital wage index from the prior year (that is, from FY 2011) as the basis for the FY 2012 IPF wage index. This policy of basing a wage index on the prior year's pre-floor, pre-reclassified IPPS hospital wage index has been followed by other Medicare payment systems, such as hospice and inpatient rehabilitation facilities. By continuing with our established policy, we remained consistent with other Medicare payment systems.

We proposed to change the IPF wage index methodology to align the IPF PPS wage index with the same wage data timeframe used by the IPPS for FY 2020 and subsequent years. Specifically, we proposed to use the pre-floor, pre-reclassified IPPS hospital wage index from the fiscal year concurrent with the IPF fiscal year as the basis for the IPF wage index. For example, the FY 2020 IPF wage index would be based on the FY 2020 pre-floor, pre-reclassified IPPS hospital wage index rather than on the FY 2019 pre-floor, pre-reclassified IPPS hospital wage index.

We explained in the proposed rule (84 FR 16973), that using the concurrent pre-floor, pre-reclassified IPPS hospital wage index would result in the most up-to-date wage data being the basis for the IPF wage index. It would also result in more consistency and parity in the wage index methodology used by other Medicare payment systems. The Medicare SNF PPS already uses the concurrent IPPS hospital wage index data as the basis for the SNF PPS wage index. Thus, the wage adjusted Medicare payments of various provider types would be based upon wage index data from the same timeframe. CMS proposed similar policies to use the concurrent pre-floor, pre-reclassified IPPS hospital wage index data in other Medicare payment systems, such as hospice and inpatient rehabilitation facilities.

For FY 2020, we also proposed to continue use the pre-floor, pre-reclassified IPPS hospital wage index as the basis for the IPF wage index.

We received 1 comment on our proposal to align the IPF wage index data timeframe with that of the IPPS, by using the concurrent pre-floor, pre-reclassified IPPS hospital wage index as the basis for the IPF wage index for FY 2020 and subsequent years.

Comment: A commenter wrote that he was not opposed to the proposal to eliminate the 1-year lag in the wage index data, but had issues with the data itself. The commenter was opposed to using the FY 2020 IPPS wage index data file discussed in the FY 2020 IPPS proposed rule because the data excluded several hospitals which had wage data based upon regional rather

than local labor market rates. The commenter felt this exclusion was inappropriate and that it would negatively affect certain IPFs.

Response: We appreciate the comment, however, we are finalizing our proposal to use the *concurrent* pre-floor, pre-reclassified IPPS hospital wage index as the basis for IPF wage index for FY 2020 and subsequent years. For FY 2020, we are also finalizing our proposal to continue to use the pre-floor, pre-reclassified IPPS hospital wage index as the basis for the IPF wage index. We believe it is the best available data to use as a proxy for an IPF wage index. This pre-floor, pre-reclassified IPPS hospital wage index is also the most appropriate wage index as IPFs compete in the same labor market as IPPS hospitals; this wage index best reflects the variation in local labor costs of IPFs in the various geographic areas using the most recent IPPS hospital wage data (data from hospital cost reports for the cost reporting period beginning during FY 2016) without any geographic reclassifications, floors, or other adjustments. We will apply the FY 2020 IPF wage index to payments beginning October 1, 2019.

We identified a slight error in the proposed rule wage index values after the FY 2020 IPF PPS proposed rule was published. A programming error caused the data for all providers in a single county to be included twice, which affected the national average hourly rate, and therefore affected nearly all wage index values. We have changed the programming logic so this error cannot occur again. In addition, we corrected the classification of one

provider in North Carolina that was erroneously identified as being in an urban CBSA. We also standardized our procedures for rounding, to ensure consistency. The correction to the NPRM wage index data was not completed until after the comment period closed on June 17, 2019. This final rule reflects the corrected and updated wage index data.

We are finalizing this change to the IPF wage index methodology to implement it in a budget-neutral manner, so that total IPF payments will not be affected. However, as shown in Table 15, there will be distributional effects. Table 15 compares the estimated payments calculated using the FY 2020 IPF wage index based on the IPPS hospital wage index data from the prior fiscal year (the current methodology) with the estimated payments calculated using the FY 2020 IPF wage index based on concurrent IPPS hospital wage index data (the proposed change in methodology which we are finalizing). Due to budget neutrality, the effect on total estimated FY 2020 IPF payments is zero. Table 15 shows that urban IPFs are estimated to experience a smaller increase in payments by finalizing the proposed methodology (0.03 percent increase) compared to if we had maintained the current methodology (0.09 percent increase). Rural IPFs are estimated to have a smaller decrease in estimated payments by finalizing the proposed methodology (0.20 percent decrease) compared to if we had maintained the current methodology (0.54 percent decrease).

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**Table 15. Distributional Effects of the Change to the IPF Wage Index Methodology
[Percent Change in Columns 3 and 4]**

Facility by Type	Number of Facilities	Estimated Impact of Wage Index Update Under Current Methodology	Estimated Impact of Wage Index Update Under Proposed & Finalized Methodology
(1)	(2)	(3)	(4)
All Facilities	1,581	0.00	0.00
Total Urban	1,260	0.09	0.03
Urban unit	783	0.05	-0.06
Urban hospital	477	0.13	0.13
Total Rural	321	-0.54	-0.20
Rural unit	255	-0.62	-0.24
Rural hospital	66	-0.34	-0.10
By Type of Ownership:			
Freestanding IPFs			
Urban Psychiatric Hospitals			
Government	121	-0.19	-0.19
Non-Profit	100	0.18	0.08
For-Profit	256	0.18	0.21
Rural Psychiatric Hospitals			
Government	32	-0.56	-0.30
Non-Profit	15	-0.31	-0.47
For-Profit	19	-0.23	0.10
IPF Units			
Urban			
Government	115	0.28	0.19
Non-Profit	509	0.00	-0.09
For-Profit	159	0.02	-0.15
Rural			
Government	68	-0.53	-0.08

Non-Profit	136	-0.48	-0.13
For-Profit	51	-1.06	-0.68
By Teaching Status:			
Non-teaching	1,390	-0.03	-0.05
Less than 10% interns and residents to beds	107	0.07	0.13
10% to 30% interns and residents to beds	61	0.40	0.30
More than 30% interns and residents to beds	23	0.17	0.71
By Region:			
New England	104	-0.25	-0.83
Mid-Atlantic	229	0.19	0.06
South Atlantic	239	-0.12	-0.24
East North Central	270	-0.30	-0.34
East South Central	159	-0.65	-0.70
West North Central	115	-0.10	0.37
West South Central	236	-0.05	-0.04
Mountain	105	-0.87	-0.78
Pacific	124	1.51	2.08
By Bed Size:			
Psychiatric Hospitals			
Beds: 0-24	86	-0.01	-0.14
Beds: 25-49	86	-0.11	0.00
Beds: 50-75	91	-0.12	0.04
Beds: 76 +	280	0.22	0.20
Psychiatric Units			
Beds: 0-24	593	-0.25	-0.17
Beds: 25-49	268	0.01	-0.12
Beds: 50-75	111	0.22	0.06
Beds: 76 +	66	0.04	0.03

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To provide additional information to IPFs about the effect of implementing this change in the IPF wage index methodology on estimated payments, we have also posted a provider-level table of effects (Addendum C) on the CMS website, available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/WageIndex.html>.

We are applying the IPF wage index adjustment to the labor-related share of

the national base rate or ECT payment per treatment. The labor-related share of the national rate and ECT payment per treatment will change from 74.8 percent in FY 2019 to 76.9 percent in FY 2020. This percentage reflects the labor-related share of the 2016-based IPF market basket for FY 2020 (see section III.A.6 of this rule).

c. Office of Management and Budget Bulletins

OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. In the RY 2007 IPF PPS final rule (71 FR 27061 through 27067), we adopted the changes discussed in the OMB Bulletin No. 03-04 (June 6, 2003), which announced revised definitions for MSAs, and the creation of Micropolitan Statistical Areas and Combined Statistical Areas.

In adopting the OMB CBSA geographic designations in RY 2007, we did not provide a separate transition for the CBSA-based wage index since the IPF PPS was already in a transition period from TEFRA payments to PPS payments.

In the RY 2009 IPF PPS notice, we incorporated the CBSA nomenclature changes published in the most recent OMB bulletin that applied to the IPPS hospital wage index used to determine the current IPF wage index and stated that we expected to continue to do the same for all the OMB CBSA nomenclature changes in future IPF PPS rules and notices, as necessary (73 FR 25721). The OMB bulletins may be accessed online at <https://www.whitehouse.gov/omb/information-for-agencies/bulletins/>.

In accordance with our established methodology, we have historically adopted any CBSA changes that are published in the OMB bulletin that corresponds with the IPPS hospital wage index used to determine the IPF wage index. For the FY 2015 IPF wage index, we used the FY 2014 pre-floor, pre-reclassified IPPS hospital wage index to adjust the IPF PPS payments. On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for MSAs, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2000 Census, and provided guidance on the use of the delineations of these statistical areas. A copy of this bulletin may be obtained at <https://www.whitehouse.gov/omb/information-for-agencies/bulletins/>.

Because the FY 2014 pre-floor, pre-reclassified IPPS hospital wage index did not reflect the statistical area revisions set forth in OMB Bulletin 13–01, the FY 2015 IPF PPS wage index, which was based on the FY 2014 pre-floor, pre-reclassified IPPS hospital wage index, did not reflect OMB's new area delineations based on the 2010 Census. According to OMB, "[t]his bulletin provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the **Federal Register** (75 FR 37246 through 37252) and Census Bureau data." These OMB Bulletin changes are reflected in the FY 2015 pre-floor, pre-reclassified IPPS hospital wage index, upon which the FY 2016 IPF wage index was based. We adopted these new OMB CBSA

delineations in the FY 2016 IPF wage index and subsequent IPF wage indexes.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provided minor updates to, and superseded, OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. The updates provided in the attachment to OMB Bulletin No. 15–01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. The complete list of statistical areas incorporating these changes is provided in OMB Bulletin No. 15–01. A copy of this bulletin may be obtained at <https://www.whitehouse.gov/omb/information-for-agencies/bulletins/>. OMB Bulletin No. 15–01 establishes revised delineations for the Nation's Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas. The bulletin also provides delineations of Metropolitan Divisions as well as delineations of New England City and Town Areas.

In accordance with our longstanding policy, the IPF PPS continues to use the latest labor market area delineations available as soon as is reasonably possible to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), the updated labor market area definitions from OMB Bulletin 15–01 were implemented under the IPPS beginning on October 1, 2016 (FY 2017). Therefore, we implemented these revisions for the IPF PPS beginning October 1, 2017 (FY 2018), consistent with our historical practice of modeling IPF PPS adoption of the labor market area delineations after IPPS adoption of these delineations (historically the IPF wage index has been based upon the pre-floor, pre-reclassified IPPS hospital wage index from the prior year).

On August 15, 2017, OMB announced in OMB Bulletin No. 17–01 that one Micropolitan Statistical Area now qualifies as a Metropolitan Statistical Area. The new urban CBSA is as follows:

- Twin Falls, Idaho (CBSA 46300).

This CBSA is comprised of the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho. Prior to this redesignation, Jerome County and Twin Falls County, Idaho were classified as rural. The OMB bulletin is available on the OMB website at <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf>.

With the change made by OMB Bulletin No. 17–01, these two counties are now designated as urban, and any IPFs in those areas will change their status from being rural to being urban. We adopted these new OMB designations in FY 2020 as they are included in the FY 2020 pre-floor, pre-reclassified IPPS hospital wage index upon which the FY 2020 IPF wage index is proposed to be based. That is, the FY 2020 pre-floor, pre-reclassified IPPS hospital wage index, which is the basis of the final FY 2020 IPF wage index, will include this new OMB designation.

Therefore, the 17 percent IPF rural adjustment will cease for IPF providers in these two counties. Currently, there is a single IPF in new CBSA 46300, which will lose its 17 percent rural adjustment as a result of being redesignated as urban. However, the FY 2020 IPF wage index value for CBSA 46300 is 0.8291, which is 3.5 percent higher than the rural wage index value for Idaho (0.8009). As such, the loss of the 17 percent IPF wage index adjustment will be mitigated in part by the increase in the wage index value when changing from the rural Idaho wage index value to the urban CBSA 46300 wage index value. Given that the loss of the rural adjustment will be mitigated in part by the increase in wage index value, and that only a single IPF is affected by this change, we do not believe it is necessary to transition this provider from its rural to newly urban status.

Thus, we are finalizing our proposal to adopt this new OMB designation in the proposed IPF wage index for FY 2020 and for subsequent fiscal years. The FY 2020 IPF wage index already includes the OMB delineations that were adopted in prior fiscal years. The FY 2020 IPF wage index (including the CBSA update from OMB Bulletin No. 17–01) is located on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/WageIndex.html>.

d. Solicitation of Public Comments on the IPF Wage Index

Historically, we have calculated the IPF PPS wage index values using unadjusted wage index values from another provider setting. Stakeholders have occasionally commented on certain aspects of the IPF PPS wage index values and their impact on payments. We solicited comments on concerns stakeholders may have regarding the wage index used to adjust IPF PPS payments and suggestions for possible updates and improvements to the geographic adjustment of IPF PPS payments. We did not receive any comments.

e. Adjustment for Rural Location

In the November 2004 IPF PPS final rule, we provided a 17 percent payment adjustment for IPFs located in a rural area. This adjustment was based on the regression analysis, which indicated that the per diem cost of rural facilities was 17 percent higher than that of urban facilities after accounting for the influence of the other variables included in the regression. This 17 percent adjustment has been part of the IPF PPS each year since the inception of the IPF PPS. For FY 2020, we are finalizing our proposal to continue to apply a 17 percent payment adjustment for IPFs located in a rural area as defined at § 412.64(b)(1)(ii)(C). A complete discussion of the adjustment for rural locations appears in the November 2004 IPF PPS final rule (69 FR 66954).

f. Budget Neutrality Adjustment

Changes to the wage index are made in a budget-neutral manner so that updates do not increase expenditures. Therefore, for FY 2020, we are finalizing our proposal to continue to apply a budget-neutrality adjustment in accordance with our existing budget-neutrality policy. This policy requires us to update the wage index in such a way that total estimated payments to IPFs for FY 2020 are the same with or without the changes (that is, in a budget-neutral manner) by applying a budget neutrality factor to the IPF PPS rates. We use the following steps to ensure that the rates reflect the update to the wage indexes (based on the FY 2016 hospital cost report data) and the labor-related share in a budget-neutral manner:

Step 1. Simulate estimated IPF PPS payments, using the FY 2019 IPF wage index values (available on the CMS website) and labor-related share (as published in the FY 2019 IPF PPS final rule (83 FR 38579)).

Step 2. Simulate estimated IPF PPS payments using the FY 2020 IPF wage

index values (available on the CMS website) and FY 2020 labor-related share (based on the latest available data as discussed previously).

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2. The resulting quotient is the FY 2020 budget-neutral wage adjustment factor of 1.0026.

Step 4. Apply the FY 2020 budget-neutral wage adjustment factor from step 3 to the FY 2019 IPF PPS federal per diem base rate after the application of the market basket update described in section III.A.4 of this rule, to determine the FY 2020 IPF PPS federal per diem base rate.

2. Teaching Adjustment

In the November 2004 IPF PPS final rule, we implemented regulations at § 412.424(d)(1)(iii) to establish a facility-level adjustment for IPFs that are, or are part of, teaching hospitals. The teaching adjustment accounts for the higher indirect operating costs experienced by hospitals that participate in graduate medical education (GME) programs. The payment adjustments are made based on the ratio of the number of full-time equivalent (FTE) interns and residents training in the IPF and the IPF's average daily census (ADC).

Medicare makes direct GME payments (for direct costs such as resident and teaching physician salaries, and other direct teaching costs) to all teaching hospitals including those paid under a PPS, and those paid under the TEFRA rate-of-increase limits. These direct GME payments are made separately from payments for hospital operating costs and are not part of the IPF PPS. The direct GME payments do not address the estimated higher indirect operating costs teaching hospitals may face.

The results of the regression analysis of FY 2002 IPF data established the basis for the payment adjustments included in the November 2004 IPF PPS final rule. The results showed that the indirect teaching cost variable is significant in explaining the higher costs of IPFs that have teaching programs. We calculated the teaching adjustment based on the IPF's "teaching variable," which is $(1 + (\text{the number of FTE residents training in the IPF} / \text{the IPF's ADC}))$. The teaching variable is then raised to 0.5150 power to result in the teaching adjustment. This formula is subject to the limitations on the number of FTE residents, which are described later in this section of this rule.

We established the teaching adjustment in a manner that limited the incentives for IPFs to add FTE residents for the purpose of increasing their

teaching adjustment. We imposed a cap on the number of FTE residents that may be counted for purposes of calculating the teaching adjustment. The cap limits the number of FTE residents that teaching IPFs may count for the purpose of calculating the IPF PPS teaching adjustment, not the number of residents teaching institutions can hire or train. We calculated the number of FTE residents that trained in the IPF during a "base year" and used that FTE resident number as the cap. An IPF's FTE resident cap is ultimately determined based on the final settlement of the IPF's most recent cost report filed before November 15, 2004 (publication date of the IPF PPS final rule). A complete discussion of the temporary adjustment to the FTE cap to reflect residents added due to hospital closure and by residency program appears in the RY 2012 IPF PPS proposed rule (76 FR 5018 through 5020) and the RY 2012 IPF PPS final rule (76 FR 26453 through 26456).

In the regression analysis, the logarithm of the teaching variable had a coefficient value of 0.5150. We converted this cost effect to a teaching payment adjustment by treating the regression coefficient as an exponent and raising the teaching variable to a power equal to the coefficient value. We note that the coefficient value of 0.5150 is based on the regression analysis holding all other components of the payment system constant. A complete discussion of how the teaching adjustment was calculated appears in the November 2004 IPF PPS final rule (69 FR 66954 through 66957) and the RY 2009 IPF PPS notice (73 FR 25721). As with other adjustment factors derived through the regression analysis, we do not plan to rerun the teaching adjustment factors in the regression analysis until we more fully analyze IPF PPS data as part of the IPF PPS refinement we discuss in section IV of this rule. Therefore, in this FY 2020 final rule, we are finalizing our proposal to continue to retain the coefficient value of 0.5150 for the teaching adjustment to the federal per diem base rate.

3. Cost of Living Adjustment for IPFs Located in Alaska and Hawaii

The IPF PPS includes a payment adjustment for IPFs located in Alaska and Hawaii based upon the area in which the IPF is located. As we explained in the November 2004 IPF PPS final rule, the FY 2002 data demonstrated that IPFs in Alaska and Hawaii had per diem costs that were disproportionately higher than other IPFs. Other Medicare prospective

payment systems (for example: The IPPS and LTCH PPS) adopted a COLA to account for the cost differential of care furnished in Alaska and Hawaii.

We analyzed the effect of applying a COLA to payments for IPFs located in Alaska and Hawaii. The results of our analysis demonstrated that a COLA for IPFs located in Alaska and Hawaii would improve payment equity for these facilities. As a result of this analysis, we provided a COLA in the November 2004 IPF PPS final rule.

A COLA for IPFs located in Alaska and Hawaii is made by multiplying the non-labor-related portion of the federal per diem base rate by the applicable COLA factor based on the COLA area in which the IPF is located.

The COLA factors through 2009 were published by the Office of Personnel Management (OPM), and the OPM memo showing the 2009 COLA factors is available at <https://www.chcoc.gov/content/nonforeign-area-retirement-equity-assurance-act>.

We note that the COLA areas for Alaska are not defined by county as are the COLA areas for Hawaii. In 5 CFR 591.207, the OPM established the following COLA areas:

- City of Anchorage, and 80-kilometer (50-mile) radius by road, as measured from the federal courthouse.
- City of Fairbanks, and 80-kilometer (50-mile) radius by road, as measured from the federal courthouse.

- City of Juneau, and 80-kilometer (50-mile) radius by road, as measured from the federal courthouse.

- Rest of the State of Alaska.

As stated in the November 2004 IPF PPS final rule, we update the COLA factors according to updates established by the OPM. However, sections 1911 through 1919 of the Nonforeign Area Retirement Equity Assurance Act, as contained in subtitle B of title XIX of the National Defense Authorization Act (NDAA) for FY 2010 (Pub. L. 111–84, October 28, 2009), transitions the Alaska and Hawaii COLAs to locality pay. Under section 1914 of NDAA, locality pay was phased in over a 3-year period beginning in January 2010, with COLA rates frozen as of the date of enactment, October 28, 2009, and then proportionately reduced to reflect the phase-in of locality pay.

When we published the proposed COLA factors in the RY 2012 IPF PPS proposed rule (76 FR 4998), we inadvertently selected the FY 2010 COLA rates, which had been reduced to account for the phase-in of locality pay. We did not intend to propose the reduced COLA rates because that would have understated the adjustment. Since the 2009 COLA rates did not reflect the phase-in of locality pay, we finalized the FY 2009 COLA rates for RY 2010 through RY 2014.

In the FY 2013 IPPS/LTCH final rule (77 FR 53700 through 53701), we established a new methodology to update the COLA factors for Alaska and Hawaii, and adopted this methodology for the IPF PPS in the FY 2015 IPF final rule (79 FR 45958 through 45960). We adopted this new COLA methodology for the IPF PPS because IPFs are hospitals with a similar mix of commodities and services. We think it is appropriate to have a consistent policy approach with that of other hospitals in Alaska and Hawaii. Therefore, the IPF COLAs for FY 2015 through FY 2017 were the same as those applied under the IPPS in those years. As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53700 and 53701), the COLA updates are determined every 4 years, when the IPPS market basket labor-related share is updated. Because the labor-related share of the IPPS market basket was updated for FY 2018, the COLA factors were updated in FY 2018 IPPS/LTCH rulemaking (82 FR 38529). As such, we also updated the IPF PPS COLA factors for FY 2018 (82 FR 36780 through 36782) to reflect the updated COLA factors finalized in the FY 2018 IPPS/LTCH rulemaking. We are finalizing our proposal to continue to apply the same COLA factors in FY 2020 that were used in FY 2018 and FY 2019.

TABLE 16—COMPARISON OF IPF PPS COST-OF-LIVING ADJUSTMENT FACTORS: IPFS LOCATED IN ALASKA AND HAWAII

Area	FY 2015 through FY 2017	FY 2018 through FY 2020
Alaska:		
City of Anchorage and 80-kilometer (50-mile) radius by road	1.23	1.25
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23	1.25
City of Juneau and 80-kilometer (50-mile) radius by road	1.23	1.25
Rest of Alaska	1.25	1.25
Hawaii:		
City and County of Honolulu	1.25	1.25
County of Hawaii	1.19	1.21
County of Kauai	1.25	1.25
County of Maui and County of Kalawao	1.25	1.25

The IPF PPS COLA factors for FY 2020 are also shown in Addendum A to this final rule, available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacIPPS/tools.html>.

4. Adjustment for IPFs with a Qualifying Emergency Department (ED)

The IPF PPS includes a facility-level adjustment for IPFs with qualifying EDs. We provide an adjustment to the federal per diem base rate to account for the costs associated with maintaining a full-

service ED. The adjustment is intended to account for ED costs incurred by a psychiatric hospital with a qualifying ED or an excluded psychiatric unit of an IPPS hospital or a CAH, for preadmission services otherwise payable under the Medicare Hospital Outpatient Prospective Payment System (OPPS), furnished to a beneficiary on the date of the beneficiary's admission to the hospital and during the day immediately preceding the date of admission to the IPF (see § 413.40(c)(2)), and the overhead cost of maintaining

the ED. This payment is a facility-level adjustment that applies to all IPF admissions (with one exception which we described), regardless of whether a particular patient receives preadmission services in the hospital's ED.

The ED adjustment is incorporated into the variable per diem adjustment for the first day of each stay for IPFs with a qualifying ED. Those IPFs with a qualifying ED receive an adjustment factor of 1.31 as the variable per diem adjustment for day 1 of each patient stay. If an IPF does not have a qualifying

ED, it receives an adjustment factor of 1.19 as the variable per diem adjustment for day 1 of each patient stay.

The ED adjustment is made on every qualifying claim except as described in this section of the proposed rule. As specified in § 412.424(d)(1)(v)(B), the ED adjustment is not made when a patient is discharged from an IPPS hospital or CAH and admitted to the same IPPS hospital's or CAH's excluded psychiatric unit. We clarified in the November 2004 IPF PPS final rule (69 FR 66960) that an ED adjustment is not made in this case because the costs associated with ED services are reflected in the DRG payment to the IPPS hospital or through the reasonable cost payment made to the CAH.

Therefore, when patients are discharged from an IPPS hospital or CAH and admitted to the same hospital's or CAH's excluded psychiatric unit, the IPF receives the 1.19 adjustment factor as the variable per diem adjustment for the first day of the patient's stay in the IPF. For FY 2020, we are finalizing our proposal to continue to retain the 1.31 adjustment factor for IPFs with qualifying EDs. A complete discussion of the steps involved in the calculation of the ED adjustment factor in our November 2004 IPF PPS final rule (69 FR 66959 through 66960) and the RY 2007 IPF PPS final rule (71 FR 27070 through 27072).

E. Other Payment Adjustments and Policies

1. Outlier Payment Overview

The IPF PPS includes an outlier adjustment to promote access to IPF care for those patients who require expensive care and to limit the financial risk of IPFs treating unusually costly patients. In the November 2004 IPF PPS final rule, we implemented regulations at § 412.424(d)(3)(i) to provide a per-case payment for IPF stays that are extraordinarily costly. Providing additional payments to IPFs for extremely costly cases strongly improves the accuracy of the IPF PPS in determining resource costs at the patient and facility level. These additional payments reduce the financial losses that would otherwise be incurred in treating patients who require more costly care, and therefore, reduce the incentives for IPFs to under-serve these patients. We make outlier payments for discharges in which an IPF's estimated total cost for a case exceeds a fixed dollar loss threshold amount (multiplied by the IPF's facility-level adjustments) plus the federal per diem payment amount for the case.

In instances when the case qualifies for an outlier payment, we pay 80 percent of the difference between the estimated cost for the case and the adjusted threshold amount for days 1 through 9 of the stay (consistent with the median LOS for IPFs in FY 2002), and 60 percent of the difference for day 10 and thereafter. The adjusted threshold amount is equal to the outlier threshold amount adjusted for wage area, teaching status, rural area, and the COLA adjustment (if applicable), plus the amount of the Medicare IPF payment for the case. We established the 80 percent and 60 percent loss sharing ratios because we were concerned that a single ratio established at 80 percent (like other Medicare PPSs) might provide an incentive under the IPF per diem payment system to increase LOS in order to receive additional payments.

After establishing the loss sharing ratios, we determined the current fixed dollar loss threshold amount through payment simulations designed to compute a dollar loss beyond which payments are estimated to meet the 2 percent outlier spending target. Each year when we update the IPF PPS, we simulate payments using the latest available data to compute the fixed dollar loss threshold so that outlier payments represent 2 percent of total estimated IPF PPS payments.

2. Update to the Outlier Fixed Dollar Loss Threshold Amount

In accordance with the update methodology described in § 412.428(d), we updated the fixed dollar loss threshold amount used under the IPF PPS outlier policy. Based on the regression analysis and payment simulations used to develop the IPF PPS, we established a 2 percent outlier policy, which strikes an appropriate balance between protecting IPFs from extraordinarily costly cases while ensuring the adequacy of the federal per diem base rate for all other cases that are not outlier cases.

Based on an analysis of the latest available data (the March 2019 update of FY 2018 IPF claims) and rate increases, we believe it is necessary to update the fixed dollar loss threshold amount to maintain an outlier percentage that equals 2 percent of total estimated IPF PPS payments. We are updating the IPF outlier threshold amount for FY 2020 using FY 2018 claims data and the same methodology that we used to set the initial outlier threshold amount in the RY 2007 IPF PPS final rule (71 FR 27072 and 27073), which is also the same methodology that we used to update the outlier

threshold amounts for years 2008 through 2019. Based on an analysis of these updated data, we estimate that IPF outlier payments as a percentage of total estimated payments are approximately 2.23 percent in FY 2019. Therefore, we are finalizing our proposal to update the outlier threshold amount to \$14,960 to maintain estimated outlier payments at 2 percent of total estimated aggregate IPF payments for FY 2020. This final rule update is an increase from the FY 2019 threshold of \$12,865.

We received one comment on our proposed update to the outlier threshold.

Comment: A commenter was concerned that the 13.4 percent proposed increase in the outlier threshold was too steep to implement in a single year, and suggested that when an increase in the outlier threshold is necessary, it should be limited to no more than 5 percent in any given year.

Response: The outlier fixed dollar threshold amount is calculated by simulating aggregate payments and using an iterative process to determine a threshold that results in outlier payments being equal to 2 percent of total payments under the simulation. To determine the IPF outlier threshold amount for FY 2020 we estimated the FY 2020 IPF PPS aggregate and outlier payments using the most recent claims available (March 2019 update of the FY 2018 MedPAR claims) and the FY 2020 final payment rates. The outlier threshold was varied in this simulation until estimated outlier payments equaled 2 percent of estimated aggregate payments. Based on the regression analysis and payment simulations used to develop the IPF PPS, we established a 2 percent outlier policy in our November 2004 IPF PPS final rule (69 FR 66960 through 66962), which strikes an appropriate balance between protecting IPFs from extraordinarily costly cases while ensuring the adequacy of the federal per diem base rate for all other cases that are not outlier cases. This outlier fixed dollar loss threshold update methodology is based on longstanding IPF payment policy and is described in detail in the RY 2007 IPF PPS final rule (71 FR 27072 and 27073). To continue to maintain this established 2 percent outlier policy, for this final rule we must raise the IPF PPS outlier fixed dollar threshold amount from \$12,865 to \$14,960. If the fixed dollar threshold amount increase was limited to 5 percent for FY 2020 as suggested by the commenter we would not meet the established 2 percent outlier policy. Our IPF PPS outlier policy limiting outlier payments to a defined percentage of total payments is

consistent with the outlier policies in other Medicare payment systems.

3. Update to IPF Cost-to-Charge Ratio Ceilings

Under the IPF PPS, an outlier payment is made if an IPF's cost for a stay exceeds a fixed dollar loss threshold amount plus the IPF PPS amount. In order to establish an IPF's cost for a particular case, we multiply the IPF's reported charges on the discharge bill by its overall cost-to-charge ratio (CCR). This approach to determining an IPF's cost is consistent with the approach used under the IPPS and other PPSs. In the FY 2004 IPPS final rule (68 FR 34494), we implemented changes to the IPPS policy used to determine CCRs for IPPS hospitals, because we became aware that payment vulnerabilities resulted in inappropriate outlier payments. Under the IPPS, we established a statistical measure of accuracy for CCRs to ensure that aberrant CCR data did not result in inappropriate outlier payments.

As we indicated in the November 2004 IPF PPS final rule (69 FR 66961), we believe that the IPF outlier policy is susceptible to the same payment vulnerabilities as the IPPS; therefore, we adopted a method to ensure the statistical accuracy of CCRs under the IPF PPS. Specifically, we adopted the following procedure in the November 2004 IPF PPS final rule:

- Calculated two national ceilings, one for IPFs located in rural areas and one for IPFs located in urban areas.
- Computed the ceilings by first calculating the national average and the standard deviation of the CCR for both urban and rural IPFs using the most recent CCRs entered in the most recent Provider Specific File available.

For FY 2020, we are finalizing our proposal to continue to follow this methodology.

To determine the rural and urban ceilings, we multiplied each of the standard deviations by 3 and added the result to the appropriate national CCR average (either rural or urban). The upper threshold CCR for IPFs in FY 2020 is 2.0239 for rural IPFs, and 1.7263 for urban IPFs, based on CBSA-based geographic designations. If an IPF's CCR is above the applicable ceiling, the ratio is considered statistically inaccurate, and we assign the appropriate national (either rural or urban) median CCR to the IPF.

We apply the national median CCRs to the following situations:

- New IPFs that have not yet submitted their first Medicare cost report. We continue to use these national median CCRs until the facility's

actual CCR can be computed using the first tentatively or final settled cost report.

- IPFs whose overall CCR is in excess of three standard deviations above the corresponding national geometric mean (that is, above the ceiling).

- Other IPFs for which the Medicare Administrative Contractor (MAC) obtains inaccurate or incomplete data with which to calculate a CCR.

We are finalizing our proposal to continue to update the FY 2020 national median and ceiling CCRs for urban and rural IPFs based on the CCRs entered in the latest available IPF PPS Provider Specific File. Specifically, for FY 2020, to be used in each of the three situations listed previously, using the most recent CCRs entered in the CY 2019 Provider Specific File, we provide an estimated national median CCR of 0.5720 for rural IPFs and a national median CCR of 0.4370 for urban IPFs. These calculations are based on the IPF's location (either urban or rural) using the CBSA-based geographic designations. A complete discussion regarding the national median CCRs appears in the November 2004 IPF PPS final rule (69 FR 66961 through 66964).

IV. Update on IPF PPS Refinements

For RY 2012, we identified several areas of concern for future refinement, and we invited comments on these issues in the RY 2012 IPF PPS proposed and final rules. For further discussion of these issues and to review the public comments, we refer readers to the RY 2012 IPF PPS proposed rule (76 FR 4998) and final rule (76 FR 26432).

We have delayed making refinements to the IPF PPS until we have completed a thorough analysis of IPF PPS data on which to base those refinements. Specifically, we will delay updating the adjustment factors derived from the regression analysis until we have IPF PPS data that include as much information as possible regarding the patient-level characteristics of the population that each IPF serves. We have begun and will continue the necessary analysis to better understand IPF industry practices so that we may refine the IPF PPS in the future, as appropriate. Our preliminary analysis has also revealed variation in cost and claim data, particularly related to labor costs, drugs costs, and laboratory services. Some providers have very low labor costs, or very low or missing drug or laboratory costs or charges, relative to other providers. As we noted in the FY 2016 IPF PPS final rule (80 FR 46693 through 46694), our preliminary analysis of 2012 to 2013 IPF data found that over 20 percent of IPF stays

reported no ancillary costs, such as laboratory and drug costs, in their cost reports, or laboratory or drug charges on their claims. Because we expect that most patients requiring hospitalization for active psychiatric treatment will need drugs and laboratory services, we again remind providers that the IPF PPS federal per diem base rate includes the cost of all ancillary services, including drugs and laboratory services.

On November 17, 2017, we issued Transmittal 12, which made changes to the hospital cost report form CMS-2552-10 (OMB No. 0938-0050), and included the requirement that cost reports from psychiatric hospitals include certain ancillary costs, or the cost report will be rejected. On January 30, 2018, we issued Transmittal 13, which changed the implementation date for Transmittal 12 to be for cost reporting periods ending on or after September 30, 2017. For details, we refer readers to see these Transmittals, which are available on the CMS website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/index.html>. CMS suspended the requirement that cost reports from psychiatric hospitals include certain ancillary costs effective April 27, 2018, in order to consider excluding all-inclusive rate providers from this requirement. CMS issued Transmittal 15 on October 19, 2018, reinstating the requirement that cost reports from psychiatric hospitals, except all-inclusive rate providers, include certain ancillary costs.

We only pay the IPF for services furnished to a Medicare beneficiary who is an inpatient of that IPF (except for certain professional services), and payments are considered to be payments in full for all inpatient hospital services provided directly or under arrangement (see 42 CFR 412.404(d)), as specified in 42 CFR 409.10.

We will continue to analyze data from claims and cost reports that do not include ancillary charges or costs, and will be sharing our findings with CMS Office of the Center for Program Integrity and CMS Office of Financial Management for further investigation, as the results warrant. Our refinement analysis is dependent on recent precise data for costs, including ancillary costs. We will continue to collect these data and analyze them for both timeliness and accuracy with the expectation that these data will be used in a future refinement. It is currently our intent to explore refinements to the adjustments in future rulemaking. Since we did not propose refinements, for FY 2020 we will continue to use the existing adjustment factors.

V. Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

A. Background and Statutory Authority

We refer readers to the FY 2019 IPF PPS final rule (83 FR 38589) for a discussion of the background and statutory authority² of the IPFQR Program.

B. Covered Entities

In the FY 2013 IPPS/LTCH-PPS final rule (77 FR 53645), we established that the IPFQR Program's quality reporting requirements cover those psychiatric hospitals and psychiatric units paid under Medicare's IPF PPS (§ 412.404(b)). Generally, psychiatric hospitals and psychiatric units within acute care and critical access hospitals that treat Medicare patients are paid under the IPF PPS. Consistent with previous regulations, we continue to use the term IPF to refer to both inpatient psychiatric hospitals and psychiatric units. This usage follows the terminology in our IPF PPS regulations at § 412.402. For more information on covered entities, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645).

C. Previously Finalized Measures and Administrative Procedures

The current IPFQR Program includes 13 measures. For more information on these measures, we refer readers to the following final rules:

- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53646 through 53652);

² We note that the statute uses the term "rate year" (RY). However, beginning with the annual update of the inpatient psychiatric facility prospective payment system (IPF PPS) that took effect on July 1, 2011 (RY 2012), we aligned the IPF PPS update with the annual update of the ICD codes, effective on October 1 of each year. This change allowed for annual payment updates and the ICD coding update to occur on the same schedule and appear in the same **Federal Register** document, promoting administrative efficiency. To reflect the change to the annual payment rate update cycle, we revised the regulations at 42 CFR 412.402 to specify that, beginning October 1, 2012, the RY update period would be the 12-month period from October 1 through September 30, which we refer to as a "fiscal year" (FY) (76 FR 26435). Therefore, with respect to the IPFQR Program, the terms "rate year," as used in the statute, and "fiscal year" as used in the regulation, both refer to the period from October 1 through September 30. For more information regarding this terminology change, we refer readers to section III. of the RY 2012 IPF PPS final rule (76 FR 26434 through 26435).

- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50889 through 50897);
- The FY 2015 IPF PPS final rule (79 FR 45963 through 45975);
- The FY 2016 IPF PPS final rule (80 FR 46695 through 46714);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57238 through 57247); and
- The FY 2019 IPF PPS final rule (83 FR 38590 through 38606).

For more information on previously adopted procedural requirements, we refer readers to the following rules:

- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53653 through 53660);
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50897 through 50903);
- The FY 2015 IPF PPS final rule (79 FR 45975 through 45978);
- The FY 2016 IPF PPS final rule (80 FR 46715 through 46719);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57248 through 57249);
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38471 through 38474); and
- The FY 2019 IPF PPS final rule (83 FR 38606 through 38608).

D. IPFQR Program Measures

1. Measure Selection Process

Before being proposed for inclusion in the IPFQR Program, measures are placed on a list of measures under consideration (MUC), which is published annually by December 1 on behalf of CMS by the National Quality Forum (NQF). Following publication on the MUC list, the Measure Applications Partnership (MAP), a multi-stakeholder group convened by the NQF, reviews the measures under consideration for the IPFQR Program, among other Federal programs, and provides input on those measures to the Secretary. We considered the input and recommendations provided by the MAP in selecting all measures for the IPFQR Program. Further details concerning the input and recommendations from the MAP for the measure proposed in the FY 2020 IPF PPS Proposed rule (Medication Continuation Following Inpatient Psychiatric Discharge, NQF #3205) are provided in Section V.D.3.

2. Removal or Retention of IPFQR Program Measures

a. Background

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38463 through 38465), we

finalized our proposals to adopt considerations for removing or retaining measures within the IPFQR Program and criteria for determining when a measure is "topped out." In the FY 2019 IPF PPS final rule (83 FR 38591 through 38593), we added one additional measure removal factor. We are not proposing any changes to these removal factors, topped-out criteria, or retention factors and refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38463 through 38465) and the FY 2019 IPF PPS final rule (83 FR 38591 through 38593) for more information. We will continue to retain measures from each previous year's IPFQR Program measure set for subsequent years' measure sets, except when we specifically propose to remove or replace a measure. We will continue to use the notice-and-comment rulemaking process to propose measures for removal or replacement, as we described upon adopting these factors in the 2018 IPPS/LTCH PPS final rule (82 FR 38464 through 38465).

b. Application of Considerations for Removal and Retention to Current Measure Set

In the FY 2018 IPPS/LTCH PPS final rule, we noted that several commenters requested that we evaluate the current measures in the IPFQR Program using the removal and retention factors that we finalized in that rule (82 FR 38464). Following this evaluation, we proposed to remove eight measures from the IPFQR Program in the FY 2019 IPF PPS proposed rule (83 FR 21118 through 21123) for the FY 2020 program year and subsequent years. In the FY 2019 IPF PPS final rule (83 FR 38593 through 38604) we finalized removal of five of these measures. In our evaluation of the IPFQR Program measure set subsequent to publication of the FY 2019 IPF PPS final rule, we have not identified additional measures to which our measure removal factors apply. Therefore, we are not proposing to remove any additional measures at this time.

The previously finalized number of measures for the FY 2021 payment determination and subsequent years totals 13.

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Table 17. Previously Finalized Measures for the FY 2020 Payment Determination and Subsequent Years

NQF #	Measure ID	Measure
0640	HBIPS-2	Hours of Physical Restraint Use
0641	HBIPS-3	Hours of Seclusion Use
0560	HBIPS-5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification
0576	FUH	Follow-up After Hospitalization for Mental Illness
N/A*	SUB-2 and SUB-2a	Alcohol Use Brief Intervention Provided or Offered and SUB-2a Alcohol Use Brief Intervention
N/A*	SUB-3 and SUB-3a	Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge
N/A*	TOB-2 and TOB-2a	Tobacco Use Treatment Provided or Offered and TOB-2a Tobacco Use Treatment
N/A*	TOB-3 and TOB-3a	Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge
1659	IMM-2	Influenza Immunization
N/A*	N/A	Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)
N/A*	N/A	Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)
N/A	N/A	Screening for Metabolic Disorders
2860	N/A	Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility

* Measure is no longer endorsed by the NQF but was endorsed at time of adoption. Section 1886(s)(4)(D)(ii) of the Act authorizes the Secretary to specify a measure that is not endorsed by the NQF as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We attempted to find available measures for each of these clinical topics that have been endorsed or adopted by a consensus organization and found no other feasible and practical measures on the topics for the IPF setting.

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3. Proposed New Quality Measure for the FY 2021 Payment Determination and Subsequent Years—Medication Continuation Following Inpatient Psychiatric Discharge (NQF #3205)

a. Background

Medication continuation is important for patients discharged from the inpatient psychiatric setting with major depressive disorder (MDD), schizophrenia, or bipolar disorder

because of significant negative outcomes associated with non-adherence to medication regimens. For example, patients with MDD who do not remain on prescribed medications are more likely to have negative health outcomes such as relapse and readmission, decreased quality of life, and increased healthcare costs.^{3,4} Patients with

³ Geddes JR, Carney SM, Davies C, et al. Relapse prevention with antidepressant drug treatment in depressive disorders: A systematic review. *Lancet*. 2003;361(9358):653–661.

schizophrenia who do not adhere to their medication regimen are more likely to be hospitalized, use emergency psychiatric services, be arrested, be victims of crimes, and consume alcohol or drugs compared to those who adhere

⁴ Glue P, Donovan MR, Kolluri S, Emir B. Metaanalysis of relapse prevention antidepressant trials in depressive disorders. *The Australian and New Zealand journal of psychiatry*. 2010;44(8):697–705.

to their medication regimen.⁵ Patients with bipolar disorder who do not adhere to their medications have increased suicide risk.⁶ For these reasons, guidelines from the American Psychiatric Association (APA) and the Department of Veterans Affairs/Department of Defense (VA/DoD), which are based on extensive literature, recommend pharmacotherapy as the primary form of treatment for patients with these conditions.^{7 8 9 10 11}

Furthermore, we believe that there are factors external to the IPF that influence filling prescriptions post-discharge in the psychiatric population. While it may not be possible to achieve complete post-discharge compliance with pharmacotherapy, there is evidence that improvements to the quality of care provided by IPFs, including discharge processes, can help to increase medication continuation rates.^{12 13 14 15 16}

⁵ Gilmer TP, Dolder CR, Lacro JP, et al. Adherence to treatment with antipsychotic medication and health care costs among Medicaid beneficiaries with schizophrenia. *The American journal of psychiatry*. 2004;161(4):692–699.

⁶ Gonzalez-Pinto A, Mosquera F, Alonso M, et al. Suicidal risk in bipolar I disorder patients and adherence to long-term lithium treatment. *Bipolar disorders*. 2006;8(5 Pt 2):618–624.

⁷ American Psychiatric Association. (2002). Practice guideline for the treatment of patients with bipolar disorder, second edition. Retrieved from: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/bipolar.pdf.

⁸ American Psychiatric Association. (2010). Practice guideline for the treatment of patients with major depressive disorder, 3rd ed. Retrieved from: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf.

⁹ American Psychiatric Association. (2010). Practice guideline for the treatment of patients with schizophrenia: 2nd ed. Retrieved from: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia.pdf.

¹⁰ U.S. Department of Veterans Affairs, & U.S. Department of Defense. (2016). Management of major depressive disorder (MDD). Retrieved from: <http://www.healthquality.va.gov/guidelines/MH/mdd/VADoDMDDCPGINAL82916.pdf>.

¹¹ U.S. Department of Veterans Affairs & U.S. Department of Defense. (2010) VA/DOD clinical practice guideline for management of bipolar disorder in adults. Retrieved from: http://www.healthquality.va.gov/guidelines/MH/bd/bd_305_full.pdf.

¹² Haddad PM, Brain C, Scott J. Nonadherence with antipsychotic medication in schizophrenia: challenges and management strategies. Patient related outcome measures. 2014;5:43–62.

¹³ Hung CI. Factors predicting adherence to antidepressant treatment. Current opinion in psychiatry. 2014;27(5):344–349.

¹⁴ Lanouette NM, Folsom DP, Sciolla A, Jeste DV. Psychotropic medication nonadherence among United States Latinos: a comprehensive literature review. *Psychiatric services* (Washington, DC). 2009;60(2):157–174.

¹⁵ Mitchell AJ. Understanding Medication Discontinuation in Depression. *BMedSci Psychiatric Times*. 2007;24(4).

¹⁶ Sylvia LG, Hay A, Ostacher MJ, et al. Association between therapeutic alliance, care satisfaction, and pharmacological adherence in bipolar disorder. *Journal of clinical psychopharmacology*. 2013;33(3):343–350.

These interventions include patient education, enhanced therapeutic relationships, shared decision-making, and text-message reminders, with multidimensional approaches resulting in the best outcomes.

We proposed to adopt the Medication Continuation Following Inpatient Psychiatric Discharge measure (NQF #3205) for the FY 2020 payment determination and subsequent years in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20122 through 20126) to address this important clinical topic. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38465 through 38470), we did not finalize adoption of the Medication Continuation Following Inpatient Psychiatric Discharge measure (NQF #3205), because we recognized that this measure may place undue burden on facilities that were updating processes to account for previously adopted measures despite being calculated from claims data, which should not require additional information collection burden. We did not want to place undue burden on facilities, especially small, rural facilities, and we wished to accommodate the need for facilities to develop and implement innovative efforts, such as updating their processes and clinical workflows, for this measure.

At that time, we stated that we would consider proposing this measure again in future rulemaking. We note that since the FY 2018 IPPS/LTCH PPS final rule, we have removed five measures from the IPFQR Program (83 FR 38593 through 38602), reducing burden on IPFs by approximately 546,000 hours and \$20 million (83 FR38610 through 38611), and IPFs have had an additional 2 years to familiarize themselves with the remaining IPFQR Program measure set and to update processes and clinical workflows accordingly. Therefore, we believe that it is now appropriate to propose this measure for the IPFQR Program again.

Since the FY 2018 IPPS/LTCH PPS final rule, we have not made any changes to the Medication Continuation Following Inpatient Psychiatric Discharge (NQF #3205) measure's specifications. However, we have taken steps to improve upon the suitability of this measure for the IPFQR Program. First, we considered recommendations and comments received on the Medication Continuation Following Inpatient Psychiatric Discharge (NQF #3205) measure from the FY 2018 IPPS/LTCH PPS final rule (82 FR 38468 through 38470). We provide more detail about these comments.

Second, since the FY 2018 IPPS/LTCH PPS final rule, we have provided

additional information about this measure to the MAP and to the NQF, including reliability and validity testing. The measure was subsequently endorsed by NQF. We continue to believe that this measure evaluates a process with a demonstrated quality gap, because in testing this measure, we found that the range of performance between the 10th percentile and the 80th percentile facility performance was between 67 percent and 88 percent. We found that if all facilities had at least the median rate then 16,000 additional Medicare beneficiaries would fill prescriptions for an evidence-based medication to manage their condition following discharge.¹⁷ Furthermore, we believe this measure has the potential to benefit patients by encouraging facilities to adopt interventions to improve post discharge medication continuation rates with no additional reporting burden to IPFs.

