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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 927

[Doc. No. AMS-SC-18-0048; SC18-927-1 FR]

Pears Grown in Oregon and Washington; Increased Assessment Rate for Fresh Pears

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule implements a recommendation from the Fresh Pear Committee (Committee) to increase the assessment rate established for the 2018–2019 and subsequent fiscal periods. The assessment rate will remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Effective December 13, 2018.

FOR FURTHER INFORMATION CONTACT: Barry Broadbent, Marketing Specialist, or Gary Olson, Regional Director, Northwest Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (503) 326–2724, Fax: (503) 326–7440, or Email: Barry.Broadbent@ams.usda.gov or GaryD.Olson@ams.usda.gov.

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: Richard.Lower@ams.usda.gov.

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, amends regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This rule is issued under Marketing Order No. 927, as amended (7 CFR part 927), regulating the handling

of pears grown in Oregon and Washington. Part 927, (referred to as “the Order”) is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the “Act.” The Committee locally administers the Order and is comprised of growers and handlers operating within the area of production, and a public member.

The Department of Agriculture (USDA) is issuing this final rule in conformance with Executive Orders 13563 and 13175. This rule falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review. Additionally, because this rule does not meet the definition of a significant regulatory action, it does not trigger the requirements contained in Executive Order 13771. See OMB’s Memorandum titled “Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled ‘Reducing Regulation and Controlling Regulatory Costs’” (February 2, 2017).

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the Order now in effect, Oregon and Washington pear handlers are subject to assessments. Funds to administer the Order are derived from such assessments. The assessment rate established by this rule will be applicable to all assessable pears for the 2018–2019 fiscal period, and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA’s ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

The Order provides authority for the Committee, with the approval of USDA, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members are familiar with the Committee’s needs and with the costs of goods and services in their local area and are in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting where all directly affected persons have an opportunity to participate and provide input.

This rule increases the assessment rate from \$0.449 to \$0.463 per 44-pound standard box or equivalent of fresh “summer/fall” and “winter” pears handled for the 2018–2019 and subsequent fiscal periods. The higher rate is necessary to fully cover the Committee’s 2018–2019 fiscal period budgeted expenditures. The Committee has had to draw from its monetary reserve to partially fund program activities during the last two fiscal periods. Drawing from reserves to fund operations on an on-going basis is not a sustainable strategy. Therefore, increasing the continuing assessment rate will allow the Committee to fully fund budgeted expenses and replenish its financial reserve.

The Committee met on May 31, 2018, and unanimously recommended 2018–2019 fiscal period expenditures of \$9,213,133 and an assessment rate of \$0.463 per standard box or equivalent of fresh “summer/fall” and “winter” pears handled. In comparison, last year’s budgeted expenditures were \$9,282,059. The new assessment rate of \$0.463 is \$0.014 higher than the \$0.449 rate previously in effect. The Committee recommended the assessment rate increase because expenditures have exceeded assessment revenue in the previous two fiscal periods.

The major expenditures recommended by the Committee for the 2018–2019 fiscal period include \$550,790 for contracted administration by Pear Bureau Northwest, \$190,700 for administrative expenses, \$771,643 for production research and market development, and \$7,700,000 for promotion and paid advertising for both “summer/fall” and “winter” varieties of fresh pears. In comparison, major expenses for the 2017–2018 fiscal period included \$512,928 for contracted

administration, \$232,200 for administrative expenses, \$836,931 for production research and market development, and \$7,700,000 for promotion and paid advertising.

The assessment rate recommended by the Committee was derived by considering anticipated expenses, expected shipments, and the amount of funds available in the authorized reserve. Anticipated income derived from handler assessments of \$9,260,000 (20 million standard boxes or equivalent at \$0.463 per box) should be adequate to cover budgeted expenses of \$9,213,133, with any excess funds used to replenish the Committee's monetary reserve. Funds in the reserve (currently \$1,096,332) will be kept within the maximum permitted by § 927.42(a) and will not exceed the expenses of approximately one fiscal period.

The assessment rate established in this rule will continue in effect indefinitely unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other available information.

Although this assessment rate will be in effect for an indefinite period, the Committee will continue to meet prior to or during each fiscal period to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of Committee meetings are available from the Committee or USDA. Committee meetings are open to the public and interested persons may express their views at these meetings. USDA will evaluate Committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking would be undertaken as necessary. The Committee's budget for subsequent fiscal periods will be reviewed and, as appropriate, approved by USDA.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially

small entities acting on their own behalf.

There are approximately 827 growers of fresh pears in the production area and approximately 38 handlers subject to regulation under the Order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts less than \$750,000, and small agricultural service firms are defined as those whose annual receipts are less than \$7,500,000 (13 CFR 121.201).

According to data from USDA Market News, the industry, and the Committee, for the 2016–17 season, the weighted average f.o.b. price for Oregon–Washington fresh pears was approximately \$26.99 per standard 44-pound box. Total shipments for that period were 17,878,219 standard boxes or equivalent. Using the number of handlers, and assuming a normal distribution, the majority of handlers may have average annual receipts of more than \$7,500,000 (\$26.99 per box times 17,878,219 equals \$482,533,130 divided by 38 handlers equals \$12,698,240 per handler).

In addition, based on National Agricultural Statistics Service data, the industry produced 441,950 tons of fresh pears in the production area during the 2016–2017 season, with an average grower price of \$797 per ton. Based on the average grower price, production, and the total number of Oregon–Washington fresh pear growers, and assuming a normal distribution, the average annual grower revenue is below \$750,000 (\$797 per ton times 441,950 tons equals \$352,234,150 divided by 827 growers equals \$425,918 per grower). Thus, the majority of Oregon and Washington fresh pear handlers may be classified as large entities, while the majority of growers may be classified as small entities.

This rule increases the assessment rate collected from handlers for the 2018–2019 and subsequent fiscal periods from \$0.449 to \$0.463 per standard box or equivalent of Oregon and Washington fresh “summer/fall” and “winter” pears handled. The Committee unanimously recommended 2018–2019 fiscal period expenditures of \$9,213,133 and the \$0.463 per standard box or equivalent assessment rate. The assessment rate of \$0.463 is \$0.014 higher than the rate for the 2017–2018 fiscal period. The quantity of assessable fresh “summer/fall” and “winter” pears for the 2018–2019 fiscal period is estimated at 20 million standard boxes or equivalent. Thus, the \$0.463 rate should provide \$9,260,000 in assessment income. Income derived from handler assessments should be

adequate to cover budgeted expenses, with any excess funds used to replenish the Committee's monetary reserve.