In response to our proposal in the FY 2018 IPPS/LTCH PPS proposed rule, many comments focused on the potential undue burden of the measure given the fact that many facilities were still updating processes to account for previously adopted measures (82 FR 38469). Between the FY 2018 IPPS/LTCH PPS final rule and this proposed rule, we have not adopted any new measures into the program. We believe that IPFs no longer need to update processes to account for previously adopted measures because they have had 2 years to complete all such updates. Therefore, we believe that there is less burden associated with the IPFQR program than when we proposed to adopt this measure in the FY 2018 IPPS/LTCH PPS proposed rule.

Some commenters also expressed concern that patients may experience barriers to filling prescriptions that are beyond the control of IPFs (82 FR 38469 through 38470). While we believe that there are factors external to an IPF that influence filling prescriptions after a patient is discharged, as the methodology report for the measure indicates,¹⁸ IPFs can also undertake interventions to improve the likelihood of a patient's medication continuation post-discharge.

In response to comments that the affected population may be too small to

¹⁷ https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version_1-0-Inpatient_Psychiatric_Facility_Medication_Continuation_Public.Zip.

¹⁸ https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version_1-0-Inpatient_Psychiatric_Facility_Medication_Continuation_Public.Zip

report meaningful data because it is limited to Medicare patients enrolled in Parts A, B, and D (82 FR 38469 through 38470), we note that the NQF found this measure to be valid and reliable,¹⁹ indicating that the size of the population is sufficient to report meaningful data. These commenters additionally expressed that because the measure is limited to Medicare patients enrolled in Parts A, B, and D, there may not be a performance gap because these patients do not experience the same access barriers as other inpatient psychiatric populations. However, we note that in their endorsement review of the measure, the NQF found that there was evidence of a performance gap in the quality area that was addressed by the measure even though the measure is limited to patients enrolled in Medicare A, B, and D.²⁰

Finally, in response to comments that the measure had not completed full endorsement review by NQF (82 FR 38469), the measure is now fully endorsed by the NQF as discussed in more detail in Section B of this rule. Further, in its review of the measure for endorsement, the NQF standing committee agreed that there is evidence that lack of adherence to medication leads to relapse and negative outcomes and that claims data related to medication adherence are directly correlated to outcomes.²¹

b. Overview of Measure

The Medication Continuation Following Inpatient Psychiatric Discharge measure (NQF #3205) assesses whether patients admitted to IPFs with diagnoses of MDD, schizophrenia, or bipolar disorder filled at least one evidence-based medication prior to discharge or during the post-discharge period. As detailed in the following discussion, the NQF endorsed this measure on June 28, 2017. For more information about this measure, we refer readers to the measure specifications in the measure technical report https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version_1-0_Inpatient_Psychiatric_Facility_Medication_Continuation_Public.zip or the measure's NQF page (<https://www.qualityforum.org/QPS/3205>).

In compliance with section 1890A(a)(2) of the Act, this measure was included in a publicly available

document: "List of Measures under Consideration for December 1, 2016" (<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/Measures-under-Consideration-List-for-2016.pdf>). The MAP Hospital Workgroup concluded in its December 2016 meeting that the measure addressed a critical quality objective, was evidence-based, and would contribute to efficient use of resources.²² One Workgroup member commented that it was appropriate to hold IPFs accountable for patients filling a prescription for an evidence-based medication post-discharge.

The MAP Hospital Workgroup classified the measure as "Refine and Resubmit Prior to Rulemaking."²³ The measure received this classification because the MAP recommended that measure testing be completed to demonstrate reliability and validity at the facility level in the hospital setting and that the measure be submitted to NQF for review and endorsement.²⁴ The MAP also requested additional details on the measure, such as: (1) The definition of medication dispensation; (2) how the facility would know whether the medication was dispensed; and (3) how the measure would be impacted if Medicare Part D coverage is optional.²⁵ The methodology report for the measure (<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/Measures-under-Consideration-List-for-2016.pdf>) that we finalized, includes the results of reliability and validity testing, and additional measure updates that occurred after the MAP review. This newest methodology report also provides the additional details requested by the MAP at the December 2016 meeting. This includes the specific medication list, which is based on APA and VA/DoD practice guidelines for each medication.^{26 27 28 29 30} and

information about how facilities can help patients fill prescriptions for medications to ensure that the facility knows that the prescription has been filled. Additionally, the methodology report provides details about measure performance among patients with Part D and the performance gap for this patient population.

This measure was submitted to NQF for endorsement on December 16, 2016. Consistent with the recommendation from the December 2016 MAP meeting that testing for reliability and validity should be completed, in Spring 2017 we refined our NQF submission by providing the complete results of all testing for NQF's review of the measure for endorsement. The measure received NQF endorsement on June 28, 2017.³¹

This measure supports the CMS Meaningful Measure Area "promote effective prevention and treatment of chronic disease," which includes the meaningful measure area of "prevention, treatment, and management of mental health." The measure would also complement the portfolio of facility-level measures in the IPFQR Program that assess the transition from the inpatient to outpatient setting; Follow-Up After Hospitalization for Mental Illness; Thirty-day All Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility; Transition Record with Specified Elements Received by Discharged Patients; and Timely Transmission of Transition Record.

c. Data Sources

The proposed Medication Continuation Following Inpatient Psychiatric Discharge measure (NQF #3205) uses Medicare fee-for-service (FFS) claims to identify whether patients admitted to IPFs with diagnoses of MDD, schizophrenia, or bipolar disorder filled at least one evidence-based medication such that they would have medication for use post-discharge. The performance period for this measure is 24 months. For example, for

²² MAP Hospital Workgroup, Preliminary Analysis Worksheet, December 2016. <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=84199>.

²³ <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=84452>.

²⁴ <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=84452>.

²⁵ <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=84452>.

²⁶ American Psychiatric Association. (2010). Practice guideline for the treatment of patients with major depressive disorder, 3rd ed. Retrieved from: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf.

²⁷ American Psychiatric Association. (2002). Practice guideline for the treatment of patients with bipolar disorder, second edition. Retrieved from: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/bipolar.pdf.

²⁸ American Psychiatric Association. (2010). Practice guideline for the treatment of patients with schizophrenia: 2nd ed. Retrieved from: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia.pdf.

²⁹ U.S. Department of Veterans Affairs & U.S. Department of Defense. (2016). Management of major depressive disorder (MDD). Retrieved from: <http://www.healthquality.va.gov/guidelines/MH/mdd/VADoDMDDCPGFINAL82916.pdf>.

³⁰ U.S. Department of Veterans Affairs & U.S. Department of Defense. (2010) VA/DOD clinical practice guideline for management of bipolar disorder in adults. Retrieved from: http://www.healthquality.va.gov/guidelines/MH/bd/bd_305_full.pdf.

³¹ <https://www.qualityforum.org/QPS/3205>.

¹⁹ <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=85831>.

²⁰ <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=85831>.

²¹ <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=85831>.

the FY 2021 payment determination, the performance period will include discharges between July 1, 2017 and June 30, 2019.³²

d. Measure Calculation

The numerator for the measure includes discharges for patients with a principal diagnosis of MDD, schizophrenia, or bipolar disorder in the denominator who were dispensed at least one evidence-based outpatient medication within 2 days prior to discharge through 30 days post-discharge. The denominator for the measure includes Medicare fee-for-service (FFS) beneficiaries with Part D coverage aged 18 years and older discharged to home or home health care from an IPF with a principal diagnosis of MDD, schizophrenia, or bipolar disorder. The denominator excludes discharges for patients who:

- Received Electroconvulsive Therapy (ECT) during the inpatient stay or 30 day post-discharge period;
- Received Transcranial Magnetic Stimulation (TMS) during the inpatient stay or follow-up;
- Were pregnant during the inpatient stay;
- Had a secondary diagnosis of delirium; or
- Had a principal diagnosis of schizophrenia with a secondary diagnosis of dementia.

For more information about the development of the measure, including rationale for the 2 day prior to 30 day post-discharge period and the denominator exclusions, we refer readers to the measure technical report (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version1-0_Inpatient_Psychiatric_Facility_Medication_Continuation_Public.zip).

We invited public comment on our proposal to adopt the Medication Continuation Following Inpatient Psychiatric Discharge (NQF #3205) measure for the FY 2021 payment determination and subsequent years as discussed.

Comment: Several commenters expressed support for the Medication Continuation Following Inpatient Psychiatric Discharge (NQF #3205) measure specifically noting that it is an NQF-endorsed measure that addresses an important clinical topic with a demonstrated quality gap. Several of

these commenters noted that the measure will help facilities identify interventions for post-discharge medication compliance, thereby improving care transitions. Some commenters further expressed that the measure aligns with the goal of not increasing provider burden.

Response: We thank these commenters for their support.

Comment: Some commenters recommended that CMS not adopt the Medication Continuation Following Inpatient Psychiatric Discharge (NQF #3205) measure because this measure imposes burden on facilities.

Response: We do not believe that this measure imposes any data reporting burden on facilities because it is calculated by CMS using data submitted on Medicare Parts A, B, and D claims. We acknowledge that to improve performance on this measure there may be costs or burden associated with updating clinical workflows to improve discharge planning and counseling on the importance of medication continuation. However, because of the severity of the negative health outcomes associated with medication discontinuation for this patient population, we believe that these updates are part of providing high quality inpatient psychiatric care.

Comment: Some commenters recommended that CMS not adopt Medication Continuation Following Inpatient Psychiatric Discharge (NQF #3205) because they believe that restricting the denominator to patients who have Medicare Parts A, B, and D coverage makes the population size too small to be meaningful.

Response: During measure testing, the denominator was restricted to patients who have Medicare Parts A, B, and D coverage during measure testing and results showed that the majority of providers met the 75 case minimum threshold required to obtain an overall reliability score of at least 0.7, which is the minimum acceptable reliability rating. Furthermore, the NQF standing committee evaluated this when considering the measure for endorsement and determined that the measure meets their scientific acceptability criteria.³³

Comment: Some commenters recommended that CMS not adopt this measure because they believe that the measure assesses patient behavior (that is, filling prescriptions) as opposed to provider quality and therefore does not

produce data that will help consumers select facilities.

Response: We recognize that there are factors external to the IPF that influence filling prescriptions post-discharge in the psychiatric population. While it may not be possible to achieve complete post-discharge compliance with pharmacotherapy, there is evidence that improvements to the quality of care for patients in the IPF setting, including the discharge processes, can help to increase medication continuation rates.^{34 35 36 37 38} These interventions include patient education, enhanced therapeutic relationships, shared decision-making, and text-message reminders, with multidimensional approaches resulting in the best outcomes. We note that in testing the measure, the measure developer found a median score of 79.6% and an approximate 21-percentage point difference between the 10th and 90th percentiles. This means that in the 10th percentile facilities, depending on their condition, 60.0 to 63.9 percent of patients (with Medicare Parts A, B, and D) fill prescriptions for evidence-based medications, whereas in the 90th percentile facilities 89.7 to 95.5 percent of such patients fill prescriptions for evidence-based medications.³⁹ We believe that this performance gap, coupled with the ability of facilities to provide interventions to improve medication continuation, indicate that the measure does provide meaningful information about the quality of care provided to patients.

Comment: Several commenters recommended that CMS not adopt the Medication Continuation Following Inpatient Discharge (NQF #3205) measure because these commenters believe prescription fills do not actually reflect medication adherence.

³⁴ Haddad PM, Brain C, Scott J. Nonadherence with antipsychotic medication in schizophrenia: challenges and management strategies. Patient related outcome measures. 2014;5:43–62.

³⁵ Hung CI. Factors predicting adherence to antidepressant treatment. Current opinion in psychiatry. 2014;27(5):344–349.

³⁶ Lanouette NM, Folsom DP, Sciolla A, Jeste DV. Psychotropic medication nonadherence among United States Latinos: a comprehensive literature review. Psychiatric services (Washington, DC). 2009;60(2):157–174.

³⁷ Mitchell AJ. Understanding Medication Discontinuation in Depression. BMedSci Psychiatric Times. 2007;24(4).

³⁸ Sylvia LG, Hay A, Ostacher MJ, et al. Association between therapeutic alliance, care satisfaction, and pharmacological adherence in bipolar disorder. Journal of clinical psychopharmacology. 2013;33(3):343–350.

³⁹ https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version_1-0_Inpatient_Psychiatric_Facility_Medication_Continuation_Public.zip.

³² If data availability or operational issues prevent use of this performance period, we would announce the updated performance period through sub-regulatory communications including announcement on a CMS website and/or on our applicable listservs.

³³ http://www.qualityforum.org/Projects/a-b/Behavioral_Health_2016-2017/Draft_Report_for_Comment.aspx.

Response: While we agree with commenters that it is possible that patients may fill prescriptions and then not take the medication, or take it incorrectly, we believe that the measure is a good indicator of patient adherence to medication regimens. The NQF Standing Committee for Behavioral Health evaluated the potential for patients to fill their prescriptions but not be adherent to the medication regimen during their review of the measure and found that most studies related to adverse events for medication non-compliance used the filling of a prescription as a proxy for medication adherence,⁴⁰ which aligns with this measure's methodology.

Comment: One commenter recommended that CMS not adopt this measure because facilities cannot internally track performance on this measure and therefore cannot identify performance gaps that require interventions.

Response: We believe that this measure will help facilities identify performance gaps that require interventions by making this data available to facilities. We also note that the American Psychiatric Association's (APA's) and Department of Veterans Affairs and Department of Defense (VA/DoD) practice guidelines for depressive disorder, bipolar disorder, and schizophrenia provide strategies for facilities to implement to help patients fill prescriptions prior to discharge so that the facility can track whether the prescription has been filled.^{41 42 43 44 45}

Comment: Several commenters expressed the belief that this measure is not appropriate for the inpatient psychiatric setting and suggested that

this or a similar measure be considered for the outpatient setting instead because these commenters believe that outpatient providers have more influence on patients' post-discharge care.

Response: We agree with the commenters that outpatient providers do have more influence on a patient's post-discharge care in the long term; however this measure is specified to address the short term period immediately following discharge from the IPF prior to the patient's follow-up with an outpatient provider (which, according to data collected through the Follow-Up After Hospitalization for Mental Illness (NQF #0576) measure, will be more than 30 days post-discharge nearly half of all patients).⁴⁶ Therefore, we do not agree that this measure would be more appropriate for the outpatient setting. This measure addresses care provided during the discharge planning phase of care, which occurs within the IPF to facilitate a safe care transition until the patient can be seen by an outpatient provider. We note that the period immediately following discharge from a psychiatric hospital is a high-risk period for patients, and has been linked to an increased risk of adverse outcomes, including suicide.^{47 48} We believe it is vital that patients have continuity of pharmacotherapy consistent with the prescriptions provided by their inpatient providers until they can develop a long-term care plan with their outpatient providers.

Comment: One commenter expressed concern that because this measure's patient population has Medicare Parts A, B, and D coverage, these patients do not experience the same barriers to access experienced by patients without similar health insurance coverage and therefore the measure may not provide meaningful data.

Response: We agree that the patients included in the measure may not experience the same barriers to access to medications that some other patients encounter because they have insurance and low-income Medicare patients qualify for additional support to help pay for medications. However, as previously noted, in the measure technical report,⁴⁹ the claims data used

for analysis and testing of this measure demonstrated ample opportunity for improvement in medication continuation rates for patients with Medicare Parts A, B, and D, with median medication continuation rates of 79% and a variation of 21 percentage points between the 10th and 90th percentile facilities. Further, considering that the Medicare population may have lower barriers to access, we would expect to see higher medication continuation rates and less variation in performance across facilities.

In addition, we note that while the measure denominator includes only patients with Medicare Parts A, B, and D, all patients can benefit from the evidence-based interventions that facilities may implement to improve medication adherence.

Comment: One commenter requested clarification of how CMS will assess prescription refills for patients who do not have Part D.

Response: We note that the denominator of this measure is restricted to patients who have Medicare Parts A, B, and D coverage. Therefore, we will not assess prescription refills for patients who do not have Part D coverage because they are not in the measure's patient population.

Comment: One commenter expressed concern that the measure will not capture medication continuity for patients who filled 90-day supplies prior to admission.

Response: During measure testing, we found that the number of patients who filled a 90-day prescription in the 90 days prior to admission was small. Specifically, 5.5 percent of those with major depressive disorder had a 90-day prescription at some point in the 90 days prior to admission, 2.8 percent of those with bipolar disorder had such a prescription, and 1.2 percent of those with schizophrenia had such a prescription. Furthermore, we believe that medications are often adjusted during the inpatient stay, and patients may need to fill a new prescription following discharge even if they have medications at home. Therefore, we believe that the patient population with appropriate pharmacotherapy due to 90-day prescriptions prior to admission is very small and does not necessitate any changes to the measure specifications.

Comment: One commenter expressed concern that 2 days prior to discharge is too brief a period and recommended expanding the period to 5 days prior to discharge.

Response: When we developed and tested this measure, we found that most

⁴⁰ http://www.qualityforum.org/Projects/a-b/Behavioral_Health_2016-2017/Draft_Report_for_Comment.asp.

⁴¹ American Psychiatric Association. (2010). Practice guideline for the treatment of patients with major depressive disorder, 3rd ed. Retrieved from: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf.

⁴² American Psychiatric Association. (2002). Practice guideline for the treatment of patients with bipolar disorder, second edition. Retrieved from: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/bipolar.pdf.

⁴³ American Psychiatric Association. (2010). Practice guideline for the treatment of patients with schizophrenia: 2nd ed. Retrieved from: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia.pdf.

⁴⁴ U.S. Department of Veterans Affairs & U.S. Department of Defense. (2016). Management of major depressive disorder (MDD). Retrieved from: <http://www.healthquality.va.gov/guidelines/MH/mdd/VADoDMDDCPGINAL82916.pdf>.

⁴⁵ U.S. Department of Veterans Affairs & U.S. Department of Defense. (2010) VA/DoD clinical practice guideline for management of bipolar disorder in adults. Retrieved from: http://www.healthquality.va.gov/guidelines/MH/bd/bd_305_full.pdf.

⁴⁶ <https://www.medicare.gov/hospitalcompare/psych-measures.html>.

⁴⁷ <https://www.ncbi.nlm.nih.gov/pubmed/27654151>.

⁴⁸ <https://psychnews.psychiatryonline.org/doi/full/10.1176/appi.pn.2017.7a17>.

⁴⁹ https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version_1-0_Inpatient_Psychiatric_Facility_Medication_Continuation_Public.zip.

outpatient medications filled during the inpatient stay are filled one day prior to discharge.⁵⁰ In consulting with clinical experts, we found that discharge planning, including filling prescriptions, could start as early as two days prior to discharge. These experts unanimously agreed to extend the follow-up period to include two days prior to discharge.⁵¹ Because most medications filled during the stay are filled one day prior to discharge and discharge planning typically starts two days prior to discharge we believe that this measure period is appropriate.

Comment: Several commenters requested clarification of whether the data would be publicly reported annually or every two years because the measure has a two year performance period. These commenters further expressed concern that if data is reported annually the data may misrepresent facilities with recent improvement.

Response: The IPFQR Program publicly displays all measure data annually (78 FR 50897 through 50898 and 81 FR 57248 through 57249). For this measure we will post the data annually using a two-year performance period, similar to our reporting of the Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility (NQF #2860) measure. As an example, for both measures the intended performance period for FY 2021 reporting is July 1, 2017 through June 30, 2019. For FY

2022 reporting the performance period is July 1, 2018 through June 30, 2020. We note that these periods do overlap; however we believe that facilities with recent improvement will be distinguishable because their scores will show year-over-year improvement.

Comment: One commenter expressed concern that facilities without outpatient pharmacies may be at a performance disadvantage because they cannot ensure that patients fill prescriptions prior to discharge.

Response: We believe that many of the interventions to improve performance on this measure (for example, patient education at discharge, therapeutic alliance, text message reminders, etc.) are applicable to all facilities, regardless of whether they have an outpatient pharmacy on premises. Furthermore, we note that the practice guidelines for these conditions provide strategies for facilities to implement to help patients fill prescriptions prior to discharge so that the facility can track whether the prescription has been filled.^{52 53 54 55 56}

⁵² American Psychiatric Association. (2010). Practice guideline for the treatment of patients with major depressive disorder, 3rd ed. Retrieved from: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf.

⁵³ American Psychiatric Association. (2002). Practice guideline for the treatment of patients with bipolar disorder, second edition. Retrieved from: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/bipolar.pdf.

⁵⁴ American Psychiatric Association. (2010). Practice guideline for the treatment of patients with schizophrenia: 2nd ed. Retrieved from: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia.pdf.

⁵⁵ U.S. Department of Veterans Affairs & U.S. Department of Defense. (2016). Management of major depressive disorder (MDD). Retrieved from: <http://www.healthquality.va.gov/guidelines/MH/mdd/VADoDMDDCPGFINAL82916.pdf>.

Comment: One commenter requested that CMS provide guidance on what medications are considered evidence-based medications for these conditions.

Response: The measure technical report available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version_1-0_Inpatient_Psychiatric_Facility_Medication_Continuation_Public.zip has a detailed list of medications for each condition. As part of routine measure maintenance, we will evaluate and update this list on a recurrent basis.

Final Rule Action: After consideration of the public comments, we are finalizing as proposed the adoption of the Medication Continuation Following Inpatient Psychiatric Discharge (NQF #3205) measure for the FY 2021 payment determination and subsequent years.

4. Summary of Previously Finalized and Newly Proposed Measures for the FY 2021 Payment Determination and Subsequent Years

The previously finalized number of measures for the FY 2021 payment determination and subsequent years totals 13. In this final rule, we are adopting one additional measure for the FY 2021 payment determination and subsequent years which, brings the total to 14, as shown in table 18.

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⁵⁶ U.S. Department of Veterans Affairs & U.S. Department of Defense. (2010) VA/DOD clinical practice guideline for management of bipolar disorder in adults. Retrieved from: http://www.healthquality.va.gov/guidelines/MH/bd/bd_305_full.pdf.

⁵⁰ https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version_1-0_Inpatient_Psychiatric_Facility_Medication_Continuation_Public.zip.

⁵¹ Ibid.

Table 18. Previously Finalized and Newly Proposed Measures for the FY 2021 Payment Determination and Subsequent Years

NQF #	Measure ID	Measure
0640	HBIPS-2	Hours of Physical Restraint Use
0641	HBIPS-3	Hours of Seclusion Use
0560	HBIPS-5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification
0576	FUH	Follow-up After Hospitalization for Mental Illness
N/A*	SUB-2 and SUB-2a	Alcohol Use Brief Intervention Provided or Offered and SUB-2a Alcohol Use Brief Intervention
N/A*	SUB-3 and SUB-3a	Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge
N/A*	TOB-2 and TOB-2a	Tobacco Use Treatment Provided or Offered and TOB-2a Tobacco Use Treatment
N/A*	TOB-3 and TOB-3a	Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge
1659	IMM-2	Influenza Immunization
N/A*	N/A	Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)
N/A*	N/A	Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)
N/A	N/A	Screening for Metabolic Disorders
2860	N/A	Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility
3205	N/A	Medication Continuation following Discharge from an IPF

* Measure is no longer endorsed by the NQF but was endorsed at time of adoption. Section 1886(s)(4)(D)(ii) of the Act authorizes the Secretary to specify a measure that is not endorsed by the NQF as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We attempted to find available measures for each of these clinical topics that have been endorsed or adopted by a consensus organization and found no other feasible and practical measures on the topics for the IPF setting.

BILLING CODE 4120-01-C**5. Possible IPFQR Program Measures and Topics for Future Consideration**

As we have previously indicated in the FY 2015 IPF PPS final rule (79 FR 45974 through 45975), we seek to develop a comprehensive set of quality measures to be available for widespread

use for informed decision-making and quality improvement in the IPF setting. In the FY 2020 IPF PPS proposed rule, we sought public comments on possible new measures or new measure topics. We welcomed all comments but expressed particular interest in comments on future adoption of one or more measures of patient experience of

care based on a consumer survey, especially such as the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey, and potential future measures and topics as part of CMS' Meaningful Measures Framework.

a. Future Adoption a Patient Experience of Care Survey

In past assessments of the IPFQR Program Measure Set, we identified Patient Experience of Care as a measure gap area for this program (78 FR 50897, 79 FR 45964 through 45965, and 83 FR 38596 through 38597), which is consistent with input from past public comment (77 FR 53653). When we adopted the “Assessment of Patient Experience of Care Measure” for the FY 2016 payment determination and subsequent years, we noted that in addition to serving as an indicator of quality within IPFs, information gathered through the collection of this measure would be helpful in developing a standardized survey as a successor to the measure (79 FR 45964). When we removed the Assessment of Patient Experience of Care measure from the IPFQR Program, we stated we believe that we have now collected sufficient information to inform development of a patient experience of care measure (83 FR 38596).

At that time, several commenters expressed support for ensuring that patients have an opportunity to express their perspectives on their experience of receiving care at an IPF (83 FR 38597). Our analysis of the FY 2018 payment determination data (that is, data that represents facility assessment of patient experience of care as of December 31, 2016) collected under the Assessment of Patient Experience of Care measure shows that approximately one third of facilities use the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey⁵⁷ to assess patient experience of care. This is more than the portion of facilities using any other survey.

We sought public comment on how such providers have implemented the survey in their facilities, on whether they use the entire HCAHPS survey, or a subset of the survey questions; and if a subset, which specific questions they use. Additionally, we sought public comment on other potential surveys that commenters believe would be appropriate to adopt for the IPFQR Program. We intend to use this information to inform future development and testing of a survey-based patient experience of care measure (or measures) for the inpatient psychiatric patient population.

Comment: Many commenters supported future adoption of a patient experience of care survey. Several of

these commenters expressed concern about the potential adoption of the HCAHPS survey for this patient population, specifically noting that this survey does not include some of the unique aspects of inpatient psychiatric care including group therapy, non-physician providers, and involuntary admissions. Some commenters observed that while most IPFs use a patient experience of care survey, there is not one survey used predominantly across settings and recommended that CMS partner with providers to either develop a minimally burdensome survey or to establish a core set of questions that should be included, therefore allowing provider flexibility to ask additional questions. These commenters believe that a custom developed survey would better address the needs of the patient population and would be preferable for providers than having to switch from a setting specific survey to a survey not designed for this setting. One commenter recommended that adoption of a patient experience of care measure should be done incrementally through a voluntary data collection period to ensure feasibility of collection prior to mandatory data submission. Several commenters also noted that the HCAHPS survey modalities (phone or mail post-discharge) may limit participation and recommended additional survey modalities for this potentially more transient patient population. One commenter expressed concern that a patient experience of care measure could be misinterpreted as the current state of care when the data has been collected in the past.

Response: We thank these commenters for their input and will consider these suggestions and concerns as we seek to develop or select an appropriate patient experience of care survey for the IPF setting.

b. Other Future Measures

In the FY 2020 IPF PPS proposed rule, we also sought feedback and suggestions for future measures and topics for the IPFQR Program that align with CMS’s Meaningful Measures Framework (FY 2019 IPF PPS final rule, 83 FR 38590 through 38591).

Comment: One commenter recommended that CMS collaborate with providers to identify measure concepts and develop measures appropriate to the setting. Several commenters provided recommendations for future measure considerations; specifically measures that assess:

- Facility use of a standardized assessment of patient outcomes between admission and discharge;
- Family and caregiver engagement;

- Clinical improvement outcomes;
- Patient empowerment;
- Safety planning for patients with suicidal ideation;
- Discharge and transitions of care;
- Access to care; and
- Inpatient assaults and violence.

Response: We thank these commenters for their suggestions and will consider these concepts as we continue to develop a measure set that meets the specific needs of IPFs and inpatient psychiatric patients and their families.

E. Public Display and Review Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53653 through 53654), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50897 through 50898), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57248 through 57249) for discussion of our previously finalized public display and review requirements. We did not propose any changes to these requirements.

F. Form, Manner, and Timing of Quality Data Submission for the FY 2021 Payment Determination and Subsequent Years

1. Procedural Requirements for the FY 2021 Payment Determination and Subsequent Years

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53654 through 53655), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50898 through 50899), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38471 through 38472) for our previously finalized procedural requirements. In the FY 2020 IPF PPS proposed rule, we did not propose any changes to these policies.

2. Data Submission Requirements for the FY 2021 Payment Determination and Subsequent Years

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53655 through 53657), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50899 through 50900), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38472 through 38473) for our previously finalized data submission requirements.

Because the Medication Continuation following Discharge from an IPF (NQF #3205) measure is calculated by CMS using Medicare Fee-for-Service claims, there will be no additional data submission requirements for the FY 2021 payment determination and subsequent years. Therefore, in the FY 2020 IPF PPS proposed rule, we did not propose any changes to our previously finalized data submission policies.

⁵⁷ For more information about the HCAHPS survey, please see https://www.ahrq.gov/cahps/surveys-guidance/hospital/about/adult_hp_survey.html.

3. Reporting Requirements for the FY 2021 Payment Determination and Subsequent Years

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53656 through 53657), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50900 through 50901), and the FY 2015 IPF PPS final rule (79 FR 45976 through 45977) for our previously finalized reporting requirements. In the FY 2020 IPF PPS proposed rule, we did not propose any changes to these policies.

4. Quality Measure Sampling Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53657 through 53658), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50901 through 50902), the FY 2016 IPF PPS final rule (80 FR 46717 through 46719), and the FY 2019 IPF PPS final rule (83 FR 38607 through 38608) discussions for our previously finalized sampling policies. In the FY 2020 IPF PPS proposed rule, we did not propose any changes to these policies.

5. Non-Measure Data Collection

We refer readers to the FY 2015 IPF PPS final rule (79 FR 45973), the FY 2016 IPF PPS final rule (80 FR 46717), and the FY 2019 IPF PPS final rule (83 FR 38608) for our previously finalized non-measure data collection policies. In the FY 2020 IPF PPS proposed rule, we did not propose any changes to these policies.

6. Data Accuracy and Completeness Acknowledgement (DACA) Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658) for our previously finalized DACA requirements. In the FY 2020 IPF PPS proposed rule, we did not propose any changes to these policies.

G. Reconsideration and Appeals Procedures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658 through 53659) and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50903) for our previously finalized reconsideration and appeals procedures. In the FY 2020 IPF PPS proposed rule, we did not propose any changes to these policies.

H. Extraordinary Circumstances Exceptions (ECE) Policy

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53659

through 53660), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50903), the FY 2015 IPF PPS final rule (79 FR 45978), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38473 through 38474) for our previously finalized ECE policies. In the FY 2020 IPF PPS proposed rule, we did not propose any changes to these policies.

VI. Collection of Information Requirements

The FY 2020 IPF PPS proposed rule did not propose any new or revised “collection of information” requirements as defined under 5 CFR 1320.3 the Paperwork Reduction Act’s (PRA) implementing regulations. Nor did it contain any proposals that would have imposed any new or revised burden within the context of the PRA of 1995 (44 U.S.C. 3501 *et seq.*). However, we did make a number of burden adjustments based on updated Bureau of Labor Statistics (BLS) wage figures and more recent facility counts and estimated case data. These adjustments reduce our overall time estimate by 50,067 hours and increase our cost estimate by \$1,820,149.

A. Collection of Information Requirements for the IPFQR Program

With regard to the IPFQR Program, we are finalizing one new measure (Medication Continuation Following Inpatient Psychiatric Discharge (NQF #3205)) that impacts the FY 2021 payment determination and subsequent years. The finalized measure is calculated by CMS using IPF submitted claims data. The claims’ requirements and burden are approved by OMB under control number 0938–0050 (CMS–2552–10) for our Medicare cost report. The final measure does not impact any of the cost report’s data fields or burden estimates as all worksheets and lines remain unchanged. Similarly, this final rule does not impose any new or revised collection of information requirements or burden under OMB control number 0938–1171 (CMS–10432) which contains information about our non-claims based IPFQR Program quality measure and non-quality measure information collection/reporting requirements and burden.

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53673), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50964), the FY 2015 IPF PPS final rule (79 FR 45978 through 45980), the FY 2016 IPF PPS final rule (80 FR 46720

through 46721), the FY 2017 IPPS/LTCH PPS⁵⁸ final rule (81 FR 57265 through 57266), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38507 through 38508), and the FY 2019 IPF PPS final rule (83 FR 38609 through 38612) for a detailed discussion of the burden for the program requirements that we have previously adopted. Information pertaining to the requirements and burden that are currently approved by OMB can be found at reginfo.gov under control numbers 0938–0050 and 0938–1171.

B. Adjustments to IPFQR Program Burden Estimates

In the FY 2019 IPF PPS final rule (83 FR 38609), we estimated that reporting measures for the IPFQR Program could be accomplished by a Medical Records and Health Information Technician (BLS Occupation Code: 29–2071) with a median hourly wage of \$18.29 per hour (as of May 2016). Since then, BLS (the Bureau of Labor Statistics) has revised their wage data with May 2017 serving as their most recent update.⁵⁹ In response, we proposed to update our cost estimates using the May 2017 figure of \$18.83 per hour, an increase of \$0.54 per hour or \$1.08 per hour when adjusted by 100 percent to account for fringe benefits and overhead. 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 ($\$18.83 \times 2 = \37.66) to estimate total cost is a reasonably accurate estimation method.

We also proposed to update our facility count and case estimates to the most recent data available. Specifically, we estimate that there are now approximately 1,679 (down from the previous estimate of 1,734) facilities and that for measures which require reporting on the entire patient population, these facilities will report on an average of 1,283 cases per facility (up from the previous estimate of 1,213). Accordingly, we proposed to adjust our currently approved cost estimate from \$125,511,558 (see tables 19, 20, and 21) to \$127,331,707 (see tables 22, 23, and 24).

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⁵⁸ We note that for operational reasons we sometimes publish IPFQR program requirements in

the IPPS/LTCH PPS proposed and final rule as opposed to the IPF PPS proposed and final rule.

⁵⁹ <https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm>.

Table 19: Currently Approved Burden: Measure Data Collection and Reporting

NQF #	Measure ID	Measure Description	Estimated Cases (per facility)	Effort per Case (hours)	Annual Effort (per facility) (hours)	IPFs	Annual Effort (Total) (hours)	Cost (\$)
0640	HBIPS-2	Hours of Physical Restraint Use	1,213	0.25	303.25	1,734	525,835.5	19,235,063
0641	HBIPS-3	Hours of Seclusion Use	1,213	0.25	303.25	1,734	525,835.5	19,235,063
0560	HBIPS-5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification	609	0.25	152.25	1,734	264,001.5	9,657,175
1663	SUB-2 and SUB-2a	Alcohol Use Brief Intervention Provided or Offered	609	0.25	152.25	1,734	264,001.5	9,657,175
1664	SUB-3 and SUB-3a	Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and Alcohol and Other Drug Use Disorder Treatment at Discharge	609	0.25	152.25	1,734	264,001.5	9,657,175
0576	FUH	Follow-up After Hospitalization for Mental Illness*	0	0	0	0	0	0

NQF #	Measure ID	Measure Description	Estimated Cases (per facility)	Effort per Case (hours)	Annual Effort (per facility) (hours)	IPFs	Annual Effort (Total) (hours)	Cost (\$)
1654	TOB-2 TOB-2a	Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment	609	0.25	152.25	1,734	264,001.5	9,657.175
1656	TOB-3 and TOB-3a	Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge	609	0.25	152.25	1,734	264,001.5	9,657,175
1659	IMM-2	Influenza Immunization	609	0.25	152.25	1,734	264,001.5	9,657,175
647	n/a	Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)	609	0.25	152.25	1,734	264,001.5	9,657,175

NQF #	Measure ID	Measure Description	Estimated Cases (per facility)	Effort per Case (hours)	Annual Effort (per facility) (hours)	IPFs	Annual Effort (Total) (hours)	Cost (\$)
648	n/a	Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)	609	0.25	152.25	1,734	264,001.5	9,657,175
n/a	n/a	Screening for Metabolic Disorders	609	0.25	152.25	1,734	264,001.5	9,657,175
2860	n/a	Thirty-day all-cause unplanned readmission following Psychiatric hospitalization in an Inpatient Psychiatric Facility*	0	0	0	0	0	0
TOTAL			7,907**	Varies	1,976.75	1,734	3,427,685	125,384,699

* CMS will collect this data using Medicare Part A and Part B claims; therefore these measures will not require facilities to submit data on any cases.

** This number was erroneously written as 7.907 in the proposed rule, it has been corrected to 7,907 here.

Table 20: Currently Approved Burden: Non-Measure Data Collection and Reporting

Tasks	IPFs	Hours per IPF	Total Hours for All IPFs	Wage Rate (\$/hr)	Cost per IPF (\$)	Total Cost for All IPFs (\$)
Non-measure Data Collection and Submission	1,734	2.0	3,468	36.58	73.16	126,859

Table 21: Currently Approved Burden: Total

Requirement	Respondents	Responses	Time (hours)	Cost (\$)
Measure Data Collection and Reporting	1,734	13,710,738 (7,907 responses per facility * 1,734 facilities)	3,427,685	125,384,699
Non-Measure Data Collection and Reporting	1,734	4	3,468	126,859
Notice of Participation, Data Accuracy Acknowledgement, and Vendor Authorization Form*	n/a	n/a	n/a	n/a
TOTAL	1,734	13,710,742	3,431,153	125,511,558

*The 15 minutes per measure estimate for chart abstraction under Measure Data Collection and Reporting also includes the time for completing and submitting any forms.

Table 22: Burden Adjustments: Measure Data Collection and Reporting

NQF #	Measure ID	Measure Description	Estimated Cases (per facility)	Effort per Case (hours)	Annual Effort (per facility) (hours)	IPFs	Annual Effort (Total) (hours)	Cost (\$)
0640	HBIPS-2	Hours of Physical Restraint Use	1,283	0.25	320.75	1,679	538,539.25	20,281,388
0641	HBIPS-3	Hours of Seclusion Use	1,283	0.25	320.75	1,679	538,539.25	20,281,388
0560	HBIPS-5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification	609	0.25	152.25	1,679	255,627.75	9,626,941
1663	SUB-2 and SUB-2a	Alcohol Use Brief Intervention Provided or Offered	609	0.25	152.25	1,679	255,627.75	9,626,941
1664	SUB-3 and SUB-3a	Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and Alcohol and Other Drug Use Disorder Treatment at Discharge	609	0.25	152.25	1,679	255,627.75	9,626,941
0576	FUH	Follow-up After Hospitalization for Mental Illness*	0	0	0	0	0	0

NQF #	Measure ID	Measure Description	Estimated Cases (per facility)	Effort per Case (hours)	Annual Effort (per facility) (hours)	IPFs	Annual Effort (Total) (hours)	Cost (\$)
1654	TOB-2 TOB-2a	Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment	609	0.25	152.25	1,679	255,627.75	9,626,941
1656	TOB-3 and TOB-3a	Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge	609	0.25	152.25	1,679	255,627.75	9,626,941
1659	IMM-2	Influenza Immunization	609	0.25	152.25	1,679**	255,627.75	9,626,941
647	n/a	Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)	609	0.25	152.25	1,679	255,627.75	9,626,941

NQF #	Measure ID	Measure Description	Estimated Cases (per facility)	Effort per Case (hours)	Annual Effort (per facility) (hours)	IPFs	Annual Effort (Total) (hours)	Cost (\$)
648	n/a	Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)	609	0.25	152.25	1,679	255,627.75	9,626,941
n/a	n/a	Screening for Metabolic Disorders	609	0.25	152.25	1,679	255,627.75	9,626,941
2860	n/a	Thirty-day all-cause unplanned readmission following Psychiatric hospitalization in an Inpatient Psychiatric Facility*	0	0	0	0	0	0
TOTAL			7,907**	Varies	2,011.75	1,679	3,377,728	127,205,245

* CMS will collect this data using Medicare Part A and Part B claims; therefore these measures will not require facilities to submit data on any cases.

** The number of facilities submitting data for IMM-2 was erroneously written as 1,734 in the proposed rule and has been corrected to 1,679 here; the total number of responses was erroneously written as 7,907 in the proposed rule and has been corrected to 8,047 here..

Table 23: Burden Adjustments: Non-Measure Data Collection and Reporting

Tasks	IPFs	Hours per IPF	Total Hours for All IPFs	Wage Rate (\$/hr)	Cost per IPF (\$)	Total Cost for All IPFs (\$)
Non-measure Data Collection and Submission	1,679	2.0	3,358	37.66	75.32	126,462

Table 24: Burden Adjustments: Total

Requirement	Respondents	Responses	Time (hours)	Cost (\$)
Measure Data Collection and Reporting	1,679	13,510,913 (8,047 responses per facility * 1,679 facilities)**	3,377,728	127,205,245
Non-Measure Data Collection and Reporting	1,679	4	3,358	126,462
Notice of Participation, Data Accuracy Acknowledgement, and Vendor Authorization Form*	n/a	n/a	n/a	n/a
TOTAL	1,679	13,510,917**	3,381,086	127,331,707

*The 15 minutes per measure estimate for chart abstraction under Measure Data Collection and Reporting also includes the time for completing and submitting any forms.

** The total number of responses has been corrected by multiplying the facility number by the correct case number (i.e., 8,047 cases as opposed to 7,097 cases).

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As mentioned at the beginning of this section, the adjustments are in response to updates to BLS wage figures and more recent facility counts and estimated case data. They are not a result of any of the provisions proposed in the FY 2020 IPF PPS proposed rule. The adjusted burden figures will be submitted to OMB for approval under control number 0938-1171 (CMS-10432) as a non-substantive change.

We did not receive any public comments on our proposed burden estimates.

C. Submission of PRA-Related Comments

We invited public comments on our proposed burden adjustments as well as on any of the information collection requirements/burden set out under OMB control number 0938-1171.

We did not receive any public comments on our proposed burden estimates.

VII. Regulatory Impact Statement

A. Statement of Need

This rule finalizes updates to the prospective payment rates for Medicare inpatient hospital services provided by

IPFs for discharges occurring during FY 2020 (October 1, 2019 through September 30, 2020). We are finalizing our proposal to apply the 2016-based IPF market basket increase of 2.9 percent, less the productivity adjustment of 0.4 percentage point as required by 1886(s)(2)(A)(i) of the Act, and further reduced by 0.75 percentage point as required by sections 1886(s)(2)(A)(ii) and 1886(s)(3)(E) of the Act, for a final total FY 2020 payment rate update of 1.75 percent. In this final rule, we revised and rebased the IPF market basket to reflect a 2016 base year. We also aligned the IPF wage index data with the concurrent IPPS wage index data by removing the 1-year lag of the pre-floor, pre-reclassified IPPS hospital wage index upon which the IPF wage index is based. We also updated the IPF labor-related share and the IPF wage index including adoption of a new OMB designation. Finally, we updated the IPFQR Program for the FY 2021 payment determination and subsequent years.

B. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning

and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96 354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition,

jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This final rule is not economically significant under Executive Order 12866, within the meaning of section 3(f)(1) of the Executive Order. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed this final rule, and the Departments have provided the following assessment of their impact.

We estimate that the total impact of these changes for FY 2020 payments compared to FY 2019 payments will be a net increase of approximately \$65 million. This reflects an \$75 million increase from the update to the payment rates (+\$125 million from the second quarter 2019 IGI forecast of the 2016-based IPF market basket of 2.9 percent, –\$15 million for the productivity adjustment of 0.4 percentage point, and –\$35 million for the “other adjustment” of 0.75 percentage point), as well as a \$10 million decrease as a result of the update to the outlier threshold amount. Outlier payments are estimated to change from 2.23 percent in FY 2019 to 2.00 percent of total estimated IPF payments in FY 2020.

C. Anticipated Effects

In this section, we discuss the historical background of the IPF PPS and the impact of this final rule on the Federal Medicare budget and on IPFs.

1. Budgetary Impact

As discussed in the November 2004 and RY 2007 IPF PPS final rules, we applied a budget neutrality factor to the federal per diem base rate and ECT payment per treatment to ensure that total estimated payments under the IPF PPS in the implementation period would equal the amount that would have been paid if the IPF PPS had not been implemented. The budget neutrality factor includes the following

components: Outlier adjustment, stop-loss adjustment, and the behavioral offset. As discussed in the RY 2009 IPF PPS notice (73 FR 25711), the stop-loss adjustment is no longer applicable under the IPF PPS.

As discussed in section III.D.1 of this final rule, we are updating the wage index and labor-related share in a budget neutral manner by applying a wage index budget neutrality factor to the federal per diem base rate and ECT payment per treatment. Therefore, the budgetary impact to the Medicare program of this final rule will be due to the market basket update for FY 2020 of 2.9 percent (see section III.A.4 of this final rule) less the productivity adjustment of 0.4 percentage point required by section 1886(s)(2)(A)(i) of the Act; further reduced by the “other adjustment” of 0.75 percentage point under sections 1886(s)(2)(A)(ii) and 1886(s)(3)(E) of the Act; and the update to the outlier fixed dollar loss threshold amount.

We estimate that the FY 2020 impact will be a net increase of \$65 million in payments to IPF providers. This reflects an estimated \$75 million increase from the update to the payment rates and a \$10 million decrease due to the update to the outlier threshold amount to set total estimated outlier payments at 2.0 percent of total estimated payments in FY 2020. This estimate does not include the implementation of the required 2.0 percentage point reduction of the market basket increase factor for any IPF that fails to meet the IPF quality reporting requirements (as discussed in section V.A. of this final rule).

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, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most IPFs and most other providers and suppliers are small entities, either by nonprofit status or having revenues of \$7.5 million to \$38.5 million or less in any 1 year, depending on industry classification (for details, refer to the SBA Small Business Size Standards found at http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf). Individuals and states are not included in the definition of a small entity.

Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary IPFs or the proportion of IPFs’ revenue derived from Medicare payments. Therefore, we assume that all IPFs are considered small entities.

The Department of Health and Human Services generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA. As shown in Table 25, we estimate that the overall revenue impact of this final rule on all IPFs is to increase estimated Medicare payments by approximately 1.5 percent. As a result, since the estimated impact of this final rule is a net increase in revenue across almost all categories of IPFs, the Secretary has determined that this final rule will have a positive revenue impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. As discussed in section VII.C.1 of this final rule, the rates and policies set forth in this final rule will not have an adverse impact on the rural hospitals based on the data of the 255 rural excluded psychiatric units and 66 rural psychiatric hospitals in our database of 1,581 IPFs for which data were available. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately \$154 million. This final rule does not impose spending costs on state, local, or tribal governments in the aggregate, or by the private sector of \$154 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This final rule will not have a substantial effect on state and local governments.

2. Impact on Providers

To show the impact on providers of the changes to the IPF PPS discussed in this final rule, we compare estimated payments under the IPF PPS rates and factors for FY 2020 versus those under

FY 2019. We determined the percent change in the estimated FY 2020 IPF PPS payments compared to the estimated FY 2019 IPF PPS payments for each category of IPFs. In addition, for each category of IPFs, we have included the estimated percent change in payments resulting from the update to the outlier fixed dollar loss threshold amount; the updated wage index data including the updated labor-related share; and the market basket update for FY 2020, as adjusted by the productivity adjustment according to section 1886(s)(2)(A)(i) of the Act, and the “other adjustment” according to sections 1886(s)(2)(A)(ii) and 1886(s)(3)(E) of the Act.

To illustrate the impacts of the FY 2020 changes in this final rule, our analysis begins with a FY 2019 baseline

simulation model based on FY 2018 IPF payments inflated to the midpoint of FY 2019 using IHS Global Inc.’s second quarter 2019 forecast of the market basket update (see section III.A.4 of this final rule); the estimated outlier payments in FY 2019; the FY 2019 IPF wage index; the FY 2019 labor-related share; and the FY 2019 percentage amount of the rural adjustment. During the simulation, total outlier payments are maintained at 2 percent of total estimated IPF PPS payments.

Each of the following changes is added incrementally to this baseline model in order for us to isolate the effects of each change:

- The update to the outlier fixed dollar loss threshold amount.
- The FY 2020 IPF wage index and the FY 2020 labor-related share.

- The market basket update for FY 2020 of 2.9 percent less the productivity adjustment of 0.4 percentage point in accordance with section 1886(s)(2)(A)(i) of the Act and further reduced by the “other adjustment” of 0.75 percentage point in accordance with sections 1886(s)(2)(A)(ii) and 1886(s)(3)(E) of the Act, for a payment rate update of 1.75 percent.

Our final column comparison in Table 25 illustrates the percent change in payments from FY 2019 (that is, October 1, 2018, to September 30, 2019) to FY 2020 (that is, October 1, 2019, to September 30, 2020) including all the payment policy changes in this final rule.

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Table 25. FY 2020 IPF PPS Final Payment Impacts
[Percent Change in Columns 3 through 5]

Facility by Type	Number of Facilities	Outlier	CBSA Wage Index & Labor Share	Total Percent Change¹
(1)	(2)	(3)	(4)	(5)
All Facilities	1,581	-0.23	0.00	1.51
Total Urban	1,260	-0.24	0.03	1.54
Urban unit	783	-0.37	-0.06	1.32
Urban hospital	477	-0.08	0.13	1.81
Total Rural	321	-0.19	-0.20	1.34
Rural unit	255	-0.25	-0.24	1.23
Rural hospital	66	-0.06	-0.10	1.61
By Type of Ownership:				
Freestanding IPFs				
Urban Psychiatric Hospitals				
Government	121	-0.40	-0.19	1.21
Non-Profit	100	-0.09	0.08	1.75
For-Profit	256	-0.02	0.21	1.94
Rural Psychiatric Hospitals				
Government	32	-0.13	-0.30	1.36
Non-Profit	15	-0.10	-0.47	1.20
For-Profit	19	0.00	0.10	1.84
IPF Units				
Urban				
Government	115	-0.67	0.19	1.26
Non-Profit	509	-0.36	-0.09	1.29
For-Profit	159	-0.16	-0.15	1.43
Rural				
Government	68	-0.22	-0.08	1.42
Non-Profit	136	-0.32	-0.13	1.26

For-Profit	51	-0.14	-0.68	0.91
By Teaching Status:				
Non-teaching	1,390	-0.19	-0.05	1.51
Less than 10% interns and residents to beds	107	-0.34	0.13	1.54
10% to 30% interns and residents to beds	61	-0.61	0.30	1.44
More than 30% interns and residents to beds	23	-0.78	0.71	1.67
By Region:				
New England	104	-0.25	-0.83	0.67
Mid-Atlantic	229	-0.33	0.06	1.47
South Atlantic	239	-0.17	-0.24	1.33
East North Central	270	-0.20	-0.34	1.20
East South Central	159	-0.16	-0.70	0.87
West North Central	115	-0.27	0.37	1.85
West South Central	236	-0.16	-0.04	1.53
Mountain	105	-0.15	-0.78	0.80
Pacific	124	-0.38	2.08	3.49
By Bed Size:				
Psychiatric Hospitals				
Beds: 0-24	86	-0.04	-0.14	1.56
Beds: 25-49	86	-0.05	0.00	1.70
Beds: 50-75	91	-0.03	0.04	1.75
Beds: 76 +	280	-0.11	0.20	1.85
Psychiatric Units				
Beds: 0-24	593	-0.33	-0.17	1.22
Beds: 25-49	268	-0.27	-0.12	1.36
Beds: 50-75	111	-0.38	0.06	1.42
Beds: 76 +	66	-0.48	0.03	1.31

¹ This column includes the impact of the updates in columns (3) and (4) above, and of the IPF market basket increase factor for FY 2020 (2.9 percent), reduced by 0.4 percentage point for the productivity adjustment as required by section 1886(s)(2)(A)(i) of the Act, and reduced by 0.75 percentage point in accordance with sections 1886(s)(2)(A)(ii) and 1886(s)(3)(E) of the Act.

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3. Impact Results

Table 25 displays the results of our analysis. The table groups IPFs into the categories listed here based on characteristics provided in the Provider of Services (POS) file, the IPF provider specific file, and cost report data from the Healthcare Cost Report Information System:

- Facility Type.
- Location.

- Teaching Status Adjustment.
- Census Region.
- Size.

The top row of the table shows the overall impact on the 1,581 IPFs included in this analysis. In column 3, we present the effects of the update to the outlier fixed dollar loss threshold amount. We estimate that IPF outlier payments as a percentage of total IPF payments are 2.23 percent in FY 2019. Thus, we are adjusting the outlier threshold amount in this final rule to set

total estimated outlier payments equal to 2.0 percent of total payments in FY 2020. The estimated change in total IPF payments for FY 2020, therefore, includes an approximate 0.23 percent decrease in payments because the outlier portion of total payments is expected to decrease from approximately 2.23 percent to 2.0 percent.

The overall impact of this outlier adjustment update (as shown in column

3 of Table 25), across all hospital groups, is to decrease total estimated payments to IPFs by 0.23 percent. The largest decrease in payments is estimated to be –0.78 percent for teaching IPFs with more than 30 percent interns and residents to beds.

In column 4, we present the effects of the budget-neutral update to the IPF wage index and the Labor-Related Share (LRS). This represents the effect of using the concurrent hospital wage data and taking into account the updated OMB delineations. That is, the impact represented in this column reflects the update from the FY 2019 IPF wage index to the final FY 2020 IPF wage index, which includes basing the FY 2020 IPF wage index on the FY 2020 pre-floor, pre-reclassified IPPS hospital wage index data, updating the OMB designations for two counties in Idaho, and updating the LRS from 74.8 percent in FY 2019 to 76.9 percent in FY 2020. We note that there is no projected change in aggregate payments to IPFs, as indicated in the first row of column 4, however, there will be distributional effects among different categories of IPFs. For example, we estimate the largest increase in payments to be 2.08 percent for Pacific IPFs, and the largest decrease in payments to be 0.83 percent for New England IPFs.

Finally, column 5 compares our estimates of the total final changes reflected in this final rule for FY 2020 to the estimates for FY 2019 (without these changes). The average estimated increase for all IPFs is approximately 1.5 percent. This estimated net increase includes the effects of the 2016-based market basket update of 2.9 percent reduced by the productivity adjustment of 0.4 percentage point, as required by section 1886(s)(2)(A)(i) of the Act and further reduced by the “other adjustment” of 0.75 percentage point, as required by sections 1886(s)(2)(A)(ii) and 1886(s)(3)(E) of the Act. It also includes the overall estimated 0.23 percent decrease in estimated IPF outlier payments as a percent of total payments from the final update to the outlier fixed dollar loss threshold amount. Column 5 also includes the distributional effects of the updates to the IPF wage index and the labor-related share.

IPF payments are estimated to increase by 1.54 percent in urban areas and 1.34 percent in rural areas. Overall, IPFs are estimated to experience a net increase in payments as a result of the updates in this final rule. The largest payment increase is estimated at 3.49 percent for IPFs in the Pacific region.

Comment: One commenter wrote that the proposed 1.7 percent estimated total

IPF update was not sufficient to cover the costs of medical inflation and the growing demand for IPF services. This commenter was concerned that the update could negatively impact the financial viability of IPFs and jeopardize access.

Response: Total IPF payments were estimated to increase by 1.7 percent in the FY 2020 IPF PPS proposed rule. This 1.7 percent increase is a combination of the effects of the proposed market basket update for FY 2020 and the proposed update to the outlier threshold.

The final FY 2020 estimated increase in payments is based on a more recent estimate of the final 2016-based IPF market basket percentage increase of 2.9 percent, a more recent estimate of the MFP adjustment of 0.4 percentage point, less the 0.75 percentage point reduction (in accordance with sections 1886(s)(2)(A)(ii) and 1886(s)(3)(E) of the Act) and impact of the outlier threshold, for a total payment update of 1.75 percent.

The 2.9 percentage increase of the IPF market basket represents the FY 2020 projected increase in prices of the relative inputs used to furnish IPF services to Medicare beneficiaries. The forecasted prices of the individual inputs are based on IGI's most recent 2nd quarter 2019 forecast of the price proxies in the market basket. IGI is a nationally recognized economic and financial forecasting firm that has received multiple awards for their macroeconomic forecast accuracy of major economic indicators. CMS uses IGI's price forecasts in all of the FFS market baskets used for payment updates and has used the forecasts produced by this company for many years. In this FY 2020 final rule, we are also updating the cost weights for the IPF market basket, from 2012 to 2016, which captures changes in relative costs due to quantity and intensity. We therefore believe that the IPF market basket represents an appropriate measure of input price inflation that is expected to be realized by IPFs in FY 2020.

As stated, the Act mandates that the market basket update (which accounts for input price inflation) be adjusted for multifactor productivity and a 0.75 percentage point legislatively required adjustment. CMS does not have the authority to alter these payment adjustments, but we note that under the current law at 1886(s)(3)(E), FY 2020 is the last year that the 0.75 percentage point “other” adjustment will be made.

Estimated IPF payments are also reduced by 0.23 percent as a result of the update to the outlier threshold.

Based on an updated analysis of the most recent IPF claims data for this final rule we now estimate that IPF outlier payments as a percentage of total estimated payments will be approximately 2.23 percent in FY 2019. Since this percentage exceeds our established 2 percent IPF outlier policy we are adjusting the outlier threshold amount to set total estimated outlier payments equal to 2 percent of total estimated payments in FY 2020. The estimated change in total IPF payments for FY 2020 includes an approximate 0.23 percent decrease in payments because the estimated outlier portion of total payments is estimated to decrease from 2.23 percent to 2 percent.

4. Effect on Beneficiaries

Under the IPF PPS, IPFs will receive payment based on the average resources consumed by patients for each day. We do not expect changes in the quality of care or access to services for Medicare beneficiaries under the FY 2020 IPF PPS, but we continue to expect that paying prospectively for IPF services will enhance the efficiency of the Medicare program.

5. Effects of Updates to the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

As discussed in section V. of this final rule and in accordance with section 1886(s)(4)(A)(i) of the Act, we will implement a 2 percentage point reduction in the market basket update when calculating the FY 2021 national per diem rate for discharges from IPFs that have failed to comply with the IPFQR Program requirements for the FY 2021 payment determination. In section III.B. of this final rule, we discuss how the 2 percentage point reduction will be applied. For the FY 2019 payment determination (that is, data submitted in CY 2018), of the 1,679 IPFs eligible for the IPFQR Program, 50 did not receive the full market basket update due to reasons specific to the IPFQR Program; 24 of these IPFs chose not to participate and 26 did not meet the requirements of the Program. Thus, we estimate similar numbers for the FY 2021 payment determination and that the IPFQR Program will have a negligible impact on overall IPF payments in FY 2021.

We are finalizing provisions that impact the FY 2021 payment determination and subsequent years. We refer readers to section VI. of this final rule for details discussing information collection requirements for the IPFQR Program. We will closely monitor the effects of this quality reporting program on IPFs and help facilitate successful reporting outcomes through ongoing

stakeholder education, national trainings, and a technical help desk.

6. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final 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 this final rule, we assume that the total number of unique commenters on the most recent IPF proposed rule from FY 2020 (84 FR 16948) will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule. It is possible that not all commenters reviewed the FY 2020 IPF proposed rule in detail, and it is also possible that some reviewers chose not to comment on that proposed rule. For these reasons we thought that the number of commenters would be a fair estimate of the number of reviewers of this final rule. We solicited comments on this assumption.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule; therefore, for the purposes of our estimate, we assume that each reviewer reads approximately 50 percent of this final rule.

Using the May, 2018 mean (average) wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this final rule is \$109.36 per hour, including overhead and fringe benefits (<https://www.bls.gov/oes/current/oes119111.htm>). Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 1.4 hours for the staff to review half of this final rule. For each IPF that reviews the final rule, the estimated cost is (1.4 hours × \$109.36) or \$153.10. Therefore, we estimate that the total cost of reviewing this final rule is \$3,674.40 (\$153.10 × 24 reviewers).

We received one comment on our assumption about the number of reviewers of the IPF PPS proposed rule.

Comment: One commenter wrote that CMS should consider the number of downloads of the IPF proposed rule in calculating regulatory review costs, since many reviewers may read the rule but not submit a comment. The commenter also noted that some organizations may download the rule

once and distribute copies to others to read. This commenter suggested that CMS consider the greater of the number of downloads or of the number of unique commenters as a fair estimate of the number of reviewers. This commenter believes that this method would be a fairer assumption of the number of reviewers.

Response: We appreciate the commenter's input on our methodology. We have acknowledged that our method provides an estimate that could overstate or understate the costs of reviewing the rule. We do not believe this suggested methodology would improve the accuracy of the estimate. We do not currently have the ability to track the number of times the IPF rule is downloaded, and if we did, to know how many of those downloads are by those who are providers or similar stakeholders. We also prefer to use a methodology for estimating the number of reviewers that is consistent with the methodology that other Medicare payment systems use. As such, we will continue to use the number of commenters on the most recent proposed rule as the basis for our review cost estimate.

D. Alternatives Considered

The statute does not specify an update strategy for the IPF PPS and is broadly written to give the Secretary discretion in establishing an update methodology. Therefore, we are updating the IPF PPS using the methodology published in the November 2004 IPF PPS final rule; applying the 2016-based IPF PPS market basket update for FY 2020 of 2.9 percent, reduced by the statutorily required multifactor productivity adjustment of 0.4 percentage point and the “other adjustment” of 0.75 percentage point, along with the wage index budget neutrality adjustment to update the payment rates; finalizing a FY 2020 IPF wage index which is fully based upon the OMB CBSA designations from Bulletin 17–01 and which uses the FY 2020 pre-floor, pre-reclassified IPPS hospital wage index as its basis; and finalizing changes to the IPFQR Program.

E. Accounting Statement

As required by OMB Circular A–4 (available at www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf), in Table 26, we have prepared an accounting statement showing the classification of the expenditures

associated with the updates to the IPF wage index and payment rates in this final rule. Table 26 provides our best estimate of the increase in Medicare payments under the IPF PPS as a result of the changes presented in this final rule and based on the data for 1,581 IPFs in our database.

TABLE 26—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

[Change in estimated impacts from FY 2019 IPF PPS to FY 2020 IPF PPS]

Category	Transfers
Annualized Monetized Transfers.	\$65 million.
From Whom to Whom? ..	Federal Government to IPF Medicare Providers.

F. Congressional Review Act

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

G. Regulatory Reform Analysis Under Executive Order 13771

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” This final rule is not expected to be subject to the requirements of Executive Order 13771 because it is estimated to result in no more than *de minimis* costs as described previously and thus is not a regulatory action for the purposes of E.O. 13771.

H. Conclusion

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Dated: July 26, 2019 .

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 26, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 418

Medicare Program; FY 2020 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 418

[CMS-1714-F]

RIN 0938-AT71

Medicare Program; FY 2020 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements

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

ACTION: Final rule.

SUMMARY: This final rule updates the hospice wage index, payment rates, and cap amount for fiscal year 2020. This rule also rebases the continuous home care, general inpatient care, and the inpatient respite care per diem payment rates in a budget-neutral manner to more accurately align Medicare payments with the costs of providing care. In addition, this rule modifies the election statement by requiring an addendum that includes information aimed at increasing coverage transparency for patient under a hospice election. Finally, this rule includes changes to the Hospice Quality Reporting Program.

DATES: These regulations are effective on October 1, 2019.

FOR FURTHER INFORMATION CONTACT: For general questions about hospice payment policy, send your inquiry via email to: hospicepolicy@cms.hhs.gov.

Debra Dean-Whittaker, (410) 786-0848 for questions regarding the CAHPS® Hospice Survey.

Cindy Massuda, (410) 786-0652 for questions regarding the hospice quality reporting program.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose

This final rule makes updates to the hospice wage index, payment rates, and cap amount for fiscal year (FY) 2020, as required under section 1814(i) of the Social Security Act (the Act). This rule also rebases the continuous home care (CHC), general inpatient care (GIP), and inpatient respite care (IRC) per diem payment rates in a budget neutral manner to more accurately align payments with the costs of providing care, using the hospice payment reform authority under section 1814(i)(6) of the Act. This rule changes the hospice wage index to remove the 1-year lag in data

by using the current year's hospital wage data to establish the hospice wage index. In addition, this rule modifies the hospice election statement by requiring an addendum that includes information aimed at increasing coverage transparency for patients under a hospice election. Finally, this rule includes changes to the Hospice Quality Reporting Program.

B. Summary of the Major Provisions

Section III.A.2 of this final rule describes the FY 2020 hospice per diem payment rebasing methodology, cost reports and calculations. Using the hospice payment reform authority under section 1814(i)(6) of the Act, section III.A.3 of this final rule rebases the FY 2020 per diem payment rates for CHC, IRC, and GIP levels of care. As required in section 1814(i)(6)(D)(ii) of the Act, any changes to hospice payment rates must be done in a budget neutral manner. As such, section III.A.3 also finalizes a reduction to the routine home care (RHC) payment amounts for FY 2020 in order to maintain overall budget neutrality. Section III.B.1 of this rule eliminates the 1-year lag of the pre-floor, pre-reclassified hospital wage index that is used in calculating the hospice wage index. Section III.B.2 updates the hospice wage index and makes the application of the updated wage data budget neutral for all four levels of hospice care. In section III.B.3 of this rule, we discuss the FY 2020 hospice payment update percentage of 2.6 percent. Section III.B.4 outlines the final FY 2020 hospice payment rates. Section III.B.5 of this final rule updates the hospice cap amount for FY 2020 by the hospice payment update percentage discussed in section III.B.3 of this rule. Section III.C modifies the hospice election statement content requirements at § 418.24(b) to increase coverage transparency for patients under a hospice election by notifying beneficiaries if there are services that will not be covered by the hospice.

Finally, in section III.E of this rule, we discuss updates to the Hospice Quality Reporting Program (HQRP), including: The development of claims-based and outcome measures, measure concepts, and the hospice assessment tool. We also provide updates on the public reporting change for the "Hospice Visits When Death is Imminent" measure pair, the posting of publicly available government data to the CMS Hospice Compare website, and the CAHPS® Hospice Survey.

C. Summary of Impacts

The overall economic impact of this final rule is estimated to be \$520 million

in increased payments to hospices for FY 2020.

II. Background

A. Hospice Care

Hospice care is a comprehensive, holistic approach to treatment that recognizes the impending death of a terminally ill individual and warrants a change in the focus from curative care to palliative care for relief of pain and for symptom management. Medicare regulations define "palliative care" as patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice (42 CFR 418.3). Palliative care is at the core of hospice philosophy and care practices, and is a critical component of the Medicare hospice benefit.

The goal of hospice care is to help terminally ill individuals continue life with minimal disruption to normal activities while remaining primarily in the home environment. A hospice uses an interdisciplinary approach to deliver medical, nursing, social, psychological, emotional, and spiritual services through a collaboration of professionals and other caregivers, with the goal of making the beneficiary as physically and emotionally comfortable as possible. Hospice is compassionate beneficiary and family/caregiver-centered care for those who are terminally ill.

As referenced in our regulations at § 418.22(b)(1), to be eligible for Medicare hospice services, the patient's attending physician (if any) and the hospice medical director must certify that the individual is "terminally ill," as defined in section 1861(dd)(3)(A) of the Act and our regulations at § 418.3; that is, the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course. The regulations at § 418.22(b)(3) require that the certification and recertification forms include a brief narrative explanation of the clinical findings that support a life expectancy of 6 months or less.

Under the Medicare hospice benefit, the election of hospice care is a patient choice and once a terminally ill patient elects to receive hospice care, a hospice interdisciplinary group is essential in the seamless provision of services. These hospice services are provided primarily in the individual's home. The hospice interdisciplinary group works

with the beneficiary, family, and caregivers to develop a coordinated, comprehensive care plan; reduce unnecessary diagnostics or ineffective therapies; and maintain ongoing communication with individuals and their families about changes in their condition. The beneficiary's care plan will shift over time to meet the changing needs of the individual, family, and caregiver(s) as the individual approaches the end of life.

If, in the judgment of the hospice interdisciplinary team, which includes the hospice physician, the patient's symptoms cannot be effectively managed at home, then the patient is eligible for general inpatient care (GIP), a more medically intense level of care. GIP must be provided in a Medicare-certified hospice freestanding facility, skilled nursing facility, or hospital. GIP is provided to ensure that any new or worsening symptoms are intensively addressed so that the beneficiary can return to his or her home and continue to receive routine home care. Limited, short-term, intermittent, inpatient respite care (IRC) is also available because of the absence or need for relief of the family or other caregivers. Additionally, an individual can receive continuous home care (CHC) during a period of crisis in which an individual requires continuous care to achieve palliation or management of acute medical symptoms so that the individual can remain at home. CHC may be covered for as much as 24 hours a day, and these periods must be predominantly nursing care, in accordance with our regulations at § 418.204. A minimum of 8 hours of nursing care, or nursing and aide care, must be furnished on a particular day to qualify for the continuous home care rate (§ 418.302(e)(4)).

Hospices must comply with applicable civil rights laws,¹ including section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act, under which covered entities must take appropriate steps to ensure effective communication with patients and patient care representatives with disabilities, including the provisions of auxiliary aids and services. Additionally, they must take reasonable steps to ensure meaningful access for individuals with limited English proficiency, consistent with Title VI of the Civil Rights Act of 1964. Further information about these

requirements may be found at: <http://www.hhs.gov/ocr/civilrights>.

B. Services Covered by the Medicare Hospice Benefit

Coverage under the Medicare Hospice benefit requires that hospice services must be reasonable and necessary for the palliation and management of the terminal illness and related conditions. Section 1861(dd)(1) of the Act establishes the services that are to be rendered by a Medicare-certified hospice program. These covered services include: Nursing care; physical therapy; occupational therapy; speech-language pathology therapy; medical social services; home health aide services (now called hospice aide services); physician services; homemaker services; medical supplies (including drugs and biologicals); medical appliances; counseling services (including dietary counseling); short-term inpatient care in a hospital, nursing facility, or hospice inpatient facility (including both respite care and procedures necessary for pain control and acute or chronic symptom management); continuous home care during periods of crisis, and only as necessary to maintain the terminally ill individual at home; and any other item or service which is specified in the plan of care and for which payment may otherwise be made under Medicare, in accordance with Title XVIII of the Act.

Section 1814(a)(7)(B) of the Act requires that a written plan for providing hospice care to a beneficiary who is a hospice patient be established before care is provided by, or under arrangements made by, that hospice program; and that the written plan be periodically reviewed by the beneficiary's attending physician (if any), the hospice medical director, and an interdisciplinary group (described in section 1861(dd)(2)(B) of the Act). The services offered under the Medicare hospice benefit must be available to beneficiaries as needed, 24 hours a day, 7 days a week (section 1861(dd)(2)(A)(i) of the Act).

Upon the implementation of the hospice benefit, the Congress also expected hospices to continue to use volunteer services, though these services are not reimbursed by Medicare (see section 1861(dd)(2)(E) of the Act). As stated in the FY 1983 Hospice Wage Index and Rate Update proposed rule (48 FR 38149), the hospice interdisciplinary group should comprise paid hospice employees as well as hospice volunteers, and that "the hospice benefit and the resulting Medicare reimbursement is not intended to diminish the voluntary

spirit of hospices." This expectation supports the hospice philosophy of community based, holistic, comprehensive, and compassionate end-of-life care.

C. Medicare Payment for Hospice Care

Sections 1812(d), 1813(a)(4), 1814(a)(7), 1814(i), and 1861(dd) of the Act, and our regulations in 42 CFR part 418, establish eligibility requirements, payment standards and procedures; define covered services; and delineate the conditions a hospice must meet to be approved for participation in the Medicare program. Part 418, subpart G, provides for a per diem payment in one of four prospectively-determined rate categories of hospice care (routine home care (RHC), CHC, IRC, and GIP), based on each day a qualified Medicare beneficiary is under hospice care (once the individual has elected). This per diem payment is to include all of the hospice services and items needed to manage the beneficiary's care, as required by section 1861(dd)(1) of the Act. There has been little change in the hospice payment structure since the benefit's inception. The per diem rate based on level of care was established in 1983, and this payment structure remains today with some adjustments, as noted below.

1. Omnibus Budget Reconciliation Act of 1989

Section 6005(a) of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101-239) amended section 1814(i)(1)(C) of the Act and provided changes in the methodology concerning updating the daily payment rates based on the hospital market basket percentage increase applied to the payment rates in effect during the previous federal fiscal year.

2. Balanced Budget Act of 1997

Section 4441(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33) established that updates to the hospice payment rates beginning FY 2002 and subsequent FYs be the hospital market basket percentage increase for the FY.

3. FY 1998 Hospice Wage Index Final Rule

The FY 1998 Hospice Wage Index final rule (62 FR 42860), implemented a new methodology for calculating the hospice wage index and instituted an annual Budget Neutrality Adjustment Factor (BNAF) so aggregate Medicare payments to hospices would remain budget neutral to payments calculated using the 1983 wage index.

¹ Hospices are also subject to additional Federal civil rights laws, including the Age Discrimination Act, Section 1557 of the Affordable Care Act, and conscience and religious freedom laws.

4. FY 2010 Hospice Wage Index Final Rule

The FY 2010 Hospice Wage Index and Rate Update final rule (74 FR 39384) instituted an incremental 7-year phase-out of the BNAF beginning in FY 2010 through FY 2016. The BNAF phase-out reduced the amount of the BNAF increase applied to the hospice wage index value, but was not a reduction in the hospice wage index value itself or in the hospice payment rates.

5. The Affordable Care Act

Starting with FY 2013 (and in subsequent FYs), the market basket percentage update under the hospice payment system referenced in sections 1814(i)(1)(C)(ii)(VII) and 1814(i)(1)(C)(iii) of the Act is subject to annual reductions related to changes in economy-wide productivity, as specified in section 1814(i)(1)(C)(iv) of the Act.

In addition, sections 1814(i)(5)(A) through (C) of the Act, as added by section 3132(a) of the Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148), required hospices to begin submitting quality data, based on measures specified by the Secretary of the Department of Health and Human Services (the Secretary), for FY 2014 and subsequent FYs. Beginning in FY 2014, hospices that fail to report quality data have their market basket percentage increase reduced by 2 percentage points.

Section 1814(a)(7)(D)(i) of the Act, as added by section 3132(b)(2) of the PPACA, required, effective January 1, 2011, that a hospice physician or nurse practitioner have a face-to-face encounter with the beneficiary to determine continued eligibility of the beneficiary's hospice care prior to the 180th day recertification and each subsequent recertification, and to attest that such visit took place. When implementing this provision, we finalized in the FY 2011 Hospice Wage Index final rule (75 FR 70435) that the 180th day recertification and subsequent recertifications would correspond to the beneficiary's third or subsequent benefit periods. Further, section 1814(i)(6) of the Act, as added by section 3132(a)(1)(B) of the PPACA, authorized the Secretary to collect additional data and information determined appropriate to revise payments for hospice care and other purposes. The types of data and information suggested in the PPACA could capture accurate resource utilization, which could be collected on claims, cost reports, and possibly other mechanisms, as the Secretary determined to be appropriate. The data

collected could be used to revise the methodology for determining the payment rates for RHC and other services included in hospice care, no earlier than October 1, 2013, as described in section 1814(i)(6)(D) of the Act. In addition, we were required to consult with hospice programs and the Medicare Payment Advisory Commission (MedPAC) regarding additional data collection and payment revision options.

6. FY 2012 Hospice Wage Index Final Rule

In the FY 2012 Hospice Wage Index final rule (76 FR 47308 through 47314) we announced that beginning in 2012, the hospice aggregate cap would be calculated using the patient-by-patient proportional methodology, within certain limits. We allowed existing hospices the option of having their cap calculated through the original streamlined methodology, also within certain limits. As of FY 2012, new hospices have their cap determinations calculated using the patient-by-patient proportional methodology. If a hospice's total Medicare payments for the cap year exceed the hospice aggregate cap, then the hospice must repay the excess back to Medicare.

7. FY 2015 Hospice Wage Index and Payment Rate Update Final Rule

The FY 2015 Hospice Wage Index and Rate Update final rule (79 FR 50452) finalized a requirement that the Notice of Election (NOE) be filed within 5 calendar days after the effective date of hospice election. If the NOE is filed beyond this 5-day period, hospice providers are liable for the services furnished during the days from the effective date of hospice election to the date of NOE filing (79 FR 50474). Similar to the NOE, the claims processing system must be notified of a beneficiary's discharge from hospice or hospice benefit revocation within 5 calendar days after the effective date of the discharge or revocation (unless the hospice has already filed a final claim) through the submission of a final claim or a Notice of Termination or Revocation (NOTR).

The FY 2015 Hospice Wage Index and Rate Update final rule (79 FR 50479) also finalized a requirement that the election form include the beneficiary's choice of attending physician and that the beneficiary provide the hospice with a signed document when he or she chooses to change attending physicians.

In addition, the FY 2015 Hospice Wage Index and Rate Update final rule (79 FR 50496) provided background, eligibility criteria, survey respondents,

and implementation of the Hospice Experience of Care Survey for informal caregivers. Hospice providers were required to begin using this survey for hospice patients as of 2015.

Finally, the FY 2015 Hospice Wage Index and Rate Update final rule required providers to complete their aggregate cap determination not sooner than 3 months after the end of the cap year, and not later than 5 months after, and remit any overpayments. Those hospices that failed to timely submit their aggregate cap determinations had their payments suspended until the determination is completed and received by the Medicare contractor (79 FR 50503).

8. IMPACT Act of 2014

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185) became law on October 6, 2014. Section 3(a) of the IMPACT Act mandated that all Medicare certified hospices be surveyed every 3 years beginning April 6, 2015 and ending September 30, 2025. In addition, section 3(c) of the IMPACT Act requires medical review of hospice cases involving beneficiaries receiving more than 180 days of care in select hospices that show a preponderance of such patients; section 3(d) of the IMPACT Act contains a new provision mandating that the cap amount for accounting years that end after September 30, 2016, and before October 1, 2025 be updated by the hospice payment update rather than using the consumer price index for urban consumers (CPI-U) for medical care expenditures.

9. FY 2016 Hospice Wage Index and Payment Rate Update Final Rule

In the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47172), we created two different payment rates for RHC that resulted in a higher base payment rate for the first 60 days of hospice care and a reduced base payment rate for subsequent days of hospice care. We also created a Service Intensity Add-on (SIA) payment payable for services during the last 7 days of the beneficiary's life, equal to the CHC hourly payment rate multiplied by the amount of direct patient care provided by a registered nurse (RN) or social worker that occurs during the last 7 days (80 FR 47177).

In addition to the hospice payment reform changes discussed, the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47186) implemented changes mandated by the IMPACT Act, in which the cap amount for accounting years that end after September 30, 2016

and before October 1, 2025 is updated by the hospice payment update percentage rather than using the CPI-U. This was applied to the 2016 cap year, starting on November 1, 2015 and ending on October 31, 2016. In addition, we finalized a provision to align the cap accounting year for both the inpatient cap and the hospice aggregate cap with the fiscal year for FY 2017 and thereafter. Finally, the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47144) clarified that hospices must report all diagnoses of the beneficiary on the hospice claim as a part of the ongoing data collection efforts for possible future hospice payment refinements.

10. FY 2017 Hospice Wage Index and Payment Rate Update Final Rule

In the FY 2017 Hospice Wage Index and Rate Update final rule (81 FR 52160), we finalized several new policies and requirements related to the HQR. First, we codified our policy that if the National Quality Forum (NQF) made non-substantive changes to specifications for HQR measures as part of the NQF's re-endorsement process, we would continue to utilize the measure in its new endorsed status, without going through new notice-and-comment rulemaking. We would continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed measures we have adopted for the HQR; determinations about what constitutes a substantive versus non-substantive change would be made on a measure-by-measure basis. Second, we finalized two new quality measures for the HQR for the FY 2019 payment determination and subsequent years: Hospice Visits when Death is Imminent Measure Pair and Hospice and Palliative Care Composite Process Measure-Comprehensive Assessment at Admission (81 FR 52173). The data collection mechanism for both of these measures is the HIS, and the measures were effective April 1, 2017. Regarding the CAHPS® Hospice Survey, we finalized a policy that hospices that receive their CMS Certification Number (CCN) after January 1, 2017 for the FY 2019 Annual Payment Update (APU) and January 1, 2018 for the FY 2020 APU will be exempted from the Hospice Consumer Assessment of Healthcare Providers and Systems (CAHPS®) requirements due to newness (81 FR 52182). The exemption is determined by CMS and is for 1 year only.

D. Trends in Medicare Hospice Utilization

Since the implementation of the hospice benefit in 1983, there has been

substantial growth in hospice utilization. The number of Medicare beneficiaries receiving hospice services has grown from 513,000 in FY 2000 to over 1.5 million in FY 2018. Medicare hospice expenditures have risen from \$2.8 billion in FY 2000 to approximately \$18.7 billion in FY 2018. CMS' Office of the Actuary (OACT) projects that hospice expenditures are expected to continue to increase, by approximately 8.5 percent annually, reflecting an increase in the number of Medicare beneficiaries, more beneficiary awareness of the Medicare hospice benefit for end-of-life care, and a growing preference for care provided in home and community-based settings.

As a part of our ongoing analysis of hospice utilization trends, we examined the distribution of total hospice days by level of care. A review of claims over the last 10 years shows that RHC remains the highest utilized level of care, accounting for an average of 97.6 percent of total hospice days; GIP accounting for 1.7 percent of total hospice days; CHC accounting for 0.4 percent of total hospice days; and, IRC accounting for 0.3 percent of total hospice days.

There have also been notable changes in the diagnosis patterns among Medicare hospice enrollees. At the time of the implementation of the Medicare hospice benefit, cancer diagnoses were the most frequently reported diagnoses. However, there has been a significant increase in the reporting of neurologically-based diagnoses, including Alzheimer's disease, which has been the top-reported diagnosis on hospice claims since 2014. In the FY 2014 hospice final rule (78 FR 48242), we clarified that "Debility" or "adult failure to thrive" should not be used as a principal hospice diagnosis on the Hospice claim form per ICD-9-CM Coding Guidelines. Since this clarification, there has been an increase in the reporting of neurological conditions as the principal diagnosis on hospice claims. Our ongoing analysis of diagnosis reporting trends finds that neurological and organ-based failure conditions remain top-reported principal diagnoses.

In the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47201), we clarified that hospices are to report all diagnoses identified in the initial and comprehensive assessments on hospice claims, whether related or unrelated to the terminal prognosis of the individual, effective October 1, 2015. Analysis of FY 2018 hospice claims show that 100 percent of claims included at least one diagnosis, 90.3 percent of claims included at least two

diagnoses, and 82.1 percent of claims included at least three diagnoses.

III. Provisions of the Final Rule

A. Rebasing of the Continuous Home Care, Inpatient Respite Care, and General Inpatient Care Payment Rates for FY 2020

1. Background

Sections 1812(d), 1813(a)(4), 1814(a)(7), 1814(i), and 1861(dd) of the Act, and our regulations in part 418, establish eligibility requirements, payment standards and procedures; define covered services; and delineate the conditions a hospice must meet to be approved for participation in the Medicare program. Part 418, subpart G, provides for a per diem payment in one of four prospectively-determined rate categories of hospice care (RHC, CHC, IRC, and GIP), based on each day a qualified Medicare beneficiary is under a hospice election. These per diem payments include reimbursement for all of the hospice services and items needed to manage the beneficiary's care, as required by section 1861(dd)(1) of the Act. There has been little change in the hospice payment structure since the benefit's inception. The per diem rate based on level of care was established in 1983, and this payment structure remains today.

We originally set the base payment rates for each level of care in 1983 using information from a relatively small set (n=26) of hospices that were participating in a CMS hospice demonstration. As a result of technological changes to providing hospice care that have occurred since the early 1980's, as well as changes in the patient population that uses the hospice benefit, it is possible that the current per diem payment rates for the Medicare hospice benefit do not align accurately with the costs of providing care. Since the establishment of the hospice benefit, the base payment rates have been updated through the years to primarily account for inflation, but we have not implemented any large scale changes to reflect non-inflationary changes in costs over time, with the exception of the bifurcation of the RHC payment rate and the creation of the SIA payment finalized in the FY 2016 Hospice Wage Index and Payment Rate Update final rule implemented on January 1, 2016 (80 FR 47142). For over a decade, MedPAC and other organizations reported findings that suggested that the hospice benefit's fixed per-diem payment system was inconsistent with the true variance of service costs over the course of an episode.

In the FY 2020 proposed rule (84 FR 17577) we described the information that was collected on hospice claims effective April 1, 2014 and additional changes in reporting requirements over the following years.² The revised cost report expands data collection requirements to supply greater detail related to hospice costs by level of care. Hospices are required to report all direct patient care costs by multiple cost categories into the respective level of care. MedPAC, the Government Accountability Office (GAO), and the Office of the Inspector General (OIG) have all recommended that CMS collect more comprehensive data to better evaluate trends in utilization of the Medicare hospice benefit.

Effective for cost reporting periods beginning on or after October 1, 2014, freestanding hospices are required to file the revised hospice cost report (Form CMS–1984–14). Provider-based hospices began using the revised cost report form for cost reporting periods beginning on or after October 1, 2015. The revised cost report expands data collection requirements to supply greater detail related to hospice costs by level of care. Hospices are required to report all direct patient care costs by multiple cost categories into the respective level of care. Within the revised cost report changes in 2014, there were modifications in the manner in which general service costs and statistical information is accumulated by the hospice and an expansion of the general service cost centers. Instructions for completing the freestanding hospice cost report (Form CMS–1984–14) are found in the Medicare Provider Reimbursement Manual—Part 2, Chapter 43.³

In its March 2018 Report to the Congress, MedPAC stated Medicare's payment rates for the CHC, IRC and GIP levels of care appear to be lower than the average and median costs per day for freestanding providers and suggested that rebalancing the payment rates may be warranted.⁴ Additionally, we received public comments on past rules that indicated the payment rates for CHC, IRC and GIP are much different

from the average costs of providing those levels of care.

2. Methodology and Analysis of Costs per Day for Continuous Home Care, Inpatient Respite Care, and General Inpatient Care

a. Hospice Cost Report Data

Using information collected from the revised hospice cost report, for the first time, we are able to estimate hospices' average costs per day by level of care. As required by section 1814(i)(1)(A) of the Act, payment for hospice services must be an amount equal to the costs which are reasonable and related to providing hospice care, or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations. Therefore, given that we now have several years' worth of cost report data from the revised hospice cost report, we calculated the average costs per day by level of care and compared such costs to the per diem payment rates by level of care to determine if there is a misalignment between payment and costs and whether the per diem payment rates for CHC, IRC, and GIP should be rebased. To conduct this analysis, we used a variety of different data sources, including cost reports and hospice claims data. In the FY 2020 proposed rule, we provided a walkthrough of the methodology and analysis of costs per day for continuous home care, inpatient respite care, and general inpatient care (84 FR 17578). For this final rule, although we used more recent cost report and claims data (still covering FY 2017), the methodology to calculate such costs remains the same as in the FY 2020 proposed rule.

Our analysis was based on information obtained from the Healthcare Cost Report Information System (HCRIS). The hospice cost report data contains cost and statistical data for freestanding and provider-based hospice providers. To determine the average per-day costs of providing hospice services, we conducted initial analysis of both freestanding and provider-based hospice cost reports.⁵

As mentioned in the FY 2020 proposed rule (84 FR 17578), to create the initial analytic file, we took a number of data cleaning steps to exclude certain hospices such as excluding a small number of hospices (as represented by CCN) that had multiple FY 2017 cost reports in the HCRIS cost report data file (exclusion 1). For those hospices, we kept the cost

report that covered the greatest length of time in FY 2017.⁶ We eliminated SNF, HHA, and hospital cost reports that did not contain a hospice CCN (exclusion 2); and we eliminated cost reports (as represented by CCN) due to the same CCN listed multiple times (that is, there might be two separate reports of RHC costs for the same CCN within a provider-based cost report, or a CCN appeared in a freestanding cost report as well as appeared in a provider based cost report)(exclusion 3). In order to limit each hospice to one single cost report, we selected the cost report with the highest RHC cost.⁷

Next, we constructed a series of flags to identify hospice cost reports that did not fill out fields that we would expect hospices to report (for example, nursing services). We identified those cost report fields using information from the Provider Reimbursement Manual—Part 2, Provider Cost Reporting Forms and Instructions, Chapter 43, Form CMS–1984–14, Transmittal 3, dated April 13, 2018, that updated cost reporting instructions for freestanding hospice cost reports.⁸ These instructions describe a number of new Level I edit conditions that required freestanding hospices to fill out certain parts of their cost reports effective for freestanding hospice cost reports with a reporting period that ended on or after December 31, 2017.

Finally, to remove outliers from this analysis, we applied another set of exclusions as described in the FY 2019 Hospice Wage Index and Payment Rate Update proposed rule (83 FR 20948). For each calculated outcome (for example, average RHC costs per day), we excluded those values that are above the 99th percentile and those values that are below the 1st percentile. We refer to this trim as the “1% Trim”. After applying the trimming exclusions, including the Level I edits, 1,232 freestanding hospice cost reports remained as noted in Table 1 below:

² CMS Transmittal 2864. Additional Data Reporting Requirements for Hospice Claims. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2864CP.pdf>.

³ The Provider Reimbursement Manual—Part 2. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935.html>.

⁴ Medicare Payment Advisory Commission (MedPAC). “Hospice Services.” *Report to the Congress: Medicare Payment Policy*. Washington, DC. March 2018. P. 341. http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch12_sec.pdf?sfvrsn=0.

⁶ We determined the length of the cost report by subtracting the cost reports fiscal year begin date from the cost reports fiscal year end date.

⁷ For example, in one home health agency-based cost report, the home health agency reported costs for the same hospice CCN three different times on the same cost report.

⁸ Medicare Provider Reimbursement Manual—Part 2, Provider Cost Reporting Forms and Instructions, Chapter 43, Form CMS–1984–14. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R3P243.pdf>.

⁵ Cost reports from FY 2017 had a start date on or after October 1, 2016 and before October 1, 2017.

TABLE 1—NUMBER OF FY 2017 FREESTANDING HOSPICE COST REPORTS AFTER THE LEVEL I EDITS EXCLUSION AND 1% TRIM

Level of care	Number of cost reports after exclusions	Number of days by level of care (FY2017)
RHC	1,109	43,255,420
GIP	817	790,195
CHC	440	187,554
IRC	915	135,384

Note: We begin with the 3,223 freestanding cost reports that remained after applying exclusions in 1–3. After applying the Level I edits, 1,232 freestanding cost reports remained. Not all cost reports contain information on each level of care. Numbers noted above indicate the number of cost reports available for analysis for each level of care after all exclusions, including the 1% trim are applied.

b. Hospice Claims Data

We created an analytic data set based on Medicare hospice claims downloaded from the Chronic Condition Data Warehouse—Virtual Research Data Center (CCW VRDC) to examine hospice utilization on specific days during FY 2017. We assigned a wage index (using the FY 2017 hospice wage indices) to each day of hospice service based on the core-based statistical area (CBSA) where a particular day's hospice services took place.⁹ We merged information from the June 2018 release of the CMS Provider of Services (POS) file to identify characteristics of each hospice including: Ownership type, census division (based on the hospice's state), and whether the hospice's main office was located either in an urban or rural

location. This data was used in the subsequent section in calculating costs per day by level of care.

c. Calculating Costs per Day by Level of Care

In order to compute the average cost per day for each level of care using information from the freestanding hospice cost reports, after applying the exclusions, we made several adjustments to the average cost calculations, as described in the FY 2020 proposed rule (84 FR 17580).

It is important to calculate average costs after removing any regional differences that may be driven by wages, otherwise we would over-adjust for wage differences across regions. For example, we remove the wage differences in RHC costs by calculating the following value for each hospice:

Adjusted RHC cost per day = (RHC cost per day from 2017 cost reports) * (0.6871) / (Hospice's average wage index for all RHC days in FY 2017) + (RHC cost per day from 2017 cost reports) * (1 – 0.6871)

Note: 0.6871 is the labor share used to wage index adjust RHC payments.

We perform a similar calculation for the other levels of care using the corresponding cost per day from FY 2017 cost reports and the appropriate labor share for CHC, IRC, and GIP. For example, the adjusted GIP cost per day uses the same formula, but instead includes GIP cost per day from FY 2017 cost reports, the hospice's average wage index for all GIP days in the formula, and the GIP labor share of 64.01 percent.

Due to exclusions mentioned previously, not all hospices that submitted claims during FY 2017 have a corresponding cost report in our final sample. As a result, the characteristics of the sample of cost reports used to calculate average cost per day for each level of care do not necessarily match up with the characteristics of all

hospices that submitted claims during FY 2017. If not accounted for, our sample of cost reports may over represent certain types of hospices. To correct for this, we categorize each hospice in our sample by facility type,¹⁰ ownership type,¹¹ urban/rural status,¹² and size.¹³

For each category of hospices and the calculations for each level of care, we use the following steps:

1. Using claims, we compute the total number of days provided in FY 2017 by all hospices within a particular category;
2. We compute the total number of days, as reported on the claims provided in FY 2017, using only the hospices in our trimmed sample of cost reports within a particular category; and

3. For each level of care and each category of hospices, we construct a ratio using the value in Step 1 over the value in Step 2.

For each cost report in our sample, we multiply each provider's days (as reported on claims) by level of care by the ratio in order to make the sample cost reports more representative of the overall population of hospices. We then multiply the provider's average per diem cost as reported on the cost report times the number of adjusted days from the prior step to yield total costs by level of care for that provider. We then compute the weighted average for each level of care by summing across hospices the total costs by level of care divided by the sum of the adjusted days across the cost reports in our sample.¹⁴

$$\text{Weighted Average IRC Cost Per Day} = \frac{\sum_{i=1}^n \text{Cost}_i * \text{Number of Days}_i}{\sum_{i=1}^n \text{Number of Days}_i}$$

Medicare pays for the CHC level of care using a per hour rate instead of a per day rate. We calculated each hospice's hourly cost of CHC by taking their CHC cost per day from the hospice

cost report and dividing it by their average number of hours of CHC provided on CHC days occurring in FY 2017 as reported on each hospice's claims. Each hospice's CHC cost per

hour (adjusted by average number of hours of CHC) is then averaged (using the weighted average formula discussed above) across all hospices in our sample to create the overall average of CHC cost

⁹ FY 2017 Final Hospice Wage Index. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Hospice-Wage-Index/FY-2017-Final-Hospice-Wage-Index.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending>.

¹⁰ Freestanding versus provider-based.

¹¹ We only divide the freestanding cost reports into ownership type categories. We use the ownership type categories from the POS: For-profit, government, non-profit, and other. Due to limited sample size we do not break out the provider-based hospices into ownership type.

¹² Urban/rural status is reported on the POS and corresponds to the mailing address of the hospice.

¹³ We divide hospices into three categories based on their number of RHC days in FY 2017: Large (>=20,000 RHC days), medium (3,500–19,999 RHC days), and small (0–3,499 RHC days).

¹⁴ The formula describes the average cost per day calculation for IRC, however, the same formula can be adapted for each level of care.

per hour. To convert the CHC cost per hour into a CHC cost per day we multiply the average CHC cost per hour by 24 hours. It is important to note that each hospice's hourly CHC cost is based on their average number of CHC minutes per day, which is less than 24 hours. That means a full CHC per day payment (which covers 24 hours) will be larger than the average CHC cost per day (which covers a time period less than 24 hours). Applying all of the steps as described above and in the FY 2020 proposed rule, average costs per day by level of care in FY 2017 are listed in Table 2 below:

TABLE 2—AVERAGE COST PER DAY BY LEVEL OF CARE, FY 2017

Level of care	Average cost per day
RHC	\$130.85
CHC (24 Hours)	1,307.76
CHC (Per Hour)	54.49
IRC	441.03

TABLE 2—AVERAGE COST PER DAY BY LEVEL OF CARE, FY 2017—Continued

Level of care	Average cost per day
GIP	952.56

The current payment system pays hospices a two-tiered rate for RHC. RHC days during the first 60 days are paid a higher per diem rate compared to any RHC days after day 60. Hospice do not report RHC costs separately for the first 60 days versus RHC days after day 60. However, we can estimate the RHC costs in the first 60 days versus after 60 days by making the same assumption that was made to calculate the two-tiered payment. That is, in the FY 2016 hospice final rule (80 FR 47166), we calculated resource use ratios to determine the differences in resource utilization for the first 60 days and any RHC days after day 60. For the creation of the two-tiered RHC rate (80 FR 47166), the following ratios were used:

- *Days 1 through 60:* The ratio of average resource use for RHC days in days 1 through 60 to average resource use across all RHC days was 1.2603 to 1.

- *Days 61 and beyond:* The ratio of average resource use for RHC days after day 60 to the average resource use across all RHC days was 0.8722 to 1.

We multiplied the labor share component of the average cost per day for RHC in FY 2017 by the corresponding resource use ratio to calculate the average cost per day for the first 60 days and any RHC days after 60 days. We only applied the resource ratio to the labor share component because the resource ratio is calculated using minutes of direct patient care as reported on the claims. This approach is consistent with what was done in the FY 2016 hospice final rule (80 FR 47166) to construct the two-tiered payment. The resulting average cost per day for RHC is shown in Table 3.

TABLE 3—AVERAGE RHC COSTS
[FY 2017 per day for days 1 through 60 and days 61+]

RHC level of care	Average cost per day	Resource use ratio (only applied to the labor share, which is 68.71% of the RHC payment rate)	Average cost per day in FY2017 (based on days of RHC)
Days 1–60	\$130.85	1.2603	\$154.25
Days 61+	130.85	0.8722	119.36

To determine if there is any misalignment between the average costs of providing CHC, IRC and GIP and the per diem payment rates for these levels of care, we inflated the average costs in FY 2017 to FY 2019 dollars. We did this

by multiplying the average FY 2017 costs by level of care by the hospice market basket update for FY 2018 (82 FR 36649) and FY 2019 (83 FR 38630) less the multifactor productivity (MFP) adjustments corresponding to each year.