The major expenditures recommended by the Committee for the 2018–2019 fiscal period include \$550,790 for contracted administration by Pear Bureau Northwest, \$190,700 for administrative expenses, \$771,643 for production research and market development, and \$7,700,000 for promotion and paid advertising for both “summer/fall” pears and “winter” pears. Budgeted expenses for these items in the 2017–2018 fiscal period were \$512,928, \$232,200, \$836,931, and \$7,700,000, respectively.

The higher assessment rate is necessary to fully cover the Committee's 2018–2019 fiscal period budgeted expenditures. The Committee has had to draw from its monetary reserve to partially fund program activities during the 2016–2017 and 2017–2018 fiscal periods. Drawing from its financial reserve to fund operations on an ongoing basis is not a sustainable strategy. Increasing the continuing assessment rate will allow the Committee to fully fund budgeted expenses and replenish its financial reserve.

Prior to arriving at this budget and assessment rate, the Committee considered maintaining the current assessment rate of \$0.449 per standard box or equivalent. However, leaving the assessment unchanged would not have generated sufficient revenue to meet the Committee's 2018–2019 fiscal period budgeted expenses of \$9,213,133, and would have required the Committee to continue to deplete its financial reserve. Based on estimated shipments, the recommended assessment rate of \$0.463 per standard box or equivalent should provide \$9,260,000 in assessment income. The Committee determined assessment revenue should be adequate to cover budgeted expenses for the 2018–2019 fiscal period. Any excess assessment revenue will be allocated to replenish the Committee's monetary reserve. Reserve funds will be kept within the amount authorized in the Order.

A review of historical information and preliminary information pertaining to the upcoming fiscal year indicates that the average grower price for the 2018–2019 season should be approximately \$800 per ton of fresh pears. Therefore, the estimated assessment revenue for the 2018–2019 fiscal period as a percentage of total grower revenue is about 2.6 percent.

This action increases the assessment obligation imposed on handlers. While assessments impose some additional costs on handlers, the costs are minimal

and uniform on all handlers. Some of the additional costs may be passed on to growers. However, these costs are offset by the benefits derived by the operation of the Order. In addition, the Committee's meeting was widely publicized throughout the Oregon and Washington fresh pear industry. All interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the May 31, 2018, meeting was a public meeting and all entities, both large and small, were able to express views on this issue.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Order's information collection requirements have been previously approved by the OMB and assigned OMB No. 0581-0189 Fruit Crops. No changes in those requirements are necessary as a result of this action. Should any changes become necessary, they would be submitted to OMB for approval.

This rule imposes no additional reporting or recordkeeping requirements on either small or large Oregon and Washington fresh pear handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this final rule.

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

A proposed rule concerning this action was published in the **Federal Register** on August 28, 2018 (83 FR 43799). Copies of the proposed rule were also mailed or sent via facsimile to all Oregon and Washington fresh pear handlers. The proposal was made available through the internet by USDA and the Office of the Federal Register. A 30-day comment period ending September 27, 2018, was provided for interested persons to respond to the proposal. One comment was received during the comment period. The commenter was in favor of the regulation. Accordingly, no changes will be made to the rule as proposed, based on the comment received.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: <http://www.ams.usda.gov/rules-regulations/moa/small-businesses>.

Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendation submitted by the Committee and other available information, it is hereby found that this rule, will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 927

Marketing agreements, Pears, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 927 is amended as follows:

PART 927—PEARS GROWN IN OREGON AND WASHINGTON

■ 1. The authority citation for 7 CFR part 927 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. In § 927.236, the introductory text and paragraphs (a) and (b) are revised to read as follows:

§ 927.236 Assessment rate.

On and after July 1, 2018, the following base rates of assessment for fresh pears are established for the Fresh Pear Committee:

(a) \$0.463 per 44-pound net weight standard box or container equivalent for any or all varieties or subvarieties of fresh pears classified as “summer/fall”;

(b) \$0.463 per 44-pound net weight standard box or container equivalent for any or all varieties or subvarieties of fresh pears classified as “winter”;

* * * * *

Dated: November 7, 2018.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2018-24728 Filed 11-9-18; 8:45 am]

BILLING CODE 3410-02-P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 249

[Release No. 34-84541; File No. S7-23-15]

RIN 3235-AL66

Regulation of NMS Stock Alternative Trading Systems

AGENCY: Securities and Exchange Commission.

ACTION: Final rule; technical correction.

SUMMARY: This document makes technical corrections to a rule that was published in the **Federal Register** on August 7, 2018. The Commission adopted amendments to the regulatory requirements in Regulation ATS under the Securities Exchange Act of 1934 applicable to alternative trading systems (“ATSs”) that trade National Market System (“NMS”) stocks (hereinafter referred to as “NMS Stock ATSs”), which included, among other items, Form ATS-N. This document is being published to correct a citation contained in the adopted language of Part III, Item 15.a of Form ATS-N.

DATES: Effective November 13, 2018.

FOR FURTHER INFORMATION CONTACT:

Tyler Raimo, Senior Special Counsel, at (202) 551-6227; Matthew Cursio, Special Counsel, at (202) 551-5748; Marsha Dixon, Special Counsel, at (202) 551-5782; Jennifer Dodd, Special Counsel, at (202) 551-5653; David Garcia, Special Counsel, at (202) 551-5681; or Megan Mitchell, Special Counsel, at (202) 551-4887; Office of Market Supervision, Division of Trading and Markets, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-7010.

SUPPLEMENTARY INFORMATION: We are making a technical amendment to Part III, Item 15.a of Form ATS-N under 17 CFR 249.640.

List of Subjects in 17 CFR Part 249

Brokers, Reporting and recordkeeping requirements, Securities.

Statutory Authority and Text of Amendments

For the reasons set out above, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

■ 1. The authority citation for part 249 continues to read in part as follows:

Authority: 15 U.S.C. 78a *et seq.* and 7201 *et seq.*; 12 U.S.C. 5461 *et seq.*; 18 U.S.C. 1350; Sec. 953(b), Pub. L. 111-203, 124 Stat. 1904; Sec. 102(a)(3), Pub. L. 112-106, 126 Stat. 309 (2012); Sec. 107, Pub. L. 112-106, 126 Stat. 313 (2012), and Sec. 72001, Pub. L. 114-94, 129 Stat. 1312 (2015), unless otherwise noted.

* * * * *

■ 2. Amend Form ATS-N (referenced in § 249.640) by revising Part III, Item 15.a to read as follows:

Note: The text of Form ATS-N does not, and this amendment will not, appear in the Code of Federal Regulations.

Form ATS-N

* * * * *

Item 15: Display

a. Does the NMS Stock ATS operate as an Electronic Communication Network as defined in Rule 600(b)(23) of Regulation NMS?

Yes No

* * * * *

Dated: November 6, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–24549 Filed 11–9–18; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2018–C–4117]

Sensient Colors, LLC; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Sensient Colors, LLC, proposing that the color additive regulations be amended to provide for the safe use of an aqueous extract of butterfly pea flower (*Clitoria ternatea*) as a color additive in various food categories, at levels consistent with good manufacturing practice.

DATES: The color additive petition was filed on October 4, 2018.

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this document into the “Search” box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Stephen DiFranco, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2710.

SUPPLEMENTARY INFORMATION: Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 8C0313) submitted by Exponent, Inc. on behalf of Sensient Colors, LLC, 1150 Connecticut Ave. NW, Suite 1100, Washington, DC 20036. The petition

proposes to amend the color additive regulations in part 73 (21 CFR part 73), “Listing of Color Additives Exempt From Certification,” to provide for the safe use of an aqueous extract of butterfly pea flower (*Clitoria ternatea*) as a color additive in: (1) Alcoholic beverages (liquor, liqueurs, and flavored alcoholic beverages); (2) ready-to-drink non-alcoholic beverages; (3) liquid coffee creamers (dairy and non-dairy); (4) ice cream and frozen dairy desserts; (5) fruit preparation in yogurt; (6) chewing gum; (7) coated nuts; (8) hard candy; and (9) soft candy, at levels consistent with good manufacturing practice.

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(k) because the substance is intended to remain in food through ingestion by consumers and is not intended to replace macronutrients in food. In addition, the petitioner has stated that, to their knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: November 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24662 Filed 11–9–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2018–0964]

Safety Zone; Allegheny River, Miles 0.0–1.0, Pittsburgh, PA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the Pittsburgh Downtown Partnership/Light Up Night Fireworks to provide for the safety of persons, vessels, and the marine environment on the navigable waters of the Allegheny River, miles 0.0 to 1.0, extending the entire width of the river. Our regulation for marine events within the Eighth Coast Guard District identifies the regulated area for this event in Pittsburgh, PA. During the

enforcement period, entry into, transiting, or anchoring in the safety zone is prohibited to all vessels not registered with the sponsor as participants or official patrol vessels, unless specifically authorized by the Captain of the Port Marine Safety Unit Pittsburgh (COTP) or a designated representative.

DATES: The regulations in 33 CFR 165.801 Table 1, line 37 will be enforced from 9 p.m. through 11:30 p.m. on November 16, 2018.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Petty Officer Jennifer Haggins, Marine Safety Unit Pittsburgh, U.S. Coast Guard; telephone 412–221–0807, email Jennifer.L.Haggins@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a temporary safety zone for the Pittsburgh Downtown Partnership/Light Up Night Fireworks in 33 CFR 165.801 Table 1 titled “Sector Ohio Valley Annual and Recurring Safety Zones”, line 37 from 9 p.m. through 11:30 p.m. on November 16, 2018. This action is being taken to provide for the safety of persons, vessels, and the marine environment on the navigable waters of the Allegheny River during this event. Our regulation for marine events within the Eighth Coast Guard District, § 165.801 specifies the location of the regulated area for the Pittsburgh Downtown Partnership/Light Up Night Fireworks. Entry into the safety zone is prohibited unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh (COTP) or a designated representative. Persons or vessels desiring to enter into or passage through the safety zone must request permission from the COTP or a designated representative. They can be reached on VHF FM channel 16. If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

In addition to this notice of enforcement in the **Federal Register**, the COTP or a designated representative will inform the public through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), Marine Safety Information Bulletins (MSIBs), and/or through other means of public notice as appropriate at least 24 hours in advance of enforcement.

Dated: October 29, 2018.

A.W. Demo,

Commander, U.S. Coast Guard, Captain of the Port Marine Safety Unit Pittsburgh.

[FR Doc. 2018–24624 Filed 11–9–18; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 55**

[EPA-R01-OAR-2018-0011; FRL-9983-52-Region 1]

Outer Continental Shelf Air Regulations; Consistency Update for Massachusetts**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is updating a portion of the Outer Continental Shelf (OCS) Air Regulations. Requirements applying to OCS sources located within 25 miles of states' seaward boundaries must be updated periodically to remain consistent with the requirements of the corresponding onshore area (COA), as mandated by section 328(a)(1) of the Clean Air Act. The portion of the OCS air regulations that is being updated pertains to the requirements for OCS sources for which Massachusetts is the designated COA. The Commonwealth of Massachusetts' requirements discussed in this document will be incorporated by reference into the Code of Federal Regulations and listed in the appendix to the federal OCS air regulations.

DATES: This rule is effective on December 13, 2018. The incorporation by reference of certain publications listed in this rule is approved by the Director of the Federal Register as of December 13, 2018.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA-R01-OAR-2018-0011. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available at <https://www.regulations.gov> or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Office of Ecosystem Protection, Air Quality Planning Unit, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Eric Wortman, Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA Region 1, 5 Post Office Square (Mail Code OEP05-2), Boston, MA 02109, (617) 918-1624, wortman.eric@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document whenever “we,” “us,” or “our” is used, we mean EPA.

Table of Contents

- I. Background and Purpose
- II. Response to Comments
- III. Final Action
- IV. Incorporation by Reference
- V. Statutory and Executive Order Reviews

I. Background and Purpose

On September 4, 1992, the EPA promulgated 40 CFR part 55,¹ which established requirements to control air pollution from OCS sources in order to attain and maintain federal and state ambient air quality standards and to comply with the provisions of part C of title I of the CAA. The regulations at 40 CFR part 55 apply to all OCS sources offshore of the states except those located in the Gulf of Mexico west of 87.5 degrees longitude. Section 328 of the CAA requires that for such sources located within 25 miles of a state's seaward boundary, the requirements shall be the same as would be applicable if the sources were located in the COA. Because the OCS requirements are based on onshore requirements, and onshore requirements may change, section 328(a)(1) requires that the EPA update the OCS requirements as necessary to maintain consistency with onshore requirements.

On February 12, 2018 (83 FR 5971), the EPA published a Notice of Proposed Rulemaking (NPRM) proposing to incorporate various Massachusetts air pollution control requirements into 40 CFR part 55. Pursuant to 40 CFR 55.12, consistency reviews will occur (1) at least annually; (2) upon receipt of a Notice of Intent (NOI) under 40 CFR 55.4; or (3) when a state or local agency submits a rule to the EPA to be considered for incorporation by reference in 40 CFR part 55. This action is being taken in response to the submittal of a NOI on December 11, 2017 by Vineyard Wind, LLC.