The estimated average costs for FY 2019 (that is, taking the average FY 2017 cost per day by each level of care inflated to FY 2019 dollars) is detailed in Table 4.

TABLE 4—ESTIMATED AVERAGE COSTS (FY 2019) FOR CHC, IRC, AND GIP

Level of care	FY 2017 average costs	FY 2018 hospice market basket update less productivity adjustment	FY 2019 hospice market basket update less productivity adjustment	FY 2019 estimated average costs
CHC (per Hour)	\$54.49	x1.021	x1.021	\$56.80
IRC	441.03	x1.021	x1.021	459.75
GIP	952.56	x1.021	x1.021	992.99

We also analyzed the average costs of RHC for the first 60 days and any RHC days after day 60 inflated from FY 2017 dollars to FY 2019 dollars by applying

the hospice market basket update for FY 2018 and FY 2019 less the MFP adjustments corresponding to each year. The estimated average costs for RHC by

days for FY 2019 is shown in Table 5 below.

TABLE 5—ESTIMATED AVERAGE COSTS FOR RHC (FY 2019) DAYS 1 THROUGH 60 AND DAYS 61+

Level of care	FY 2017 average costs	FY 2018 hospice market basket update less productivity adjustment	FY 2019 hospice market basket update less productivity adjustment	FY 2019 estimated average costs
RHC Days 1–60	\$154.25	x1.021	x1.021	\$160.80
RHC Days 61+	119.36	x1.021	x1.021	124.43

We then compared the FY 2019 average costs for CHC, IRC and GIP to the FY 2019 payment rates for these three levels of care. Our analysis shows that there is a misalignment between average costs and payment for these

three levels of care. Table 6 below shows the percent of total hospice days by level of care; the estimated average FY 2019 costs by level of care; the current FY 2019 per diem payment rates; and the estimated percent increase

to the payment rates to more accurately align the per diem payments for CHC, IRC and GIP with the costs of providing these levels of care.

TABLE 6—COMPARISON OF FY 2019 AVERAGE COSTS TO PAYMENTS FOR CHC, IRC, AND GIP

Level of care	Percent of days by level of care in FY 2018 *	Estimated FY 2019 average costs per day	FY 2019 per diem payment rates	Estimated percent payment increase needed to align with costs
CHC	0.2	\$1,363.26/\$56.80 (per hour).	\$997.38/\$41.56	+36.6
IRC	0.3	\$459.75	176.01	+161.2
GIP	1.3	\$992.99	758.07	+31.0

* **Note:** We used the FY 2018 percent of days by level of care as this is the most current data available.

We also compared the FY 2019 average costs for RHC for the first 60 days and for any RHC days after day 60 to the FY 2019 payment rates for RHC and the percentage difference between payment and average costs. The percent

difference between costs and payment represents how much we would need to reduce the RHC payments in order to align payments with costs. The results are shown in Table 7 below. However, we did not propose to rebase the RHC

payment rates as any changes to the CHC, IRC, and GIP payment rates must be done in a budget-neutral manner as required by law.

TABLE 7—COMPARISON OF FY 2019 AVERAGE COSTS TO PAYMENT FOR RHC

Level of care	Estimated FY 2019 average costs per day	FY 2019 payment rates	Percent difference between costs and payment
RHC Days 1–60	\$160.80	\$196.25	– 18.1
RHC Days 61+	124.43	154.21	– 19.3

3. Rebasing of the CHC, IRC, and GIP Payment Rates for FY 2020

As described in the proposed rule (84 FR 17582) and in this final rule, the average costs of providing CHC, IRC and GIP are significantly higher than the payment amounts for these three levels of care. Using the hospice payment reform authority under section 1814(i)(6) of the Act, in the FY 2020 proposed rule., we proposed to rebase the payment rates for CHC, IRC, and GIP by setting these payment amounts equal to the FY 2019 estimated average costs per day, as described in the methodology above, before application of the hospice payment update percentage outlined in section III.B.3 of

this final rule. Using the updated cost report and claims data as shown previously in this final rule, the rebased payment rates for CHC, IRC, and GIP are as follows:

TABLE 8—REBASED PAYMENT RATES FOR CHC, IRC, AND GIP *

Level of care	Rebased payment rates *
Continuous Home Care (CHC).	\$56.80 per hour/ \$1,363.26 (per day).**
Inpatient Respite Care (IRC).	\$437.86.***
General Inpatient Care (GIP).	\$992.99.

* Prior to application of the hospice payment update of 2.6 percent outlined in section III.B.3 of this final rule.

** Based on a full CHC per day payment (which covers 24 hours).

*** IRC payment rate accounts for 5 percent coinsurance (\$459.75/1.05 = \$437.86).

Section 1813(a)(4)(A)(ii) of the Act states that the amount payable for hospice care shall be reduced in the case of respite care provided by (or under arrangements made by) the hospice program, by a coinsurance amount equal to 5 percent of the amount estimated by the hospice program (in accordance with regulations of the Secretary) to be equal to the amount of payment under section 1814(i) to that program for respite care. To ensure payments (both paid by Medicare and collected from the beneficiary via coinsurance) under a rebased IRC rate

equal the average per-diem cost of IRC, we set the rebased IRC payment rate equal to the average per-diem cost of IRC divided by 1.05. The amount of the individual's coinsurance liability for respite care during a hospice coinsurance period may not exceed the inpatient hospital deductible applicable for the year in which the hospice coinsurance period began. The individual hospice coinsurance period begins on the first day an election is in effect for the beneficiary and ends with the close of the first period of 14 consecutive days on each of which an election is not in effect for the beneficiary.

Section 1814(i)(6)(D)(ii) of the Act requires that any revisions to the methodology for determining the payment rates for other services included in hospice care to be done in a budget-neutral manner in the fiscal year in which such revisions in payment are implemented as would have been made for care in the fiscal year if such revisions had not been implemented. The results of the calculations demonstrated in the FY 2020 proposed rule (84 FR 17583) show that in order to rebase the payment rates for the CHC, IRC, and GIP levels of care in a budget-neutral manner, the RHC payment rates would need to be reduced by 2.71 percent. The 2.71 percent reduction would be applied to the RHC payment rates for the first 60 days and RHC days after day 60. However, using more recent claims data for this final rule, these same calculations show that the actual reduction to the RHC payment rate would need to be 2.72 percent. To calculate the 2.72 percent reduction to the RHC payment rates, we first calculated two sets of payments using different payment parameters.

1. Total payments for hospice days provided during FY 2018 under the existing FY 2019 payment rates and FY 2019 wage indices.

2. Total payments for hospice days provided during FY 2018 under a new RHC payment rate and the rebased payment rates for CHC, IRC, and GIP.

We set the RHC payment rate in step (2) equal to the value that makes total payments between step (1) and step (2) equivalent. We calculate that rate using the following steps:

1. We calculate the difference in Medicare payments when using the rebased CHC, IRC, and GIP payment rates instead of the payment rates in place during FY 2019.

2. We calculate one minus the value from Step (1) over the RHC payments

made under the payment rates in place during FY 2019.¹⁵

3. We multiply the value in Step (2) by each RHC payment rate (the first 60 days and any RHC days after day 60) in place during FY 2019 to establish the budget-neutral RHC payment rates (the first 60 days and any RHC days after day 60).

The calculated payment rates in Step (3) will make the total payments made under the rebased FY 2019 payment rates equal to the total payments made under the existing FY 2019 payment rates. Essentially, the reduction is the weighted difference between non-RHC costs and payments divided by the weighted RHC payments, where the weights are the percent of days by level of care.

The results of this calculation demonstrate that in order to rebase the payment rates for the CHC, IRC, and GIP levels of care in a budget neutral manner, the RHC payment rates would need to be reduced by 2.72 percent. The 2.72 percent reduction would be applied to the RHC payment rates for the first 60 days and RHC days after day 60 (that is, we would take each of the RHC payment rates and multiply by the 0.9728 to determine the FY 2019 RHC payment rates).

Therefore, in order to offset the increases in payment rates to the CHC, IRC, and GIP levels of care, we would reduce the RHC payment rates by 2.72 percent in order to implement rebasing in a budget-neutral manner in FY 2020. However, reducing the RHC payment rate to a level equal to the estimated RHC costs would require a reduction in the RHC payment rate that exceeds the 2.72 percent. Therefore, while we are rebasing the per diem payment rates for CHC, GIP, and IRC to more accurately align the payment with costs, the reduction to the RHC payment rates is not considered rebasing as the 2.72 percent reduction does not bring the RHC payment in alignment with the costs of providing this level of care. The purpose of the 2.72 percent reduction to the RHC payment rates is to ensure that the revisions to the payment rates for CHC, GIP and IRC are made in a budget-neutral manner, in accordance with the law.

We received 113 unique comments regarding the rebasing methodology and

analysis, as well as the rebased payment rates for CHC, IRC, and GIP. Most of these comments were from hospices, industry associations and other relevant stakeholders, including comments from the Medicare Payment Advisory Commission (MedPAC). These comments are summarized below along with our responses:

Comment: Several commenters were supportive of CMS' proposal to rebase the per diem payment amounts for CHC, GIP and IRC in order to ensure that payments are closer to the estimated cost of providing each level of care. Commenters stated that rebasing the rates for these three levels of care addresses concerns that hospices lose money on the increased costs of providing more complex medical management. These commenters stated that hospices often have to pay contractors and the facilities providing this increased level of care more than the payment rates the hospices are currently receiving. Further, commenters suggested that, were CMS to finalize this proposal, the potential increase in availability of hospices to provide these levels of care would benefit patients and their caregivers. A few commenters stated that rebasing the CHC, GIP, and IRC rates would benefit rural hospices who have fewer facilities and contractors with which to provide this care.

Response: We thank commenters for their thoughtful review and support of our efforts to better align hospice costs of providing care for patients receiving CHC, GIP, and IRC and to support hospices working with outside contractors and facilities. We agree that rebasing these rates would adequately cover the costs of providing these higher intensity levels of care, could ensure that hospices have access to the providers needed to comply with the hospice Conditions of Participation (CoPs), and promote patient access to all levels of care.

Comment: CMS received several comments about the large number of cost reports eliminated with exclusion 2 (that is, we eliminated SNF, HHA and hospital cost reports that did not contain a hospice CCN) and as reported in Table 2 of the proposed rule (84 FR 17578). Many commenters also mentioned that CMS used cost reports for FY 2017 and applied Level I edits; however, the edits went into effect for cost reporting periods that ended on or after December 31, 2017. These commenters expressed concern that CMS applied the Level I edits to freestanding and provider-based cost reports even though the edits were not applicable to provider-based cost

¹⁵ Using the average per-diem costs generated from our sample of freestanding hospice cost reports, rebasing CHC, IRC, and GIP results in extra payments of \$468,223,480.70 for those levels of care. The RHC payments that were made under the payment rates in place during FY 2019 were \$17,238,380,386.58. One minus the value of the extra payments over the RHC payments equals 0.9728.

reports for 2017 or subsequent cost reports thus stating we shouldn't use them in our analysis. Several commenters recommended that CMS include provider-based cost reports as the sample size used for the analysis and methodology is relatively small. These commenters suggested that using larger sample of cost reports by incorporating cost reports from provider-based hospices when rebasing CHC, IRC and GIP per diem rates would provide more robust and accurate information.

Response: For the FY 2020 final rule, CMS updated the FY 2017 cost reports using the hospice cost report file <http://downloads.cms.gov/Files/hcris/HOSPC14-ALL-YEARS.zip> from the proposed rule (84 FR 17578). There are 4,195 hospice cost reports as of June 21, 2019 versus 4,125 from the proposed rule. We describe, in detail, in this final rule and in the FY 2020 hospice proposed rule (84 FR 17570), all of the exclusions applied to hospice cost reports to estimate the average cost per day by level of care. And in this final rule, we remind commenters that the final sample of cost reports is higher than described in the proposed rule (1,232 cost reports for this final rule compared to 1,120 in the proposed rule). We note that most SNFs do not have a hospice CCN associated with it, so most of the SNF cost reports were dropped. We believe that eliminating these SNF cost reports with no associated hospice CCN would more accurately filter out those costs not related to the cost of providing hospice care and where much of the reported costs may be for the provision of SNF services. Additionally, we considered proposing to use freestanding and provider-based cost reports to rebase CHC, IRC, and GIP payment rates, rather than just using freestanding cost reports. However, when we analyzed both freestanding and provider-based cost reports, the results tend to be similar. On average, incorporating provider-based cost reports results in higher costs than the cost reports for freestanding hospices only, as shown in Table 27 of the FY 2020 hospice proposed rule (84 FR 17616).

Similarly, when we rebased the national, standardized 60-day episode payment rate for home health agencies beginning in CY 2014, we estimated costs using only freestanding HHA cost reports for the same reasons detailed in the FY 2020 hospice proposed rule (that is, freestanding cost reports reflect actual hospice costs and not those additional costs borne from the parent entity). Therefore, it is not unprecedented in Medicare payment

systems to use only freestanding cost reports, rather than including provider-based cost reports for rebasing purposes.

Additionally, in MedPAC's March 2018 report to Congress, MedPAC stated that overhead costs allocated from the parent provider are included in the costs for provider-based hospices, which contributes to provider-based hospices having higher costs than freestanding hospices. If freestanding hospices are able to provide high-quality care at a lower cost than provider-based hospices, payment rates should be set accordingly, and the higher costs of provider-based hospices should not be a reason for increasing Medicare payment rates. Ultimately, we used freestanding cost reports to estimate the average cost per day by level of care.

As detailed in the FY 2020 proposed rule, we also applied Level I edits (and removed certain reports with missing data from our sample) manually because not all FY 2017 freestanding cost reports had a reporting period that ended on or after December 31, 2017. We decided to apply Level I edits based on suggestions by industry representatives to apply certain edits to force adherence to certain cost-reporting principles that could lead to the reporting of higher-quality cost data. Therefore, we believe it is most technically appropriate to apply the Level I edits. Furthermore, we show in Table 26 of the proposed rule (84 FR 17616) that the differences in costs between including and not including exclusions based on the Level I edits were minimal for RHC, CHC, and GIP. The difference between applying Level I edits versus not applying the edits is less than one dollar for RHC, CHC, and GIP. However, the IRC cost per day between the two trimming methodologies was more pronounced, but still not significantly so. In looking at FY 2017 estimated average per day costs using all of the trimming exclusions, and as shown in Table 26 in the proposed rule, the cost for IRC was \$438.97; applying all of the trimming exclusions, excluding the Level I edits, the cost for IRC was \$467.78 (a 6.6% increase). Therefore, for purposes of estimating the costs by level of care, we believe that applying the Level I edits is appropriate given these edits are now applied for hospice cost reports and there was minimal effect on the average costs per day.

Comment: Several commenters stated that many hospices do not accurately or consistently complete cost reports, thus rendering the data inaccurate. These commenters stated that because of the inaccuracies in the cost reports, CMS should not use hospice cost reports as

the source of data to estimate costs. Several commenters mentioned concerns about the accuracy of the cost report data in the FY 2017 cost reports that CMS used for their analysis and methodology. A few commenters stated that CMS did not provide additional information about which provider's data was used.

Response: We remind hospices that each hospice cost report is required to be certified by the medical officer or hospice administrator. The hospice Medicare Cost Report (MCR) form (CMS-1984-14) includes a dated and signed statement indicating that all information is true, correct, and prepared from the books and records of the provider in accordance with applicable instructions, except as noted. Additionally, as required by section § 413.24(f)(4)(iv)(A) the cost report must be signed by either the Chief Financial Officer or the Administrator. If there are errors within a cost report, they must be filed on time and if there is any type of problem with it that cannot be addressed timely, the MAC may withhold Medicare payments. Therefore, we expect and it is required that hospice cost reports contain accurate and complete data on which to base our analyses.

As always, we encourage providers to fill out the Medicare cost reports as accurately as possible. The Provider Reimbursement Manual¹⁵ provides detailed instructions on filling out the cost reports. CMS further encourages hospice providers to contact the appropriate Medicare Administrative Contractor (MAC) if additional instruction or assistance is needed. Furthermore, as the cost reports are to reflect all of the costs associated with providing hospice care by level of care, we believe that it is the most appropriate mechanism in which to estimate costs for rebasing payment rates.

Our cost report analysis was based on information obtained from the Healthcare Cost Report Information System (HCRIS). As mentioned in the proposed rule (84 FR 17578), the hospice cost report data contains cost and statistical data for freestanding and provider-based hospice providers. For the proposed rule, we used HCRIS data files from December 31, 2018. For this final rule we used more up to date cost report data from March 31, 2019. The updated data contains 4,195 hospice cost reports versus 4,125 from the

¹⁵ The Provider Reimbursement Manual—Part 2. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935.html>.

proposed rule. In our analysis, we used Worksheet S–2 to determine if the provider-based cost reports had a hospice CCN. Information regarding costs per day by level of care came from worksheet O8 for provider-based cost reports and worksheet C for freestanding cost reports. Information needed to construct the level I edits came from worksheet A for freestanding cost reports and worksheet O and O5 for provider-based cost reports. We feel confident that the cost reports that the hospice providers submit are accurate and that the signatures obtained by the administrator and or Officer are true, correct, complete, and prepared from the books and records of the provider in accordance with applicable instructions.

Comment: Several commenters disagreed with the proposal to rebase the CHC, IRC, and GIP payment rates stating that the reduction in the RHC payment rate in order to maintain budget neutrality effectively turns the rebasing proposal into a rate cut even after the proposed payment update. These commenters stated that this would create financial and staffing hardships for hospices, especially smaller rural hospices. Some commenters stated that payment adjustments that more accurately capture and compensate for differences in costs of providing hospice services in rural versus urban communities may first be necessary before CMS rebases payment rates. A few commenters stated that the effect of rebasing will be felt unevenly across providers, depending on the amount of GIP, CHC and IRC being provided by an individual hospice and that CMS should ensure that payment adjustments adequately account for differences in costs based on geography.

Response: Section 1814(i)(6)(D)(ii) of the Act requires that any revisions to the hospice payment rates be done in a budget neutral manner. Meaning the revisions in payment for GIP, IRC and CHC must result in the same estimated aggregate expenditures had the revisions not been implemented. After applying the FY 2020 hospice payment update of 2.6 percent and accounting for the rebasing of the GIP, IRC and CHC payment rates (which requires a 2.72 percent reduction to the RHC payment rate) the net result would only be a reduction of 0.19 percent to the RHC payment rate. That reduction equates to approximately 37 cents on RHC days 1 through 60 and 29 cents on days 61 plus (compared to the FY 2019 RHC payment rates). Given that MedPAC in their recent March 2019 Report recommended a 2 percent reduction to the hospice base payment rates and

projects Medicare hospice margins to be 10.1 percent for 2019, we feel the reduction to the RHC payment rate would not create financial hardships for hospices. Furthermore, in their March 2019 report, and their comments on the proposed rule, MedPAC reported that the aggregate 2016 Medicare margin, which is an indicator of the adequacy of Medicare payments relative to providers' costs, was 10.9 percent, up from 9.9 percent in 2015. They stated that hospice costs per day vary substantially by type of provider, which is one reason for differences in hospice margins across provider types. In 2016, hospice costs per day across all hospice providers were about \$149 on average, a slight decrease from \$150 in the previous year. Some of the decline in cost per day is accounted for by a shift in the mix of hospice days, with the share of days accounted for by routine home care (the lowest cost level of care) increasing in 2016. Freestanding hospices had lower costs per day than provider-based hospices (that is, home health-based hospices and hospital based hospices). For-profit, above-cap, and rural hospices also had lower average costs per day than their respective counterparts.

Our regulations at § 418.306(c) require each labor market to be established using the most current hospital wage data available, including any changes made by Office of Management and Budget (OMB) to the Metropolitan Statistical Areas (MSAs) definitions. The appropriate wage index value is applied to the labor portion of the hospice payment rate based on the geographic area in which the beneficiary resides when receiving RHC or CHC. The appropriate wage index value is applied to the labor portion of the payment rate based on the geographic location of the facility for beneficiaries receiving GIP or IRC. Overall, rural hospices would have a slight decrease (estimated to be less than 1 percent) in payments as a result of the rebased payment rates for CHC, GIP, and IRC. However, rural, non-profit HHAs will see an increase in payments, compared to rural for-profit HHAs who will see a slight decrease in payments as a result of the rebased rates.

Comment: Several commenters, including a national industry group, agreed that while the CHC, IRC, and GIP payment rates need to be increased, they expressed concern that CMS needs to examine any negative impact on access to care.

Response: We disagree that increasing the rates for CHC, IRC, and GIP would have a negative impact on access to care. Conversely, we believe that

aligning the payment with the cost of providing care should have a positive effect on access to needed levels of care. We believe that hospices who currently cannot provide adequate CHC will now have the resources to hire adequate staff to ensure patients needing CHC level of care will have the needed nursing support during a time of symptom crisis. Likewise, for those hospices who do not have their own freestanding, inpatient unit, we believe the higher payment rates for IRC and GIP will afford them more latitude when negotiating contracts with skilled nursing facilities and hospitals to best meet the needs of their patients requiring inpatient levels of care. However, we will continue to monitor the effects of these rebased rates to determine if there are any notable shifts in the provision of care or any other perverse utilization patterns that would warrant any program integrity or survey actions.

Comment: Many commenters suggested to postpone any rebasing for 2 years so that CMS has enough time to validate cost reports and accuracy of data to support the changes, or at the very least, implement a phased-in approach to increasing the payment rates for CHC, IRC, and GIP payment rates and reducing the RHC payment rates.

Response: While we understand why some hospices would prefer to postpone or phase-in rebasing of the CHC, IRC, and GIP payments and the corresponding reduction to RHC payments to maintain budget neutrality, we disagree with either of these approaches as this would not align payment with the costs of providing the higher intensity levels of care.

We will continue to monitor utilization with implementation of these rebased rates to see if there are any trends that may warrant other appropriate actions, including program integrity measures. Furthermore, a phased-in approach would require a recalculation of the RHC amount each year based on the most recent utilization of CHC, IRC and GIP. If there was an increase in utilization of those levels (CHC, IRC, GIP) we would then have to further adjust the RHC rate to account for the increase in utilization, which could further reduce the RHC rate. Likewise, even with the 2.72 percent reduction to the RHC rates, the payment for both days 1–60 and days 61+ still exceeds the cost of providing this level of care, as shown in Table 7 in this final rule.

Comment: Several commenters noted that the changes to the IRC per diem payments would make it easier to

provide respite care to patients and their families needing such support. One commenter noted that the rebasing of GIP would have a positive impact on those hospices that provide GIP in their own freestanding facilities. Hospice providers stated that this change would allow their freestanding facility to operate with positive margins for the first time. Other commenters remarked that the increased IRC rates will enable them to find nursing facilities willing to contract with them for respite stays. A large number of commenters stated that upward adjustment for CHC, GIP, and IRC is warranted given the misalignment between payment and costs.

Response: We appreciate these comments and agree that rebasing the IRC payment rate may result in greater access to inpatient respite care for terminally ill patients and their families. Likewise, the rebasing proposals help to align payment with the cost of providing care and we believe that this proposal is responsive to industry concerns and challenges related to providing these higher intensity levels of care.

Comment: Many hospices, along with MedPAC, noted concerns about creating incentives for hospices to improperly expand the use of inpatient levels of care as a result of rebasing. They suggested considering a prospective payment adjustment to GIP to maintain budget neutrality if aggregate payments increase as a result of these payment changes. MedPAC also expressed concern about the proposed increase in the GIP payment rate provided in a skilled nursing facility (SNF) and urged CMS to maintain the current payment rate of GIP provided in SNFs. MedPAC cited reports from hospice providers that it costs less to contract for GIP in a SNF than with a hospital. A few other commenters suggested that CMS reconsider increasing the GIP per diem payment rate in skilled nursing facilities (SNFs). They suggested that an increase in the payment rate for GIP would likely make providing GIP in SNFs quite profitable and could create incentives for more hospice providers to furnish GIP in SNFs. They further note that GIP care in the SNF setting tends to be less resource intensive and less costly than in a hospital or hospice facility.

Response: We believe that the rebased rates will help appropriately increase access to care but we are aware of the perverse incentives that could occur with increases in payment rates. We recognize that there may be an increase in utilization of these higher intensity levels of care but we believe that this may be appropriate to meet patient care

needs. We remind stakeholders that there are criteria for receiving these higher levels of care which may potentially buffer any inappropriate increases in utilization. Continuous home care may be provided only during a period of crisis as necessary to maintain an individual at home. Either homemaker or home health aide (hospice aide) services or both may be covered on a 24-hour continuous basis during periods of crisis but care during these periods must be predominantly nursing care. A period of crisis is a period in which a patient requires continuous care to achieve palliation or management of acute medical symptoms. The hospice must provide a minimum of 8 hours of care during a 24-hour day, which begins and ends at midnight. This care need not be continuous; for example, 4 hours could be provided in the morning and another 4 hours in the evening. In addition to the 8 hour minimum, the services provided must be predominantly nursing care, provided by either an RN, an LPN, or an LVN. Respite care is short-term inpatient care provided to the individual only when necessary to relieve the family members or other persons who normally care for the individual at home. Respite care may be provided only on an occasional basis and may not be reimbursed for more than 5 consecutive days at a time. Payment for the sixth and any subsequent day of respite care is made at the routine home care rate, and the patient would be liable for room and board. Respite care cannot be provided to hospice patients who reside in a facility (such as a long term care nursing facility). Provision of respite care depends upon the needs of the patient and of the patient's caregiver (and is subject to the regulatory limitations set out at § 418.302(e)(5)). And finally, GIP is allowed when the patient's medical condition warrants a short term inpatient stay for pain control or acute or chronic symptom management that cannot feasibly be provided in other settings.

To address MedPAC and other stakeholder comments regarding the difference in the provision of GIP in a SNF compared to an inpatient hospital, we note the current cost report does not allocate costs for GIP by site of service. Additionally, our analysis has shown that very few GIP days are provided in a SNF compared to other freestanding facilities and inpatient hospitals. Likewise, the types of hospices providing GIP in a SNF may be different in other ways compared to hospices that do not provide GIP in a SNF. It is

possible those differences are correlated with the costs.

Additionally, we continue to expect hospices to provide care in accordance with the individualized plan of care as required by the hospice CoPs at § 418.56. This means that we do not expect that hospices would move patients into higher intensity levels of care solely to receive higher payments. As mentioned in the proposed rule, we believe that rebasing the per diem payment amounts for CHC, GIP, and IRC is appropriate in order to align payments with cost of providing care. Likewise, potential, subsequent increases in utilization would not necessarily be inappropriate. Hospice providers still need to meet the necessary requirements stated in section 1861(dd) of the Act and the hospice CoPs, which require that hospice agencies regardless of size, location or other organizational or market characteristics must be able to provide all four levels of hospice care. As part of our routine monitoring of hospice utilization, we will continue to closely analyze any changes in the patterns of care in response to these rebased payment rates to determine if any additional actions are warranted.

Comment: Several commenters suggested that CMS should increase its oversight of hospice providers not delivering the services required under the hospice CoPs and exhibiting inappropriate practices highlighted by the OIG and the MedPAC.

Response: We note that compliance with the hospice CoPs is monitored through the survey process. The IMPACT Act of 2014 currently requires hospice survey/recertifications every 3 years. Survey protocols and Interpretive Guidelines are established to provide guidance to personnel conducting surveys of hospices. They serve to clarify and/or explain the intent of the regulations. All surveyors are required to use them in assessing compliance with federal requirements.¹⁶ There are different types of surveys including survey for initial certification for participation in Medicare; a recertification survey which are unannounced and must verify compliance with all the regulatory requirements contained at §§ 418.52 thru 418.116; a post-survey onsite revisit is to reevaluate the specific care and services that were cited during a previous survey that cannot be adequately assessed by mail, telephone

¹⁶ State Operations Manual Appendix M—Guidance to Surveyors: Hospice. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_m_hospice.pdf.

or electronic contact, or; a complaint investigation in which a survey is conducted to investigate and resolve a complaint against a hospice. We believe that there are already systems in place to ensure compliance with the hospice CoPs and we will continue to coordinate with the State Agencies to identify any ongoing concerns as they relate to the CoPs and to determine whether any additional oversight mechanisms need to be in place. We are committed to encouraging providers to supply the best quality care in the most appropriate ways, and we will continue to work to incentivize and monitor for the most appropriate practices in the hospice provider community.

Comment: Several commenters expressed concern that increasing the rates for IRC and GIP will result in contracted facilities raising the rates they charge hospices to provide these levels of care. Stakeholders remarked that these are essentially “pass-through payments” to contracted providers and would require hospice providers to bear the cost of providing these services while taking a large reduction to the RHC reimbursements. Some commenters stated that IRC and GIP can be supplied by hospice in various ways resulting in wide differences in costs for providing these levels of care. Commenters asserted that a small proportion of hospices operate hospice inpatient units directly, while some others are system or SNF-based and secure inpatient care through a parent entity. They suggested that the vast majority of hospice providers, more than 75 percent, enter into contracts with local hospitals or other facilities and therefore costs for inpatient days vary significantly. One commenter suggested that the estimated cost of IRC reported in the proposed rule does not accurately reflect the average cost of providing this level of care as it is being affected by high cost outliers and therefore the rebased payment rate may be inaccurate.

Response: We remind stakeholders that CMS does not have the authority to mandate specific contractual agreements between hospices and other entities which have entered into an agreement to provide arranged hospice services. Hospices are required, in accordance with the CoPs at §§ 418.100 and 418.108, to be able to provide all levels of hospice care. This means it is the responsibility of hospices to secure the necessary contracts to provide inpatient

levels of care if the hospice does not provide them in their own freestanding facility. As such, hospices would have to negotiate appropriate rates with the contracted providers to ensure that the hospice has sufficient resources to provide the necessary care.

To address the comment about IRC cost outliers, in the proposed rule, we trimmed the top and bottom 1 percent of cost reports, which excluded some outliers and have done so for the final rule. We recognize that IRC does have a wide distribution with outliers (even after taking out the top and bottom 1 percent). While there may be some high-cost outliers that affect the estimated, average cost of IRC, we remind stakeholders that utilization of IRC is low, accounting for 0.3 percent of total hospice days and it would not take many outliers to impact the estimated costs of providing this level of care. As such, we would not want to make any further exclusions to only one particular level of care. Additionally, we note that the rebased payment rate for IRC excludes the 5 percent coinsurance for each day of respite care. However, commenters on the proposed rule stated that most hospices do not collect this coinsurance from beneficiaries. Therefore, overall payment to hospices for IRC is even further reduced in those circumstances when hospices do not collect this coinsurance.

Final Decision: After considering the comments received in response to the proposed rule and for the reasons discussed above, we are finalizing our proposal to rebase the payment rates for CHC and GIP and set these rates equal to their average FY 2019 costs per day as shown in Table 8 of this final rule. We are finalizing rebasing of IRC payment rates and setting this rate equal to the estimated FY 2019 average costs per day, with a reduction of 5 percent to the FY 2019 average cost per day to account for coinsurance, also as shown in Table 8 of this final rule. Lastly, we are finalizing a 2.72 percent reduction to the RHC payment rates to offset the increases to CHC, IRC, and GIP payment rates to implement this policy in a budget-neutral manner in accordance with section 1814(i)(6) of the Act.

B. FY 2020 Hospice Wage Index and Rate Update

1. Wage Index Lag Elimination

Historically, we have calculated the hospice wage index values by using the

prior fiscal year's pre-floor, pre-reclassified hospital wage index. In an effort to align with the Inpatient Prospective Payment System (IPPS) and other payment systems, in the FY 2020 hospice proposed rule (84 FR 17584), we proposed to change the hospice wage index methodology. Specifically, we proposed to change from our established policy of using the pre-floor, pre-reclassified acute care hospital wage index from the prior fiscal year as the basis for the hospice wage index, and instead to align with the same timeframe used by the IPPS and other payment systems. In other words, we proposed to use the pre-floor, pre-reclassified hospital wage index from the current fiscal year as the basis for the hospice wage index. Under this proposal, the FY 2020 hospice wage index would be based on the FY 2020 pre-floor, pre-reclassified IPPS hospital wage index rather than on the FY 2019 pre-floor, pre-reclassified IPPS hospital wage index.

Using the concurrent pre-floor, pre-reclassified hospital wage index would result in the most up-to-date wage data being the basis for the hospice wage index, increasing payment accuracy. It would also result in more consistency and parity in the wage index methodology used by Medicare. Medicare's skilled nursing facility (SNF), home health and inpatient hospital prospective payment systems already use the most current wage index data as the basis for their wage indices. Thus, the wage-adjusted Medicare payments of various provider types would be based upon wage index data from the same timeframe. We are considering similar policies to use the concurrent pre-floor, pre-reclassified hospital wage index data in other Medicare payment systems, such as inpatient psychiatric facilities and inpatient rehabilitation facilities.

Overall, the impact between the FY 2020 wage index with the 1-year lag and the proposed FY 2020 wage index removing the 1-year lag is 0.0 percent due to the wage index standardization factor, which ensures that wage index updates and revisions are implemented in a budget-neutral manner. The anticipated impact on Medicare hospice payments due to the change in the wage index methodology can be found in Table 9 below.

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Table 9: Impact on Medicare Hospice Payments, FY 2020 Hospice Wage Index With and Without 1 year Lag

Hospice Subgroup	Hospices	FY 2020 Wage Index with 1-year Lag Minus FY 2019 Wage Index (Percentage Change)	FY 2020 Wage Index without 1-Year Lag Minus FY 2020 Wage Index with 1-Year Lag (Percentage Change)
All Hospices	4,599	0.0%	0.0%
Facility Type and Control			
Freestanding/Non-Profit	602	-0.1%	0.0%
Freestanding/For-Profit	2,843	0.1%	0.0%
Freestanding/Government	39	0.1%	-0.3%
Freestanding/Other	325	-0.2%	0.1%
Facility/HHA Based/Non-Profit	396	-0.3%	-0.1%
Facility/HHA Based/For-Profit	196	-0.2%	-0.1%
Facility/HHA Based/Government	101	-0.3%	-0.1%
Facility/HHA Based/Other	97	0.0%	0.1%
Subtotal: Freestanding Facility Type	3,809	0.0%	0.0%
Subtotal: Facility/HHA Based Facility Type	790	-0.2%	-0.1%
Subtotal: Non-Profit	998	-0.1%	0.0%
Subtotal: For Profit	3,039	0.1%	0.0%
Subtotal: Government	140	-0.1%	-0.2%
Subtotal: Other	422	-0.2%	0.1%
Facility Type and Control: Rural			
Freestanding/Non-Profit	154	0.0%	0.2%
Freestanding/For-Profit	329	0.1%	-0.1%
Freestanding/Government	20	-0.3%	-0.3%
Freestanding/Other	45	-0.2%	0.0%
Facility/HHA Based/Non-Profit	157	-0.4%	-0.2%
Facility/HHA Based/For-Profit	47	0.0%	-0.2%
Facility/HHA Based/Government	74	0.0%	0.0%
Facility/HHA Based/Other	54	-0.8%	0.3%
Facility Type and Control: Urban			
Freestanding/Non-Profit	448	-0.1%	0.0%
Freestanding/For-Profit	2,514	0.1%	0.0%
Freestanding/Government	19	0.2%	-0.3%
Freestanding/Other	280	-0.2%	0.1%
Facility/HHA Based/Non-Profit	239	-0.3%	0.0%
Facility/HHA Based/For-Profit	149	-0.3%	-0.1%

Facility/HHA Based/Government	27	-0.5%	-0.2%
Facility/HHA Based/Other	43	0.2%	0.0%
Facility Location: Urban or Rural			
Rural	880	-0.1%	0.0%
Urban	3,719	0.0%	0.0%
Facility Location: Region of the Country (Census Division)			
New England	158	-0.5%	-0.7%
Middle Atlantic	282	-0.2%	-0.2%
South Atlantic	558	-0.1%	-0.1%
East North Central	546	-0.4%	-0.1%
East South Central	264	-0.2%	-0.2%
West North Central	406	-0.3%	0.3%
West South Central	887	0.3%	-0.1%
Mountain	462	-0.5%	0.1%
Pacific	990	0.9%	0.6%
Outlying	46	-1.3%	-0.2%
Facility Size			
0 - 3,499 RHC Days (Small)	1,004	0.4%	0.2%
3,500-19,999 RHC Days (Medium)	2,131	0.1%	0.0%
20,000+ RHC Days (Large)	1,464	0.0%	0.0%

Note: 6 hospices with claims in FY 2018 were dropped from the analysis because they had no information on their location, facility type, or ownership status in the December 2018 POS file.

Source: FY 2018 hospice claims data from the CCW Research Identifiable Files (RIFs), accessed May 2019.

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2. FY 2020 Hospice Wage Index

The hospice wage index is used to adjust payment rates for hospice agencies under the Medicare program to reflect local differences in area wage levels, based on the location where services are furnished. The hospice wage index utilizes the wage adjustment factors used by the Secretary for purposes of section 1886(d)(3)(E) of the Act for hospital wage adjustments. Our regulations at § 418.306(c) require each labor market to be established using the most current hospital wage data available, including any changes made by Office of Management and Budget (OMB) to the Metropolitan Statistical Areas (MSAs) definitions.

In the FY 2020 proposed rule (84 FR 17586), we proposed to use the current FY's hospital wage index data to calculate the hospice wage index values. For FY 2020, the proposed hospice wage index would be based on the FY 2020 hospital pre-floor, pre-reclassified wage index. This means that the hospital wage data used for the hospice wage index are not adjusted to take into account any geographic reclassification

of hospitals including those in accordance with section 1886(d)(8)(B) or 1886(d)(10) of the Act. The appropriate wage index value is applied to the labor portion of the hospice payment rate based on the geographic area in which the beneficiary resides when receiving RHC or CHC. The appropriate wage index value is applied to the labor portion of the payment rate based on the geographic location of the facility for beneficiaries receiving GIP or IRC.

In the FY 2006 Hospice Wage Index final rule (70 FR 45135), we adopted the policy that, for urban labor markets without a hospital from which hospital wage index data could be derived, all of the Core-Based Statistical Areas (CBSAs) within the state would be used to calculate a statewide urban average pre-floor, pre-reclassified hospital wage index value to use as a reasonable proxy for these areas. For FY 2020, the only CBSA without a hospital from which hospital wage data can be derived is 25980, Hinesville-Fort Stewart, Georgia. The FY 2020 wage index value Hinesville-Fort Stewart, Georgia is 0.8322. Please note that CBSA 16180 Carson City, NV had no provider wage

data for the FY 2020 proposed hospice rule (84 FR 17586). However, this CBSA now has provider wage data for the updated final wage index file. The new wage index value for CBSA 16180 is 1.0070.

There exist some geographic areas where there were no hospitals, and thus, no hospital wage data on which to base the calculation of the hospice wage index. In the FY 2008 Hospice Wage Index final rule (72 FR 50217 through 50218), we implemented a methodology to update the hospice wage index for rural areas without hospital wage data. In cases where there was a rural area without rural hospital wage data, we use the average pre-floor, pre-reclassified hospital wage index data from all contiguous CBSAs, to represent a reasonable proxy for the rural area. The term "contiguous" means sharing a border (72 FR 50217). Currently, the only rural area without a hospital from which hospital wage data could be derived is Puerto Rico. However, for rural Puerto Rico, we would not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity

to one another of almost all of Puerto Rico's various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas); instead, we would continue to use the most recent wage index previously available for that area. For FY 2020, we propose to continue to use the most recent pre-floor, pre-reclassified hospital wage index value available for Puerto Rico, which is 0.4047, subsequently adjusted by the hospice floor.

As described in the August 8, 1997 Hospice Wage Index final rule (62 FR 42860), the pre-floor and pre-reclassified hospital wage index is used as the raw wage index for the hospice benefit. These raw wage index values are subject to application of the hospice floor to compute the hospice wage index used to determine payments to hospices. Pre-floor, pre-reclassified hospital wage index values below 0.8 are adjusted by a 15 percent increase subject to a maximum wage index value of 0.8. For example, if County A has a pre-floor, pre-reclassified hospital wage index value of 0.3994, we would multiply 0.3994 by 1.15, which equals 0.4593. Since 0.4593 is not greater than 0.8, then County A's hospice wage index would be 0.4593. In another example, if County B has a pre-floor, pre-reclassified hospital wage index value of 0.7440, we would multiply 0.7440 by 1.15 which equals 0.8556. Because 0.8556 is greater than 0.8, County B's hospice wage index would be 0.8.

We identified a slight error in the proposed rule wage index values after the FY 2020 Hospice Wage Index and Payment Rate Update proposed rule was published. A programming error caused the data for all providers in a single county to be included twice, which affected the national average hourly rate, and therefore affected nearly all wage index values. We have changed the programming logic so this error cannot occur again. In addition, we corrected the classification of one provider in North Carolina that was erroneously identified as being in an urban CBSA. We also standardized our procedures for rounding, to ensure consistency. The correction to the proposed rule wage index data was not completed until after the comment period closed June 18, 2019. This final rule reflects the corrected and updated wage index data. The final hospice wage index applicable for FY 2020 (October 1, 2019 through September 30, 2020) is available on our website at: <https://www.cms.gov/Medicare/Medicare-Fee->

[for-Service-Payment/Hospice/Hospice-Wage-Index.html](#).

We received approximately 22 comments on the FY 2020 hospice index proposals from various stakeholders including hospices, national industry associations and MedPAC. A summary of these comments and our responses to those comments appear below:

Comment: Several commenters expressed support for the wage index lag elimination. Several commenters stated that changing the lag with the Hospital Wage Index will help hospices be more competitive in the labor market, allow wages to track closer to market shifts, and allow hospices to compete in tight labor markets. One commenter expressed support for CMS' efforts to eliminate differences between provider types by removing the time lag. A few commenters suggested the proposed changes to the wage index calculations would provide consistency with the other Medicare payment systems. One commenter suggested that the existing lag makes it difficult for agencies and companies operating in multiple states. One commenter stated that there is value in consistency across provider types so that all providers can compete in same labor pool. The commenter further asserted that hospices may be able to provide input to hospitals on proposed wage index values. One commenter expressed support for eliminating the lag year and recognizes the value in having wage index consistency across provider types to enhance the ability of all employers in a given area to compete for staff from the same labor pool. The commenter further asserted that elimination of the lag year also provides some potential for hospices to provide input to local hospitals when proposed wage index values appear to undervalue the cost of labor in a geographic area.

Response: While we appreciate the commenters' careful review of the proposal and the support for the removal of the wage index lag elimination, we reiterate that using the most current year's data will most accurately adjust payment to account for geographic wage differences.

Comment: Several commenters suggested utilizing a transitional year wage index value that is a 50–50 blend of the lag year value and FY 2020 wage index value. One commenter suggested that a transitional wage index would provide some relief from substantial negative impact that many providers would experience by going directly to the FY 2020 wage index. The commenter further asserted that wage index values for the other regions under

a blend would still exceed the values they would have been assigned in FY 2019. One commenter recommended a phase-in to the removal over multiple years to minimize the disruption of the impact on the industry. The commenter further asserted that a phase-in is appropriate given the significant redistribution created by the proposed change. One commenter stated that while not opposed to removing the 1-year lag as other types use the most current wage index in calculating their indices, the commenter is concerned that the proposed rule does not provide additional adjustments.

Response: While we appreciate commenters' suggestion to create a transitional wage index that is a 50–50 blend of FY 2019 and FY 2020 wage index values, we believe that it is important to use the most recent data to increase payment accuracy. We also believe it is important to stay in alignment with other CMS payment systems so that there is parity and consistency in the wage index methodology.

Comment: A few commenters expressed concern that removing the 1-year lag would have a negative impact on hospices. One commenter suggested that removing the lag would have a negative short-term impact on hospices due to a shorter time period for providers to plan in cases where the wage index drops substantially. One commenter stated that the current 1-year lag allows hospices to plan for wage index changes which would be far more difficult if changes were based on the current year's wage index. One commenter stated that the proposal disadvantages providers because they would no longer have advance warning of wage index changes. The commenter further asserted that providers will be unable to plan for any significant shifts (particularly negative shifts). One commenter stated that elimination of the lag year allows hospices a much shorter period of time to adapt or adjust their financial expectations and absorb the impact of negative wage index swings, particularly swings under which the wage index value for an area drops precipitously.

Response: We disagree that removing the 1-year lag would have a negative impact on hospices and we refer commenters to Table 9 of this final rule to see the impact with and without the 1 year wage index lag. We continue to believe that using the most current year's wage index would improve overall payment accuracy.

Final Decision: After considering the comments we received on the elimination of the wage index lag, we

are finalizing the removal of the 1 year wage index lag. We are finalizing that we will use the current year's wage index to geographically wage adjust hospice payments, so for the FY 2020 hospice per diem payment rates, these will be geographically wage-adjusted using the FY 2020 wage index. Using the most current up to date information will increase payment accuracy and result in more consistency and parity in the wage index methodology used by Medicare.

We also received comments on the hospice wage index in general and these are summarized below, along with our responses.

Comment: Several commenters suggested that providers be guaranteed a wage index value that does not drop below the rural wage index applicable in their state of operation.

Response: The hospice wage index does not contain a rural floor provision. Section 4410(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) provides that the area wage index applicable to any hospital that is located in an urban area of a state may not be less than the area wage index applicable to hospitals located in rural areas in that state. This rural floor provision is specific to hospitals. Because the hospital rural floor applies only to hospitals, and not to hospices, we continue to believe the use of the pre-floor and pre-reclassified hospital wage index results in the most appropriate adjustment to the labor portion of the hospice payment rates. This position is longstanding and consistent with other Medicare payment systems (for example, SNF PPS, IRF PPS, and HH PPS). The hospice floor is applicable to all CBSAs, both rural and urban. Pre-floor, pre-reclassified hospital wage index values below 0.8 are adjusted by a 15 percent increase subject to a maximum wage index value of 0.8.

Comment: One commenter expressed concern that hospitals currently receive special consideration in a number of ways, but hospices and other small provider types are not granted the same considerations. The commenter suggested that creating value that is consistent across provider types will ensure that providers can compete in same labor pool. One commenter expressed concern that the current wage index system does not provide parity to all providers competing for the same professionals from the same labor pool. One commenter expressed concern that hospitals are allowed to reclassify and post-acute care facilities are at a disadvantage when competing for employees. The commenter suggested that until CMS can create a hospice

specific wage index methodology, CMS should equalize rates between hospitals and post-acute care. One commenter expressed concern that while the same data are used to establish the basic wage index values applicable to most provider types, hospitals are permitted to seek geographic reclassification from their assigned geographic area (thereby receiving higher wage adjustments to their payments).

Response: The current statute and regulations that govern the hospice payment system do not currently provide a mechanism for allowing hospices to seek geographic reclassification. The reclassification provision is found in section 1886(d)(10)(C)(i) of the Act, which states, “The Board shall consider the application of any subsection (d) hospital requesting that the Secretary change the hospital’s geographic classification” This provision is only applicable to hospitals as defined in section 1886(d) of the Act. In addition, we do not believe that using hospital reclassification data would be appropriate, as these data are specific to the requesting hospitals and they may or may not apply to a given hospice.

Comment: One commenter expressed concern that wage index values, at some times and in some localities, are subject to significant year-to-year swings. This volatility has a disproportionate impact on not-for-profit hospice programs that have smaller operating margins and therefore less ability to absorb large cost swings. One commenter expressed appreciation for adjustments in wages that recognize the need to recruit and contain a stable workforce for hospice. However, the commenter also expressed concern that for programs with tight margins, the continued compression of rates will result in more limited choices of hospice providers, particularly in rural areas and non profit hospices. One commenter expressed concern that hospice payment rules adopt the hospital wage index (HWI) of the Medicare Inpatient Hospital Prospective Payment Systems (IPPS) which can make Medicare payments to Hospices volatile when there are changes in the hospital wage costs, particularly in rural communities. The commenter further asserted that the HWI is threatening the financial stability of several hospices in Washington State and potentially across the country, including precipitous reductions in Medicare reimbursement having nothing to do with local factors, but triggered instead by organizational changes at nearby hospitals. The commenter suggested that the wage index should be based on wages and hours of labor directly tied to Medicare

Part A services. One commenter stated that the wage index varies for their southern service areas, with significant year to year swings. One commenter expressed concern that providers experience swings in wage index values from year to year, and they are often surprised by the variation in their rates.

Response: The annual changes in the wage index reflect real variations in costs of providing care in various geographic locations. We utilize efficient means to ensure and review the accuracy of the hospital cost report data and resulting wage index. The hospice wage index is derived from the pre-floor, pre-reclassified wage index, which is calculated based on cost report data from hospitals. All Inpatient Prospective Payment System (IPPS) hospitals must complete the wage index survey (Worksheet S–3, Parts II and III) as part of their Medicare cost reports. Cost reports will be rejected if Worksheet S–3 is not completed. In addition, our Medicare contractors perform desk reviews on all hospitals’ Worksheet S–3 wage data, and we run edits on the wage data to further ensure the accuracy and validity of the wage data. Our review processes result in an accurate reflection of the applicable wages for the areas given. In addition, we finalized a hospice wage index standardization factor in FY 2017 (81 FR 52156) to ensure overall budget neutrality when updating the hospice wage index with more recent hospital wage data. Applying a wage index standardization factor to hospice payments will eliminate the aggregate effect of annual variations in hospital wage data. Our policy of utilizing a hospice wage index standardization factor provides a safeguard to the Medicare program as well as to hospices because it will mitigate fluctuations in the wage index by ensuring that wage index updates and revisions are implemented in a budget neutral manner.

Comment: One commenter expressed concern that hospices in Montgomery County, Maryland are at a long-term competitive disadvantage due to a Medicare hospice federal payment inequity involving core-based statistical areas (CBSAs). The commenter suggested that the out migration adjustment referenced in section 505 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 be applied to the hospice wage index. Section 505 introduced a hospital wage index adjustment that is based on commuting patterns. One commenter stated that CMS’s and OMB’s decision to view the current CBSA area designation in the “aggregate” for a

large geographic region like NYC (making it a NY and New Jersey area) fails to account for the higher costs faced by New York providers. The commenter also disagreed with CMS's assertion that OMB's CBSA designations are reasonable and appropriate, reflecting the most recent available geographic classifications, and suggested wholesale revisions and reform of the hospice and home health wage index to more accurately reflect local market conditions.

Response: We further believe that using the most current OMB delineations will increase the integrity of the hospice wage index by creating a more accurate representation of geographic variation in wage levels. We recognize that the OMB cautions that the delineations should not be used to develop and implement federal, state, and local nonstatistical programs and policies without full consideration of the effects of using these delineations for such purposes. As discussed in the OMB Bulletin No. 03–04 (June 6, 2003), the OMB stated that, “In cases where there is no statutory requirement and an agency elects to use the Metropolitan, Micropolitan, or Combined Statistical Area definitions in nonstatistical programs, it is the sponsoring agency's responsibility to ensure that the definitions are appropriate for such use. When an agency is publishing for comment a proposed regulation that would use the definitions for a nonstatistical purpose, the agency should seek public comment on the proposed use.”¹⁷ While we recognize that OMB's geographic area delineations are not designed specifically for use in nonstatistical programs or for program purposes, including the allocation of federal funds, we continue to believe that the OMB's geographic area delineations represent a useful proxy for differentiating between labor markets and that the geographic area delineations are appropriate for use in determining Medicare hospice payments. In implementing the use of CBSAs for hospice payment purposes in our FY 2006 final rule (70 FR 45130), we considered the effects of using these delineations. We have used CBSAs for determining hospice payments for 13 years (since FY 2006). In addition, other provider types, such as IPPS hospital, home health, SNF, IRF), and the ESRD program, have used CBSAs to define

their labor market areas for the last decade.

Comment: MedPAC recommended that the Congress repeal the existing hospital wage index and instead implement a market-level wage index for use across other prospective payment systems, including certain post-acute care providers. MedPAC suggested that their recommended wage index would: Use wage data from all employers and industry-specific occupational weights, adjust for geographic differences in the ratio of benefits to wages, adjust at the county level and smooth large differences between counties, and include a transition period to mitigate large changes in wage index values. Several commenters recommended that CMS should develop a wage index model in line with the system recommended by MedPAC. One commenter questioned whether the hospital wage index sufficiently takes into account the labor costs associated with the extensive travel routinely required in the delivery of hospice care. The commenter further asserted that the travel costs are even higher on a per-patient per-day basis for hospices that serve rural populations with large catchment areas, where patients may be located in remote and geographically isolated areas. The commenter suggested that CMS should analyze cost data to determine the extent to which costs vary based on geographic setting and should incorporate findings from its analysis into payment through appropriate payment adjustments, in order to protect and promote access to hospice care for rural beneficiaries with terminal illness.

Response: We appreciate MedPAC's recommendations; however, we do not have the authority to repeal the existing hospital wage index absent Congressional action. We note that our regulations at § 418.306(c) require that each hospice's labor market is determined based on definitions of Metropolitan Statistical Areas (MSAs) issued by OMB. We will issue annually, in the **Federal Register**, a hospice wage index based on the most current available CMS hospital wage data, including changes to the definition of MSAs. The urban and rural area geographic classifications are defined in § 412.64(b)(1)(ii)(A) through (C). The payment rates established by us are adjusted by the Medicare contractor to reflect local differences in wages according to the revised wage data. Any changes to the way we adjust hospice payments to account for geographic wage differences would have to go through the rulemaking with comment

process. We note that in the proposed rule, we did solicit requests for information to explore alternate ways to wage-adjust payments. We will review all comments for any consideration in future rulemaking.

To address the comment whether the hospital wage index sufficiently takes into account the labor costs associated with, the extensive travel routinely required in the delivery of hospice care, we note that the hospital wage index reflects the area wages and does not factor in any travel expenses. We recognize that hospices do incur travel expenses and with the rebasing of the CHC, IRC, and GIP payment rates finalized in this rule, such expenses were captured to more accurately align payment with the cost of providing care.

Final Decision: After considering the comments received in response to the proposed rule and for the reasons discussed above, we are finalizing our proposal to use the current year's pre-floor, pre-reclassified hospital inpatient wage index as the wage adjustment to the labor portion of the hospice rates. For FY 2020, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2014 and before October 1, 2015 (FY 2015 cost report data). The wage index applicable for FY 2020 is available on our website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Hospice-Wage-Index.html>. The hospice wage index for FY 2020 will be effective October 1, 2019 through September 30, 2020.

3. FY 2020 Hospice Payment Update Percentage

Section 4441(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) amended section 1814(i)(1)(C)(ii)(VI) of the Act to establish updates to hospice rates for FYs 1998 through 2002. Hospice rates were to be updated by a factor equal to the inpatient hospital market basket percentage increase set out under section 1886(b)(3)(B)(iii) of the Act, minus 1 percentage point. Payment rates for FYs since 2002 have been updated according to section 1814(i)(1)(C)(ii)(VII) of the Act, which states that the update to the payment rates for subsequent FYs must be the inpatient market basket percentage increase for that FY.

Section 3401(g) of the Affordable Care Act mandated that, starting with FY 2013 (and in subsequent FYs), the hospice payment update percentage would be annually reduced by changes in economy-wide productivity as specified in section 1886(b)(3)(B)(xi)(II) of the Act. The statute defines the productivity adjustment to be equal to

¹⁷ Bulletin 05–02, Update of Statistical Area Definitions and Guidance on Their Uses. February 2005. https://www.whitehouse.gov/wp-content/uploads/2017/11/bulletins_fy05_b05-02.pdf.

the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP).

The hospice payment update percentage for FY 2020 is based on the estimated inpatient hospital market basket update of 3.0 percent (based on IHS Global Inc.'s second-quarter 2019 forecast with historical data through the first quarter 2019). Due to the requirements at sections 1886(b)(3)(B)(xi)(II) and 1814(i)(1)(C)(v) of the Act, the estimated inpatient hospital market basket update for FY 2020 of 3.0 percent must be reduced by a MFP adjustment as mandated by Affordable Care Act (currently estimated to be 0.4 percentage point for FY 2020). In effect, the hospice payment update percentage for FY 2020 is 2.6 percent.

Currently, the labor portion of the hospice payment rates is as follows: For RHC, 68.71 percent; for CHC, 68.71 percent; for General Inpatient Care, 64.01 percent; and for Respite Care, 54.13 percent. The non-labor portion is equal to 100 percent minus the labor portion for each level of care. Therefore, the non-labor portion of the payment rates is as follows: For RHC, 31.29 percent; for CHC, 31.29 percent; for General Inpatient Care, 35.99 percent; and for Respite Care, 45.87 percent. Beginning with cost reporting periods starting on or after October 1, 2014, freestanding hospice providers are required to submit cost data using CMS Form 1984–14 (<https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Hospice-2014.html>). We continue to analyze this data for possible use in updating the labor portion of the hospice payment rates. Any changes to the labor portions would be proposed in future rulemaking and would be subject to public comments.

While a majority of the comments received were about the rebasing methodology and analysis, we did receive a few comments regarding the hospice payment update percentage. Our responses to those comments are below:

Comment: MedPAC recognizes that CMS is required by statute to propose an increase to the FY 2020 base rates of 2.7 percent, however they noted that in their 2019 report to Congress, they recommended that Congress reduce the aggregate level of payment to hospices for FY 2020 by 2 percent.

Response: We appreciate the comment, however, we do not have the statutory authority to use an alternate methodology to determine the amount

of the annual payment updates to hospice payment rates.

Comment: One commenter stated that for organizations that rely on contractual arrangements to meet their inpatient care requirements, the budget neutrality component that lowers the RHC payment rates effectively turns the rebasing proposal into a rate cut even after the proposed 2.7 percent payment update.

Response: We note that we are statutorily required, as set forth in section 1814(i)(1)(C)(ii)(VII) of the Act, to update the hospice rates annually by the inpatient market basket percentage increase for that FY.

Final Decision: We are finalizing the hospice payment update percentage for FY 2020 as proposed. Based on IHS Global, Inc.'s updated forecast of the inpatient hospital market basket update and the multifactor productivity adjustment, the hospice payment update percentage for FY 2020 is equal to 2.6 percent for hospices that submit the required quality data and 0.6 percent (FY 2020 hospice payment update of 2.6 percent minus 2 percentage points) for hospices that do not submit the required data.

4. FY 2020 Rebased Hospice Payment Rates

There are four hospice payment categories, all of which are distinguished by the location and intensity of the services provided. The base payments are adjusted for geographic differences in wages by multiplying the labor share, which varies by category, of each base rate by the applicable hospice wage index. A hospice is paid the RHC rate for each day the beneficiary is enrolled in hospice, unless the hospice provides CHC, IRC, or GIP. CHC is provided during a period of patient crisis to maintain the patient at home; IRC is short-term care to allow the usual caregiver to rest and be relieved from caregiving; and GIP is provided to treat symptoms that cannot be managed in another setting.

As discussed in the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47172), we implemented two different RHC payment rates, one RHC rate for the first 60 days and a second RHC rate for days 61 and beyond. In addition, in that final rule, we implemented a Service Intensity Add-on (SIA) payment for RHC when direct patient care is provided by a RN or social worker during the last 7 days of the beneficiary's life. The SIA payment is equal to the CHC hourly rate multiplied by the hours of nursing or social work provided (up to 4 hours

total) that occurred on the day of service, if certain criteria are met. In order to maintain budget neutrality, as required under section 1814(i)(6)(D)(ii) of the Act, the new RHC rates were adjusted by a SIA budget neutrality factor.

As discussed in the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47177), we will continue to make the SIA payments budget neutral through an annual determination of the SIA budget neutrality factor (SBNF), which will then be applied to the RHC payment rates. The SBNF will be calculated for each FY using the most current and complete utilization data available at the time of rulemaking. For FY 2020, this calculation reflects the proposed increase in the hourly rate for CHC as a result of rebasing, discussed in section III.A.3 of this final rule.

In the FY 2017 Hospice Wage Index and Rate Update final rule (81 FR 52156), we initiated a policy of applying a wage index standardization factor to hospice payments in order to eliminate the aggregate effect of annual variations in hospital wage data. In order to calculate the wage index standardization factor, we simulate total payments using the proposed FY 2020 hospice wage index (no lag) and compare it to our simulation of total payments using the FY 2019 hospice wage index. By dividing payments for each level of care using the FY 2020 wage index (no lag) by payments for each level of care using the FY 2019 wage index, we obtain a wage index standardization factor for each level of care (the first 60 RHC days and RHC days after day 60 and, CHC, IRC, and GIP). The wage index standardization factors for each level of care are shown in the Tables 10 and 12 below.

As discussed in section III.A.3, we are finalizing rebasing of the per diem payment rates for CHC, IRC, and GIP levels of care. As mentioned above and outlined in the Affordable Care Act, hospice payment reform must be done in a budget-neutral manner. In order to rebase the per diem payment amounts for CHC, IRC, and GIP in a budget-neutral manner, as described in section III.A.3, increases to the CHC, IRC, and GIP per diem payment amounts will be offset by corresponding decreases to the RHC per diem payment amounts to maintain overall budget neutrality.

The FY 2020 RHC per diem payment rates are the FY 2019 rebased payment rates, reduced by a budget neutrality factor as a result of rebasing of the CHC, IRC, and GIP payment amounts, adjusted by the SIA budget neutrality factor, adjusted by the wage index standardization factor, and increased by

the 2.6 percent hospice payment update percentage as shown in Table 10. The FY 2020 rebased CHC, IRC, and GIP per diem payment rates are equal to the FY

2019 rebased payment rates, adjusted by the wage index standardization factor and increased by the hospice payment

update percentage (2.6 percent) as shown in Table 11.
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Table 10: FY 2020 Hospice RHC Payment Rates

Code	Description	FY 2019 Rebased Payment Rates*	SIA Budget Neutrality Factor	Wage Index Standardization Factor**	FY 2020 Hospice Payment Update	FY 2020 Payment Rates
651	Routine Home Care (days 1-60)	\$190.91	X 0.9924	X 1.0006	X 1.026	\$194.50
651	Routine Home Care (days 61+)	\$150.02	X 0.9982	X 1.0005	X 1.026	\$153.72

* FY 2019 RHC rate for days 1-60 = \$196.25 * 0.9728 = \$190.91. FY 2019 RHC rate for days 61+ = \$154.21 * 0.9728 = \$150.02.

**Transition from FY 2019 Wage Index to FY 2020 Wage Index without 1-Year Lag.

Table 11: FY 2020 Hospice CHC, IRC, and GIP Payment Rates

Code	Description	FY 2019 Rebased Payment Rates	Wage Index Standardization Factor*	FY 2020 Hospice Payment Update	FY 2020 Payment Rates
652	Continuous Home Care Full Rate = 24 hours of care	\$1,363.26 (\$56.80/hourly rate)	X .9978	X 1.026	\$1,395.63 (\$58.15/hourly rate)
655	Inpatient Respite Care	\$437.86	X 1.0019	X 1.026	\$450.10
656	General Inpatient Care	\$992.99	X 1.0024	X 1.026	\$1,021.25

*Transition from FY 2019 Wage Index to FY 2020 Wage Index without 1-Year Lag.

Sections 1814(i)(5)(A) through (C) of the Act require that hospices submit quality data, based on measures to be specified by the Secretary. In the FY 2012 Hospice Wage Index final rule (76 FR 47320 through 47324), we implemented a Hospice Quality Reporting Program as required by section 3004 of the Affordable Care Act.

Hospices were required to begin collecting quality data in October 2012, and submit that quality data in 2013. Section 1814(i)(5)(A)(i) of the Act requires that beginning with FY 2014 and each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality

data submission requirements with respect to that FY. The FY 2020 rates for hospices that do not submit the required quality data is updated by the FY 2020 hospice payment update percentage of 2.6 percent minus 2 percentage points. These rates are shown in Tables 12 and 13.

Table 12: FY 2020 Hospice RHC Payment Rates for Hospices That DO NOT Submit the Required Quality Data

Code	Description	FY 2019 Rebased Payment Rates*	SIA Budget Neutrality Factor	Wage Index Standardization Factor**	FY 2020 Hospice Payment Update of 2.6% minus 2 percentage points = +0.6%	FY 2020 Payment Rates
651	Routine Home Care (days 1-60)	\$190.91	X 0.9924	X 1.0006	X 1.006	\$190.71
651	Routine Home Care (days 61+)	\$150.02	X 0.9982	X 1.0005	X 1.006	\$150.72

* FY 2019 RHC payment rates adjusted to rebase CHC, IRC, and GIP in the following manner: FY 2019 RHC rate for days 1-60 = \$196.25 * 0.9728 = \$190.91. FY 2019 RHC rate for days 61+ = \$154.21 * 0.9728 = \$150.02.

**Transition from FY 2019 Wage Index to FY 2020 Wage Index without 1-Year Lag.

Table 13: FY 2020 Hospice CHC, IRC, and GIP Payment Rates for Hospices That DO NOT Submit the Required Quality Data

Code	Description	FY 2019 Rebased Payment Rates	Wage Index Standardization Factor*	FY 2020 Hospice Payment Update of 2.6% minus 2 percentage points = +0.6%	FY 2020 Payment Rates
652	Continuous Home Care Full Rate = 24 hours of care	\$1,363.26 (\$56.80=hourly rate)	X .9978	X 1.006	\$1,368.42 (\$57.02= hourly rate)
655	Inpatient Respite Care	\$437.86	X 1.0019	X 1.006	\$441.32
656	General Inpatient Care	\$992.99	X 1.0024	X 1.006	\$1,001.35

*Transition from FY 2019 Wage Index to FY 2020 Wage Index without 1-Year Lag.

Final Decision: We are finalizing the FY 2020 payment rates in accordance with statutorily mandated requirements.

5. Hospice Cap Amount for FY 2020

As discussed in the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47183), we implemented changes mandated by the IMPACT Act of 2014 (Pub. L. 113–185). Specifically, for accounting years that end after September 30, 2016, and before October 1, 2025, the hospice cap is updated by the hospice payment update percentage rather than using the CPI–U. The hospice cap amount for the FY 2020 cap year will be \$29,964.78, which is equal to the FY 2019 cap amount (\$29,205.44) updated by the FY 2020 hospice payment update percentage of 2.6 percent. A summary of the comments we received regarding the hospice cap amount and our responses to those comments appear below:

Comment: A few commenters suggested that geographical differences should be considered when calculating the annual cap amounts. One commenter stated that the cap discriminates against providers with higher daily reimbursement rates because the cap is applied on a national basis, without regard to the geographical location of the patient. Another commenter suggested adjusting the hospice cap amounts for wage index in the same manner that the per diem payments are adjusted. This commenter further asserted that wage adjusting the payments and not the cap has the effect of reversing the wage index, since the caps will be reached (and exceeded) more quickly in high wage labor markets than in low wage labor markets. The commenter suggested that this creates an unintended penalty or benefit to a hospice based on where it is located, not on the quality or efficiency of the care provided.

Response: We appreciate the commenters' suggestion that we consider geographical differences when calculating the annual cap amount. However, the restriction set forth in section 1814(i)(2)(B) of the Act, as amended by section 3(d) of the IMPACT Act, does not give us discretion to adjust the cap amount.

Comment: One commenter recommended that funds allocated for the cap amount increase instead be applied to reducing the cut to the RHC. The commenter suggested that holding the cap at its current level would also likely hold down margins from high-margin hospices. A few commenters also suggested that lowering the aggregate cap amount for all hospices by at least 10 percent from the FY 2019

amount would be a better way to control hospice spending.

Response: We appreciate the commenter's suggestion that we lower the annual cap amount. However, the restriction set forth in section 1814(i)(2)(B) of the Act, as amended by section 3(d) of the IMPACT Act, does not give us discretion to adjust the cap amount.

Comment: One commenter suggested the cap amount be used to explore questionable practices by hospices. Specifically, this commenter was referring to hospices that come up to the cap limit, but do not exceed it, because they are deliberately discharging beneficiaries solely to avoid any overpayments. This commenter also stated that CMS should further investigate those hospices that routinely exceed the cap limit to see if there is any aberrant patterns of care that may warrant targeted program integrity efforts. The commenter stated that CMS could use its program integrity authority using claims and quality data to address this issue with little additional burden to hospice agencies.

Response: We appreciate the commenter's suggestion to consider looking into the practices of hospices that regularly reach or exceed the annual aggregate cap amount to target further program integrity investigations. We remind stakeholders that under the Medicare hospice benefit, § 418.26(a)(1), (2), and (3), there are limited reasons why a hospice can discharge a beneficiary alive: The beneficiary decides to revoke the hospice benefit; the beneficiary transfers to another hospice; or, the beneficiary is no longer terminally ill. Hospice care is provided to beneficiaries who are nearing the end of life and provides comfort for the dying, neither hastening death nor prolonging life by attempting to cure the terminal illness. Discharging a beneficiary solely to avoid exceeding the cap limit is in violation of the regulations at § 418.26 and may cause undue distress and potential harm to terminally ill patients who would have to seek care outside of the hospice benefit. We will closely monitor this issue and address any identified concerns, if necessary.

Final Decision: We are finalizing the update to the hospice cap in accordance with statutorily mandated requirements.

C. Election Statement Content Modifications and Addendum To Provide Greater Coverage Transparency and Safeguard Patient Rights

1. Background

In the FY 2020 hospice proposed rule (84 FR 17589), we provided background on the holistic nature of the services provided under the Medicare hospice benefit, as well as the current statutory and regulatory requirements for care planning and patient rights. We stated that in order to make an informed choice about whether to receive hospice care, the patient, family, and caregiver must have an understanding of what services are going to be provided by the hospice and that, because there is no longer a reasonable expectation for a cure, care should now focus on comfort and quality of life. The services covered under the Medicare hospice benefit are comprehensive such that, upon election, the individual waives all rights to Medicare payment for services related to the treatment of the individual's condition with respect to which a diagnosis of terminal illness has been made, except when provided by the designated hospice or attending physician. Because of the significance of this decision, the terminally ill individual must elect hospice care in order to receive services under the Medicare hospice benefit. Since we first implemented the Medicare hospice benefit in 1983, it has been our general view that the waiver required by law requires hospices to provide virtually all the care that is needed by terminally ill patients (48 FR 56010).

Additionally, in the FY 2015 proposed rule (79 FR 26555), we described the eligibility, certification, and election requirements for receipt of hospice services as set forth at 42 CFR 418.20, 418.22 and 418.24. We also emphasized that in reaching a decision to certify that the patient is terminally ill, the hospice medical director must consider the principal diagnosis of the patient, all other health conditions, whether related or unrelated to the terminal condition, and all clinically relevant information supporting all diagnoses. The clinical information and other documentation that support the medical prognosis must accompany the written certification and must be filed in the individuals' hospice medical record in accordance with the regulations at § 418.22(b)(2) and the hospice CoPs at § 418.102(b). Once a beneficiary is certified as terminally ill, he or she becomes eligible to elect hospice care under the Medicare hospice benefit.

Because the receipt of hospice services under the Medicare hospice

benefit is dependent upon the eligible beneficiary electing to receive hospice care, the regulations at § 418.24 provide the requirements of the hospice election statement. The election statement must include the identification of the designated hospice and attending physician (if any); the individual's or representative's acknowledgement that he or she has been given a full understanding of the palliative rather than curative nature of hospice care; and the individual's or representative's acknowledgement that the individual waives the right to Medicare payment for services related to the terminal illness and related conditions, except when provided by the designated hospice or attending physician. Services unrelated to the terminal illness and related conditions remain eligible for Medicare coverage and payment outside of the hospice benefit.

Once the beneficiary has elected hospice care, the hospice conducts an initial assessment visit in advance of furnishing care. During this visit, the hospice must provide the patient or representative with a spoken and written notice of the patient's rights and responsibilities as required by the CoPs at § 418.52. Our rules state that the beneficiary has the right to be involved in developing his or her hospice plan of care; receive information about the services covered under the hospice benefit; and receive information about the scope of services that the hospice will provide and specific limitations on those services. The hospice program must assure the patient that its staff will protect patients' rights and will involve patients in decisions about their care, treatment and services.¹⁸ Likewise, the regulations at § 476.78(b)(3) state that providers must inform Medicare beneficiaries at the time of admission, in writing, that the care for which Medicare payment is sought will be subject to Quality Improvement Organization (QIO) review.

Additionally, the hospice CoPs at § 418.54(c) provide the content requirements for the initial and comprehensive assessments used to identify patient, family, and caregiver needs for physical, emotional, psychosocial, and spiritual care. As part of the comprehensive assessment, the hospice is required to assess the patient for complications and risk factors, which can affect care planning. The needs identified in these assessments drive the development and revisions of

an individualized written plan of care for each patient as required by the CoPs at § 418.56. Collectively, the interdisciplinary team (IDG), in consultation with the patient's attending physician (if any), makes care plan decisions for each patient to ensure that each care plan is individualized to meet the unique needs of each hospice beneficiary. The plan of care also must reflect patient, family, and caregiver preferences, goals, and interventions based on the problems identified in the initial, comprehensive, and updated comprehensive assessments. The plan of care must include all services necessary for the palliation and management of the terminal illness and related conditions and the CoPs at § 418.56(c) detail the plan of care content requirements. However, though hospices are responsible for providing all services needed for palliation and management of the terminal illness and related conditions, the 2008 Hospice Conditions of Participation final rule (73 FR 32088, June 5, 2008) states that while needs unrelated to the terminal illness and related conditions are not the responsibility of the hospice, the hospice may choose to furnish services for those needs regardless of responsibility (73 FR 32114). If a hospice does not choose to furnish services for those needs unrelated to the terminal illness and related conditions, the hospice is to document such needs and communicate and coordinate with those health care providers who are identified as caring for the unrelated needs, as set out at § 418.56(e)(5). To ensure comprehensive and coordinated care, at § 418.56(e) we require hospices to have a communication system that allows for the exchange of information with other non-hospice health care providers who are furnishing care unrelated to the terminal illness and related conditions.

We also require hospices to designate a registered nurse (RN) who is a member of the IDG to coordinate implementation of the comprehensive plan of care. The designated RN must assure that coordination of care and continuous assessment of patient, family, and caregiver needs occur among staff providing services to the patient, family, and caregiver so that all IDG members are kept informed of the patient/family's status.¹⁹ The goal of a coordinated communication process and a designated nurse coordinator is to

adequately ensure that each patient's hospice care is coordinated both within the hospice and with other health care providers.

2. Services Unrelated to the Terminal Illness and Related Conditions

In the FY 2020 hospice proposed rule, we reiterated our long-standing position that services unrelated to the terminal illness and related conditions should be exceptional, unusual and rare given the comprehensive nature of the services covered under the Medicare hospice benefit as articulated upon the implementation of the benefit (48 FR 56008, 56010, December 16, 1983). To the extent that individuals receive services outside of the Medicare hospice benefit during a hospice election, Medicare coverage is determined by whether or not the services are for the treatment of a condition completely unrelated to the individual's terminal illness and related conditions (48 FR 38146, 38148, August 22, 1983). In the FY 2020 hospice proposed rule, we detailed numerous anecdotal reports from beneficiaries, families, the Medicare Ombudsman's office, and non-hospice providers where hospice patients were obtaining needed items, services, and drugs outside of the hospice benefit because they had been told that hospice would not cover these items, services, and drugs, as the hospice had determined that they were unrelated to the terminal illness and related conditions. Many of these anecdotal reports state that the beneficiaries and families believed that these items, services, and drugs were related to the terminal illness and related conditions and thought that they should have been provided by the hospice. The beneficiaries and/or the families stated that they did not know they would have to seek care outside of the hospice benefit for these conditions because the hospice did not tell them these items, services, and drugs would not be furnished by the hospice until the patient needed them. We remind stakeholders that the Medicare Beneficiary Ombudsman (MBO) is charged with supporting CMS' customer service and administration efforts by receiving and responding to beneficiary and other stakeholder inquiries and complaints, working with partners to provide outreach and education to beneficiaries, and providing recommendations for improving the administration of Medicare. The MBO also provides an annual report to

¹⁸ State Operations Manual Appendix M—Guidance to Surveyors: Hospice. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_m_hospice.pdf.

¹⁹ State Operations Manual Appendix M—Guidance to Surveyors: Hospice. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_m_hospice.pdf.

Congress that are posted on the MBO website.²⁰

In accordance with the hospice CoPs at § 418.56(e)(5), and in alignment with continuity of care principles,²¹ the ongoing sharing of information with other non-hospice healthcare providers and suppliers furnishing services unrelated to the terminal illness and related conditions is necessary to ensure coordination of services and to meet the patient, family, and caregiver needs. The coordination requirements include that the hospice must develop and maintain a system of communication and integration amongst all providers furnishing care to the terminally ill patient. This communication helps to minimize fragmented care and to improve quality of life. Part of that communication process is the clear identification of what the related and unrelated conditions are and who is responsible for providing reasonable and necessary services for those conditions. As is the preferred practice for care coordination and communication,²² both hospice and non-hospice providers typically document these discussions, which then becomes part of the patient's medical record with each provider. Accordingly, all Medicare providers and suppliers must be able to provide medical documentation to support payment for services billed (sections 1815(a) and 1833(e) of the Act). For non-hospice providers or suppliers billing Medicare for services received by hospice beneficiaries unrelated to their terminal illness and related conditions, this includes being able to provide documentation from the hospice listing the conditions (and thus items, drugs, and services) the hospice determined to be unrelated and documented as such on the hospice plan of care.

While hospices are required by the CoPs to have a system of communication with non-hospice providers to furnish such information, we have heard anecdotally from non-hospice providers stating that they are unable to reach or do not receive return

calls from the hospice to discuss the hospice beneficiary's coordination of services that the hospice has determined unrelated to his or her terminal illness and related condition(s). Likewise, we have also received anecdotal reports from hospices who state they were unaware that patients had received care from non-hospice providers. In these reports, the hospice would first learn of this outside care when non-hospice providers would contact the hospice seeking reimbursement. If this care was related to the terminal illness and related conditions and the hospice did not make arrangements for such care, the beneficiary would be liable for the costs of receiving that care. Additionally, if non-hospice providers bill Medicare for services that potentially should have been the coverage responsibility of hospice, Medicare could be making duplicative payments for care related to the terminal illness and related conditions, as described in the June, 2012 OIG report²³ identifying situations where Medicare may have been paying twice for prescription drugs for hospice beneficiaries.

In previous years' hospice proposed rules, we have included data on non-hospice expenditures for beneficiaries under a hospice election. These total non-hospice expenditures include beneficiary cost-sharing amounts. For Parts A and B, the beneficiary cost-sharing amounts in FY 2017 totaled approximately \$138 million and for Part D, the beneficiary cost-sharing totaled approximately \$68.6 million (83 FR 20946 through 20947). We believe that this is a substantial financial burden being placed on terminally ill individuals for services that potentially should have been covered by hospice. This suggests that hospice beneficiaries may be incurring unnecessary financial burden as they are having to seek out and pay for items and services for pain and symptom relief—services that hospice should be furnishing and covering.

However, in spite of the data provided and reiteration of longstanding policy regarding the comprehensive nature of hospice services covered under Medicare, we continue to have concerns that these decisions as to what hospices will cover and not cover are based on a more narrow view of the overall condition of the individual, as is evidenced by the non-trivial amount of items, services, and drugs for potentially

related conditions provided by non-hospice providers to beneficiaries under a hospice election.

3. Election Statement Content Modifications and Addendum To Provide Greater Coverage Transparency and Safeguard Patient Rights

The regulations, as described previously, require the hospice to include all services needed for the palliation and management of the terminal illness and related conditions on the individualized hospice plan of care, and the plan of care should also identify the conditions or symptoms that the hospice determines to be “unrelated” so hospices can provide ongoing sharing of information with other non-hospice healthcare providers who may be furnishing services unrelated to the terminal illness and related conditions.²⁴ Although hospices are required to educate each patient and the primary caregiver(s) on the services identified on the plan of care and document the patient's or representative's level of understanding, involvement, and agreement with the plan of care, the incidence of anecdotal reports and the amount and nature of the non-hospice services being billed to Medicare outside of the hospice benefit suggests that hospice beneficiaries may not be fully informed, at the time of admission or throughout the hospice election, of the items, services, and drugs the hospice has determined to be unrelated to their terminal illness and related conditions. We believe this is necessary information for patients and their families to make informed care decisions and to anticipate any financial liability associated with needed items, services, and drugs not provided under the Medicare hospice benefit. Not having this information may result in a lack of coverage transparency and where beneficiaries are unaware of their financial liability while under a hospice election for those items, services, and drugs the hospice has determined to be unrelated to their terminal prognosis.

Therefore, in the FY 2020 hospice proposed rule (84 FR 17570), we proposed to modify the hospice election statement content requirements at § 418.24(b) to increase coverage transparency for patients under a hospice election. In addition to the existing election statement content requirements at § 418.24(b), we proposed that hospices also would be

²⁰ Medicare Beneficiary Ombudsman (MBO). <https://www.cms.gov/Center/Special-Topic/Ombudsman/Medicare-Beneficiary-Ombudsman-Home.html>.

²¹ Uijena, A., Schersa, H., Schellevis, F., van den Bosch, W. How unique is continuity of care? A review of continuity and related concepts. *Family Practice* 2012; 29:264–271 doi:10.1093/fampra/cmr104.

²² National Quality Forum (NQF), Preferred Practices and Performance Measures for Measuring and Reporting Care Coordination: A Consensus Report, Washington, DC: NQF; 2010. https://www.qualityforum.org/Publications/2010/10/Preferred_Practices_and_Performance_Measures_for_Measuring_and_Reporting_Care_Coordination.aspx.

²³ Medicare Could Be Paying Twice for Prescription Drugs for Beneficiaries in Hospice (A–06–10–00059). June 28, 2012. <https://oig.hhs.gov/oas/reports/region6/61000059.pdf>.

²⁴ State Operations Manual Appendix M—Guidance to Surveyors: Hospice https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_m_hospice.pdf. (L-Tag 538)

required to include the following on the election statement:

- Information about the holistic, comprehensive nature of the Medicare hospice benefit.

- A statement that, although it would be rare, there could be some necessary items, drugs, or services that will not be covered by the hospice because the hospice has determined that these items, drugs, or services are to treat a condition that is unrelated to the terminal illness and related conditions.

- Information about beneficiary cost-sharing for hospice services.

- Notification of the beneficiary's (or representative's) right to request an election statement addendum that includes a written list and a rationale for the conditions, items, drugs, or services that the hospice has determined to be unrelated to the terminal illness and related conditions and that immediate advocacy is available through the BFCC-QIO if the beneficiary (or representative) disagrees with the hospice's determination.

Likewise, we proposed to make the corresponding regulations text changes at § 418.24(b).

Additionally, we proposed a new requirement where hospices would be required, but only upon request, to provide to the beneficiary (or representative) an election statement addendum (hereafter called "the addendum") with a list and rationale for the conditions items, services, and drugs that the hospice has determined as unrelated to the terminal illness and related conditions. Similarly, we proposed that hospices would be required to provide the addendum, upon request, to other non-hospice providers that are treating such conditions, and Medicare contractors who request such information. We proposed that if the addendum is requested at the time of hospice election, the hospice must provide this information, in writing, to the individual (or representative) within 48 hours of the request. Furthermore, we proposed that if this addendum is requested during the course of hospice care, the hospice must provide this information, in writing, immediately to the requesting individual (or representative), non-hospice provider, or Medicare contractor, as this information should be readily available in the beneficiary's hospice medical record. During the course of hospice care, if there are changes to the plan of care that result in a determination that a new illness or condition has arisen, we proposed that hospices would be required to issue an updated addendum to the patient (or representative)

reflecting whether or not items, services and supplies related to the new illness or condition will be provided by the hospice. We also proposed that hospices would be exempt from completing this addendum if the beneficiary died within 48 hours of the election date of hospice care.

The purpose of the proposed addendum is to inform beneficiaries and their families of hospice-determined non-covered conditions, items, services, and drugs to provide full coverage transparency to hospice patients and their families to assist in making treatment decisions. Likewise, the addendum would help facilitate communication and benefit coordination between hospices and non-hospice providers.

We proposed that hospices would develop and design the addendum to meet their needs, similar to how hospices develop their own hospice election statement. We proposed the addendum would be titled "Patient Notification of Hospice Non-Covered Items, Services, and Drugs." We proposed that the addendum would include the following information:

1. Name of the hospice;
2. Beneficiary's name and hospice medical record identifier;
3. Identification of the beneficiary's terminal illness and related conditions;
4. A list of the beneficiary's current diagnoses/conditions present on hospice admission (or upon plan of care update, as applicable) and the associated items, services, and drugs, not covered by the hospice because they have been determined by the hospice to be unrelated to the terminal illness and related conditions;
5. A written clinical explanation, in language the beneficiary and his or her representative can understand, as to why the identified conditions, items, services, and drugs are considered unrelated to the terminal illness and related conditions and not needed for pain or symptom management. This clinical explanation would be accompanied by a general statement that the decision as to whether or not conditions, items, services, and drugs is related is made for each patient and that the beneficiary should share this clinical explanation with other health care providers from which they seek services unrelated to their terminal illness and related conditions;
6. References to any relevant clinical practice, policy, or coverage guidelines.

7. Information on the following domains:

- a. Purpose of Addendum.
- b. Right to Immediate Advocacy.

8. Name and signature of Medicare hospice beneficiary (or representative) and date signed, along with a statement that signing this addendum (or its updates) is only acknowledgement of receipt of the addendum (or its updates) and not necessarily the beneficiary's agreement with the hospice's determinations.

We proposed to add the election statement modifications and the election statement addendum content requirements to the regulations at § 418.24.

Finally, we proposed that the signed addendum (and any signed updates) would be a new condition for payment. We also stated that this would not mean that in order to meet this condition for payment that the beneficiary (or representative), or non-hospice provider must agree with the hospice's determination. For purposes of this condition for payment, we proposed that the signed addendum is only acknowledgement of the beneficiary's (or representative's) receipt of the addendum (or its updates) and this payment requirement would be met if there was a signed addendum (and any signed updates) in the requesting beneficiary's medical record with the hospice. This addendum would not be required to be submitted with any hospice claims. Likewise, the hospice beneficiary (or representative) would not have to separately consent to the release of this information to non-hospice providers furnishing services for unrelated conditions as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule allows those doctors, nurses, hospitals, laboratory technicians, and other health care providers that are covered entities to use or disclose protected health information, such as X-rays, laboratory and pathology reports, diagnoses, and other medical information for treatment purposes without the patient's express authorization. This includes sharing the information to consult with other providers, including providers who are not covered entities, to treat a different patient, or to refer the patient (45 CFR 164.506).

Ninety-two unique stakeholders submitted their comments on the proposed modifications to the election statement content requirements and the proposed election statement addendum. These stakeholders included hospices, national and state industry associations, individual commenters, as well as the Medicare Payment Advisory Commission (MedPAC).

Election Statement Modifications

While many commenters supported the modifications to the election statement content requirements, several had concerns regarding these changes. These comments, along with our responses, are summarized below.

Comment: Several commenters, including MedPAC, supported the proposal to modify the hospice election statement content requirements to increase coverage transparency for patients under a hospice election. Commenters agreed with CMS' efforts to educate and empower patients to make informed decisions. They reiterated the importance of beneficiaries and their families understanding what is covered by the hospice benefit and being informed of the resources available to appeal decisions by hospice providers if they have concerns or disagree with coverage determinations made by their hospice provider.

Response: We appreciate these comments and thank commenters for their thoughtful review and support of our efforts to provide patients with complete information regarding payment and cost-sharing obligations as well as implications for other providers.

Comment: One commenter disagreed with the proposal that the election statement include information on individual cost-sharing for hospice services. This commenter stated that hospices are permitted, but not required, to impose small coinsurance payments for hospice drugs and inpatient respite care, and that most hospices do not charge patients for this coinsurance. This commenter remarked that including this information on the election statement would be confusing for patients and burdensome for hospices to have to explain. Other commenters suggested that additional language should be added to the election statement to indicate that Medicare continues to pay for any such unrelated items under traditional Medicare benefits.

Response: To provide full transparency regarding hospice coverage under the Medicare hospice benefit, we believe that the election statement should include information that there may be individual cost-sharing for certain hospice services while under a hospice election. We did not propose specific language requirements for communicating information on cost-sharing for hospice services and we believe this information can be communicated simply and in a straightforward fashion to beneficiaries. For example, a general statement saying that while under a hospice election

there may be cost-sharing for hospice medications and inpatient respite allows beneficiaries to ask the hospice for more information on such cost-sharing, if needed. Likewise, if a hospice does not charge any coinsurance for hospice drugs of inpatient respite care, it could include such a statement on their election statements.

As for the suggestion that CMS should require hospices to indicate that there is coverage for unrelated items, services, and drugs on the election statement itself, hospices can add whatever language they feel best communicates information to the beneficiary about coverage under the Medicare hospice benefit as long as such information is in accordance with the hospice regulations. This could include a disclaimer statement that unrelated items, services, and drugs may be covered through other Medicare benefits. We note that in 2016, we provided a model election statement as part of a MLN Matters® article (SE1631)²⁵ in which there is a statement that reads: "I understand that services not related to my terminal illness or related conditions will continue to be eligible for coverage by Medicare." Hospices could adopt such language on the election statement to best meet their needs and to adequately communicate this information to beneficiaries and their families at the time of hospice election. One industry commenter stated that many hospices already use this model election statement and simple modifications to this election statement could be easily achieved to satisfy the proposed changes to the election statement content requirements.

Election Statement Addendum

Comment: Several commenters stated that the time of hospice election is an overwhelming and confusing time for individuals and their families. Commenters remarked that the addendum might have the unintended consequence of further overwhelming and frightening patients and their families, giving the impression that patients would not be given the symptom-controlling medications that they need. Some commenters believe that the addendum may delay access to needed services because of the time it would take to make these determinations and consult with the

IDG and could potentially deter individuals from electing the benefit.

Response: The services covered under the Medicare hospice benefit are comprehensive such that, upon election, the individual waives all rights to Medicare payment for services related to the treatment of the individual's condition with respect to which a diagnosis of terminal illness has been made, except when provided by the designated hospice or attending physician. Since we first implemented the Medicare hospice benefit in 1983, it has been our general view that the waiver required by law requires hospices to provide virtually all the care that is needed for terminally ill patients (48 FR 56010). As such, we understand that the decision to elect hospice is not one that is taken lightly and it is because of the significance of this decision that we believe individuals and their families need to have full disclosure and coverage transparency regarding the services provided and not provided by the hospice as they approach the end of life.

The hospice CoPs at § 418.52(a) require that during the initial assessment visit, in advance of furnishing care, the hospice must provide the patient or representative with verbal (meaning spoken) and written notice of the patient's rights and responsibilities in a language and manner that the patient understands. Furthermore, hospices are to inform the beneficiary of the services covered under the Medicare hospice benefit, as well as the scope of such services. The intent of this standard was to ensure that patients were aware of their potential out-of-pocket costs for hospice care, such as co-payments, so that they would not be surprised by financial concerns at this stressful time (73 FR 32097). Therefore, hospices are already tasked with providing detailed information on hospice services and limitations to those services to the patient upon election of the benefit. We believe that the addendum further complements these requirements by ensuring that the hospice informs them of any items, services, or drugs which the terminally ill individual would have to seek outside of the benefit.

Because of the longstanding requirements to communicate the breadth of the Medicare hospice benefit to individuals and their families prior to the provision of any hospice services, we do not believe that providing full coverage transparency at the time of hospice election would generally deter or unnecessarily overwhelm individuals from electing hospice, thereby limiting access to such services. Terminally ill

²⁵ Sample Hospice Election Statement. MLN Matters® Number: SE1631 Revised. December 2016. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1631.pdf>.

individuals and their families are making decisions for how the individual chooses to live out their remaining days at the end of life.

As the hospice model of care is for palliation and comfort, rather than for a cure, the Medicare hospice benefit must be elected by the terminally ill individual who is agreeing to this model of care, as well as waiving the right to Medicare payment for items, services and drugs for the treatment of the terminal illness and related conditions. The purpose of the addendum as noted in the proposed and this final rule is to provide for coverage transparency to help ensure individuals are fully informed when making such a decision. If, after receiving information about all of the items, services, and drugs the hospice will and will not cover, the individual chooses not to elect the benefit (or to discontinue the benefit), then the individual has made an informed choice based on his or her goals and preferences of care. Hospices should be able to communicate this information in a clear, thoughtful, and compassionate manner in accordance with the spirit of hospice philosophy where the individual and the family are the center of the care team. In doing so, the hospice will have made every effort to ensure patients are aware of all services covered and not covered by the hospice. We believe that an informed beneficiary will make the most appropriate choice to meet his or her needs and it is the hospice's responsibility to provide this information to support and promote beneficiary choice and access to needed services.

Comment: A few commenters disagreed with providing a written clinical reason for why certain diagnoses/conditions, items, services, and drugs are not covered to beneficiaries (or their representatives) and non-hospice providers. These commenters stated that hospices may be inconsistent with using evidence-based rationale or may use different sources to support their determinations. Others voiced concerns over disagreements between non-hospice providers and hospice providers on the unrelated determinations and stated this may result in debate regarding the hospice physician's reasoning. Commenters stated that varying clinical opinions between hospice and non-hospice providers may delay the provision of items, services, and drugs.

Response: We believe it is not only important to inform beneficiaries of what items, services, and drugs the hospice will not be covering because they have determined these items,

services, and drugs to be unrelated to the terminal illness and related conditions, but why the hospice has made this determination. As noted previously, beneficiaries are making a choice to elect hospice care and we believe it to be of utmost importance to promote transparency, autonomy, and patient choice, and patients need to understand the rationale for decisions being made that affect their care. While we proposed that hospices would provide a clinical rationale as part of the proposed addendum, we did not propose requirements as to specific sources of such information as we believe that hospices would use evidence-based information to communicate the rationale to patients in a manner in which they understand. There is a large quantity of available information and hospices can choose to use supporting materials to best communicate the clinical rationale to their patients. We do not expect that this would mean hospices would have to provide complex or technical supporting information to patients to rationalize their determinations. However, similar to hospices explaining what items, services, and drugs are related to the palliation and management of the terminal illness and related conditions, we also believe that they have the expertise to explain to patients why certain items, services and drugs are not related. Furthermore, while there may be debate between hospices and non-hospice providers regarding whether or not certain items, services, or drugs are unrelated, we believe that the addendum provides a tool to steer the debate and prompt meaningful communication and care coordination between all providers rendering care to terminally ill beneficiaries.

We agree with the hospice industry's views that hospice care is "the nation's first coordinated care model" and should show how the health care system can work at its best for patients at the end of life.²⁶ We think that an important part of this care coordination is communication with non-hospice providers who are also providing care to the patient, in order to ensure that continuity of care and access to needed services is part of the decision-making process and we do not anticipate any delay in the furnishing of items, services, and drugs due to the provision of this information to the patient.

²⁶ NHPCO Op-ed: "Coordinated Care Is More Than a Buzzword for Hospice Providers", April 24, 2018. <https://morningconsult.com/opinions/coordinated-care-more-than-buzzword-for-hospice-providers/>

Similarly, the hospice CoPs at 418.56(e)(5) require that hospices provide for an ongoing sharing of information with other non-hospice healthcare providers furnishing services unrelated to the terminal illness and related conditions.

Comment: Overall, while commenters did not disagree in general with the proposal of the election statement addendum, the majority of commenters stated concern with the proposed timeframe with which the hospice would be required to provide the patient and caregiver such information. Commenters indicated that 48 hours after the time of hospice election is insufficient considering that the hospice has 5 days to complete the comprehensive assessment. Commenters noted that prior to the comprehensive assessment, hospices may not have a complete patient profile, including the services or medications a patient is currently utilizing. These commenters stated that this may require hospices to anticipate covered and non-covered services, which would lead to an inaccurate election statement addendum. Commenters stated that this fails to provide patients with the information the election statement addendum is intended to convey. A few commenters stated that the 48 hour timeframe would not allow adequate time to consult with the patient's certifying physician and/or the medical director regarding medications and treatments, or to provide a written clinical explanation of why the medications or services are unrelated. Other commenters noted that nurses may be required to complete and print the election statement addendum in the patient's home, where clinical practice and policy guidelines may not be readily accessible, and would necessitate the hospice providing nurses with printers. Similarly, commenters stated that this timeframe may pose problems meeting signature requirements if the patient or representative does not return the signed election statement addendum within the required timeframe. Another commenter suggested that this may require a costly electronic solution or modifications to the existing electronic medical record (EMR).

Response: We understand the concern regarding the proposed 48 hour timeframe for providing the addendum if requested at the time of a hospice election. We recognize that in order to provide the patient or representative with the most accurate information, and ensure the usefulness of the proposed addendum, it would be beneficial to align the timeframe of the completion of

the addendum with the timeframe requirement of the completion of the comprehensive assessment, that is, if an addendum is requested at the time of a hospice election, the hospice would have 5 calendar days to provide the addendum to the requesting beneficiary (or representative). This would allow hospices sufficient time to assess all of the patient and family needs, establish the individualized plan of care, and make decisions about any items, services, or drugs they will not be covering, as they have determined them to be unrelated to the terminal illness and related conditions. Furthermore, if a beneficiary requests the addendum at the time of hospice election and dies within 5 days from the start of the hospice election, the hospice would not be required to furnish such addendum as this requirement would be deemed as being met in this circumstance.