The EPA reviewed the rules for inclusion in 40 CFR part 55 to ensure that they are rationally related to the

attainment or maintenance of federal or state ambient air quality standards and compliance with part C of title I of the CAA, that they are not designed expressly to prevent exploration and development of the OCS, and that they are potentially applicable to OCS sources. *See* 40 CFR 55.1. The EPA has also evaluated the rules to ensure they are not arbitrary or capricious. *See* 40 CFR 55.12(e). In addition, the EPA has excluded administrative or procedural rules,² and requirements that regulate toxics which are not related to the attainment and maintenance of federal and state ambient air quality standards.

Section 328(a) of the CAA requires that the EPA establish requirements to control air pollution from OCS sources located within 25 miles of states' seaward boundaries that are the same as onshore requirements. To comply with this statutory mandate, the EPA must incorporate applicable onshore rules into 40 CFR part 55 as they exist onshore. This limits the EPA's flexibility in deciding which requirements will be incorporated into 40 CFR part 55 and prevents the EPA from making substantive changes to the requirements it incorporates. As a result, the EPA may be incorporating rules into 40 CFR part 55 that do not conform to all of the EPA's state implementation plan (SIP) guidance or certain requirements of the CAA. Consistency updates may result in the inclusion of state or local rules or regulations into 40 CFR part 55, even though the same rules may ultimately be disapproved for inclusion as part of the SIP. Inclusion in the OCS rule does not imply that a rule meets the requirements of the CAA for SIP approval, nor does it imply that the rule will be approved by the EPA for inclusion in the SIP.

On March 9, 2018, the Commonwealth of Massachusetts amended certain regulatory provisions that pertained to the EPA's February 12, 2018 proposed rulemaking. On May 9, 2018, the EPA reopened the comment period for 30 days and provided notice that the EPA modified the proposed regulatory text for incorporation by reference in this action. *See* 83 FR 21254 (May 9, 2018). The EPA also added the March 9, 2018 amended regulations at 310 CMR 7.00 to the docket as part of reopening the comment period to give all interested

¹ The reader may refer to the Notice of Proposed Rulemaking, December 5, 1991 (56 FR 63774), and the preamble to the final rule promulgated September 4, 1992 (57 FR 40792) for further background and information on the OCS regulations.

² Each COA which has been delegated the authority to implement and enforce part 55 will use its administrative and procedural rules as onshore. However, in those instances where the EPA has not delegated authority to implement and enforce part 55, the EPA will use its own administrative and procedural requirements to implement the substantive requirements. *See* 40 CFR 55.14(c)(4).

persons the opportunity to comment on the incorporation by reference of the amended regulations at 310 CMR 7.00.³

Other specific requirements of the consistency update and the rationale for EPA's proposed action are explained in the February 12, 2018 NPRM and the May 9, 2018 reopening of comment period document and will not be restated here.

II. Response to Comments

In response to the February 12, 2018 NPRM and the May 9, 2018 reopening of the comment period, we received a number of anonymous comments that address subjects outside the scope of our final action, do not explain (or provide a legal basis for) how the final action should differ in any way, and make no specific mention of the final action, *i.e.* incorporation by reference of the relevant Commonwealth of Massachusetts regulations into 40 CFR part 55. This action is required by the CAA and EPA's regulations, based on Vineyard Wind, LLC's NOI. Consequently, the comments referenced above are not germane to this rulemaking and require no further response.

The EPA received one relevant comment from the Commonwealth of Massachusetts that referred specifically to the proposed rulemaking on the consistency update for Massachusetts to the outer continental shelf regulations.

Comment: The commenter indicated that the Massachusetts regulations at 310 Code of Massachusetts Regulations (CMR) 7.21: Sulfur Dioxide Emissions Limitations and 310 CMR 7.22: Sulfur Dioxide Emissions Reductions for the Purpose of Reducing Acid Rain should be removed from the Part 55 Consistency Update because those sections were rescinded in the Commonwealth's March 9, 2018 amendments to 310 CMR 7.00.

Response: The EPA agrees with the commenter and has removed Sections 7.21 and 7.22 from the regulatory text that includes incorporation by

reference. Sections 7.21 and 7.22 were inadvertently included in the May 9, 2018 reopening of comment period document in error and have been removed from the regulatory text that includes incorporation by reference in this final action.

III. Final Action

The EPA is taking final action to incorporate the rules potentially applicable to OCS sources for which the Commonwealth of Massachusetts will be the COA. The rules that the EPA is taking final action to incorporate are applicable provisions of (1) 310 CMR 4.00: Timely Action Schedule and Fee Provisions; (2) 310 CMR 6.00: Ambient Air Quality Standards for the Commonwealth of Massachusetts; (3) 310 CMR 7.00: Air Pollution Control; and (4) 310 CMR 8.00: The Prevention and/or Abatement of Air Pollution Episode and Air Pollution Incident Emergencies, as amended through March 9, 2018. The rules that EPA is taking final action to incorporate will replace the rules previously incorporated into 40 CFR part 55 for Massachusetts. *See* 75 FR 51950; August 24, 2010.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the Code of Massachusetts Regulations described in the amendments to 40 CFR part 55 set forth below. The EPA has made, and will continue to make, these documents generally available through <https://www.regulations.gov> and at the EPA Region 1 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to establish requirements to control air pollution from OCS sources located within 25 miles of states' seaward boundaries that are the same as onshore air pollution control requirements. To comply with this statutory mandate, the EPA must incorporate applicable onshore rules into 40 CFR part 55 as they exist onshore. *See* 42 U.S.C. 7627(a)(1); 40 CFR 55.12. Thus, in promulgating OCS consistency updates, the EPA's role is to maintain consistency between OCS regulations and the regulations of onshore areas, provided that they meet the criteria of the CAA. Accordingly,

this action simply updates the existing OCS requirements to make them consistent with requirements onshore, without the exercise of any policy direction by the EPA. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- This action is not an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866;
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), 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, nor does it impose substantial direct compliance costs on tribal governments or preempt tribal law.

Under the provisions of the Paperwork Reduction Act, 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

³ The EPA is required to submit a true copy of the regulations, attested by the Commonwealth of Massachusetts, to the Office of the Federal Register for incorporation by reference in the final rule. The EPA obtained a true copy of the amended regulations in effect as of March 9, 2018. The Commonwealth of Massachusetts State Bookstore bundles 310 CMR 6.00, 310 CMR 7.00, and 310 CMR 8.00 into a single package for the purpose of attesting a true copy. Although the regulations at 310 CMR 6.00 and 310 CMR 8.00 were not part of the March 9, 2018 amendments, the EPA updated the effective date for 310 CMR 6.00-8.00 in the regulatory text for incorporation by reference for consistency with the updated true copy of the regulations. The true copy of the regulations for 310 CMR 6.00-8.00 obtained by the EPA is included in the docket for this action.

information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in 40 CFR part 55 and, by extension, this update to the rules, and has assigned OMB control number 2060–0249. OMB approved the EPA Information Collection Request (ICR) No. 1601.08 on September 18, 2017.⁴ The current approval expires September 30, 2020. The annual public reporting and recordkeeping burden for collection of information under 40 CFR part 55 is estimated to average 643 hours per response, using the definition of burden provided in 44 U.S.C. 3502(2).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 14, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 55

Environmental protection, Administrative practice and procedure, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Outer continental shelf, Ozone, Particulate matter, Permits, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: November 1, 2018.

Alexandra Dunn,
Regional Administrator, EPA Region 1.

Part 55 of chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 55—OUTER CONTINENTAL SHELF AIR REGULATIONS

■ 1. The authority citation for part 55 continues to read as follows:

Authority: Section 328 of the Clean Air Act (42 U.S.C. 7401 *et seq.*) as amended by Public Law 101–549.

■ 2. Section 55.14 is amended by revising paragraph (e)(11)(i)(A) to read as follows:

§ 55.14 Requirements that apply to OCS sources located within 25 miles of States’ seaward boundaries, by State.

* * * * *

(e) * * *

(11) * * *

(i) * * *

(A) Commonwealth of Massachusetts Requirements Applicable to OCS Sources, March 9, 2018.

* * * * *

■ 3. Appendix A to part 55 is amended by revising paragraph (a)(1) under the heading “Massachusetts” to read as follows:

Appendix A to Part 55—Listing of State and Local Requirements Incorporated by Reference Into Part 55, by State

* * * * *

Massachusetts

(a) * * *

(1) The following Commonwealth of Massachusetts requirements are applicable to OCS Sources, March 9, 2018, Commonwealth of Massachusetts—Department of Environmental Protection.

The following sections of 310 CMR 4.00, 310 CMR 6.00, 310 CMR 7.00 and 310 CMR 8.00:

310 CMR 4.00: Timely Action Schedule and Fee Provisions

Section 4.01: Purpose, Authority and General Provisions (Effective 3/24/2017)

Section 4.02: Definitions (Effective 3/24/2017)

Section 4.03: Annual Compliance Assurance Fee (Effective 3/24/2017)

Section 4.04: Permit Application Schedules and Fee (Effective 3/24/2017)

Section 4.10: Appendix: Schedules for Timely Action and Permit Application Fees (Effective 3/24/2017)

310 CMR 6.00: Ambient Air Quality Standards for the Commonwealth of Massachusetts

Section 6.01: Definitions (Effective 3/9/2018)

Section 6.02: Scope (Effective 3/9/2018)

Section 6.03: Reference Conditions (Effective 3/9/2018)

Section 6.04: Standards (Effective 3/9/2018)

310 CMR 7.00: Air Pollution Control

Section 7.00: Statutory Authority; Legend; Preamble; Definitions (Effective 3/9/2018)

Section 7.01: General Regulations to Prevent Air Pollution (Effective 3/9/2018)

Section 7.02: U Plan Approval and Emission Limitations (Effective 3/9/2018)

Section 7.03: U Plan Approval Exemptions: Construction Requirements (Effective 3/9/2018)

Section 7.04: U Fossil Fuel Utilization Facilities (Effective 3/9/2018)

Section 7.05: U Fuels All Districts (Effective 3/9/2018)

Section 7.06: U Visible Emissions (Effective 3/9/2018)

Section 7.07: U Open Burning (Effective 3/9/2018)

Section 7.08: U Incinerators (Effective 3/9/2018)

Section 7.09: U Dust, Odor, Construction and Demolition (Effective 3/9/2018)

Section 7.11: U Transportation Media (Effective 3/9/2018)

Section 7.12: U Source Registration (Effective 3/9/2018)

Section 7.13: U Stack Testing (Effective 3/9/2018)

Section 7.14: U Monitoring Devices and Reports (Effective 3/9/2018)

Section 7.18: U Volatile and Halogenated Organic Compounds (Effective 3/9/2018)

Section 7.19: U Reasonably Available Control Technology (RACT) for Sources of Oxides of Nitrogen (NO_x) (Effective 3/9/2018)

Section 7.24: U Organic Material Storage and Distribution (Effective 3/9/2018)

Section 7.25: U Best Available Controls for Consumer and Commercial Products (Effective 3/9/2018)

Section 7.26: Industry Performance Standards (Effective 3/9/2018)

Section 7.60: U Severability (Effective 3/9/2018)

Section 7.00: Appendix A (Effective 3/9/2018)

Section 7.00: Appendix B (Effective 3/9/2018)

Section 7.00: Appendix C (Effective 3/9/2018)

310 CMR 8.00: The Prevention and/or Abatement of Air Pollution Episode and Air Pollution Incident Emergencies

Section 8.01: Introduction (Effective 3/9/2018)

Section 8.02: Definitions (Effective 3/9/2018)

Section 8.03: Air Pollution Episode Criteria (Effective 3/9/2018)

Section 8.04: Air Pollution Episode Potential Advisories (Effective 3/9/2018)

Section 8.05: Declaration of Air Pollution Episodes and Incidents (Effective 3/9/2018)

Section 8.06: Termination of Air Pollution Episodes and Incident Emergencies (Effective 3/9/2018)

Section 8.07: Emission Reductions Strategies (Effective 3/9/2018)

Section 8.08: Emission Reduction Plans (Effective 3/9/2018)

Section 8.15: Air Pollution Incident Emergency (Effective 3/9/2018)

⁴ OMB’s approval of the ICR can be viewed at www.reginfo.gov.

Section 8.30: Severability (Effective 3/9/2018)

* * * * *

[FR Doc. 2018-24648 Filed 11-9-18; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0694; FRL-9985-32]

Cyantraniliprole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyantraniliprole in or on multiple commodities which are identified and discussed later in this document. The Interregional Research Project No. 4 (IR-4) and DuPont Crop Protection requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 13, 2018. Objections and requests for hearings must be received on or before January 14, 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-2017-0694, 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: RDPRNotices@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. To access the OCSPP test guidelines referenced in this document electronically, please go to <https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp> and select "Test Methods and Guidelines."