We also understand that if the beneficiary, representative, non-hospice provider, or Medicare contractor requests an addendum at any time during the course of hospice care (that is, after the election of hospice), the hospice would need sufficient time for the IDG to adequately review the patient's plan of care and review any decisions on those items, services, or drugs they have determined to be unrelated to the individual's terminal illness and related conditions. As such, we believe that the hospice should have additional time to complete the addendum, rather than the proposal to require the hospice to provide it immediately upon request during the course of hospice care. Because the hospice has already completed the comprehensive assessment and has begun providing care, we believe 72 hours after a patient, representative, non-hospice provider or Medicare contractor request for such information represents a sufficient timeframe for reviewing the patient record and completing the addendum if this information is requested during the course of hospice care. As the plan of care should identify the conditions or symptoms that the hospice determines to be "unrelated," this information should be readily accessible to the hospice in order to allow for the timely completion of the addendum. Expanding the timeframe for completion would ensure that the hospice has adequate time to determine those items, services, and drugs that are unrelated, complete the written addendum, and provide this information to the patient (or his or her representative).

As detailed in the FY 2020 hospice proposed rule, we proposed that each individual hospice develop and

incorporate the addendum into their current admissions process in a way that best meets the hospices' needs, as well as providing this information as quickly as possible considering the potential for beneficiary cost-sharing. Likewise, non-hospice providers should have timely access to this information in order to promote continuity of care and communication amongst all patient providers and to ensure appropriate claims submission.

Comment: Many commenters suggested modifying the current Advance Beneficiary Notice of Non-coverage (ABN) (Form CMS-R-131) or the Home Health Change of Care Notice (HHCCN) (Form CMS-10280) to be hospice-specific to communicate unrelated information regarding items, services, and drugs, rather than requiring hospices to develop a new form. One industry association suggested a "Hospice Change of Care Notice" be developed and provided to patients and representatives upon request to meet the requirements for communication about items and services determined to be unrelated to the terminal prognosis. This commenter suggested providing this form after the initial and comprehensive assessment has been completed, the plan of care has been established, and members of the IDG have agreed upon the unrelated items and services.

Others suggested offering patients (and their representatives), upon request, a list of known diagnoses unrelated to the terminal illness and related conditions with the recommendation that this list could be updated through the course of care if any new unrelated diagnoses/conditions became known. These commenters stated that this would improve transparency and hold hospices more accountable for documenting and communicating these unrelated diagnoses to the patient and representative. A few commenters suggested the need for a patient/representative statement acknowledging that the patient or patient representative has reviewed the items, services, and medications with the hospice representative in order to protect the hospice from inadvertently excluding any medications or treatments the patient is receiving at the time of admission, but that may not be revealed. Commenters also suggested that the patient be required to acknowledge that a new election statement addendum would be signed if additional non-covered items, services, or medications were identified during the course of treatment.

Additionally, commenters noted that the addendum should address items, services and drugs that may be related, but that the hospice is not covering, for example a generic drug over a brand name drug due to patient preference or if a patient requests to continue using a specific drug that the hospice determines is no longer providing medical benefit to the patient. A few commenters recommended using the Medicare form, Hospice Information for Medicare Part D (OMB Form 0938-1269) stating that most hospices already use this form and that requiring a separate addendum is redundant and not necessary. Conversely, a few commenters stated that the aforementioned Part D form is fraught with issues and there is inconsistency with its use amongst hospices and Part D plan sponsors. A few commenters stated that this proposal is unreasonable because no other healthcare provider is required to furnish references for any decision that the provider makes regarding services not provided nor requires a patient to sign a detailed document listing what will not be provided.

Response: We agree with commenters that the list of items, services, and drugs not covered by the hospice because they have determined them to be unrelated to the terminal illness and related conditions should be in a format that communicates this information to patients and their representatives in the most clear and unobtrusive way possible. As stated earlier, we believe that hospices should develop this addendum, with the required content elements, to best meet their patients' needs and to align with their current admission processes and other business procedures. We disagree with commenters about using a modified ABN to communicate information about hospice non-covered items, services and drugs determined to be unrelated to the terminal illness and related conditions. The ABN, Form CMS-R-131, is issued by providers (including independent laboratories, home health agencies, and hospices), physicians, practitioners, and suppliers to Original Medicare (fee for service—FFS) beneficiaries in situations where Medicare payment is expected to be denied. The ABN is issued in order to transfer potential financial liability to the Medicare beneficiary in certain instances. Guidelines for issuing the ABN are published in the Medicare Claims Processing Manual, Chapter 30, Section 50.²⁷ As such, the purpose of

²⁷ Medicare Claims Processing Manual Chapter 30—Financial Liability Protections. <https://www.cms.gov/medicare/claims/processingmanual>

the ABN is to inform beneficiaries of the listed items and services that Medicare is not expected to approve, and the specific denial reason (that is, not medically reasonable and necessary), whereas, the proposed hospice addendum is intended to inform beneficiaries of items and services that the hospice will not cover as the hospice has determined them to be unrelated to the terminal illness and related conditions, and therefore, subject to coverage under other Medicare benefits. Similarly, mandatory use of the ABN is very limited for hospices. The three situations that would require issuance of the ABN by a hospice are:

- Ineligibility because the beneficiary is not determined to be “terminally ill” as defined in § 1879(g)(2) of the Act;
- Specific items or services that are billed separately from the hospice payment, such as physician services, are not reasonable and necessary as defined in either § 1862(a)(1)(A) or § 1862(a)(1)(C); or
- The level of hospice care is determined to be not reasonable or medically necessary as defined in § 1862(a)(1)(A) or § 1862(a)(1)(C), specifically for the management of the terminal illness and/or related conditions.

An ABN is not required to be given to a beneficiary for items and services unrelated to the terminal illness and related conditions. Additionally, an ABN cannot be issued to transfer liability to the beneficiary when Medicare would otherwise pay for items and services. Because the purpose of the ABN is to notify beneficiaries of Medicare non-coverage and shift financial liability for payment of such services to the beneficiary, we believe that modifying the ABN for purposes of notifying the beneficiary of items, services, and drugs not covered by the hospice as unrelated, may be more confusing for patients in understanding exactly what the hospice is communicating and how to seek coverage from other benefits.

The Home Health Change of Care Notice (HHCCN) is provided to beneficiaries to notify them of home health plan of care changes. That is, the HHCCN is given to a beneficiary where there is a reduction or termination of services listed on the home health plan of care due to physician/provider orders or limitations of the HHA providing the specific service. While we agree that the HHCCN has some similar components of the proposed addendum (for

example, the addendum would inform beneficiaries of changes to non-covered items and services and the reason for the change), there are also inherent differences between the HHCCN and the proposed addendum. As stated in the FY 2020 hospice proposed rule (84 FR 17594), the purpose of the proposed addendum is to inform beneficiaries and their families of those items, services, and drugs determined by the hospice to be unrelated to the terminal illness and related conditions, and therefore, not covered by hospice. In other words, these are determined not to be hospice items, services or drugs related to the terminal illness, and therefore, would not be considered the hospice’s responsibility to provide. We believe that the addendum should clearly state that these are items, services, and drugs that the hospice has determined to be unrelated and therefore, not covered by the hospice. However, as we are proposing that hospices develop their own addendum, there is nothing prohibiting them from mirroring forms such as the HHCCN to facilitate clear communication between the hospice beneficiary and their representative, as long as the addendum includes the required elements.

The suggested “Hospice Change of Care Notice” sounds very much like the proposed addendum given the purpose of this suggested change of care notice is to communicate similar information as the addendum. However, the timeframes accompanying the suggested “Hospice Change of Care Notice” allow more time to complete the initial and comprehensive assessment, establish the plan of care with IDG input and secure agreement of those items unrelated to the terminal illness and related conditions. As described above, we agree that the timeframe for completion of the requested addendum should more accurately align with already existing requirements. However, as stated above, we believe that the addendum should be clear in its purpose that these are items, services, and drugs the hospice has determined to be unrelated to the terminal illness and therefore not the hospice’s coverage responsibility, but may be covered under other Medicare benefits.

We believe that 5 days to complete the addendum, if requested at the time of a hospice election, should provide adequate time for all of these activities to occur and is in alignment with the timeframe requirements at § 418.54(b) for completion of the comprehensive assessment. We remind hospices that the hospice CoPs at § 418.54(b) require that the RN, in consultation with the other members of the IDG, considers the

information gathered from the initial assessment as they develop the plan of care and the group determines who should visit the patient/family during the first 5 days of hospice care in accordance with patient/family needs and desires, and the hospice’s own policies and procedures. A hospice does not have to wait 5 days to complete the comprehensive assessment as hospices may choose to complete the comprehensive assessment earlier than 5 days after the effective date of the election (for example, the hospice may complete the comprehensive assessment at the same time as the initial assessment). Care planning begins as soon as the individual elects hospice care and much of the care planning and the decision-making occurs throughout this period of time, so we believe that completing the addendum within 5 days of the hospice election (or within 72 hours if the addendum is requested during the course of hospice care) is not unreasonable.

While some commenters suggested adding statements to the addendum to acknowledge that the patient or patient representative has reviewed the items, services, and medications with the hospice representative in order to protect the hospice from inadvertently excluding any medications or treatments the patient is receiving at the time of admission, and to acknowledge that a new addendum would be signed if additional non-covered items, services, or medications are identified during the course of treatment, we proposed that the addendum would include a statement that the addendum is subject to review and shall be updated, as applicable, in writing, to the beneficiary (or representative). Additionally, we proposed that the addendum would include a statement that signing the addendum (and any updates) is only an acknowledgement of receipt of the addendum and not necessarily the beneficiary’s agreement with the hospice’s determinations (84 FR 17595). If the beneficiary (or representative) requests the addendum at the time of the hospice election (that is, at the time of admission to hospice), hospices could include language on the addendum that those unrelated conditions, items, services, and drugs are those the hospice has identified as present on admission and that any changes to this list (due to new, changing, or inadvertently excluded conditions, items, services, and drugs) would be reflected in written updates to the addendum. While we expect hospices to be as thorough as possible when completing the election statement

addendum, we recognize that there may be times when they are not aware of all of the individual's conditions/diagnoses at the time of the hospice election, which could result in information inadvertently excluded on the addendum. Consequently, hospices have the option to make updates to the addendum, if necessary, to include such conditions, items, services and drugs they determine to be unrelated throughout the course of a hospice election. We believe that the requirements proposed and these suggestions would mitigate hospices' concerns regarding any items, services, or drugs that may have been inadvertently excluded when completing the addendum.

Given that hospices would develop their own addendum, hospices may add additional language to inform beneficiaries that the addendum reflects the most accurate information that they have at the time the addendum is completed and that updates would be provided, in writing, if there are any changes that would need to be included based on any new information.

While some commenters stated that addendum should also address those items, services, and drugs that may be related, but that the hospice is not covering, for example a brand name drug as opposed to a hospice formulary drug, or if a patient requests to continue using a specific drug that the hospice determines is no longer providing medical benefit to the patient, we do not think the addendum is the appropriate mechanism to communicate this information. The individualized hospice plan of care is developed in accordance with patient preferences and goals in mind, including those related to drugs. Decisions about those items, services, and drugs should be made based on collaboration between members of the interdisciplinary group (IDG), the patient's attending physician (if any), as well as the patient and their family. This decision-making would include determinations of what is reasonable and necessary to meet the care plan goals. We remind stakeholders that when a beneficiary elects the hospice benefit, he or she agrees to forego the right to Medicare payment for services related to the terminal illness and related conditions unless provided by the hospice. This would mean that if a beneficiary wants to use a brand name drug instead of its' generic equivalent, or wants to continue a drug that the hospice has determined to no longer be reasonable and necessary, the beneficiary is liable for payment for the drug. The purpose of the addendum is to inform the beneficiary of those items,

services and drugs the hospice has determined to be unrelated to the terminal illness and related conditions. The scenario described by these commenters reflects a situation in which the drug would be related to the terminal illness and related conditions but is not on the hospice formulary. Therefore, we believe it would be confusing to provide beneficiaries information on related items, services, and drugs on the addendum meant to document unrelated items, services, and drugs not covered by the hospice. While we do not routinely receive reports of beneficiaries preferring to use a brand name drug instead of a generic equivalent drug on a hospice's formulary, we are aware of a few instances in which that to be the case. Therefore, we will continue to monitor reports of these types of situations to consider whether the use of the addendum could be expanded and we would make such proposals in future rulemaking if warranted.

However, if there is a situation in which the patient wants to continue with related items, services, and drugs that the hospice has previously been providing, but that the hospice determines are no longer reasonable and necessary, or the patient decides to switch to a brand name drug rather than the generic equivalent on the hospice formulary, and the hospice provides the item, service, or drug, the hospice would provide the beneficiary with an ABN to notify the beneficiary that he or she would be financially liable. If the hospice does not continue to provide the item, service, or drug, no ABN is required to be given to the beneficiary.

If the beneficiary desires to continue taking drugs that are not covered by Medicare Part A (hospice) or Part D, then the hospice must fully inform the beneficiary of his or her financial liability. Beneficiaries may also submit quality of care complaints to a Quality Improvement Organization (QIO) when the beneficiary prefers a non-formulary drug because, for example, it's believed to be more efficacious than the formulary drug prescribed by the hospice.

Beneficiaries who disagree with such determinations may continue raising these issues through the Medicare fee-for-service appeals process if the determination relates to Part A or B coverage and the Part D appeals process if the determination relates to Part D coverage. Whether or not the hospice furnishes the drug, if the beneficiary feels that the Medicare hospice should cover the cost of the drug, the beneficiary may submit a claim for the medication directly to Medicare on

Form CMS-1490S. If the claim is denied, the beneficiary may file an appeal of that determination under the appeals process set forth in part 405, subpart I.

We note that the hospice CoPs at § 418.56 require a review of the hospice plan of care at least every 15 days, or more often as the patient conditions requires. This ensures that there are ongoing discussions with the beneficiary so that all hospice care is provided in accordance with patient needs. Similarly, the IDG should be proactive in developing each patient's plan of care by planning ahead for anticipated patient changes and needs. Decisions should reflect patient/family preferences and should not solely be a response to a crisis.²⁸ We believe that the addendum is to be used as a tool to have these discussions both at the time of hospice election, when care planning begins, and throughout the course of a hospice election, as care planning changes to meet the needs of hospice patients and their families.

Regarding the use of the current Hospice Information for Medicare Part D (OMB Form 0938-1269), we note that Part D plan sponsors currently have a prior authorization process in place for their member enrolled in hospice for the four categories of drugs (analgesics, anti-nausea, anti-anxiety, and laxatives). A voluntary, standardized prior authorization (PA) form was developed with industry input for hospices to submit to Part D plans in order to assist in:

- (1) Proactively avoiding a drug claim from rejecting at point-of-sale;
- (2) Overriding reject edit at point-of-sale; and
- (3) Communicating a change in the patient's hospice status.²⁹

Hospices currently can use the standardized PA form as a means of notifying a Part D plan that their member has elected hospice care, as well as to document specific drugs that are or are not being covered by the hospice. We don't agree that use of the Hospice Information for Medicare Part D (OMB Form 0938-1269) meets the purpose of the addendum as the Hospice Information for Medicare Part D (OMB Form 0938-1269) is exclusively for use for the identified four classes of

²⁸ State Operations Manual Appendix M—Guidance to Surveyors: Hospice. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_m_hospice.pdf.

²⁹ Hospice Information for Medicare Part D Plans, OMB-approved form (No. 0938-1269). <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/Instruction-and-Form-for-Hospice-and-Medicare-Part-D.pdf>.

drugs (analgesics, anti-nausea, anti-anxiety, and laxatives) for hospice beneficiaries who are seeking to receive these drugs through their Part D prescription coverage. Unfortunately, this particular form is not comprehensive enough to communicate those items, services, and drugs (not just the four classes) the hospice has determined to be unrelated to the terminal illness and related conditions.

However, as mentioned in the FY 2020 hospice proposed rule (84 FR 17596), we intend to work with hospices and Part D plans to develop a process in which the addendum potentially could be used at the point-of-service when hospice beneficiaries are filling drug prescriptions to ensure timely access to needed drugs. Complete documentation on the part of the hospice, coupled with timely notification of Part D sponsors, mitigates the risk for possible double payment by the Medicare program for drugs, and is anticipated to prevent Part D enrollees in hospice from having a hospice related medication billed by a pharmacy to their Part D plan, potentially subjecting the beneficiary to out-of-pocket expenses.

Comment: Several commenters report that obtaining signatures on the addendum statement would be prohibitively challenging. These commenters cited instances where it is extremely difficult obtaining the patient/representative signature for the hospice election statement and expressed concerns about having a requirement to obtain a signature again on the addendum. Reasons for these challenges included having representatives who live in a different state from the hospice beneficiary who may be unable to make healthcare decisions on his or her own, lack of readily available technology such as patients or representatives not having email accounts or access to a fax machine in order to return signed documents. Other commenters asked specific questions regarding the frequency of providing the addendum and whether the signature would be required on each version of the addendum. Another commenter remarked that other providers, such as home health agencies, are not required to obtain patient/representative signature for changes to the plan of care and stated that as the addendum would be similar to a change in the home health plan of care, requirements for the hospice addendum should be a similar process. A few commenters requested further guidance regarding the acceptance of an electronic patient signature for the addendum.

Response: We note that the hospice regulations at § 418.24(b) require that the patient or representative sign the election statement. We appreciate the challenges that commenters have identified in obtaining a signature on the election statement, however, we note that obtaining the required signatures on the election statement has been a longstanding regulatory requirement. We expect that hospices already have processes and procedures in place to ensure that required signatures are obtained, either from the beneficiary or his or her representative in the event that the beneficiary is unable to sign and we expect that the same procedures may be used for obtaining signatures on the addendum. Likewise, the hospice CoPs at § 418.52(a)(3) require that the hospice obtain the patient's or representative's signature confirming that he or she has received a copy of the notice of rights and responsibilities. Therefore, we believe that it is not unreasonable to require that the addendum also be signed to ensure that the patient is aware of the important information about hospice non-covered items, services, and drugs. As noted previously in this rule and in the proposed rule (84 FR 17608), the addendum would be signed by the beneficiary as an acknowledgement that he or she has received this information, but signing it does not mean the beneficiary agrees with the determination.

Contrary to commenters' statements that beneficiaries receiving home health services are not required to sign when there are changes to the home health plan of care, the HHCCN form (CMS Form 10280) is completed when there are changes to the home health plan of care due to a reduction or termination of home health services, and the beneficiary or representative is required to sign and date the HHCCN confirming his or her review and understanding of the notice.^{30 31} Additionally, the home health CoPs at § 484.60(c)(3)(ii) require that any revisions related to plans for the patient's discharge must be communicated to the patient, representative, caregiver, all physicians issuing orders for the HHA plan of care, and the patient's primary care practitioner or other health care professional who will be responsible for

providing care and services to the patient after discharge from the HHA (if any). We also remind stakeholders that the HHCCN references services that are or were provided under the home health plan of care. Conversely, the addendum is used to communicate items, services, and drugs that would not be on the initial (or subsequent) hospice plan of care to ensure coverage transparency where the hospice has determined that certain items, services, or drugs would not be covered (that is, furnished and paid for by the hospice) because they are unrelated to the terminal illness and related conditions.

In summary, we continue to believe that because of the significance of the decision to elect hospice care and waive the right to Medicare payment for care related to terminal illness and related conditions, the terminally ill individual (and his or her representative) must have information related to all aspects of their care, including what the hospice has determined to be "unrelated". Requiring the patient to sign the written addendum memorializes that this important information has been provided by the hospice to the beneficiary.

Comment: Several stakeholders strongly urged CMS to examine non-hospice expenditures to determine what proportion is actually the responsibility of, and within the control of, the hospice before implementing a mandatory process for hospices. Commenters noted that there are frequent instances when care is provided to hospice patients without the hospice's knowledge and the hospice discovers that the item, service, or drug has been provided only after the fact. An industry association stated that the language in the proposed rule presupposes that it is only the hospice's responsibility to communicate with other providers and offered ideas for improving the flow of communication between hospice and non-hospice providers. Commenters noted that other providers may be unaware that a patient has elected hospice and that they need to coordinate with the patient's hospice to determine whether the services are unrelated to the terminal prognosis and that these non-hospice providers must treat claims for hospice beneficiaries differently with the use of modifiers or a condition code. These commenters recommended that CMS and Medicare Administrative Contractors (MACs) provide clear guidance to physicians on billing requirements for using the GV and GW modifiers and to circulate this guidance widely in a variety of publications to promote awareness of these billing requirements as they

³⁰ Form Instructions for the Home Health Change of Care Notice (HHCCN) CMS-10280. <https://www.cms.gov/Medicare/Medicare-General-Information/BNI/Downloads/HHCCN-Form-Instructions.pdf>.

³¹ Medicare Claims Processing Manual Chapter 30—Financial Liability Protections. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c30.pdf>.

related to non-hospice care for hospice beneficiaries. Some suggested that non-hospice providers should share in the responsibility of identifying their patients who are under a hospice election. These suggestions included making Medicare system changes to allow for a shortened process that would expedite the notification of election in the Common Working File (CWF), implementing flags in the Medicare claims processing systems to notify other provider types of the hospice election and requiring these other providers to communicate and coordinate with the hospice, as well as asking beneficiaries and/or their representative if they are a hospice patient.

Response: While we agree that all participating Medicare providers should actively engage in ongoing communication and care coordination to ensure that Medicare beneficiaries receive appropriate care, the proposed rule primarily focused on the hospice's responsibility in these activities. The hospice CoPs at § 418.56(e) detail the requirements of hospice care coordination. Specifically, the hospice CoPs require that the hospice provide for an ongoing sharing of information with other non-hospice healthcare providers furnishing services unrelated to the terminal illness and related conditions. Furthermore, hospices are required to have systems in place to facilitate the exchange of information and coordination of services among staff and with other non-hospice healthcare providers. Likewise, hospices are required to have documentation in the clinical record of the sharing of information between all disciplines providing care and with other healthcare providers furnishing services to the patient.³² The goal of this coordination is to ensure that the patient's hospice plan of care is implemented, and that the hospice care is furnished in concert with other care sources to ensure that all patient needs are met (73 FR 32099). We expect the hospice plan of care to address all patient goals in some way. If a patient has a goal that is not related to the terminal illness and related conditions, and if the hospice does not intend to address this goal, then the hospice plan of care should identify the party that is responsible for meeting the unrelated goal. Furthermore, § 418.56(e) requires the hospice to actively communicate

with the outside party to ensure that the goal is addressed. Therefore, given the comprehensive nature of the Medicare hospice benefit and the CoPs regarding the pivotal role hospices are required to play in care coordination, we believe hospices are primarily responsible for communication and care coordination with non-hospice providers while a beneficiary is under a hospice election. Likewise, the requirement that care is provided under the direction of an IDG means that the approach to patient care under hospice is holistic and requires the hospice to be primarily responsible for the medical, emotional, and spiritual care of the individual.

To address comments regarding physician education on the appropriate use of the GW and GV modifiers, we remind stakeholders that CMS does routinely provide information on various aspects of the Medicare program include educational materials on Medicare benefits and claims processing. There is a MLN Matters® article, "Hospice Related Services—Part B", intended for physicians submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries who are in a hospice period of coverage.³³ Likewise, the Medicare claims processing manual, chapter 11, "Processing Hospice Claims" includes detailed information on the appropriate use of the GW and GV modifiers. We believe these are the most appropriate CMS mechanisms for providing such information to physicians and other providers of services.

To address comments regarding making changes to the Medicare systems to allow for a shortened process to update the CWF, we note that CWF processing time still varies because of whether an NOE must go through the one-time out of service area (OSA) process. OSA processing occurs when a beneficiary's master record is not found on the local CWF host site for the MAC and several nightly batch cycles are required to query each of the other host sites to find it. This process is standard for all claims and cannot be revised just for hospice without creating risk for all other Medicare payments. While Electronic Data Interchange (EDI) submission of NOEs does not affect the processing time in CWF, it reduces delays caused by keying errors. Once the NOE is accepted at CWF, the hospice record is available for all providers on the HIPAA (Health

Insurance Portability and Accountability Act) Eligibility Transaction System (HETS) inquiries. The HETS allows providers to check Medicare beneficiary eligibility data in real-time. Providers are encouraged to use HETS to prepare accurate Medicare claims, determine beneficiary liability, or check eligibility for specific services.

Comment: A few commenters expressed concern over the role of the QIO when beneficiaries disagree with the hospice determination as to those items, services, and drugs. These commenters disagreed with having to include QIO information on the election statement given hospices are already required to provide information to beneficiaries regarding QIOs at hospice admission. Other commenters expressed concerns over how QIO determinations would be made, given that these determinations are within the scope of a hospice physician who has medical information in the clinical record with which to base such a determination. These commenters stated that unless the QIO reviewer is a physician with experience/training in end-of-life care and has sufficient information, the QIO reviewer could not make a determination as to whether the hospice's determination of unrelatedness is correct and appropriate. Commenters request additional clarity about the BFCC–QIO findings and how the hospice is to implement them so there is no confusion regarding the authority of the BFCC–QIO, the hospice medical director, and the MACs when determining relatedness, eligibility, and continued coverage of hospice services.

A few commenters remarked that the crux of the issue is the lack of guidelines provided by CMS as to how determinations of relatedness are made, other than it is the responsibility of the hospice physician. One commenter stated that relatedness is vague. One industry association reiterated that there is a lack of clarity around what "relatedness" means and that guidance should be updated and be more specific. This commenter stated that the repeated requests for clarification underscores the reality of how decisions are being made. This commenter went on to state that there are those hospices that have a broad, holistic view and philosophy of care that is in alignment with CMS' intent and is aligned with their organizational mission and values, though this commenter remarked that there are those hospices that take advantage of the "gray space" and manipulate the system to avoid payment of items, services, and drugs that should be the hospices' responsibility. Finally,

³² State Operations Manual Appendix M—Guidance to Surveyors: Hospice. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_m_hospice.pdf.

³³ MLN Matters® Number: SE1321, Hospice Related Services—Part B. November 2014. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1321.pdf>.

this commenter recommended that CMS work with stakeholders to develop more standardized definitions of related and unrelated in order to promote consistency of delivery across the benefit and where the need for an addendum would be unnecessary as a result.

Response: We remind stakeholders that Immediate Advocacy with the Beneficiary and Family Centered Care Quality Improvement Organization (BFCC-QIO) is an informal alternative dispute resolution process used to quickly resolve a Medicare beneficiary's (or his or her representative's) verbal complaint regarding the quality of Medicare-covered health care received or services that accompany medical care (for example, medical equipment). This process involves the BFCC-QIO directly contacting the beneficiary's practitioner or provider, usually by telephone. The process is voluntary for both the beneficiary and the provider or practitioner. The purpose of Immediate Advocacy is to provide a flexible, dialogue-based resolution process between the beneficiary and the provider.

There are specific criteria for eligibility for Immediate Advocacy. A QIO may offer Immediate Advocacy to the beneficiary prior to obtaining a written beneficiary complaint when the following criteria are met:

1. After initially screening the complaint, the QIO determines the complaint was received within 6 months from the date of service on which the care occurred concerning the complaints and:

- a. The beneficiary complains about a matter that is unrelated to the clinical quality of health care itself but that relates to items or services that accompany or are incidental to the medical care and are provided by a practitioner and/or provider (for example, beneficiary in search of or needing an intervention for resources and/or services covered by Medicare, such as a wheelchair that was not delivered, a beneficiary concerned about the quality of communication with their practitioner and/or provider); or

- b. The beneficiary complains about a matter that, while related to the clinical quality of health care the beneficiary received, does not rise to the level of being a "gross and flagrant," "substantial," or "serious or urgent" quality of care concern. This may include situations where the QIO determines that the medical information will most likely not contain evidence related to the complaint.

2. The beneficiary agrees to the disclosure of his or her name. (42 CFR 476.110(a)(3)).

3. All parties orally consent to the use of Immediate Advocacy. (42 CFR 476.110(a)(4)).

4. All parties agree to the limitations on redisclosure; namely, all communications, written and oral, exchanged during the Immediate Advocacy process must not be redisclosed without the written consent of all parties (42 CFR 476.110(c) and 480.107).

If the practitioner/provider opts NOT to participate in the Immediate Advocacy process, the QIO must immediately contact the beneficiary and give him or her the opportunity to file his or her complaint in writing.³⁴

As noted previously, the regulations at § 476.110 set forth the requirements as they relate to the Immediate Advocacy process which is meant to be an informal alternative dispute resolution process used to quickly resolve an oral complaint a Medicare beneficiary or his or her representation has regarding the quality of Medicare covered health care received. This process involves a QIO representative's direct contact with the provider and/or practitioner. When a quality of care complaint is handled through the Immediate Advocacy process, the QIO does not make clinical determinations based on whether or not it agrees with the hospice's determination about whether or not the disputed items, services, or drugs are unrelated to the terminal illness and related conditions, but rather facilitates discussion between the beneficiary and the hospice to see if the two parties can come to a satisfactory resolution. While it cannot require services be covered, provided, or be paid for by Medicare, the BFCC-QIO addresses quality of care issues for Medicare beneficiaries. Additionally, with the agreement to use Immediate Advocacy, a Peer Review is not performed. A Peer Review is a review by health care practitioners of services ordered or furnished by other practitioners in the same professional field and is generally part of the written complaint process through the QIO. If the QIO receives a written complaint, Immediate Advocacy may not be offered; rather the written complaint would be subject to the Beneficiary Complaint Review Peer Review process.³⁵ Furthermore, medical

information should not be requested from the practitioner or provider for this Immediate Advocacy process. While the goal of Immediate Advocacy is to informally and quickly resolve the beneficiary's complaint, in certain instances the beneficiary might remain dissatisfied after completion of Immediate Advocacy. Should this occur, the QIO must advise the beneficiary of his or her right to file a written complaint. Therefore, we reiterate to commenters that the role and scope of the BFCC-QIO's Immediate Advocacy authority is limited, as described in regulation.

We also remind commenters that the hospice medical director must consider all health conditions, whether related or unrelated to the terminal condition, as well as current clinically relevant information supporting all diagnoses when making the decision to admit a patient into hospice (42 CFR 418.25). Additionally, all hospice care and services furnished to patients and their families must follow the individualized written plan of care established by the hospice interdisciplinary group in collaboration with the attending physician (if any), the patient or representative, and the primary caregiver in accordance with the patient's needs if any of them so desire (42 CFR 418.56). The hospice must ensure that each patient and the primary care giver(s) receive education and training provided by the hospice as appropriate to their responsibilities for the care and services identified in the plan of care. The plan of care must specify the hospice care and services necessary to meet the patient and family-specific needs identified in the comprehensive assessment as such needs relate to the terminal illness and related conditions (42 CFR 418.56). Based on this information, each hospice makes the determination as to what items, services, or drugs are considered related to the terminal illness and related conditions, and belong on the plan of care. However, that is not to say that these determinations cannot be questioned by the beneficiary, or his or her representative. Therefore, the addendum is to provide the information on hospice determinations as to what unrelated items, services, and drugs it will not be covering to spur conversations with the patient about these determinations and the impact on the patient. In addition, Immediate Advocacy is a process in which the beneficiary can question such determinations.

³⁴ Quality Improvement Organization Manual Chapter 5—Quality of Care Review. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/qio110c05.pdf>.

³⁵ Quality Improvement Organization Manual Chapter 5—Quality of Care Review. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/qio110c05.pdf>.

www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/qio110c05.pdf.

In response to comments regarding concerns about the vagueness of “relatedness” and requests for additional CMS guidance as to what is “related” and “unrelated”, we remind commenters that since the implementation of the Medicare hospice benefit, it has been our position that virtually all of the care needed by terminally ill individuals should be provided by the hospice (48 FR 56010). As such, there should not be a voluminous list of unrelated items, services, and drugs given the comprehensive nature of hospice services under the Medicare hospice benefit and the requirement that the hospice provide care addressing the physical, medical, psychosocial, emotional, and spiritual needs of hospice patients and families facing terminal illness and bereavement. We note that in the FY 2015 hospice proposed rule (79 FR 26538) we solicited comments on definitions of “terminal illness and related conditions.” We received a significant number of comments on these definitions, with most commenters opposing CMS proposing these definitions. Commenters stated that hospices were the experts at making such clinical determinations and that the statute and hospice regulations allow for hospices to make such determinations. Commenters noted that the hospice should be the entity that establishes a process to make determinations as to what is related and unrelated to the terminal illness and related conditions on a patient-by-patient basis. Due to this feedback, we have not proposed definitions for “terminal illness or related conditions”.

We understand that national industry associations have subsequently engaged in activities with hospices to communicate a process for helping hospices make these relatedness determinations in the form of clinical decision-making process workflows.³⁶ We appreciate these efforts and ongoing dialogue amongst the hospice industry in addressing best practices in making clinical decisions to provide comprehensive and holistic care to hospice beneficiaries and their families.

Comment: Some commenters suggested that rather than implement sweeping regulations required of all hospices, CMS should implement a more targeted approach by analyzing data to identify hospices that are out of compliance with the coverage of DME

and disease-specific drugs and penalizing them directly for failure to provide such services. One commenter remarked that most hospices provide all items, services, and drugs in good faith and in accordance with Medicare regulations and therefore should not be subject to unnecessary requirements. Another commenter recommended that CMS take additional steps to identify the breadth of the issues contributing to non-hospice spending and address inappropriate spending outside of the hospice benefit accordingly. Specifically, this commenter suggested that CMS determine what proportion of hospice spending is occurring within the first few weeks of hospice care when the CMS systems have not been updated with Medicare notice of election information and where the hospice is informing non-hospice providers that the item, service, or drug is unrelated. One commenter stated that a simple solution would be to block all Medicare services without hospice approval. One commenter wrote that the addendum proposal would make hospices look like “the bad guy” in communicating those items, services, and drugs they have determined to be unrelated even if the hospice is providing this information in good faith.

Response: For those providers who do furnish all items, services and drugs for hospice patients, this requirement would be met in that there would be no request for an addendum as the hospice would be furnishing all of the patient's care needs. We remind stakeholders that the hospice regulations are applicable to all Medicare-participating hospice providers. Program integrity audits and survey actions are appropriate mechanisms to enforce the payment regulations and the CoPs. If there are identified program integrity concerns or CoP violations, the appropriate targeted actions can then be taken for those who do not meet the requirements.

To reduce the incidence of inappropriate payments for beneficiaries under a hospice election, hospices are required to submit a Notice of Election (NOE with its Medicare contractor within 5 calendar days after the effective date of the election statement. The purpose of a timely-filed the NOE is to alert the Medicare claims processing system that a beneficiary is under a hospice election to avoid inappropriate or duplicative payments to other Part A, Part B, or Part D providers, and to safeguard beneficiaries from inappropriate liability for copayments or deductibles.

We have been analyzing non-hospice spending for a number of years and have been presenting information on the

breadth of this issue in proposed and final rules (for instance, our FY 2016 hospice wage index proposed rule at 80 FR 25849, and our FY 2019 hospice wage index proposed rule at 83 FR 20946). We also note that in examining non-hospice spending, we have excluded admission and discharge dates as part of our analysis. In the future, we will consider examining other time points of non-hospice spending, including the proportion of spending that is occurring in the first 5 days of a hospice election where the claims processing system may not yet be aware of the hospice election.

We oppose blocking all beneficiary access to services ordinarily covered by Medicare without hospice approval because the complexity of instituting such a process would potentially delay access to needed items, services, and drugs.

Non-hospice providers are already required to submit claims with the appropriate modifier when furnishing services to beneficiaries under a hospice election. Non-hospice providers are required to report the GW modifier (or condition code 07 for institutional providers) to identify that services were unrelated to the terminal illness and related conditions or the GV modifier to identify that services were related to the terminal illness and related conditions. For beneficiaries enrolled in hospice, A/B MACs (B) shall deny any services on professional claims that are submitted without either the GV or GW modifier. Therefore, there is already a mechanism in place to prevent inappropriate payments during a hospice election. As we stated in the FY 2020 proposed rule (84 FR 17597), we also believe that the addendum may allow the non-hospice provider to be “without fault” if there is any question regarding an overpayment. In accordance with section 1870 of the Act, a provider is responsible for an overpayment if the provider knew or had reason to know that service(s) were not reasonable and necessary, and/or the provider did not follow correct procedures or use care in billing or receiving payment. If non-hospice providers were given access to a patient's addendum, this potentially could provide evidence under section 1870 of the Act in demonstrating that the non-hospice provider did or did not have reason to know that the services provided by the non-hospice provider were duplicative, or otherwise not reasonable and necessary (considering the service itself was otherwise reasonable and necessary and satisfied all other requirements for payment). Moreover, if a non-hospice provider submitted a claim to Medicare for

³⁶ Determining Relatedness to the Terminal Prognosis Process Flow, National Hospice and Palliative Care Organization. December 2014. https://wshpco.org/media/Relatedness_Process_Flow_FINAL_2.14.pdf.

services provided to a beneficiary that were unrelated to the terminal illness and related conditions but did not have the supporting documentation demonstrating that the services were unrelated, this could, among other things, delay payment. Having the addendum identifying the unrelated conditions, items, services, and drugs may provide the necessary documentation support that the non-hospice provider was rendering services unrelated to the terminal illness and related conditions. Therefore, the addendum could assist in more accurate claims submission, mitigate potential duplicative payments, and provide non-hospice providers with documentation to support a “without fault” determination.

Finally, we disagree that the purpose of furnishing an addendum to communicate hospice non-covered, unrelated items, services, and drugs is to make the hospice look like “the bad guy”. Again, hospices are already required to inform beneficiaries of coverage under the Medicare hospice benefit. As such, providing this information supports the philosophy of care of putting patients first, promoting patient choice, and advocating for patient autonomy.

Comment: A majority of commenters opposed the proposal that the addendum be a condition for payment. Many commenters suggested that instead of a condition for payment, the proposed addendum should be a CoP, as they believe that protection of patient rights is more appropriately reviewed under the survey oversight process. Commenters stated that in order for the proposed addendum to be a condition for payment, there would need to be a standardized process of recording any unrelated items, services, and drugs and documenting whether or not the addendum was requested in the patient’s medical record. Several commenters questioned how an addendum that is mandatory, but only upon request, could be appropriately used as a condition for payment. Many commenters expressed concern over the implications for auditing under medical review. Specifically, commenters asked how to protect themselves from claims denials if there is no addendum (or addendum updates) present in the medical record because there was no patient (or representative) or provider request. Others question whether the MACs would use the addendum for claims denials if the MAC disagrees with the hospice’s determinations. A national industry association stated that the process to determine whether the addendum was requested, when it was

requested, whether it is present, and whether the condition for payment requirement has been met, is fraught with issues. Several commenters requested that CMS develop specific protections to prevent claims denials solely because an addendum is not in the medical record and to state that the addendum would not be used to dispute determinations of relatedness which could result in claims denials. A few commenters thought that the addendum should be provided to every hospice beneficiary, whether requested or not, to protect the hospice from claims denials resulting from missing addendums in patients’ medical records. A few commenters stated that the vast majority of patients have no unrelated conditions and therefore it seems unnecessary to require such a form. Another commenter believed that the addendum would have a chilling effect at the time of hospice election and may deter admissions, especially for those patients who are reluctant to discontinue certain services and drugs, like maintenance medications.

Response: While we understand stakeholder concerns about including an addendum statement as a condition for payment, we believe this is necessary to ensure that hospices are diligent in providing this information to Medicare hospice beneficiaries on request. We regard this addendum as an important mechanism of accountability for hospices to provide coverage information to beneficiaries electing the hospice benefit. We also believe that the various reports by the OIG (for example; OEI-02-16-00570, July, 2018, “Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio,”³⁷ and A-06-10-00059, June 2012, “Medicare Could Be Paying Twice For Prescription Drugs For Beneficiaries In Hospice”)³⁸ highlight the issues with a patient’s lack of knowledge of hospices’ limitation on their coverage, and the possibility of hospices potentially not covering items, services, and drugs that should be hospices’ responsibility. We reiterate that the election statement addendum, as a condition for payment, would achieve the goal of increasing comprehensive patient education, awareness, empowerment, and coverage transparency. As stated in the FY 2020

hospice proposed rule, this does not mean that in order to meet this condition for payment that the beneficiary (or representative), or non-hospice provider must agree with the hospice’s determination. For purposes of this condition for payment, the signed addendum is only acknowledgement of the beneficiary’s (or representative’s) receipt of the addendum (or its updates) and this payment requirement would be met if there was a signed addendum (and any signed updates) in the requesting beneficiary’s medical record with the hospice. Likewise, this addendum would not be required to be submitted with any hospice claims. While we agree that this could be a CoP as opposed to a condition for payment, we continue to believe that as a condition for payment, this would ensure a more comprehensive and thoughtful approach by hospices in communicating important coverage information to beneficiaries.

We agree that it would be helpful for hospices to have a standardized documentation process for recording any unrelated items, services, and drugs and expect that many hospices may already have a documentation process in place, given the existing requirements for admission to hospice and development of the individualized plan of care. We would expect hospices to document, in some fashion, that the addendum was discussed with the patient (or representative) at the time of admission, similar to how other patient and family discussions are documented. Likewise, hospices can develop a way to document whether or not the addendum was requested at the time of hospice election (or at any time throughout the course of hospice care). This could be done in checklist format or as anecdotal notes by the nurse. However, we did not propose a specific format in which to document such conversations and hospices can develop their own processes to incorporate into their workflow. We believe that careful documentation that the addendum was discussed and whether or not it was requested would be an essential step hospices could take to protect themselves from claims denials related to any absence of an addendum (or addendum update) in the medical record.

We are aware of commenter concerns about the potential for this addendum to be used for medical review auditing purposes if it is a condition for payment. We note that there is no current process for the MACs to make determinations of “relatedness”. We remind commenters that the regulations

³⁷ Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio. July 2018. <https://oig.hhs.gov/oei/reports/oei-02-16-00570.pdf>.

³⁸ Medicare Could Be Paying Twice for Prescription Drugs for Beneficiaries in Hospice (A-06-10-00059). June 2012. <https://oig.hhs.gov/oas/reports/region6/61000059.pdf>.

afford hospices this responsibility in accordance with the CoPs at § 418.56. Therefore, the hospices' determination of those unrelated items, services, or drugs reported on the addendum could not be used solely to deny hospice claims. Nonetheless, to assuage commenter concerns about increased claims denials and documentation requests, we will collaborate with the MACs to establish clear guidelines on the use of the addendum as a condition for payment and we will propose any requirements in future rulemaking, as necessary. We do not want hospices to perceive that the purpose of this addendum is punitive against hospices, nor that it is a mechanism to deny claims; rather we want hospices to understand that the intent of this addendum is to keep patients at the forefront of their decision-making equipped with adequate information to make care choices as they approach the end of life.

While hospices can choose to provide the addendum to every electing beneficiary, we are not requiring that it is mandatory, unless the patient (or representative) requests the addendum. We encourage hospices to review their current admission processes to see how the addendum could assimilate into their procedures to help ameliorate any issues upon implementation. We believe that because hospices already should have processes in place to make determinations about those items, services, and drugs that they will not cover because they are unrelated to the terminal illness and related conditions, hospices will be able to adapt the addendum into their current processes.

Finally, we disagree that the provision of the addendum would have a "chilling effect" on hospice admissions. Generally, beneficiaries make decisions that are based on information furnished by providers rendering care. We continue to assert that the information provided in the addendum will allow beneficiaries to make those decisions to best meet their preferences and goals of care and will mitigate any unexpected need to seek services outside of the hospice and assume the associated cost-sharing. We believe beneficiaries and their families would appreciate full disclosure from the hospice as to what to expect when electing the Medicare hospice benefit.

Comment: The majority of commenters agreed that if the addendum is finalized, the effective date should be delayed until FY 2021, at minimum, in order to ensure that hospices and software vendors have adequate time to develop the addendum, modify the existing election

statement to include the new content requirements, and develop and educate on the protocols and procedural changes necessary to incorporate the addendum into hospice work flow processes, as well as work with non-hospice providers to ensure compliance.

Response: We understand that making modifications to the election statement and developing an addendum to accompany the election statement will take time for hospices to create, educate staff, and incorporate into current admission processes. Likewise, we recognize that there are some additional logistical and operation considerations (see response below) that we will need to consider and communicate to the hospice industry to help ensure a more seamless implementation. Therefore, we will finalize an effective date of FY 2021 for the election statement modifications and the addendum. This delayed effective date will allow sufficient time for us to develop a model election statement addendum to provide the industry as they move forward making the changes to their own election statements and as they develop an addendum to communicate those items, services, and drugs they will not be covering because they have determined them to be unrelated to the terminal illness and related conditions. This additional year will allow hospices to make any current process and software changes to incorporate the addendum into their workflow.

Comment: Many commenters stated that CMS underestimated the amount of time it would take for the nurse to complete the addendum stating that 10 minutes is an insufficient amount of time to extrapolate this information from the existing documentation. A few commenters stated that this would take between 20 and 30 minutes to complete. Others stated that this is not just a process of extrapolating the information, but that this is often a process of information gathering as not all relevant information is readily available at the time of the initial assessment. However, a few commenters believed that even though the timeframe to complete the addendum would be longer than 10 minutes, they suggested that the addendum should not be optional but patients (or their representatives) should be provided this detailed list as this is critical to the care process, patient empowerment, quality of care, and transparency. One commenter stated that the addendum proposal would be improved by adding appropriate reimbursement for the time and process redesign needed to make this a successful addition to hospice practice.

Additionally, the majority of commenters stated that this would significantly increase burden for hospices, as well as for patients and their families and could potentially impede access to care stating that this conflicts with CMS' Patients over Paperwork initiative. Commenters cited such concerns as the increase in time spent gathering, documenting, and communicating this information, as well as providing copies of such information, in writing, to patients, their representatives, non-hospice providers, and Medicare contractors.

Response: While we understand commenter concerns over the time it takes to complete the addendum, we remind hospices that the addendum is not a requirement for every electing beneficiary. Several commenters stated that because they do provide such a comprehensive range of services most beneficiaries would not need an addendum. We continue to believe that once a beneficiary elects the hospice benefit, most items, services, and drugs would be for the palliation and management of the terminal illness and related conditions and that there would be few things that would be unrelated.

Furthermore, because hospices should already be considering those items, services, and drugs they have determined to be unrelated as part of the admission and care planning process, we believe that providing such information, in writing, to the beneficiary (or representative) should not take a significant amount of time. Additionally, hospices would develop their own addendums, in a format that suits them to best meet the requirements and patient needs while minimizing operational burden. We also stated in the proposed rule that we would develop a model addendum to help hospices in developing their own. Several commenters stated that most hospices use the current model election statement so we trust that hospices would take advantage of the model addendum to help mitigate any burden in developing their own addendum to meet this requirement.

Additionally, we are finalizing expansion of the time to complete the addendum to 5 days in accordance with the timeframe to complete the comprehensive assessment. This means that if a requesting beneficiary dies within the first 5 days of the hospice election, hospices would not be required to complete any requested addendum as this requirement would be deemed as being met in this circumstance. Given that almost 28 percent of beneficiaries die within the first 5 days of hospice care, this would

further reduce hospice burden. We have recalculated the burden estimate in section IV. of this final rule to account for the expanded timeframe to complete the addendum where there would be fewer eligible elections subject to this requirement and thus, less burden on hospices.

We agree with those commenters who stated that the addendum would be critical in the care process and would promote patient empowerment, quality of care, and transparency. However, we are not making this a mandatory requirement for all hospice elections; we reiterate that the requirement is that the addendum would be provided only upon request as we believe this would best achieve coverage transparency without imposing undue burden on hospices. Likewise, because we believe that hospices should already have processes in place to make determinations of unrelatedness, additional payment should not be made for completion of the addendum.

Finally, while we recognize that the addendum, may result in a small increase in operational burden for some hospices, we believe this burden is outweighed by our initiative to put patients first. We believe that if a requirement results in promoting patient choice, autonomy, and coverage transparency then it is within the framework of this initiative.

Comment: In addition to the comments summarized above, we received numerous comments from hospices, industry associations, and other stakeholders who stated concerns with operational and logistical aspects of the addendum policy. Furthermore, commenters wrote that CMS drastically underestimated the operational complexity and the impact this particular requirement would have on hospice providers and patients.

Generally, commenters had questions on the logistics of delivering the addendum to the patient and family within 48 hours, the clinician who would be responsible for delivering the addendum, and whether this would require the nurse to have a mobile printer to deliver such information. Others asked what the expectations would be when there are changes to the plan of care after admission; whether the timeframe is based on when CMS accepts the election or when the provider submits the NOE; what provisions would be made for weekends and holidays; what education would be provided to MACs and the BFCC-QIOs regarding their role in this process; how CMS would expect evidence that the unrelated items, services, and drugs were discussed at admission or at other

time points during a hospice election; documentation requirements in the medical record referencing the addendum, including who requested such information and when; what CMS means when we state that the clinical rationale should be provided in “language a beneficiary can understand”; how CMS would determine whether the clinical rationale is adequately supported; and how differences between clinical opinion between the hospice physician and non-hospice providers would be handled.