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-2017-0694 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before January 14, 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-2017-0694, 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 <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 <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of March 21, 2018 (83 FR 12311) (FRL-9974-76), 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 7E8631) by The Interregional Research Project No. 4 (IR-4), Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.672 be amended by establishing tolerances for residues of the insecticide, cyantraniliprole, 3-bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-methyl-6-(((methylamino)carbonyl)phenyl)-1H-pyrazole-5-carboxamide, in or on Berry, low growing, except strawberry, subgroup 13-07H, except blueberry, lowbush and lingonberry at 0.08 parts per million (ppm) (proposal to replace an existing tolerance at the same level that is only for imported Berry, low growing, except strawberry, subgroup 13-07H, with a tolerance supporting both domestic production and imported low growing berries, except strawberries); *Brassica*, leafy greens, subgroup 4-16B at 30 ppm; Caneberry subgroup 13-07A at 4.0 ppm; Celtsuce at 20 ppm; Coffee, green bean at 0.05 ppm (proposal to replace an existing tolerance at the same level that is only for imported Coffee, green bean with a tolerance supporting both domestic production and imported coffee); Florence fennel at 20 ppm; Kohlrabi at 3.0 ppm; Leafy greens subgroup 4-16A at 20 ppm; Leaf petiole vegetable subgroup 22B at 20 ppm; and Vegetable,

Brassica, head and stem, group 5–16 at 3.0 ppm. Upon the establishment of the above tolerances, IR–4 proposed to remove existing tolerances in 40 CFR part 180.672 in or on the following commodities: *Brassica* head and stem, subgroup 5A at 3.0 ppm; *Brassica* leafy vegetables, subgroup 5B at 30 ppm; and Vegetable, leafy, except *Brassica*, group 4 at 20 ppm.

In the **Federal Register** of April 11, 2018 (83 FR 15528) (FRL–9975–57), 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 7F8622) by DuPont Crop Protection, Stine-Haskell Research Center, P.O. Box 30, Newark, DE 19714–0030. The petition requested that 40 CFR 180.672 be amended by establishing tolerances for residues of the insecticide cyantraniliprole, 3-bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-methyl-6-[[[(methylamino)carbonyl]phenyl]-1H-pyrazole-5-carboxamide], in or on Rice, hulls at 0.05 ppm; Rice, straw at 0.015 ppm; Soybean, forage at 15 ppm; Soybean, hay at 50 ppm; Soybean, hulls at 1 ppm; Soybean, seed at 0.4 ppm; and Aspirated grain fractions at 200 ppm. Upon the approval of the proposed tolerances in soybean forage and hay, it is proposed that the existing tolerances for indirect or inadvertent residues in soybean forage and hay be cancelled. In addition, DuPont Crop Protection requests to amend the tolerances in 40 CFR 180.672, in or on rice, grain at 0.02 ppm by replacing an existing tolerance at the same level that is only for imported grain with a tolerance supporting both domestic production and imported grain.

These documents referenced summaries of the petitions prepared by DuPont Crop Protection, the registrant, which are available in the docket, <http://www.regulations.gov>. Three comments were received on the notices of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA modified some of the tolerance levels to conform to EPA's rounding classes and revised the commodity terminology for two tolerances. These changes are explained in Unit IV.D.

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 cyantraniliprole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with cyantraniliprole 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 general, cyantraniliprole administration in mammalian test species produces both adverse and adaptive changes in the liver, thyroid gland, and adrenal cortex. With repeated dosing, consistent findings of mild to moderate increases in liver weights across multiple species (rats, mice and dogs) are observed. Dogs appear to be more sensitive than rats and mice; cyantraniliprole produces adverse liver effects (increases in alkaline phosphatase, decreases in cholesterol, and decreases in albumin) in dogs at lower dose levels than in rats. In addition, the liver effects in the dog show progressive severity with increased duration of exposure. The available data also show thyroid hormone homeostasis is altered in rats following exposure to cyantraniliprole after 28 or 90 days; however, cyantraniliprole is not a direct thyroid toxicant.

Cyantraniliprole is classified as "not likely to be carcinogenic to humans" based on the absence of increased tumor incidence in acceptable/guideline carcinogenicity studies in rats and mice, and there are no mutagenicity concerns. There are also no developmental or reproductive toxicity concerns and no offspring susceptibility concerns. Cyantraniliprole does not produce developmental toxicity in either rats or rabbits. The 2-generation reproduction study in rats shows that cyantraniliprole has no adverse effect on any reproductive parameters.

Acute and subchronic neurotoxicity studies reveal no evidence of neurotoxicity. Similarly, cyantraniliprole does not adversely impact the immune system in rats and mice. Based on the results of a 28-day dermal study in rats (as well as the dermal LD₅₀ study), cyantraniliprole does not demonstrate any appreciable toxicity via dermal exposure. The 28-day inhalation toxicity study in rats does not show any adverse systemic or portal of entry effect at the highest concentration tested (100 mg/m³, equivalent to 18 mg/kg/day).

Cyantraniliprole has no significant acute toxicity via the oral, dermal, and inhalation routes of exposure. Cyantraniliprole is not an eye or skin irritant and does not cause skin sensitization.

Specific information on the studies received and the nature of the adverse effects caused by cyantraniliprole 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 "Cyantraniliprole. Human Health Risk Assessment for Proposed Uses and Tolerance Requests on Coffee; Caneberry Subgroup 13–07A; Low Growing Berry Subgroup 13–07H, Except Strawberry, Lowbush Blueberry and Lingonberry; *Brassica* Leafy Greens Subgroup 4–16A; Leafy Greens Subgroup 4–16B; *Brassica* Head and Stem Vegetable Group 5–16; Leaf Petiole Vegetable Subgroup 22B; Celtnuce; Florence Fennel; Kohlrabi; Rice; Soybean; and Aspirated Grain Fractions" on pages 36–45 in docket ID number EPA–HQ–OPP–2017–0694.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there

is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks>.

A summary of the toxicological endpoints for cyantraniliprole used for human risk assessment is discussed in Unit III.B of the final rule published in the **Federal Register** of February 5, 2014 (79 FR 6826) (FRL-9388-7).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to cyantraniliprole, EPA considered exposure under the petitioned-for tolerances as well as all existing cyantraniliprole tolerances in 40 CFR 180.672. EPA assessed dietary exposures from cyantraniliprole 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 cyantraniliprole; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the 2003–2008 United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWWEIA). As to residue levels in food, a refined chronic (food and drinking water) dietary assessment was conducted assuming average field trial residues for all crops (except crop subgroup 1A, for which

tolerance level residues were assumed); percent crop treated (PCT) data; empirical processing factors; and default processing factors were used as appropriate.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that cyantraniliprole 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)(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:* If 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 areas.

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 average PCT for existing uses as follows: Citrus: oranges 62%, grapefruit 87%, and lemons 46%; pome fruit: apples 61% and pears 76%; stone fruits: apricots 53%, cherries 48%, peaches 41%, and plums/prunes 59%; tree nuts: almonds 72%, hazelnuts 65%, pecans 22%, pistachios 49%, and walnuts 53%; bushberries (subgroup 13–07B): blueberries 45%; fruiting vegetables: peppers 45% and tomatoes 54%; cucurbits: cantaloupes 50%, cucumbers 23%, pumpkins 18%, squash 24%, and watermelons 29%; leafy vegetables: celery 70%, lettuce 78%, and spinach 53%; *Brassica* (cole) leafy vegetables: broccoli 81%, cabbage 50%, and cauliflower 83%; onion 58%; potato 50%; oilseeds: canola 15% and sunflower 35%; corn 56%, cotton 41%; peanuts 41%; carrots 23%; soybeans 21%; strawberries 59%; vegetable crop group 7: dry beans/peas 6%, soybeans 21%, beans (snap, bush, etc.) 49%, and peas fresh/green/sweet 38%; vegetable crop group 2: sugar beets 40%; vegetable crop group 6A: soybeans 21%, beans (snap, bush, etc., string) 49%; peas fresh/green/sweet 38%; and vegetable crop group 6C: dried bean and peas 6%.

100 PCT was assumed for all other crops, including all proposed new use crops. For imported grapes (wine grapes), a 50% import estimate was used in the chronic dietary risk assessment.

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 (CDPR) 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 are derived by combining available public and private market survey data for that use, averaging across all observations, and rounding up to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the most recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

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

which cyantraniliprole 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 cyantraniliprole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of cyantraniliprole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the Pesticides in Water Calculator (PWC; version 1.52) and Pesticide Root Zone Model Ground Water (PRZM GW) for ground water and FQPA Index Reservoir Screening Tool (FIRST) for surface water, the estimated drinking water concentrations (EDWCs) of cyantraniliprole for chronic exposures for non-cancer assessments are estimated to be 24 ppb for surface water and 64 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration value of 64 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Cyantraniliprole is currently registered for the following uses that could result in residential exposures: Turf grass (including residential, recreational, and golf course turf), ornamentals, and structural buildings (including indoor crack/crevice and outdoor broadcast). EPA assessed residential exposure using the following assumptions: EPA determined that residential exposures may occur by the dermal, oral, and inhalation routes of exposures. However, since dermal hazard has not been identified for cyantraniliprole, the only exposures of concern are handler inhalation (for adults), and post-application incidental oral (for children). Residential handler exposure is expected to be short-term in duration. The turf and ornamental labels indicate that a maximum of two applications are allowed per season. Thus, intermediate-term handler exposures are not likely because of the intermittent nature of applications by homeowners. Post-application incidental oral exposures for children

may occur for short- and intermediate-term durations due to the persistence of cyantraniliprole. 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 cyantraniliprole to share a common mechanism of toxicity with any other substances, and cyantraniliprole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that cyantraniliprole 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 <https://www.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 FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence of susceptibility in developmental toxicity studies in rats and rabbits. The developmental toxicity study in rats is tested up to the limit dose (1,000 mg/kg/day). In the rabbit developmental toxicity study, decreases in fetal body weight are seen at a dose higher than that resulting in maternal

effects. In the reproductive toxicity study, increased incidence of thyroid follicular epithelium hypertrophy/hyperplasia occurs in F₁ parental animals at a dose lower than that for the parental (P) generation. A clear NOAEL (1.4 mg/kg/day) is established for F₁ parental animals, and the PODs selected for risk assessment from the dog studies (1 or 3 mg/kg/day) are protective of the effect (thyroid effect) seen in the F₁ parental animals. In addition, the submitted data support the conclusion that the effects on the thyroid are secondary to effects on the liver. As such, a comparative thyroid study is not required at this time.

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 cyantraniliprole is complete.
- ii. There is no indication that cyantraniliprole is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. There is no evidence that cyantraniliprole results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.
- iv. There are no residual uncertainties identified in the exposure databases. The exposure databases are complete or are estimated based on data that reasonably account for potential exposures. The chronic dietary food exposure assessment was a refined assessment which assumed average field trial residues for all crops (except crop subgroup 1A); PCT when available; empirical processing factors, if available, or default processing factors, as appropriate. The 2012 Residential standard operating procedures (SOPs) were previously used to assess post-application exposure to children including incidental oral exposure, and the residential post-application assessment assumed that maximum application rates are applied and that hand-to-mouth activities occur on the day of application. All of the exposure estimates are based on conservative, health-protective assumptions and are not likely to underestimate risk. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to cyantraniliprole in drinking water. EPA used similarly conservative assumptions to assess post application exposure of children as well as

incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by cyantraniliprole.

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, cyantraniliprole 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 cyantraniliprole from food and water will utilize 99% of the cPAD for children 1 to 2 years 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 cyantraniliprole 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). Cyantraniliprole 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 cyantraniliprole.

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 an aggregate MOE of 149 for children 1 to 2 years old. For adults, the oral and inhalation routes of exposure are not appropriate to be aggregated since the endpoints of concern are not common. Because EPA's level of concern for cyantraniliprole is a MOE of 100 or below, this MOE is 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). Cyantraniliprole is currently registered for uses that could result in intermediate-term residential exposure, however, the short-term aggregate risk estimate described above is protective of potential intermediate-term exposures and risks in children.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, cyantraniliprole 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 cyantraniliprole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography with tandem mass spectroscopy (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 FFDC 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, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are no established Codex MRLs on the caneberry subgroup 13-07A,

soybean, aspirated grain fractions, celtuce, Florence fennel and rice. The U.S. tolerances being established for coffee and *Brassica*, leafy greens subgroup 4-16A are harmonized with Codex. The U.S. tolerances being established for the low growing berry subgroup 13-07H; leaf petiole vegetable subgroup 22B; *Brassica* head and stem vegetable group 5-16; leafy greens subgroup 4-16B; and kohlrabi are not harmonized with Codex MRLs. The Codex MRLs established for residues of cyantraniliprole on these commodities are lower than the recommended U.S. tolerances. The U.S. tolerances cannot be harmonized because following the label use directions could result in residues above the established Codex MRLs.