Response: We realize that commenters have concerns over some of the operational and logistical details of developing and implementing an addendum to communicate, in writing, those items, services, and drugs the hospice will not cover as they have been determined by the hospice to be unrelated to the terminal illness and related conditions. As mentioned previously, hospices have asked for additional guidance and details on some of these issues including the submission of handwritten versus electronic signatures, expectations of the type of documentation expected in the medical record regarding whether or not the addendum was requested; what documentation would be requested by the MACs when an Additional Documentation Request (ADR) is made; whether the addendum could be provided in an electronic format; the provision of MAC and BFCC-QIO education, among others. Some of these issues have been addressed in previous responses in this final rule.

Because of some of the issues brought to light by commenters, we will delay the effective date for implementation of the election statement modifications and the addendum until FY 2021 to allow additional consideration of these operational and logistical issues. This will allow CMS more time to fully investigate the details brought up by commenters specifically regarding operational and auditing processes, training and education, and we will engage in rulemaking for FY 2021 as necessary to seek any additional comments on any operational or logistical proposals.

Final Decision: We are finalizing the election statement modifications as proposed. We are also finalizing our proposal that the addendum be titled “Patient Notification of Hospice Non-Covered Items, Services, and Drugs” and would include the following content requirements:

1. Name of the hospice;
2. Beneficiary’s name and hospice medical record identifier;

3. Identification of the beneficiary’s terminal illness and related conditions;

4. A list of the beneficiary’s current diagnoses/conditions present on hospice admission (or upon plan of care update, as applicable) and the associated items, services, and drugs, not covered by the hospice because they have been determined by the hospice to be unrelated to the terminal illness and related conditions;

5. A written clinical explanation, in language the beneficiary and his or her representative can understand, as to why the identified conditions, items, services, and drugs are considered unrelated to the terminal illness and related conditions and not needed for pain or symptom management. This clinical explanation would be accompanied by a general statement that the decision as to whether or not conditions, items, services, and drugs is related is made for each patient and that the beneficiary should share this clinical explanation with other health care providers from which they seek services unrelated to their terminal illness and related conditions;

6. References to any relevant clinical practice, policy, or coverage guidelines.

7. Information on the following domains:

a. *Purpose of Addendum*

b. *Right to Immediate Advocacy*

8. Name and signature of Medicare hospice beneficiary (or representative) and date signed, along with a statement that signing this addendum (or its updates) is only acknowledgement of receipt of the addendum (or its updates) and not necessarily the beneficiary’s agreement with the hospice’s determinations.

We are finalizing that the election statement modifications apply to all hospice elections but the addendum only would be furnished to beneficiaries, their representatives, non-hospice providers, or Medicare contractors who request such information. Additionally, we are finalizing our policy that if the beneficiary (or representative) requests an addendum at the time of hospice election, the hospice would have 5 days from the start of hospice care to furnish this information in writing. We are finalizing our proposal that if the beneficiary requests the election statement at the time of hospice election but dies within 5 days, the hospice would not be required to furnish the addendum as the requirement would be deemed as being met in this circumstance. If the addendum is requested during the course of hospice care (that is, after the date of the hospice election), we are finalizing that the

hospice would have 72 hours from the date of the request to provide the written addendum. We are finalizing our proposal that the election statement modifications and the addendum be effective for hospice elections beginning on and after October 1, 2020 (that is, FY 2021). As noted previously, we will continue to examine some of the operational and logistical issues highlighted by commenters to determine if any additional proposals are required for FY 2021 rulemaking.

At § 418.24(b), we are finalizing the provisions regarding the election statement modifications and the election statement addendum. In addition, we made several revisions to § 418.24. Specifically, we redesignated paragraphs (c) through (f) as paragraphs (d) through (g). This redesignation would affect two cross-references in § 418.26(c)(2) and § 418.28(c)(2). As a result, we made conforming changes to accompany the redesignations in § 418.24. Likewise, at § 418.3, we define the term BFCC-QIO as the Beneficiary and Family Centered Care Quality Improvement Organization. Because these conforming changes were not proposed in the proposed rule, we are adopting them here under a “good cause” waiver of proposed rulemaking. The specific changes we are making in the regulations simply codify the final policies we described in the proposed rule and do not reflect any additional substantive changes.

D. Request for Information Regarding the Role of Hospice and Coordination of Care at End-of-Life

In the FY 2020 Hospice Wage Index and Rate Update proposed rule (84 FR 17598), we solicited public comments on the interaction of the Medicare hospice benefit and various alternative care delivery models, including Medicare Advantage (MA), Accountable Care Organizations (ACOs), and other future models designed to change the incentives in providing care under traditional FFS Medicare. We specifically sought public comments on how hospice under Medicare FFS relates to other treatment options, how it impacts the provision of a spectrum of care for those that need supportive and palliative care before becoming hospice eligible and after, and whether rates of live discharge are a reflection of the current structure of Medicare FFS. We further solicited comments on any care coordination differences for hospice patients that received Medicare through traditional FFS prior to a hospice election, were enrolled in an MA plan prior to hospice election, or received care from providers that

participate in an ACO prior to a hospice election.

We appreciate the thoughtful input and suggestions provided by commenters in response to this request for information (RFI). We generally do not summarize or respond to comments in the final rule for requests for information as the purpose of such requests is to help CMS for future rulemaking or the development of models through CMS' Innovation Center. However, as we continue to review the comments received, we believe that the information gathered under this RFI will help inform: (1) Future CMS payment models; (2) the role of hospice with respect to ACOs; and (3) our general understanding of the traditional FFS hospice environment in relation to the increasing penetration of managed care through the MA program.

E. Updates to the Hospice Quality Reporting Program (HQRP)

1. Background and Statutory Authority

The Hospice Quality Reporting Program includes meeting the reporting requirements for both the Hospice Item Set (HIS) and Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Hospice Survey. Section 3004(c) of the Affordable Care Act amended section 1814(i)(5) of the Act to authorize a quality reporting program for hospices. Section 1814(i)(5)(A)(i) of the Act requires that beginning with FY 2014 and each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements for that FY. Depending on the amount of the annual update for a particular year, a reduction of 2 percentage points could result in the annual market basket update being less than 0 percent for a FY and may result in payment rates that are less than payment rates for the preceding FY. Any reduction based on failure to comply with the reporting requirements, as required by section 1814(i)(5)(B) of the Act, would apply only for the particular year involved. Any such reduction would not be cumulative nor be taken into account in computing the payment amount for subsequent FYs. Section 1814(i)(5)(C) of the Act requires that each hospice submit data to the Secretary on quality measures specified by the Secretary. The data must be submitted in a form, manner, and at a time specified by the Secretary.

2. Update to Quality Measure Development for Future Years

As stated in the FY 2019 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements (83 FR 38622), we launched the Meaningful Measures initiative (which identifies high priority areas for quality measurement and improvement) to improve outcomes for patients, their families, and providers while also reducing burden on clinicians and providers. The Meaningful Measures initiative is not intended to replace any existing programs, but will help programs identify and select individual measures. The Meaningful Measure Initiative areas are intended to increase measure alignment across our programs and other public and private initiatives. Additionally, it will point to high priority areas where there may be gaps in available quality measures while helping to guide our efforts to develop and implement quality measures to fill those gaps. More information about the Meaningful Measures initiative can be found at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html>.

The Meaningful Measures initiative fits well with the HQRP since it has changed little since we began with FY 2014 Hospice Wage Index and Payment Rate Update final rule (76 FR 26806). The Meaningful Measures initiative enables us to review the HQRP in order to close the gaps in quality measures to reflect the hospice industry as it has progressed to meet hospice care, including symptom management for its patients regardless of where hospice care is provided.

In the FY 2014 Hospice Wage Index and Payment Rate Update final rule (78 FR 48257), and in compliance with section 1814(i)(5)(C) of the Act, we finalized the specific collection of data items that support the following 7 National Quality Forum (NQF)-endorsed measures for hospice:

- NQF #1617 Patients Treated with an Opioid who are Given a Bowel Regimen,
- NQF #1634 Pain Screening,
- NQF #1637 Pain Assessment,
- NQF #1638 Dyspnea Treatment,
- NQF #1639 Dyspnea Screening,
- NQF #1641 Treatment Preferences,
- NQF #1647 Beliefs/Values Addressed (if desired by the patient).

We finalized the following two additional measures in the FY 2017 Hospice Wage Index and Payment Rate Update final rule, effective April 1,

2017. Data collected will, if not reported, affect payments for FY 2019 and subsequent years. (81 FR 52163 through 52173):

- Hospice Visits when Death is Imminent,
- Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission.

The Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission measure (hereafter referred to as “the Hospice Comprehensive Assessment Measure”) underwent an off-cycle review by the NQF Palliative and End-of-Life Standing Committee and successfully received NQF endorsement in July 2017. Data for the “Hospice Visits when Death is Imminent” measure pair is being collected using new items added to the HIS V2.00.0, effective April 1, 2017.

Our goal is to identify measures that provide a window into hospice care throughout the dying process, fit well with the hospice business model, and meet the objectives of the Meaningful Measures initiative. Quality measures should provide timely, understandable, comprehensive, clinically valid, and meaningful feedback to hospice leadership, all of its staff, and their different teams regardless of the hospice setting where care is provided. We solicited public input on measure concepts and actual quality measures, along with public comment on the discussions presented below.

a. Claims-Based and Outcome Quality Measure Development for Future Years

As part of Meaningful Measures initiative, we seek to develop claims-based and outcome measures as part of the future for the HQRP. While we acknowledge that there are limitations of using claims data as a source for measure development, there are several advantages to using claims data as part of a robust hospice quality reporting program. Claims-based measures place minimal burden on providers, as they do not require additional data collection and data submission. Furthermore, in contrast to self-reported data that are dependent on hospice, patient, or caregiver participation, claims data has the benefit of following a relatively consistent format and of using a standard set of pre-established codes that describe specific diagnoses, procedures, and drugs. Additionally, nearly every encounter that a patient has with the healthcare system leads to the generation of a claim, creating an abundant and standardized source of patient information. This makes claims

data widely available, relatively inexpensive, and amenable to analysis because they are readily available in an electronic format.

Medicare is the largest payer of hospice services and Medicare-certified providers predominate in hospice so it makes good sense to use claims data to reflect hospice care. Further, other settings’ quality reporting programs, such as the Inpatient Quality Reporting Program (QRP) and the post-acute care (PAC) QRPs, have adopted claims-based measures. The NQF has endorsed claims-based measures and believes they can capture quality even when not directly assessing clinical care. Although claims data have some limitations, such as incomplete reflection of care processes and patient outcomes, they will continue to be a valuable and important source of data for quality reporting for a selected set of metrics and as part of a hospice quality reporting program that includes other measures, such as HIS and CAHPS® Hospice Survey.

While not mutually exclusive of claims-based measures, we also seek to develop outcome measures as part of the Meaningful Measures initiative. Outcome measures could help with improving pain management and symptom management, which are core to hospice care. They could also help identify the value of different staff providing care at different times in hospice. For these reasons, we plan to explore the development of other claims-based and outcome measures for the HQRP to work toward the high priority areas of reducing regulatory burden and identifying gaps in care. In identifying high priority areas for future measure enhancement and development, CMS takes into consideration input from all stakeholders including: Measures Application Partnership (MAP); the Office of the Inspector General (OIG); the Medicare Payment Advisory Commission (MedPAC); Technical Expert Panels (TEP); issues raised through the Beneficiary and Family-Centered Care Quality Improvement Organization; and national priorities, such as those established by the National Priorities Partnership, the HHS Strategic Plan, the National Strategy for Quality Improvement in Healthcare, the CMS Quality Strategy, the Meaningful Measures initiative and the general public, such as through rulemaking. In addition, CMS considers feedback and input from published research and reports. We did not propose any new claims-based or outcome measures at this time. However, we solicited public comments and suggestions related to

ideas for future claims-based and outcome measure concepts and quality measures in the HQRP that could also be tied to the goals of the Meaningful Measures initiative.

A summary of the comments received regarding the future claims-based and outcome measure concepts and our responses to those comments appear below:

Comment: Several commenters support CMS efforts to develop outcome measures for hospice care. Additionally, many commenters support using claims data to develop new measures and cited the importance of a balanced measure portfolio comprising different measure types and data sources. We also received many comments in support of using data from the hospice assessment tool under development to create new patient and family outcome measures. Several commenters noted concerns about using claims data for quality measurement. Specifically the commenters noted that claims data only capture processes and not outcomes of patient care, and some commenters stated that the number of visits was not a good indicator of care quality. Commenters also stated that claims do not reflect the full scope of hospice experience because not all disciplines of the hospice team, such as volunteers or spiritual staff, are captured on a claim. Several commenters stated that claims data do not provide sufficient information to adequately represent hospice practice. Additionally, some commenters recommended that CMS modify hospice claims to capture information on all hospice disciplines such as chaplain visits.

Response: We appreciate the commenters’ support for outcome measure development and reiterate our commitment to measuring outcomes as part of the Meaningful Measures Initiative. We also appreciate the support for using a future hospice assessment tool to develop additional quality measures. We will take these recommendations under consideration as we pursue new measure development.

Regarding the limited focus of claims data, we refer readers to our discussion in the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47189) where we address those concerns regarding claims-based measures. As previously noted, claims-based measures place minimal burden on providers, as they do not require additional data collection and data submission, and follow a relatively consistent format, using standardized and established coding. Claims-based measures would be only one type of

quality measure in the QRP. This is in line with our efforts to create a broader set of quality measurement that include outcome and claims-based measures, since currently we report measures based on HIS and CAHPS® Hospice data that are process and outcome measures. We will take these comments into consideration as we continue to address the high priority areas of identifying gaps in care and reducing regulatory burden as we explore the development of other claims-based and outcome measures for the HQR.

b. Update on Claims-Based Measure Development

The FY 2018 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements, (82 FR 36638), noted that, based on input from stakeholders, CMS has identified two “high priority” areas that will be addressed by claims-based measure development: Potentially avoidable hospice care transitions and access to levels of hospice care. The potentially avoidable hospice care transitions concept was developed as a measure under consideration called “Transitions from Hospice Care, Followed by Death or Acute Care.” The goal of this measure is to identify hospices that have notably higher rates of live discharges followed shortly by death or acute care utilization, when compared to their peers. Details about this measure can be found in the FY 2017 Hospice Wage Index and Payment Rate Update and the NQF website, <http://www.qualityforum.org/map/>, where it went on the measures under consideration (MUC) list in July 2018 and was reviewed by the MAP in December 2018. At this time, we are revisiting the subject of potentially avoidable hospice care transitions. While the MAP did not support the measure as specified, MAP recognized the impact that care transitions at the end of life can have on patients and suggested a number of ways the MAP’s concerns with the measure could be mitigated. Areas that the MAP recommended included reconsidering the exclusion criteria for the measure. Specifically, they recommended that we review the exclusion for Medicare Advantage patients, as this may be excluding too many patients. Additionally, the MAP suggested adding an exclusion to allow for patient choice, as there are a number of reasons a patient may choose to transition from hospice. For example, a patient may choose to pursue additional curative treatment, have cultural beliefs that influence the definition of a good death, have limited access to primary care, or

may need to revoke the hospice benefit to avoid a financial penalty for seeking more acute care. MAP also noted that the measure may provide more useful information if it separates out the concepts addressed in the measure, as the measure may be trying to address different concepts by including both death within 30 days and admission to an acute care use within 7 days. The MAP also requested that we consider shortening the timeframe for the measure (MAP 2019, “Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care, Final Report” February 15, 2019, <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=89400>). The access to levels of hospice care measure concept is also detailed in the FY 2018 Hospice Wage Index and Payment Rate Update. After further analyses, it was determined that this measure concept as currently specified could result in hospices providing higher levels of care when it is not required by the plan of care or expected by CMS. We remain committed to developing claims-based measures that meet high priority areas and are rethinking both measures based on feedback from the MAP and our analyses. We solicited public comments on ways to further develop these two measure concepts and different measure concepts that fall under these high priority areas. A summary of those comments and our responses to the comments appear below:

While commenters supported measuring potentially-avoidable transitions and access to levels of care and agreed that these are high priority areas, they had several concerns and suggested modifying the measures, requested more detail and encouraged CMS to consider the feedback and recommendations from the National Quality Forum’s MAP in 2018 for modifying the measure specifications. They also recommended more measure testing in the measure development to help gain further support for these measures.

Comment: Several commenters noted concerns about how a hospice transitions measure would capture patient and family choices to revoke hospice in favor of other types of treatment or access to additional services. They recommended excluding from the measure live discharges when the patient elects a different hospice provider or is discharged for cause, and noted that patients’ decisions to seek acute care is outside of a hospice provider’s control. Some commenters recommended that claims data capture the reasons for a live discharge, noting

there could be many different ones. Several commenters recommended the measure be simplified by separating into two separate measures, as it is addressing different concepts by including both death within 30 days and admission to an acute care use within 7 days. They also recommended shortening the measurement period to create a stronger nexus between the hospice stay and the adverse event.

Comment: Several commenters noted that claims data do not sufficiently reflect the factors that determine appropriate provision of the various levels of hospice care and that patient and caregiver needs vary greatly. They noted that claims only indicate if the hospice has billed one of the four levels of care. They further noted that patient needs vary and the acuity information need to evaluate appropriate GIP and CHC utilization is not available in claims data. Commenters recommended looking at interdependent patterns of care and monitoring for unintended consequences, such as providing higher levels of care than needed.

Response: CMS appreciates the comments and the support for continuing to refine efforts to measure these two high priority concepts identified by the OIG in its 2018 report, entitled “Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio” and available at <https://oig.hhs.gov/oei/reports/oei-02-16-00570.asp>. We will take these comments under advisement as we continue exploring options for measuring these constructs and reiterate our commitment to working with NQF and the MAP. With respect to potentially-avoidable transitions, we are carefully considering stakeholder and MAP feedback, and are looking at multiple ways to measure this construct, including separating out the components to reduce the measure’s complexity. In our ongoing development efforts we are examining the potential impact of these measures, including any unintended consequences.

c. Update on the Hospice Assessment Tool

We discussed the plan to develop a hospice assessment tool in the FY 2018 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements, (82 FR 36638). A technical expert panel on development of such an assessment tool was held in October 2017 followed by a pilot study that began with training 9 hospice sites in December 2017. We are sincerely thankful for and appreciative of the 9

Medicare hospices that participated in the pilot study. We learned much from them during the pilot study and afterwards in lessons learned interviews. Information from that pilot study, referred to as Pilot A, can be found on the HQRP website at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/HEART.html>. We also discussed Pilot A findings, lessons learned, and goals of a hospice assessment tool at the September 2018 special open door forum (SODF). The transcript for that SODF can be found at <https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/PodcastAndTranscripts.html>. Key concepts in developing a hospice assessment tool include understanding the care needs of people through the dying process and ensuring the safety and comfort of individuals enrolled in hospice institutions nationwide. Currently, admission and discharge data from HIS are used to calculate measures in the HQRP. We would like to replace HIS and capture data with a hospice assessment instrument in order to develop quality measures and any possible future payment considerations to include bridging the gap to achieve a fuller understanding of patient care needs. While it must be recognized that hospice care differs from other PAC settings, there is a need to create a comprehensive assessment instrument for hospice care to align with other PAC settings, where feasible and practical. As such, objectives of a comprehensive assessment instrument must include the ability to establish goals of care that embrace the individual's values and preferences, and are consistent with a person-centered approach that values the person and caregiver in the care continuum with an emphasis on physical, psychosocial, spiritual, and emotional support. We continue our commitment to engaging stakeholders at regular SODF meetings and other means like the HQRP website, open door forums (ODF), webinars, and other sub-regulatory means.

One of the requests raised at the September 2018 SODF was to change the name of the hospice assessment tool from Hospice Evaluation Assessment Reporting Tool (HEART) to a name that is not as easily confused with other HQRP related tools like the Hospice Abstraction Reporting Tool (HART). We agree with this feedback since people refer to both by their same sounding acronyms and solicited public comments on the name for the hospice assessment tool.

We will keep providers informed about future measure and assessment tool development efforts and solicit key stakeholder input through regular sub-regulatory channels. Additionally, future measure concepts under development, including details regarding measure definitions, data sources, data collection approaches, and timeline for implementation will be communicated in future rulemaking.

Comment: We received several comments expressing strong support for the development of a new assessment tool for use in conducting patient assessments in real-time to assist in the plan of care and also for developing future measures to benefit hospice providers and consumers. These commenters also appreciated our ongoing and regular engagement of stakeholders via sub-regulatory means in the development process.

Commenters also expressed support for changing the name and acronym of an assessment tool, to avoid confusion. Commenters offered the following suggestions: Hospice Comprehensive Assessment Tool or the Comprehensive Assessment Tool for Hospice; Hospice Outcomes & Patient Evaluation (HOPE); Hospice Care Assessment Tool; Hospice Assessment Tool (HAT); and Evaluation and Assessment Reporting Tool for Hospice (EARTH). One commenter recommended rather than renaming the HEART (Hospice Evaluation Assessment Reporting Tool), CMS rename the Hospice Abstraction Reporting Tool (HART) to the Hospice Assessment Software Tool (HAST).

Response: We appreciate the support for and feedback on developing a new hospice assessment. We are continuing the process of developing a new hospice assessment that meets the objectives of patient-centered care. This process includes additional information gathering, including review of feedback on the HEART tool, and stakeholder engagement to develop a draft instrument for alpha testing that will ultimately support a national beta test. We intend to use rule-making to propose a timeline and process for implementing the final, tested assessment tool. We appreciate the support for wanting to use a new assessment to development outcome measures and reiterate our commitment to providing updates and engaging stakeholders through sub-regulatory means.

While HIS is a standardized mechanism for extracting medical record data, it is not a patient assessment instrument that can capture patient data in real time for use in care planning. Our goal for a hospice

assessment tool is to be more comprehensive than the HIS by capturing care needs in real-time and throughout the end of life; not just at admission and discharge. This includes flexibility to accommodate patients with varying lengths of stay. In addition, a comprehensive assessment tool will provide standardized data as all Medicare-certified hospices will be collecting the same data in standardized manner. By aligning the assessment with regular patient care, we intend to capture baseline data to support care planning and to inform quality measurement for the Hospice QRP, including outcome measures, and to support providers' quality improvement efforts. A new hospice assessment tool is intended to support quality measure development and care planning. We intend to offer training and other supports as the new tool is being prepared for implementation; the timeline for roll-out will be established through rule-making.

We also appreciate commenter's support for changing the name of the assessment under development. After reviewing the many great suggestions, we like the name, Hospice Outcomes & Patient Evaluation (HOPE). Both the full name and acronym, HOPE, captures our goals for this assessment tool. It is a patient evaluation for use by hospices and enables CMS to develop outcome measures that will help consumers in selecting hospices when publicly reported. The acronym, HOPE, also provides the sentiment of hope for patients achieving the quality of life per their goals and wishes and supported by the hospice.

Final Decision: After considering the comments received in response to the proposed rule and for the reasons discussed above, we are finalizing our proposal to call the hospice assessment tool the Hospice Outcomes & Patient Evaluation (HOPE).

3. Form, Manner, and Timing of Quality Data Submission

a. Background

Section 1814(i)(5)(C) of the Act requires that each hospice submit data to the Secretary on quality measures specified by the Secretary. Such data must be submitted in a form and manner, and at a time specified by the Secretary. Section 1814(i)(5)(A)(i) of the Act requires that beginning with the FY 2014 and for each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements for that FY.

b. Update on the CMS System for Reporting Quality Measures and Standardized Patient Assessment Data and Associated Procedural Issues

Hospices are currently required to submit HIS data to CMS using the Quality Improvement and Evaluation System (QIES) Assessment and the Submission Processing (ASAP) system. We will be migrating to a new internet Quality Improvement and Evaluation System (iQIES) as soon as FY 2020 that will enable us to make real-time upgrades, and we are designating that system as the data submission system for the Hospice QRP. Effective October 1, 2019, we will notify the public of any changes to the CMS-designated system in the future using sub-regulatory mechanisms such as web page postings, listserv messaging, and webinars. We solicited public comment on the iQIES and received no comments.

Final Decision: For the reasons discussed in the above paragraph, we will be migrating to the iQIES system as soon as FY 2020 and will provide further information regarding the migration and any future system of record changes via sub-regulatory mechanisms to make this transition as smooth as possible.

4. CAHPS® Hospice Survey Participation Requirements for the FY 2023 APU and Subsequent Years

a. Background and Description of the CAHPS® Hospice Survey

The CAHPS® Hospice Survey is a component of the CMS HQRP which is used to collect data on the experiences of hospice patients and the primary caregivers listed in their hospice records. Readers who want more information about the development of the survey, originally called the Hospice Experience of Care Survey, may refer to 79 FR 50452 and 78 FR 48261. National implementation of the CAHPS® Hospice Survey commenced January 1, 2015 as stated in the FY 2015 Hospice Wage Index and Payment Rate Update final rule (79 FR 50452).

b. Overview of the CAHPS® Hospice Survey Measures

The CAHPS® Hospice Survey measures received NQF endorsement on October 26th, 2016 (NQF #2651). We adopted these 8 survey based measures for the CY 2018 data collection period and for subsequent years. These 8 measures are publicly reported on a designated CMS website that is currently Hospice Compare.

c. Data Sources

We previously finalized the participation requirements for the FY 2020, FY 2021, and FY 2022 APUs (see 82 FR 36673). We proposed to extend the same participation requirements for the HQRP for FY 2023 and all future years. As part of the Patients Over Paperwork initiative, we solicited comments about the CAHPS® Hospice Survey questionnaire. We solicited comments regarding suggested changes, additions or deletions to the instrument that would improve its value to hospices for quality improvement and consumers for selecting a hospice.

A summary of those comments and our responses to them appear below:

Comment: Some commenters suggested that the survey was too long, too complex and duplicative. Other commenters stated that the language could be “friendlier,” that the setting of the patient’s death should determine the survey questions asked, and that the survey should be offered in a web-based version.

Response: We are currently exploring ways to simplify and shorten the survey and we are examining the feasibility of using web-based data collection in conjunction with traditional survey methods. In addition, we had a literacy-level review of the questionnaire and are reviewing what changes may be feasible to make. When we designed the survey, we considered allowing the setting of the patient’s death to determine the questions. However, the results from testing showed this would be burdensome to patients, hospices and vendors and determined a single survey would be easier to administer.

Comment: Some commenters requested changes to the timing of data collection. Most of the commenters suggested that we should start data collection sooner after the death, 45 days instead of a lag of 2 months.

Response: In the initial development of the survey, the original timeframe for sending out the survey was trying to balance respecting the difficult time the loved one was going through following the death and not waiting too long after the hospice services were provided. We will take this into consideration as we consider potential changes to the survey.

Comment: Some commenters stated that patients’ families do not make a distinction between the hospice staff and nursing home/assistance living facility staff when responding to the questionnaire.

Response: To help the respondent make these distinctions, we include specific references to the hospice

involved as part of the mail questionnaire and the telephone questionnaire script.

Comment: Several commenters requested a variety of different wording changes to the questionnaire, including changes to the response options and the addition of “not applicable” as a response. Some commenters stated that the hospice logo should be included in mailing packages.

Response: During survey development we conducted extensive cognitive interviews with potential respondents to see if they could understand the response scales. The respondents had no problems understanding or using our response options. We do not need to include “not applicable” as a response option because we provide instructions for skipping inapplicable items. We do allow hospice logos to be placed on the questionnaire for mail surveys. Please refer to the Quality Assurance Guidelines Manual on the survey website (www.hospicecahpsurvey.org).

Comment: Some commenters suggested changes to the survey exclusions, in particular the exclusion of patients who have been in hospice less than 48 hours when they died. In addition, several commenters stated that we should “give credit” for the response of “usually,” as there may be persons who are uncomfortable with absolutes such as “always.” A few commenters suggested the inclusion of questions specifically about veterans and to use ethnicity as a case-mix adjustment factor.

Response: The reason we excluded patients who die within 48 hours is because we were concerned that caregivers did not have enough experience with the hospice to provide informed responses to the survey. We do publicly report the results including responses of “usually.” We determined that we would not require the inclusion of questions specifically about veterans because it would make the survey even longer. We also note that among our case-mix adjustments are variables for the language in which the survey was administered, along with the language the caregiver reports speaking at home. The goal of case-mix adjustment is to adjust for differences in patient or caregiver characteristics that impact response tendencies. We generally do not adjust for race and ethnicity in order to not mask true differences in the quality of care across racial and ethnic groups.

Comment: Several commenters stated that we should take into consideration hospice characteristics, including rural versus urban, and hospice size.

Response: We publicly report hospice size. We consider a variety of variables, including urban and rural characteristics, when looking at quality measures. Internal analysis of our data shows that approximately eight in ten hospices that report CAHPS data are urban and about two in ten are rural. Please note that rural hospices may be more likely to qualify for size exemptions and therefore may not participate in the CAHPS® Hospice Survey.

Final Decision: We appreciate the feedback on potential changes to the CAHPS® Hospice Survey and will take these comments into consideration as we consider changes. Any potential changes will be proposed through future rulemaking.

d. Public Reporting of CAHPS® Hospice Survey Results

We began public reporting of the results of the CAHPS® Hospice Survey on Hospice Compare as of February 2018. We report the most recent 8 quarters of data on the basis of a rolling average, with the most recent quarter of data being added and the oldest quarter of data removed from the averages for each data refresh. We refresh the data 4 times a year in the months of February, May, August, and November.

e. Volume-Based Exemption for CAHPS® Hospice Survey Data Collection and Reporting Requirements

We previously finalized a volume-based exemption for CAHPS® Hospice Survey Data Collection and Reporting

requirements in the FY 2017 Hospice Wage Index and Payment Rate Update final rule (82 FR 36671). We proposed to continue our policy for a volume-based exemption for CAHPS® Hospice Survey Data Collection for FY 2021 and every year thereafter. For example, for the FY 2021 APU, hospices that have fewer than 50 survey-eligible decedents or caregivers in the period from January 1, 2018 through December 31, 2018 (reference year) are eligible to apply for an exemption from CAHPS® Hospice Survey data collection and reporting requirements (corresponds to the CY 2019 data collection period). To qualify, hospices must submit an exemption request form for the FY 2021 APU. The exemption request form is available on the official CAHPS® Hospice Survey website: <http://www.hospiceCAHPSsurvey.org>. Hospices that intend to claim the size exemption are required to submit to CMS their completed exemption request form covering their total unique patient count for the reference year (for the CY 2019 data collection period the reference year is January 1, 2018 through December 31, 2018). The due date for submitting the exemption request form for the FY 2021 APU is December 31, 2019. Exemptions for size are active for 1 year only. If a hospice continues to meet the eligibility requirements for this exemption in future FY APU periods, the organization needs to request the exemption annually for every applicable FY APU period by the final day of the calendar year. Subsequent periods will follow the

same pattern of using the year before the data collection year as the reference year for determining eligibility.

Starting with FY 2022, we proposed to provide an automatic exemption to any hospice that (1) is an active agency and (2) according to CMS data sources has served less than a total of 50 unique decedents in the reference year. The automatic exemption is good for 1 year and will be reassessed in subsequent years. Hospices with fewer than 50 unique decedents in the reference year would not be required to submit an exemption request form.

Hospices that have a total patient count of more than 50 unique decedents in the reference year, but that have a total of fewer than 50 survey-eligible decedent/caregiver pairs, will not be granted an automatic exemption. However, hospices may qualify to apply for a size exemption if they have fewer than 50 survey-eligible decedent/caregiver pairs (for example, if a patient dies in hospice care less than 48 hours after admission, they and their caregiver is not considered to be survey-eligible). Similarly, if a caregiver has an address outside the United States (U.S.) and its possessions, then that decedent/caregiver pair is not survey-eligible. Hospices may apply for a size exemption by submitting the size exemption request form as outlined above. This exemption is valid for 1 year only. If the hospice remains eligible for the size exemption, it must request the exemption annually for every applicable FY APU period. We solicited feedback on these proposals.

TABLE 14—SIZE EXEMPTION KEY DATES FY 2021 THROUGH FY 2025

Fiscal year	Data collection year	Reference year	Size exemption form submission deadline
FY 2021	2019	2018	December 31, 2019.
FY 2022	2020	2019	December 31, 2020.
FY 2023	2021	2020	December 31, 2021.
FY 2024	2022	2021	December 31, 2022.
FY 2025	2023	2022	December 31, 2023.

f. Newness Exemption for CAHPS® Hospice Survey Data Collection and Reporting Requirements

We previously finalized a one-time newness exemption for hospices that meet the criteria as stated in the FY 2017 Hospice Wage Index and Payment Rate Update final rule (81 FR 52181). In the FY 2019 Hospice Wage Index and Payment Rate Update final rule (83 FR

38642), we continued the newness exemption for FY 2023, FY 2024, FY 2025, and all future years. We encourage hospices to keep the letter they receive providing them with their CCN. The letter can be used to show when you received your number.

g. Survey Participation Requirements

We previously finalized survey participation requirements for FY 2022

through FY 2025 as stated in the FY 2018 and FY 2019 Hospice Wage Index and Payment Rate Update final rules (82 FR 36670 and 83 FR 38642 through 38643). We proposed to continue those requirements in all subsequent years. Below we reprint the Hospice Survey data submission dates finalized in the FY 2019 Hospice Wage Index and Payment Rate Update final rule (83 FR 38643).

TABLE 15—CAHPS® HOSPICE SURVEY DATA SUBMISSION DATES FOR THE APU IN FY 2023, FY 2024, AND FY 2025

Sample months (month of death)*	CAHPS® quarterly data submission deadlines**
FY 2023 APU	
CY January–March 2021 (Quarter 1)	August 11, 2021.
CY April–June 2021 (Quarter 2)	November 10, 2021.
CY July–September 2021 (Quarter 3)	February 9, 2022.
CY October–December 2021 (Quarter 4)	May 11, 2022.
FY 2024 APU	
CY January–March 2022 (Quarter 1)	August 10, 2022.
CY April–June 2022 (Quarter 2)	November 9, 2022.
CY July–September 2022 (Quarter 3)	February 8, 2023.
CY October–December 2022 (Quarter 4)	May 10, 2023.
FY 2025 APU	
CY January–March 2023 (Quarter 1)	August 9, 2023.
CY April–June 2023 (Quarter 2)	November 8, 2023.
CY July–September 2023 (Quarter 3)	February 14, 2024.
CY October–December 2023 (Quarter 4)	May 80, 2024.

* Data collection for each sample month initiates 2 months following the month of patient death (for example, in April for deaths occurring in January).

** Data submission deadlines are the second Wednesday of the submission months, which are the months August, November, February, and May.

For further information about the CAHPS® Hospice Survey, we encourage hospices and other entities to visit: <https://www.hospiceCAHPSsurvey.org>. For direct questions, contact the CAHPS® Hospice Survey Team at hospiceCAHPSsurvey@HCQIS.org or call 1 (844) 472-4621.

5. Public Display of Quality Measures and Other Hospice Data for the HQRP

a. Background

Under section 1814(i)(5)(E) of the Act, the Secretary is required to establish procedures for making any quality data submitted by hospices available to the public. These procedures shall ensure that a hospice has the opportunity to review the data that is to be made public prior to such data being made public; the data will be available on our public website. To meet the Act's requirement for making quality measure data public, we launched the Hospice Compare website in August 2017. This website allows consumers, providers, and other stakeholders to search for all Medicare-certified hospice providers and view their information and quality measure scores. Since its release, the CMS Hospice Compare website has reported 7 HIS Measures (NQF #1641, NQF #1647, NQF #1634, NQF #1637, NQF #1639, NQF #1638, and NQF #1617). In February 2018, CAHPS® Hospice Survey measures (NQF #2651) were added to the website, and in November 2018, the Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at

Admission (NQF #3235) was added to the website; please see the following rules where these topics were discussed, FY 2016 Hospice Wage Index and Payment Rate Update (80 FR 47199); FY 2017 Hospice Wage Index and Payment Rate Update (81 FR 52184); FY 2018 Hospice Wage Index and Payment Rate Update (82 FR 36675); and FY 2019 Hospice Wage Index and Payment Rate Update (83 FR 38640).

b. Update to “Hospice Visits when Death is Imminent” Measure To Be Publicly Displayed in August 2019

1. Background and Description of “Hospice Visits when Death is Imminent” Measure Pair

In the FY 2017 Hospice Wage Index and Payment Rate Update (81 FR 52163 to 52169, August 6, 2016), we finalized the “Hospice Visits when Death is Imminent” measure pair for implementation April 1, 2017. This measure pair assesses whether the needs of hospice patients and their caregivers were addressed by the hospice staff during the last days of life. The “Hospice Visits when Death is Imminent” measure pair is made up of two measures, Measure 1 and Measure 2. Measure 1 of the pair assesses the percentage of patients receiving at least 1 visit from a registered nurse, physician, nurse practitioner, or physician assistant in the last 3 days of life. Measure 2 assesses the percentage of patients receiving at least 2 visits from social workers, chaplains or

spiritual counselors, licensed practical nurses, or aides in the last 7 days of life.

2. Update to Public Reporting of the “Hospice Visits when Death is Imminent” Measure Pair

As stated in the FY 2019 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements (83 FR 38643 through 38645, August 6, 2018), quality measures are publicly reported on Hospice Compare or other CMS websites once they meet the readiness standards for public reporting, which is determined through rigorous testing for reliability, validity, and reportability. Since the proposal of the “Hospice Visits when Death is Imminent” measure pair, we have conducted further measure testing activities according to NQF guidelines and the Blueprint for the CMS Measures Management System Version 14.0 available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/BlueprintVer14.pdf>. This testing is conducted to ensure that measures demonstrate scientific acceptability (including reliability and validity) and meet the goals of the HQRP, which include distinguishing performance among hospices and contributing to better patient outcomes.

As we assessed the scientific acceptability of “Hospice Visits when Death is Imminent” measure pair, we determined that Measure 1 meets established standards for reliability,

validity, and reportability. Therefore, the measure is being publicly reported as stated in the FY 2019 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements (83 FR 38645 through 38648). Our testing of Measure 2 of the “Hospice Visits when Death is Imminent” measure pair (referred to as Measure 2) revealed that the measure did not meet readiness standards for public reporting and additional testing was needed before we could make a decision on the public reporting of Measure 2. Therefore, we decided not to publish Measure 2 of the “Hospice Visits when Death is Imminent” measure pair. See our discussion on our website: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Public-Reporting-Background-and-Announcements.html> for more information.

Although Measure 2 will not be publicly reported, we believe that Measure 2 focuses on an important aspect of quality care for imminently dying patients. Therefore, we will include quality performance data on the measure in each hospice’s confidential Quality Measure Reports and the Review and Correct Report available on the Certification and Survey Provider Enhanced Reporting (CASPER) system. Hospices will also still receive credit for reporting on Measure 2 as part of the HQRP requirements. Furthermore, Measure 2 aligns with our Meaningful Measures initiative and its quality priorities, particularly “Strengthen Person and Family Engagement as Partners in Their Care—End of Life Care according to Preferences.” While Measure 1 of the “Hospice Visits when Death is Imminent” measure pair (referred to as Measure 1) addresses case management and clinical care, Measure 2, which includes visits from social workers, chaplains or spiritual counselors, licensed practical nurses, and aides, recognizes providers’ flexibility to provide individualized care from a variety of disciplines that is in line with the patient, family, and caregiver’s preferences and goals for care and contributes to the overall well-being of the individual and others important to them at the end of life. As such, we believe that Measure 2 addresses a high-priority measure area where there is significant opportunity for improvement, as well as is meaningful to patients, clinicians, and providers alike.

We will conduct additional testing on Measure 2 to determine if and how the measure specifications may be modified or re-specified, and if the method for

displaying the measure may be adjusted, so that this measure meets the highest standards of scientific acceptability and reportability. Additional testing will also ensure that Measure 2 is thoroughly evaluated to determine that it meets the criteria for public reporting.

The results of the additional testing will inform the next steps regarding the public reporting of Measure 2 of “Hospice Visits when Death is Imminent” measure pair. As stated in the FY 2019 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements (83 FR 38643), we will inform providers of updates to testing and public reporting of quality measures, including Measure 2 of the “Hospice Visits when Death is Imminent” measure pair, through sub-regulatory channels and regular HQRP communication strategies, such as Open Door Forums, Medicare Learning Network, CMS.gov website announcements, listserv messaging, and other opportunities. We will announce any policy changes through the notice and comment rulemaking process.

Our decision not to publicly report Measure 2 of the “Hospice Visits when Death is Imminent” measure pair at this time is distinct from our interest in continuing collecting these data. Specifically, these data are needed to determine whether a measure meets all the criteria for public reporting. Continued data collection will enable us to test and modify or re-specify a measure so that these criteria are satisfied. We seek to balance these data collection effort with the section 1814(i)(5)(E) of the Act, which states, “The Secretary shall report quality measures that relate to hospice care provided by hospice programs on the internet website of the Centers for Medicare & Medicaid Services.” We believe that information required for the robust analyses to further develop this measure, modify or re-specify it to allow for public reporting justifies continuing data collection.

The data collection and submission requirements for the “Hospice Visits When Death is Imminent” measure pair will not change in order to collect the data for measure 1, which will be publicly reported beginning with FY 2019. Measure 2, which will not be publicly reported at this time, needs to be further evaluated for modification or re-specification. Measure 2 of “Hospice Visits when Death is Imminent” measure pair is calculated using items O5010, O5020 and O5030 from the HIS V2.00.0. These items collect data on hospice visits in the final 3 days of life, level of care in the final 7 days of life, and hospice visits in the three to six

days prior to death. Because the measure is not being removed from the HQRP, providers should continue to complete these items accurately and completely and submit HIS records to us in a timely manner. We require data from Section O to calculate Hospice Visits when Death is Imminent Measure 1, which will be publicly reported beginning in August 2019. Therefore, we proposed continued collection of this data to complete additional testing and to make a determination about the public reporting of Measure 2 of the “Hospice Visits when Death is Imminent” measure pair. We expect to complete our analysis by the end of FY 2020, and determine next steps for public reporting based on meeting established standards for reliability, validity, and reportability.

We are cognizant and respectful of the time and effort that hospices take to complete the HIS V2.00.0 items used to calculate and test Measure 2. We will continually evaluate the volume and robustness of the resulting data to determine when data collection is no longer required.

Comments: We received support from several commenters for our proposal to continue data collection of relevant data to support testing through September 30, 2020. We also received support for continued testing of Measure 2 of the “Hospice Visits when Death is Imminent” measure pair to evaluate if it should be publicly-reported.

Some commenters also confirmed the value of visit information for quality purposes. In addition, commenters provided suggestions for modifying Measure 2. These included addressing higher levels of care and short lengths of stay, including RN visits in the definition, and capturing whether patients and their families declined a visit during the last days of life, potentially through skip logic. Some commenters stated that Measure 1 and Measure 2 were paired metrics that should be reported together. A few commenters noted location of care and rural versus urban settings as factors that could affect measure results.

Response: We appreciate the commenters’ feedback and support for our plans to continue data collection and testing to assess options for assuring this measure meets the highest standards of scientific acceptability and reportability for public reporting. We intend to consider commenters’ specific suggestions during our testing process for this quality measure. We note that we do include urban and rural issues and location of care as we develop, modify, or re-specify this and other measures. Overall, we have found that

there is no statistical difference between the visits in urban versus rural locations and this is further supported by the literature³⁹ that supports this position.

The two visit measures are referred to as paired because they relate to the same topic of measuring visits in the last days of life by hospice disciplines. However, the measures are independent constructs and can be reported separately. The measures are each developed using different number of visits and different hospice disciplines. They are unique measures that each provide useful and distinct information for separate public reporting.

Final Decision: After considering the comments received in response to the proposed rule and for the reasons discussed in the above paragraph, we are finalizing our proposal to continue collection of this data to complete additional testing and to make a determination about the public reporting of Measure 2 of the “Hospice Visits when Death is Imminent”

measure pair. We expect to complete our analysis by the end of FY 2020, and determine next steps for public reporting based on meeting established standards for reliability, validity, and reportability. We will continue to use a variety of sub-regulatory channels and regular HQR communication strategies, such as Open Door Forums, Medicare Learning Network, CMS.gov website announcements, listserv messaging, and other opportunities, to provide ongoing updates of testing results and our plans for modifying and reporting this measure.

c. Display of Publicly Available Government Data Along With CMS and Medicare Hospice Related Data as Information for Public Reporting

1. Update To Posting of Public Use File (PUF) Data as Information for Public Reporting

In the FY 2019 Hospice Wage Index and Payment Rate Update and Hospice

Quality Reporting Requirements (83 FR 38649), we finalized plans to publicly post information from the Medicare Provider Utilization and Payment Data: Physician and Other Supplier Public Use File (PUF) and other publicly available CMS data to the Hospice Compare or other CMS website. This PUF data, along with clear text explaining the purpose and uses of this information and suggesting consumers discuss this information with their healthcare provider, displayed under a new section on Hospice Compare in May 2019. This new section precede the existing “Family Experience of Care” section on the Hospice Compare website. Tables 16 through 18 show how these data displayed on Hospice Compare.

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Table 16: Mock-up of Level of Care Provided Information on Hospice Compare

Level of care provided in calendar years 2014, 2015, and 2016	Hospice A Average Daily Census: 345 Date Certified: 04/01/1995	Hospice B Average Daily Census: 67 Date Certified: 04/01/2002	Hospice C Average Daily Census: Not available Date Certified: 04/01/2017	National Average Average Daily Census: 74
Provided Routine Home Care <u>only</u>	✓		Not Available	3.1%
Provided Routine Home Care <u>and</u> other levels of care		✓	Not Available	96.9%

Note: Information is “Not Available” for Hospice C because the hospice was Medicare-certified in 2017. PUF data currently are only available through 2016.

³⁹ Teno JM, Plotzke M, Christian T, Gozalo P. Examining Variation in Hospice Visits by

Professional Staff in the Last 2 Days of Life. JAMA

Intern Med. 2016;176(3):364–370. doi:10.1001/jamainternmed.2015.7479

Table 17: Mock-up of Primary Diagnosis Information on Hospice Compare

Medical Conditions	Hospice A Average Daily Census: 345 Date Certified: 04/01/1995	Hospice B Average Daily Census: 67 Date Certified: 04/01/2002	Hospice C Average Daily Census: Not available Date Certified: 04/01/2017	National Average Average Daily Census: 74
Cancer	18.3%	45.6%	Not Available	27.3%
Dementia	45.5%	20.7%	Not Available	21.1%
Stroke	Less than 11 patients	18.9%	Not Available	9.4%
Heart Disease	17.8%		Not Available	20.8%
Respiratory Disease		17.0%	Not Available	11.9%
Other	Less than 11 patients	Less than 11 patients	Not Available	16.1%

Note: Information is “Not Available” for Hospice C because the hospice was Medicare-certified in 2017. PUF data currently are only available through 2016. “Less than 11 patients” indicates the hospice served less than 11 patients with the indicated condition in 2016. Data for hospice providers who served between 0 and 11 patients with a particular condition is not reported in the PUF to protect personal health information and ensure publicly reported data is a reliable indication of services provided by the hospice.

Table 18: Mock-up of Location of Care Information on Hospice Compare

Location	Hospice A Average Daily Census: 345 Date Certified: 04/01/1995	Hospice B Average Daily Census: 67 Date Certified: 04/01/2002	Hospice C Average Daily Census: Not available Date Certified: 04/01/2017	National Average Average Daily Census: 74
Home	✓	✓	Not Available	99.8%
Assisted Living Facility	✓	✓	Not Available	76.1%
Nursing Facility	✓	Less than 11 patients	Not Available	60.8%
Skilled Nursing Facility	Less than 11 patients	✓	Not Available	52.5%
Inpatient Hospital Facility	✓		Not Available	31.5%
Inpatient Hospice Facility		Less than 11 patients	Not Available	17.0%
All other locations	Less than 11 patients	✓	Not Available	17.6%

Note: Information is “Not Available” for Hospice C because the hospice was Medicare-certified in 2017. PUF data currently are only available through 2016. “Less than 11 patients” indicates the hospice served less than 11 patients in the indicated location in 2016. Data for hospice providers who served between 0 and 11 patients in a particular location is not reported in the PUF to protect personal health information and ensure publicly reported data is a reliable indication of services provided by the hospice.

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2. Posting Information From Government Data Sources as Information for Public Reporting

As part of our ongoing efforts to make public reporting more meaningful and informative to our beneficiaries, their caregivers, and families, we propose to publicly post information that utilizes publicly available government data from other agencies, in addition to the data from the PUF or other CMS or Medicare sources, at some time in the future. We propose to use comparative and complementary data from other government sources as part of public reporting on Hospice Compare or other CMS websites in the future and as soon as FY 2020. Examples include information compiled by the U.S. Census Bureau, Centers for Disease Control and Prevention, Bureau of Labor

Statistics, and National Institutes of Health.

We may use information available in these public government files to augment the section described above. This section including PUF data and information from other public government data will provide additional information along with the HQRPs measures currently from the HIS and CAHPS® quality measures that are already displayed.

Any future reporting of public government data as information for public reporting will be displayed in a consumer-friendly format on Hospice Compare or other CMS website. This means we may display the data as shown in these publicly available government files or present the data after additional calculations. For example, the data could be averaged over multiple years, displayed as a

percentage rather than the raw number, or other calculations could be based on a given year or over multiple years, so the data has meaning to end-users. Furthermore, by performing these calculations, we can make the data apply to hospices broadly regardless of size, location, or other factors.

Also, we would like to note that data used from these publicly available sources are not quality measures. Rather, they present supplementary information that many consumers seek during the provider selection process and, therefore, will help them to make an informed decision. This is similar to other useful information we already publicly display under the Spotlight, Tools and Tips, and Additional Information sections on the Hospice Compare homepage. Data from publicly available data sources can serve as one more piece of information, along with

quality of care metrics from the HIS and CAHPS® Hospice Survey and other useful information, to help consumers effectively and efficiently compare hospice providers and make an informed decision about their care in a stressful time. We also believe such information may be useful to providers. For example, adding data as information from the U.S. Census Bureau in coordination with this service area from Medicare claims data may help consumers better understand the service area in which they are looking for services (for example, if there is a large population of people from a similar race or ethnicity in the area). This information may also help providers better understand their service area to see if there are any business development opportunities (for example, if there is a large population of a similar race or ethnicity, the provider may consider investing resources in better serving patients from this background).

To ensure that end-users understand that these data provide information about hospice characteristics and are not a reflection of the quality of care a hospice provides, we will, with consultation from key stakeholders, carefully craft explanatory language to ensure that consumers understand the information and how the data are meant for informational purposes only.

As we determine which publicly available government data sources we will use and how we will be using and presenting information from these sources, we will inform the public and engage with stakeholders via sub-regulatory processes, including regular HQRP communication strategies such as Open Door Forums, Medicare Learning Network, Spotlight Announcements, and other opportunities.

We solicited public comment on our proposal to post information from publicly available government sources for public reporting in the future.

A summary of those comments and our responses to them appear below:

Comment: Overall commenters supported publicly posting contextual government information to supplement the already posted CMS and Medicare public data, but several requested more detail on the specific information for posting data from other U.S. government websites and how it would be used. Some commenters recommended that there be a correlation between any other U.S. government data and the quality of hospice care or meaningful context of hospice and questioned the sources noted. They also recommended seeking stakeholder input prior to adding information for public reporting and

making sure any posted information was clearly explained.

Response: We appreciate the commenters' support and request for more detail about any additional data from public other U.S. government websites under consideration for posting publicly. We confirm our commitment to using sub-regulatory processes for soliciting and receiving ongoing stakeholder information and feedback as we develop these data. As part of this effort, we will provide mock-ups of the data for stakeholder feedback and show the relationship between the data from other U.S. government websites and hospice related data. The goal is for the information to help consumers in comparing providers. We reiterate our intent to conduct plain language testing, including distinguishing this information from quality data.

Final Decision: After considering the comments received in response to the proposed rule and for the reasons discussed in the above paragraph, we are finalizing our proposal to post information from other publicly-available U.S. government sources to publicly report in the future and as soon as FY 2020 on Hospice Compare or other CMS website.

IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). However, we can waive this notice and comment procedure if the Secretary finds, for good cause, that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons therefore in the rule. This hospice proposed rule has previously been subjected to notice and comment procedures. These corrections do not make substantive changes to this policy. Specifically, we redesignated paragraphs (c) through (f) as paragraphs (d) through (g). This redesignation would affect two cross-references in § 418.26(c) (2) and § 418.28(c) (2). As a result, we made conforming changes to accompany the redesignations in § 418.24. Likewise, at § 418.3, we define the term BFCC-QIO as the Beneficiary and Family Centered Care Quality Improvement Organization. Because these conforming changes were not proposed in the proposed rule, we are adopting them here under a "good cause" waiver of proposed rulemaking. The specific changes we are making in

the regulations simply codify the final policies we described in the proposed rule and do not reflect any additional substantive changes. Therefore, we find that undertaking further notice and comment procedures to incorporate these corrections into the final rule is unnecessary and contrary to the public interest.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-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.

Section 1814(i)(5)(C) of the Act requires that each hospice submit data to the Secretary on quality measures specified by the Secretary. This data must be submitted in a form and manner, and at a time specified by the Secretary.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. Election Statement Addendum: "Patient Notification of Hospice Non-Covered Items, Services, and Drugs"

To calculate this burden estimate, we use salary information from the Bureau of Labor Statistics (BLS) website at <https://www.bls.gov/> and include a fringe benefits package worth 100 percent of the base salary. The mean hourly wage rates are based on May, 2018 BLS data for each discipline. Table 19 contains our burden estimate assumptions for the proposed Election Statement Addendum: "Patient Notification of Hospice Non-Covered Items, Services, and Drugs" discussed in section III.C. of this final rule. The required addendum would not be required until FY 2021; that is, the addendum would be required, upon

request, for those hospice elections beginning on or after October 1, 2020. This burden estimate represents what the estimated costs would be if implemented in FY 2020. We will re-

estimate this burden in the FY 2021 proposed rule using more recent claims data to more accurately reflect costs for FY 2021 implementation. For the purposes of this estimate, we are

assuming that all beneficiaries electing the hospice benefit, and who do not die within the first 5 days of care, would request the addendum.

TABLE 19—ELECTION STATEMENT ADDENDUM: “PATIENT NOTIFICATION OF HOSPICE NON-COVERED ITEMS, SERVICES, AND DRUGS” BURDEN ESTIMATE ASSUMPTIONS

Number of Medicare-billing hospices, from FY 2017 Medicare Enrollment Database, Provider of Service files.	4,465.
Number of hospice elections in FY 2017	(1,268,497 × 0.72) = 913,318.
Hourly rate of an office employee (Executive Secretaries and Executive Administrative Assistants, 43–6011).	\$59.18 (\$29.59 × 2.00).
Hourly rate of an administrator (General and Operations Managers, 11–1021)	\$119.12 (\$59.56 × 2.00).
Hourly rate of registered nurses (Registered Nurses, 29–1141)	\$72.60 (\$36.30 × 2.00).
Hourly rate of pharmacy technicians (Pharmacy Technicians, 29–2052)	\$32.70 (\$16.35 × 2.00).

Source: FY 2017 hospice claims data. 28 percent of beneficiaries die within the first 5 days of hospice care. Hospices are exempt from completing addendum if beneficiary dies within first the first 5 days of care.

Section 1814(a) (7) of the Act requires for the first 90-day period of a hospice election the individual's attending physician (as defined in section 1861(dd)(3)(B) of the Act) (which for purposes of this subparagraph does not include a nurse practitioner), and the medical director (or physician member of the interdisciplinary group described in section 1861(dd)(2)(B) of the Act) of the hospice program providing (or arranging for) the care, each certify in writing, at the beginning of the period, that the individual is terminally ill (as defined in section 1861(dd)(3)(A) of the Act). The regulations codified at § 418.22 and § 418.25 provide the requirements regarding the certification of terminal illness and admission to hospice care. The hospice medical director must specify that the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course. Additionally, clinical information and other documentation that support the medical prognosis must accompany the certification and must be filed in the medical record with the written certification. The physician must include a brief narrative explanation of the clinical findings that supports a life expectancy of 6 months or less as part of the certification. The aforementioned regulations also require that the hospice medical director must consider both related and unrelated conditions and current clinically relevant information when making the decision to certify the individual as terminally ill. Likewise, the hospice CoPs at § 418.102(b) provide the requirements regarding the certification responsibility of the hospice medical director or hospice physician designee which includes a review of the clinical information, including both related and unrelated conditions, for each hospice patient.

In order to receive hospice services under the Medicare hospice benefit, eligible beneficiaries must elect to receive hospice care by completing an election statement. By signing this election statement, the individual acknowledges that he or she waives all rights to Medicare payments for treatment related to the terminal illness and related conditions. The content requirements for the hospice election statement are listed at § 418.24(b) and each hospice election statement must include the following information:

(1) Identification of the particular hospice and of the attending physician that will provide care to the individual. The individual or representative must acknowledge that the identified attending physician was his or her choice.

(2) The individual's or representative's acknowledgement that he or she has been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the individual's terminal illness.

(3) Acknowledgement that certain Medicare services, as set forth in § 418.24(d) of this section, are waived by the election.

(4) The effective date of the election, which may be the first day of hospice care or a later date, but may be no earlier than the date of the election statement.

(5) The signature of the individual or representative.

Once a beneficiary is certified as terminally ill and elects the Medicare hospice benefit, the hospice conducts an initial assessment visit in advance of furnishing care. During this visit, the hospice must provide the patient or representative with verbal and written notice of the patient's rights and responsibilities as required by the CoPs

at § 418.52. Likewise, the regulations at § 476.78 state that providers must inform Medicare beneficiaries at the time of admission, in writing, that the care for which Medicare payment is sought will be subject to Quality Improvement Organization (QIO) review.

The beneficiary needs identified in the initial and comprehensive assessments drive the development and revisions of an individualized written plan of care for each patient as required by the hospice CoPs at § 418.56. The hospice plan of care is established, reviewed and updated by the hospice IDG and must include all services necessary for the palliation and management of the terminal illness and related conditions. While needs unrelated to the terminal illness and related conditions are not the responsibility of the hospice, the hospice may choose to furnish services for those needs regardless of responsibility. However, if a hospice does not choose to furnish services for those needs unrelated to the terminal illness and related conditions, the hospice is to communicate and coordinate with those health care providers who are caring for the unrelated needs, as described in § 418.56(e). In accordance with the CoPs, the hospice must document the services and treatments that address how they will meet the patient and family-specific needs related to the terminal illness and related conditions in the plan of care, and those needs unrelated to the terminal illness and related conditions that are present when the patient elects hospice should also be documented. This documentation ensures that the hospice is aware of those unrelated needs and who is addressing them. This documentation provides the support for the hospices'

financial responsibility for the hospice services they will be providing. There is limited beneficiary financial liability for hospice services upon election of the Medicare hospice benefit. However, for any services received that are unrelated to the terminal illness and related conditions, the beneficiary would incur any associated copayments and coinsurance.

Hospices already are required to review, determine, and document information on unrelated conditions in accordance with the hospice regulations and CoPs. However, to ensure Medicare beneficiaries are provided disclosure of those conditions, items, services, and drugs the hospice has determined to be unrelated to the terminal illness and related conditions at the time of admission, we are finalizing additions to the regulations at § 418.24(b) and (c) for FY 2021, which will require an election statement addendum titled "Patient Notification of Hospice Non-Covered Items, Services, and Drugs" that must be issued, on request, to the patient (or representative) within 5 days of the hospice election date to ensure that Medicare beneficiaries are fully informed whether or not all items, services, and drugs identified on the hospice plan of care will be furnished by the hospice. The addendum statement would not be required if the beneficiary died within 5 days of the hospice election date. This addendum would accompany the hospice election statement and each hospice would use the required proposed elements to develop and design their own addendum to best meet their needs and the requirement. This requirement for payment would be added to the regulations at § 418.24(b) and (c) effective for hospice elections beginning on and after October 1, 2020.

The burden associated with the documentation requirement for the addendum includes the time for each hospice to develop the addendum that the hospice provides to the beneficiary (or their representative) within 5 days of election of the Medicare hospice benefit. The addendum must include the name of the issuing hospice, beneficiary's name, and hospice medical record identifier. The addendum must also allow the hospice registered nurse to document a list of non-covered conditions and associated items, services, and drugs, as well as provide a clinical explanation as to why these conditions and associated items, services, and drugs have been determined to be unrelated to the

terminal illness and related conditions. This documentation would include references to any relevant clinical practice, policy, or coverage guidelines. The addendum must include statements informing the patient as to the purpose of the addendum and information on BFCC-QIO Immediate Advocacy rights and contact information. The addendum would be signed by the beneficiary as an acknowledgement that he or she has received this information, but signing it does not mean the beneficiary agrees with the determination. We believe that the burden for the hospice associated with the election statements addendum would be the cost of developing the form and the cost of filling out the form. There is no associated burden for hospices to communicate/coordinate with non-hospice providers regarding the content of the addendum statement because the hospice CoPs, as described above, have always required hospices to have a system of communication with non-hospice providers in place. However, we believe that the election statement addendum would reduce burden for non-hospice providers through a consistent and streamlined process by which non-hospice providers can make informed treatment decisions and accurately submit claims with the appropriate condition code or modifier.

1. Estimated Hospice Burden With Election Statement Addendum

a. Estimated One-Time Form Development

We estimate a one-time burden for the development of a template election statement addendum. We estimate that it would take a hospice administrative assistant 15 minutes ($15/60 = 0.25$ hours) to develop the addendum with the required elements, and the hospice administrator 15 minutes ($15/60 = 0.25$ hours) to review the addendum. The clerical time plus administrator time equals a one-time burden of 30 minutes or ($30/60 = 0.50$ hours) per hospice. For all 4,465 hospices, the total time required would be ($0.50 \times 4,465$) = 2,232.5 hours. At \$59.18 per hour for an executive administrative assistant, the cost per hospice would be ($0.25 \times \$59.18$) = \$14.80. At \$119.12 per hour for the administrator's time, the cost per hospice would be ($0.25 \times \$119.12$) = \$29.78. Therefore, the one-time cost, per hospice, for the development of the template would be ($\$14.80 + \29.78) = \$44.58, and the total one-time cost for all hospices would be ($\$44.58 \times 4,465$) = \$199,050.

b. Estimated Time for Hospice To Complete Addendum

Per the hospice CoPs at § 418.56(a), the hospice must designate a registered nurse that is a member of the interdisciplinary group to provide coordination of care and to ensure continuous assessment of each patient's and family's needs and implementation of the interdisciplinary plan of care. The hospice CoPs at § 418.54 require that a registered nurse conduct the initial assessment, therefore, the registered nurse would be responsible for completing the addendum for each hospice election as part of the routine admission paperwork. We estimate that there would be 1,268,497 hospice elections in a year based on FY 2017 claims data. Approximately 28 percent of hospice beneficiaries die within the first 5 days after the hospice election date. Hospices would not be required to complete the election statement addendum for those hospice beneficiaries that die within 5 days of hospice election. Therefore, the estimated total number of hospice elections in FY 2020 that would require the hospice election statement addendum would be ($1,268,497 \times 0.72$) = 913,318. There are 4,465 Medicare-certified hospices, so on average there would be ($913,318/4,465$) = 205 hospice elections per hospice. The estimated burden for the hospice registered nurse to extrapolate this information from the existing documentation in the patient's hospice medical record and complete this addendum would be 10 minutes ($10/60 = 0.1667$). At \$72.60 per hour for a registered nurse over 10 minutes ($0.1667 \times \$72.60 = \12.10), we estimate the total cost of RN time to complete the addendum per hospice in FY 2020 to be ($\$12.10 \times 205$) = \$2,481, and the total cost of RN time to complete the addendum for all hospices in FY 2020 would be ($\$2,481 \times 4,465$) = \$11,077,665. The estimated total per hospice and total annual hospice cost associated with the proposed addendum (including one-time form development and total RN costs) in FY 2020 are shown in Table 20 below. These total costs would include the one-time development of the addendum, so subsequent years' costs would only include the cost for the RN to complete the addendum statement. Providing this information to the beneficiary would be part of the routine admissions process and, as such, incurs no additional burden to that process.

Table 20: FY 2020 Estimated Per Hospice and Total Hospice Costs for Election Statement Addendum

	Average # of Elections Per Hospice	Total # of Hospice Elections (based on FY 2017)
Number of Hospice Elections	205	913,318
	Average Cost Per Hospice	Total Annual Costs for All Hospices
Total # of Hospices		4,465
One-time Form Development	\$44.58	\$199,050
RN Form Completion	\$2,481	\$11,077,665
Total Hospice Estimated FY 2020 Costs		\$11,276,715

Source: FY 2017 CWF Claims Data, Medicare Enrollment Database, and Provider of Service (POS). Enrollment data.

2. Estimated Burden Reduction for Non-Hospice Providers

To ensure comprehensive and coordinated care, the CoPs at § 418.56(e) require hospices to have a communication system that allows for the exchange of information with other non-hospice health care providers who are furnishing care unrelated to the terminal illness and related conditions. Therefore, it is our expectation that hospices are already determining what is related and unrelated to the terminal illness and related conditions. The election statement addendum would add no additional burden for communicating with non-hospice providers, as this decision-making process has been a long-standing CoP requirement, as described above and in the preamble of this final rule. However, burden would be reduced for non-hospice providers, including institutional, non-institutional and pharmacy providers because less time would be spent trying to obtain needed information for treatment decisions and accurate claims submissions.

For the calculation of this burden estimate, we did drop those elections where the beneficiary died within the first 5 days. To estimate the cost burden reduction, we first calculated the

estimated current burden, in the absence of the addendum, for communicating and coordinating information regarding unrelated conditions between hospice and non-hospice providers. Next, we calculated the estimated burden, using the addendum for communicating and coordinating information regarding unrelated conditions between hospice and non-hospice providers. Finally, we analyzed the difference between the burden estimates to see if there is any overall reduction. To do this, we analyzed all Medicare Parts A and B non-hospice claims for beneficiaries under a hospice election in FY 2017. We also examined the Part D claims for drugs provided to hospice beneficiaries under a hospice election. Specifically, we analyzed the following:

- The total number of non-hospice, institutional claims with condition code 07 (to indicate the services were unrelated to the terminal illness and related conditions).
- The total number of non-hospice, non-institutional claims with “GW” modifier (to indicate the services were unrelated to the terminal illness and related conditions).
- The total number of Part D claims for beneficiaries under a hospice election.

- The average number of hospice beneficiaries per non-hospice provider with institutional claims with condition code 07.

- The average number of hospice beneficiaries per non-hospice provider with non-institutional claims with “GW” modifier.

- The average number of hospice beneficiaries per non-hospice provider with Part D claims.

To calculate the average number of hospice beneficiaries per non-hospice provider, we count the number of unique beneficiaries associated with each non-hospice provider as beneficiaries may receive services by more than one non-hospice provider. This means that some beneficiaries are double-counted. However, given this estimate is calculated based on the number of expected communication encounters between hospices and non-hospice providers, this is the appropriate approach. Because we double-counted beneficiaries, we expect that average to be larger than the ratio of unique beneficiaries to unique non-hospice providers. Table 21 below summarizes Part A, B and D claims that overlap with hospice episodes in FY 2017.

Table 21: Summary of Part A, B and D Claims that Overlap with Hospice Episodes, FY 2017

Non-Hospice Claim Type	# of Hospice Beneficiaries	# of Non-Hospice Providers	# of Hospice Providers	Average # of Hospice Benes per Non-hospice Provider
Part A & B, Non-Hospice Total	462,308	94,159	4,341	
Institutional Claims w/ 07	171,055	19,226	4,114	11.0
Non-Institutional Lines w/ GW	421,546	74,933	4,322	11.0
Part D	591,543	60,632	4,416	12.0

Source: FY 2017 Parts A, B, and D claims.

3. Burden Estimate Without Election Statement Addendum for Non-Hospice Providers

In order for non-hospice providers to make treatment decisions regarding services, items, and drugs for hospice beneficiaries and to submit the appropriate modifier or condition code on Medicare claims, they need supporting information from the hospice regarding related and unrelated conditions. As such, we first estimate the current burden associated with this communication and coordination in the absence of the election statement addendum. We believe this would require the non-hospice providers to contact the hospice and have a detailed phone call to obtain and document the information on unrelated conditions, items, services, and medications. For non-hospice providers submitting institutional claims (including inpatient acute care hospitals, SNFs, HHAs, and institutional outpatient providers), typically nurse case managers provide coordination of care for those beneficiaries in these settings who are receiving inpatient services or who are preparing to transition to a post-acute care setting or home. The estimated burden for the registered nurse to contact the hospice to obtain the needed information would be 15 minutes (15/60 = 0.25). The average number of hospice beneficiaries receiving services per institutional, non-hospice provider is 11 per year, which would mean each institutional, non-hospice provider would have an average of 11 communication encounters with hospice. The total number of institutional, non-hospice providers servicing hospice beneficiaries in FY 2017 was 19,226. At \$72.60 per hour for a registered nurse ($0.25 \times \$72.60$) = \$18.15, we estimate the total cost per institutional, non-hospice provider furnishing services to hospice beneficiaries in FY 2020 to be ($\$18.15 \times$

11) = \$199.65 and the annual total cost for all institutional, non-hospice providers in FY 2018 would be ($\$199.65 \times 19,226$) = \$3,838,471.

For non-institutional, non-hospice providers (including physicians), we also expect that a nurse would contact the hospice to obtain the needed clinical information on unrelated conditions, items, services and drugs. The estimated burden for the registered nurse to contact the hospice to obtain the needed information would be 15 minutes (15/60 = 0.25). The average number of hospice beneficiaries receiving services per non-institutional, non-hospice provider is 11 per year, which would mean each provider would have an average of 11 communication encounters with a hospice. The total number of non-institutional, non-hospice providers servicing hospice beneficiaries in FY 2017 was 74,933. At \$72.60 per hour for a registered nurse ($0.25 \times \$72.60$) = \$18.15, we estimate the total cost per non-institutional, non-hospice provider furnishing services to hospice beneficiaries in FY 2020 to be ($\$18.15 \times 11$) = \$199.65 and the annual total cost for all non-institutional, non-hospice providers in FY 2018 would be ($\$199.65 \times 74,933$) = \$14,960,373.

For pharmacies dispensing Part D drugs to hospice beneficiaries, the estimated burden for the pharmacy technician at the point of service to contact the hospice to obtain the needed clinical information regarding the drugs deemed by the hospice as unrelated to the terminal illness and related conditions would be 15 minutes (15/60 = 0.25). The average number of hospice beneficiaries receiving services per pharmacy dispensing Part D maintenance drugs is 12 per year, which would mean each pharmacy would have an average of 12 communication encounters with hospice. The total number of pharmacies dispensing Part D maintenance drugs to hospice

beneficiaries in FY 2017 was 60,632. At \$32.70 per hour for a pharmacy technician ($0.25 \times \$32.70$) = \$8.18, we estimate the total cost per pharmacy dispensing Part D maintenance drugs to be ($\$8.18 \times 12$) = \$98.16 and the annual total cost for all pharmacies dispensing Part D maintenance drugs to be ($\$98.16 \times 60,632$) = \$5,951,637. The estimated total annual burden for all non-hospice providers furnishing services, items and medications to hospice beneficiaries in FY 2020 without the availability of the hospice election statement addendum identifying unrelated conditions, items, services and drugs would be \$24,750,481 (\$3,838,471 + \$14,960,373 + \$5,951,637).

4. Burden Reduction Estimate With Election Statement Addendum for Non-Hospice Providers

However, with the availability of the "Patient Notification of Hospice Covered/Non-Covered Items, Services, and Drugs" election statement addendum, we believe this estimated burden would be reduced for non-hospice providers through a streamlining of the communication and coordination process. For institutional, non-hospice providers (those who would submit claims for unrelated services with condition code 07), the estimated burden for the registered nurse to contact the hospice to obtain the needed information would be reduced from 15 minutes in the absence of the addendum to 5 minutes (5/60 = 0.0833). The average number of hospice beneficiaries receiving services per institutional non-hospice provider is 11 per year. The total number of institutional non-hospice providers servicing hospice beneficiaries in FY 2017 was 19,226. At \$72.60 per hour for a registered nurse ($0.0833 \times \$72.60$) = \$6.05, we estimate the total cost per institutional non-hospice provider in FY 2020 to be ($\$6.05 \times 11$) = \$66.55 and the

annual total cost for all institutional non-hospice providers in FY 2020 would be $(\$66.55 \times 19,226) = \$1,279,490$ an annual decrease in burden by $(\$3,838,471 - 1,279,490) = \$2,558,981$.

For non-institutional, non-hospice providers (those who would submit claims for unrelated services with modifier GW), the estimated burden for the registered nurse to contact the hospice to obtain the needed information would be reduced to 5 minutes ($5/60 = 0.0833$). The average number of hospice beneficiaries receiving services per non-institutional, non-hospice provider is 11 per year. The total number of non-institutional, non-hospice providers servicing hospice beneficiaries in FY 2017 was 74,933. At \$72.60 per hour for a registered nurse ($0.0833 \times \$72.60$) = \$6.05, we estimate the total cost per non-institutional, non-hospice provider in FY 2020 to be $(\$6.05 \times 11) = \66.55 and the annual

total cost for all non-institutional, non-hospice providers in FY 2020 would be $(\$66.55 \times 74,933) = \$4,986,791$, an annual decrease in burden by $(\$14,960,373 - 4,986,791) = \$9,973,582$.

For pharmacies dispensing Part D drugs to hospice beneficiaries, the estimated burden for the pharmacy technician at the point of service to contact the hospice to obtain the needed clinical information regarding the drugs deemed by the hospice as unrelated to the terminal illness and related conditions would be reduced to 5 minutes ($5/60 = 0.0833$). The average number of hospice beneficiaries receiving services from pharmacies dispensing Part D maintenance drugs is 12 per year. The total number of pharmacies dispensing Part D maintenance drugs to hospice beneficiaries in FY 2017 was 60,632. At \$32.70 per hour for a pharmacy technicians ($0.0833 \times \$32.70$) = \$2.72,

we estimate the total cost per pharmacies dispensing Part D maintenance drugs to be $(\$2.72 \times 12) = \32.64 and the annual total cost for all pharmacies dispensing Part D maintenance drugs to be $(\$32.64 \times 60,632) = \$1,979,028$, an annual decrease in burden by $(\$5,951,637 - \$1,979,028) = \$3,972,609$. The estimated total annual burden for all non-hospice providers furnishing services, items and drugs to hospice beneficiaries in FY 2020 with the availability of the hospice election statement addendum identifying unrelated conditions, items, services and medication would be \$8,245,309 $(\$1,279,490 + \$4,986,791 + \$1,979,028)$ for an overall burden reduction of $(\$24,750,481 - \$8,245,309) = \$16,505,172$. The total reduction in burden for all institutional, non-institutional, and Part D pharmacy non-hospice providers is summarized in Table 22 below.

Table 22: FY 2020 Estimated Total Overall Burden Reduction for Non-Hospice Providers Using Election Statement Addendum

Non-hospice Claims	Burden without Addendum	Burden with Addendum	Estimated Burden Reduction For Non-Hospice Providers with Use of the Addendum*
Institutional Claims with Condition Code 07	\$3,838,471	\$1,279,490	\$2,558,981
Non-institutional Claims with GW Modifier	\$14,960,373	\$4,986,791	\$9,973,582
Part D Maintenance Drugs	\$5,951,637	\$1,979,028	\$3,972,609
Total Burden Reduction for Non-Hospice Providers	\$24,750,481	\$8,245,309	\$ 16,505,172

*Note: Estimated Burden Reduction for Non-hospice Providers with Use of the Addendum= Burden without Addendum (column 2) minus Burden with Addendum (column 3).

The use of the "Patient Notification of Hospice Non-Covered Items, Services, and Drugs" election statement

addendum would result in an estimated, annual net reduction in burden of \$5,228,457 $(\$11,276,715 - \$16,505,172)$

in FY 2020. Table 23 below summarizes the FY 2020 estimated total burden reduction.

Table 23: FY 2020 Estimated Total Provider Burden Reduction Using Election Statement Addendum

FY 2020 Estimated Hospice Burden for Election Statement Addendum	\$11,276,715
FY 2020 Estimated Non-hospice Provider Burden Reduction	\$16,505,172
FY 2020 Estimated Annual Net Reduction in Burden	\$5,228,457

B. Comments

We note that many commenters stated that CMS underestimated the amount of time it would take for the nurse to complete the addendum stating that 10 minutes is an insufficient amount of time to extrapolate this information from the existing documentation. A few commenters stated that this would take between 20 and 30 minutes to complete. Others stated that this is not just a process of extrapolating the information, but that this is often a process of information gathering as not all relevant information is readily available at the time of the initial assessment. However, a few commenters believed that even though the timeframe to complete the addendum would be longer than 10 minutes, they suggested that the addendum should not be optional but patients (or their representatives) should be provided this detailed list as this is critical to the care process, patient empowerment, quality of care, and transparency. However, we remind hospices that the addendum is only required if the beneficiary (or representative) requests this information, though for purposes of this burden reduction estimate we calculate it as if every eligible beneficiary requests the addendum. Additionally, there are those hospices that will cover all items, services, and drugs, and therefore, this would further reduce the number of hospice elections in which the addendum would be provided. Furthermore, if a beneficiary requests the addendum at the time of hospice election but dies within 5 days, the hospice would not be required to furnish the addendum and the requirement would be deemed as having being met in this circumstance.

C. Submission of PRA-Related Comments

We have submitted a copy of this final rule to OMB for its review of the rule's information collection and recordkeeping requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections previously discussed, visit our website at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>, or call the Reports Clearance Office at (410) 786-1326.

VI. Regulatory Impact Analysis*A. Statement of Need*

This final rule meets the requirements of our regulations at § 418.306(c) and (d), which require annual issuance, in the **Federal Register**, of the hospice wage index based on the most current available CMS hospital wage data, including any changes to the definitions of Core-Based Statistical Areas (CBSAs) or previously used Metropolitan Statistical Areas (MSAs), as well as any changes to the methodology for determining the per diem payment rates. This final rule also updates payment rates for each of the categories of hospice care, described in § 418.302(b), for FY 2020 as required under section 1814(i)(1)(C)(ii)(VII) of the Act. The payment rate updates are subject to changes in economy-wide productivity as specified in section 1886(b)(3)(B)(xi)(II) of the Act. Lastly, section 3004 of the Affordable Care Act amended the Act to authorize a quality reporting program for hospices, and this rule discusses changes in the requirements for the hospice quality reporting program in accordance with section 1814(i)(5) of the Act.

B. Overall Impacts

We estimate that the aggregate impact of the payment provisions in this final rule would result in an estimated increase of \$520 million in payments to hospices, resulting from the hospice payment update percentage of 2.6 percent for FY 2020. Section 1814(i)(6)(D)(ii) of the Act requires the final rebasing of the per diem payment rates for CHC, GIP, and IRC to be done in a budget-neutral manner in the first year of implementation. Therefore, the final rebased rates for CHC, GIP, and IRC would not result in an overall payment impact for the Medicare program as we are finalizing the reduction of the RHC payment rates to ensure that total estimated payments to hospices are budget-neutral given the increases to the CHC, GIP, and IRC payment rates. In addition, the final change in the hospice wage index to use the FY 2020 pre-floor, pre-reclassified hospital wage index (rather than the FY 2019 pre-floor, pre-reclassified hospital wage index) as the basis for the FY 2020 hospice wage index would not result in an overall payment impact for the Medicare program as annual wage index updates are now similarly implemented in a budget-neutral manner. Certain events may limit the scope or accuracy of our impact analysis, because such an analysis is susceptible to forecasting errors due to other changes in the forecasted impact time period. The nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon hospices.

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation

and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) (Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”)); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimate that this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability presents the costs and benefits of the rulemaking.

C. Anticipated Effects

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The great majority of hospitals and most other health care providers and suppliers are small entities by meeting the Small Business Administration

(SBA) definition of a small business (in the service sector, having revenues of less than \$7.5 million to \$38.5 million in any 1 year), or being nonprofit organizations. For purposes of the RFA, we consider all hospices as small entities as that term is used in the RFA. HHS’s practice in interpreting the RFA is to consider effects economically “significant” only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The effect of the FY 2020 hospice payment update percentage results in an overall increase in estimated hospice payments of 2.6 percent, or \$520 million. The distributional effects of the final FY 2020 hospice wage index do not result in a greater than 5 percent of hospices experiencing decreases in payments of 3 percent or more of total revenue. Finally, the distributional effects of the final FY 2020 increases to the CHC, IRC, and GIP per diem payment rates as a result of rebasing, offset by a decrease to the FY 2020 RHC payment rates of less than 3 percent to maintain budget neutrality in the first year of implementation, do not result in a greater than 5 percent of hospices experiencing decreases in payments of 3 percent or more of total revenue. Therefore, the Secretary has determined that this rule will not create a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This rule will only affect hospices. Therefore, the Secretary has determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. The 2019 UMRA threshold is \$154 million. This rule is not anticipated to have an effect on state, local, or tribal governments, in the aggregate, or on the private sector of \$154 million or more.

Executive Order 13132 establishes certain requirements that an agency

must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have reviewed this rule under these criteria of Executive Order 13132, and have determined that it will not impose substantial direct costs on state or local governments.

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on the published proposed rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule. It is possible that not all commenters reviewed the proposed rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this final rule.

Using the wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is \$107.38 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/current/oes_nat.htm). This final rule consists of approximately 57,000 words in its entirety. Assuming an average reading speed of 250 words per minute, it would take approximately 2 hours for the staff to review half of it. For each hospice that reviews the rule, the estimated cost is approximately \$215.00 (2 hours × \$107.38). Therefore, we estimate that the total cost of reviewing this regulation is \$32,250 (\$215.00 × 150 reviewers).

D. Detailed Economic Analysis

1. Hospice Payment Update for FY 2020

The FY 2020 hospice payment impacts appear in Table 24. We tabulate the resulting payments according to the classifications (for example, provider type, geographic region, facility size), and compare the difference between current and future payments to determine the overall impact. The first column shows the breakdown of all hospices by provider type and control (non-profit, for-profit, government, other), facility location, facility size. The

second column shows the number of hospices in each of the categories in the first column. The third column shows the effects of applying the final rebased payment rates of CHC, IRC, and GIP (and the decreased RHC rate used to achieve budget neutrality). The fourth column shows the hospice payments using FY 2018 Hospice Claims, FY 2020 rebased Payments, and FY 2020 Wage Index without the 1-Year lag. The fifth column show the final FY 2020 hospice payment update percentage of 2.6 percent as mandated by section 1814(i)(1)(C) of the Act, and is consistent for all providers. The 2.6 percent hospice payment update percentage is based on an estimated 3.0 percent inpatient hospital market basket

update, reduced by a 0.4 percentage point productivity adjustment. It is projected that aggregate payments would increase by 2.6 percent, assuming hospices do not change their service and billing practices. The sixth column shows the total impact for FY 2020. We have set the rates so the overall impact is zero percent due to the requirement that any revisions in payment are implemented in a budget-neutral manner in accordance with section 1814(i)(6)(D)(ii) of the Act (accomplished by rebasing the CHC, GIP, and IRC payment rates by a corresponding decrease to the RHC payment rates).

In addition, to assist providers in understanding the impacts of the final wage index without the lag and the

rebasings of CHC, IRC, and GIP, we are providing a provider-specific impact analysis file, which is available on our website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Hospice-Regulations-and-Notices.html>. We note that simulated payments are based on utilization in FY 2018 as seen on Medicare hospice claims (accessed from the CCW in May 2019) and only include payments related to the level of care and do not include payments related to the service intensity add-on.

As illustrated in Table 24, the combined effects of all the proposals vary by specific types of providers and by location.

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Table 24: Impact to Hospices for FY 2020

	Hospices	Rebasing of CHC, IRC, and GIP	FY 2020 Updated Wage Data Without the 1 Year Lag	FY 2020 Hospice Payment Update Percentage	Total Impact for FY 2020
All Hospices	4,599	0.0%	0.0%	2.6%	2.6%
Hospice Type and Control					
Freestanding/Non-Profit	602	1.4%	0.0%	2.6%	4.0%
Freestanding/For-Profit	2,843	-0.8%	0.0%	2.6%	1.8%
Freestanding/Government	39	0.0%	-0.3%	2.6%	2.3%
Freestanding/Other	325	0.2%	0.1%	2.6%	2.9%
Provider/HHA-Based/Non-Profit	396	0.7%	-0.1%	2.6%	3.2%
Provider/HHA-Based/For-Profit	196	-1.3%	-0.1%	2.6%	1.2%
Provider/HHA-Based/Government	101	0.4%	-0.1%	2.6%	2.9%
Provider/HHA-Based/Other	97	0.6%	0.1%	2.6%	3.3%
Subtotal: Freestanding Provider Type	3,809	0.0%	0.0%	2.6%	2.6%
Subtotal: Provider/HHA Based Provider Type	790	0.2%	-0.1%	2.6%	2.7%
Subtotal: Non-Profit	998	1.2%	0.0%	2.6%	3.8%
Subtotal: For Profit	3,039	-0.8%	0.0%	2.6%	1.8%
Subtotal: Government	140	0.2%	-0.2%	2.6%	2.6%
Subtotal: Other	422	0.3%	0.1%	2.6%	3.0%
Hospice Type and Control: Rural					
Freestanding/Non-Profit	154	0.4%	0.2%	2.6%	3.2%
Freestanding/For-Profit	329	-1.7%	-0.1%	2.6%	0.8%
Freestanding/Government	20	-0.9%	-0.3%	2.6%	1.4%
Freestanding/Other	45	-1.3%	0.0%	2.6%	1.3%
Provider/HHA-Based/Non-Profit	157	0.6%	-0.2%	2.6%	3.0%
Provider/HHA-Based/For-Profit	47	-1.6%	-0.2%	2.6%	0.8%
Provider/HHA-Based/Government	74	-0.7%	0.0%	2.6%	1.9%
Provider/HHA-Based/Other	54	-0.5%	0.3%	2.6%	2.4%
Hospice Type and Control: Urban					
Freestanding/Non-Profit	448	1.5%	0.0%	2.6%	4.1%
Freestanding/For-Profit	2,514	-0.7%	0.0%	2.6%	1.9%
Freestanding/Government	19	0.2%	-0.3%	2.6%	2.5%
Freestanding/Other	280	0.3%	0.1%	2.6%	3.0%
Provider/HHA-Based/Non-Profit	239	0.7%	0.0%	2.6%	3.3%
Provider/HHA-Based/For-Profit	149	-1.3%	-0.1%	2.6%	1.2%
Provider/HHA-Based/Government	27	1.4%	-0.2%	2.6%	3.8%
Provider/HHA-Based/Other	43	0.9%	0.0%	2.6%	3.5%

Hospice Location: Urban or Rural					
Rural	880	-0.8%	0.0%	2.6%	1.8%
Urban	3,719	0.1%	0.0%	2.6%	2.7%
Hospice Location: Region of the Country (Census Division)					
New England	158	0.0%	-0.7%	2.6%	1.9%
Middle Atlantic	282	0.2%	-0.2%	2.6%	2.6%
South Atlantic	558	2.0%	-0.1%	2.6%	4.5%
East North Central	546	0.1%	-0.1%	2.6%	2.6%
East South Central	264	-0.4%	-0.2%	2.6%	2.0%
West North Central	406	-1.5%	0.3%	2.6%	1.4%
West South Central	887	-0.5%	-0.1%	2.6%	2.0%
Mountain	462	-0.6%	0.1%	2.6%	2.1%
Pacific	990	-1.5%	0.6%	2.6%	1.7%
Outlying	46	-2.7%	-0.2%	2.6%	-0.3%
Hospice Size					
0 - 3,499 RHC Days (Small)	1,004	-1.0%	0.2%	2.6%	1.8%
3,500-19,999 RHC Days (Medium)	2,131	-1.1%	0.0%	2.6%	1.5%
20,000+ RHC Days (Large)	1,464	0.3%	0.0%	2.6%	2.9%

Source: FY 2018 hospice claims data as of May 21, 2019 from the CCW RIFs, accessed May 2019.

Region Key:

New England=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont

Middle Atlantic=Pennsylvania, New Jersey, New York;

South Atlantic=Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia

East North Central=Illinois, Indiana, Michigan, Ohio, Wisconsin

East South Central=Alabama, Kentucky, Mississippi, Tennessee

West North Central=Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota

West South Central=Arkansas, Louisiana, Oklahoma, Texas

Mountain=Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah,

Wyoming **Pacific**=Alaska, California, Hawaii, Oregon, Washington

Outlying=Guam, Puerto Rico, Virgin Islands

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2. Hospice Election Statement Addendum

This final rule includes requirements related to the election statement addendum that must be provided, upon request, to hospice beneficiaries (or representative), non-hospice providers, and Medicare contractors. This change is effective for hospice elections on and after October 1, 2020. The burden estimate for hospices to develop and complete the election statement addendum is provided in section V of this final rule. However, the election statement addendum adds no additional burden for communicating with non-hospice providers, as this decision-making process has been a long-standing CoP requirement, as described in the preamble of this rule. Furthermore, burden would be reduced for non-hospice providers, including institutional, non-institutional and

pharmacy providers because less time would be spent trying to obtain needed information for treatment decisions and accurate claims submissions. As a result of this election statement addendum, we estimate that this rule generates \$5.2 million in an annualized net reduction in burden, or \$3.7 million per year on an ongoing basis discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in FY 2021. The burden reduction estimate for the addendum is detailed in section V of this final rule and the total annual reduction is included in Table 25.

E. Accounting Statement

As required by OMB Circular A-4 (available at: <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>), in table 25, we have prepared an accounting statement showing the classification of the transfers and costs associated with the provisions of this

final rule. This table shows an estimated \$520 million in transfers to hospices in FY 2020. All expenditures are classified as transfers to hospices. Table 25 also reflects the estimated change in costs and burden for hospices and non-hospice providers as a result of the finalized election statement addendum requirements described in section III.C. Table 20 provides our best estimate of a one-time burden for hospices to develop the election statement addendum form of approximately 2,233 hours or \$199,050, as well as our estimate of the annual burden for hospices to complete the election statement addendum of approximately 746 hours or \$11 million for an estimated total burden for hospices of \$11.2 million, as described in section IV of this final rule. Additionally, we estimate a net reduction in burden for non-hospice providers of approximately 25,900 hours or \$16.5 million (see section IV of this final rule) for an

estimated overall, annualized net
reduction in burden with the proposed

election statement addendum of \$5.2
million.

**Table 25 -- Accounting Statement: Classification of Estimated Transfers and Costs,
From FY 2019 to FY 2020**

Category	Transfers
Annualized Monetized Transfers	\$ 520 million*
From Whom to Whom?	Federal Government to Medicare Hospices
Category	Costs
Annualized Monetized Net Reduction in Burden for Non-Hospice Providers with the Proposed Regulations Change at § 418.24, Election Statement Addendum	\$16.5 million
Annualized Net Burden for Hospice Providers with the One-time Form Development and Completion of Election Statement Addendum	\$11.2 million
Total Annualized Net Reduction In Burden with the Proposed Election Statement Addendum	\$5.2 million**

* The net increase of \$520 million in transfer payments is a result of the 2.6 percent hospice payment update compared to payments in FY 2019

**The total net reduction does not equal the sum of rounded components.

F. Regulatory Reform Analysis Under E.O. 13771

Executive Order 13771, entitled “Reducing Regulation and Controlling Regulatory Costs,” was issued on January 30, 2017 (82 FR 9339, February 3, 2017) and requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” This final rule is expected to be an E.O. 13771 deregulatory action with \$5.2 million in an annualized net reduction in burden, or \$3.7 million per year on an ongoing basis discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in FY 2021. The burden reduction for the addendum is detailed in section V of this final rule and the total annual net reduction in burden is included in Table 25. Details on the estimated net reduction in burden of this rule can be found in the rule’s collection of information and economic analysis.

G. Conclusion

We estimate that aggregate payments to hospices in FY 2020 will increase by \$520 million, or 2.6 percent, compared to payments in FY 2019. We estimate that in FY 2020, hospices in urban and rural areas will experience, on average, 2.7 percent and 1.8 percent increases, respectively, in estimated payments compared to FY 2019. Hospices providing services in the South Atlantic, Middle Atlantic, and East North Central regions would experience the largest estimated increases in payments of 4.5 percent, 2.6 percent, and 2.6 percent, respectively. Hospices serving patients in the West North Central and outlying regions would experience, on average, the lowest estimated increase of 1.4 percent and -0.3 percent, respectively in FY 2020 payments. We are finalizing the modifications to the election statement including the election statement addendum in this final rule with an implementation date of October 1, 2020 to allow hospices additional time to make the necessary changes to meet these requirements. We also estimate an overall net reduction in burden of \$5.2

million beginning in FY 2021 as a result of the finalized election statement addendum. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below.

PART 418—HOSPICE CARE

■ 1. The authority citation for part 418 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 418.3 is amended by adding the definition of “BFCC-QIO” to read as follows:

§ 418.3 Definitions.

* * * * *

BFCC-QIO means Beneficiary and Family Centered Care Quality Improvement Organization.

* * * * *

- 3. Section 418.24 is amended by —
- a. Revising paragraphs (b)(2) and (3);
- b. Redesignating paragraph (b)(5) as paragraph (b)(8);
- c. Adding new paragraphs (b)(5), (6), and (7);
- d. Redesignating paragraphs (c) through (f) as paragraphs (d) through (g) respectively; and
- e. Adding a new paragraph (c).

The revisions and additions read as follows:

§ 418.24 Election of hospice care.

* * * * *

(b) * * *

(2) The individual's or representative's acknowledgement that he or she has been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the individual's terminal illness and related conditions.

(3) Acknowledgement that the individual has been provided information on the hospice's coverage responsibility and that certain Medicare services, as set forth in paragraph (e) of this section, are waived by the election. For Hospice elections beginning on or after October 1, 2020, this would include providing the individual with information indicating that services unrelated to the terminal illness and related conditions are exceptional and unusual and hospice should be providing virtually all care needed by the individual who has elected hospice.

* * * * *

(5) For Hospice elections beginning on or after October 1, 2020, the Hospice must provide information on individual cost-sharing for hospice services.

(6) For Hospice elections beginning on or after October 1, 2020, the Hospice must provide notification of the individual's (or representative's) right to receive an election statement addendum, as set forth in paragraph (c) of this section, if there are conditions, items, services, and drugs the hospice has determined to be unrelated to the individual's terminal illness and related conditions and would not be covered by the hospice.

(7) For Hospice elections beginning on or after October 1, 2020, the Hospice must provide information on the Beneficiary and Family Centered Care Quality Improvement Organization

(BFCC-QIO), including the right to immediate advocacy and BFCC-QIO contact information.

* * * * *

(c) *Content of hospice election statement addendum.* For Hospice elections beginning on or after October 1, 2020, in the event that the hospice determines there are conditions, items, services, or drugs that are unrelated to the individual's terminal illness and related conditions, the individual (or representative), non-hospice providers furnishing such items, services, or drugs, or Medicare contractors may request a written list as an addendum to the election statement. If the election statement addendum is requested at the time of initial hospice election (that is, at the time of admission to hospice), the hospice must provide this information, in writing, to the individual (or representative) within 5 days from the date of the election. If this addendum is requested during the course of hospice care (that is, after the hospice election date), the hospice must provide this information, in writing, within 72 hours of the request to the requesting individual (or representative), non-hospice provider, or Medicare contractor. If there are any changes to the content on the addendum during the course of hospice care, the hospice must update the addendum and provide these updates, in writing, to the individual (or representative). The election statement addendum must include the following:

(1) The addendum must be titled "Patient Notification of Hospice Non-Covered Items, Services, and Drugs."

(2) Name of the hospice.

(3) Individual's name and hospice medical record identifier.

(4) Identification of the individual's terminal illness and related conditions.

(5) A list of the individual's conditions present on hospice admission (or upon plan of care update) and the associated items, services, and drugs not covered by the hospice because they have been determined by the hospice to be unrelated to the terminal illness and related conditions.

(6) A written clinical explanation, in language the individual (or representative) can understand, as to why the identified conditions, items, services, and drugs are considered unrelated to the individual's terminal illness and related conditions and not needed for pain or symptom management. This clinical explanation must be accompanied by a general

statement that the decision as to whether or not conditions, items, services, and drugs are related is made for each patient and that the individual should share this clinical explanation with other health care providers from which they seek items, services, or drugs unrelated to their terminal illness and related conditions.

(7) References to any relevant clinical practice, policy, or coverage guidelines.

(8) Information on the following:

(i) *Purpose of Addendum.* The purpose of the addendum is to notify the individual (or representative), in writing, of those conditions, items, services, and drugs the hospice will not be covering because the hospice has determined they are unrelated to the individual's terminal illness and related conditions.

(ii) *Right to Immediate Advocacy.* The addendum must include language that immediate advocacy is available through the Medicare Beneficiary and Family Centered Care-Quality Improvement Organization (BFCC-QIO) if the individual (or representative) disagrees with the hospice's determination.

(9) Name and signature of the individual (or representative) and date signed, along with a statement that signing this addendum (or its updates) is only acknowledgement of receipt of the addendum (or its updates) and not necessarily the individual's (or representative's) agreement with the hospice's determinations.

* * * * *

§ 418.26 [Amended]

■ 4. Section 418.26 is amended in paragraph (c)(2) by removing the reference "\$ 418.24(d)" and adding in its place the reference "\$ 418.24(e)".

§ 418.28 [Amended]

■ 5. Section 418.28 is amended in paragraph (c)(2) by removing the reference "\$ 418.24(e)(2)" and adding in its place the reference "\$ 418.24(f)(2)".

Dated: July 25, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 26, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019-16583 Filed 7-31-19; 4:15 pm]

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