C. Response to Comments

EPA received three comments in response to the Notices of Filing. The first comment indicated IR-4 and Rutgers University are profiteering by registering pesticides. The content of this comment is not material to the safety of the tolerances that are the subject of this action; pesticide registration occurs under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act. The FFDC allows any person to file a petition proposing the establishment of a tolerance, and financial benefit from associated registration of pesticides is not a factor EPA considers when determining whether a tolerance is safe.

The second comment stated, in part, that no residues should be allowed. The Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

The last comment expressed concern about pollutant loadings and relatively high costs of regulations. The commenter also mentioned the Shelby Amendment, the Freedom of Information Act and the Intergovernmental Panel on Climate Change. The comment did not raise any issue related to the Agency's safety determination for cyantraniliprole tolerances. The receipt of this comment

is acknowledged; however, this comment is not relevant to this action.

D. Revisions to Petitioned-For Tolerances

EPA modified the proposed tolerance levels for soybean, hulls and soybean, seed to conform to the Agency's rounding classes. The Agency also revised the commodity terminology to use the correct commodity definitions for Florence fennel (Fennel, Florence, fresh leaves and stalk) and Aspirated grain fractions (Grain, aspirated grain fractions).

V. Conclusion

Therefore, tolerances are established for residues of cyantraniliprole, 3-bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-methyl-6-(((methylamino)carbonyl)phenyl)-1H-pyrazole-5-carboxamide, in or on Berry, low growing, except strawberry, subgroup 13-07H, except blueberry, lowbush and lingonberry at 0.08 parts per million (ppm); *Brassica*, leafy greens, subgroup 4-16B at 30 ppm; Caneberry subgroup 13-07A at 4.0 ppm; Celtnuce at 20 ppm; Fennel, Florence, fresh leaves and stalk at 20 ppm; Grain, aspirated grain fractions at 200 ppm; Kohlrabi at 3.0 ppm; Leaf petiole vegetable subgroup 22B at 20 ppm; Leafy greens subgroup 4-16A at 20 ppm; Rice hulls at 0.05 ppm; Rice, straw at 0.015 ppm; Soybean, forage at 15 ppm; Soybean, hay at 50 ppm; Soybean, hulls at 1.0 ppm; Soybean, seed at 0.40 ppm; and Vegetable, *Brassica*, head and stem, group 5-16 at 3.0 ppm. In addition, EPA is removing the following tolerances as they are superseded by the new tolerances being established in this rulemaking: from paragraph (a) (Berry, low growing, except strawberry, subgroup 13-07H at 0.08 ppm; *Brassica* head and stem, subgroup 5A at 3.0 ppm; *Brassica* leafy vegetables, subgroup 5B at 30 ppm; and Vegetable, leafy, except *Brassica*, group 4 at 20 ppm) and from paragraph (d) (soybean, forage at 0.70 ppm and soybean, hay at 0.70 ppm). Finally, EPA is removing the footnote noting the lack of US registrations for the tolerances for coffee, green bean and rice, grain.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action

has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology

Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: October 24, 2018.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.672:

■ a. In the table to paragraph (a):

■ i. Remove the entry "Berry, low growing, except strawberry, subgroup 13-07H".

■ ii. Add alphabetically the entry "Berry, low growing, except strawberry, subgroup 13-07H, except blueberry, lowbush and lingonberry".

■ iii. Remove the entry "*Brassica* head and stem, subgroup 5A".

■ iv. Add alphabetically the entry "*Brassica*, leafy greens, subgroup 4-16B".

■ v. Remove the entry "*Brassica* leafy vegetables, subgroup 5B".

■ vi. Add alphabetically the entries: "Caneberry subgroup 13-07A" and "Celtnuce".

■ vii. Revise the entry "Coffee, green bean".

■ viii. Add alphabetically the entries: "Fennel, Florence, fresh leaves and stalk"; "Grain, aspirated grain fractions"; "Kohlrabi"; "Leaf petiole vegetable subgroup 22B"; "Leafy greens subgroup 4-16A";

■ ix. Revise the entry "Rice, grain".

■ x. Add alphabetically the entries: "Rice hulls"; "Rice, straw"; "Soybean, forage"; "Soybean, hay"; "Soybean, hulls"; "Soybean, seed"; and "Vegetable, *Brassica*, head and stem, group 5-16".

■ xi. Remove the entry "Vegetable, leafy, except *Brassica*, group 4".

■ b. Remove from the table in paragraph (d) the entries: “Soybean, forage”; and “Soybean, hay”.

The additions and revisions read as follows:

§ 180.672 Cyantraniliprole; tolerances for residues.
(a) * * *

Commodity	Parts per million
* * * * *	*
Berry, low growing, except strawberry, subgroup 13–07H, except blueberry, lowbush and lingonberry	0.08
* * * * *	*
<i>Brassica</i> , leafy greens, subgroup 4–16B	30
* * * * *	*
Caneberry subgroup 13–07A	4.0
* * * * *	*
Celtuce	20
* * * * *	*
Coffee, green bean	0.05
* * * * *	*
Fennel, Florence, fresh leaves and stalk	20
* * * * *	*
Grain, aspirated grain fractions	200
* * * * *	*
Kohlrabi	3.0
Leaf petiole vegetable subgroup 22B	20
Leafy greens subgroup 4–16A	20
* * * * *	*
Rice, grain	0.02
Rice, hulls	0.05
Rice, straw	0.015
* * * * *	*
Soybean, forage	15
Soybean, hay	50
Soybean, hulls	1.0
Soybean, seed	0.40
* * * * *	*
Vegetable, <i>Brassica</i> , head and stem, group 5–16	3.0
* * * * *	*

* * * * *

[FR Doc. 2018-24379 Filed 11-9-18; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency****44 CFR Part 64****[Docket ID FEMA-2018-0002; Internal Agency Docket No. FEMA-8555]****Suspension of Community Eligibility****AGENCY:** Federal Emergency Management Agency, DHS.**ACTION:** Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA's Community Status Book (CSB). The CSB is available at <https://www.fema.gov/national-flood-insurance-program-community-status-book>.

DATES: The effective date of each community's scheduled suspension is the third date ("Susp.") listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Adrienne L. Sheldon, PE, CFM, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 400 C Street SW, Washington, DC 20472, (202) 212-3966.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities

agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59.

Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the **Federal Register**.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA's initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required

floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. FEMA has determined that the community suspension(s) included in this rule is a non-discretionary action and therefore the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) does not apply.

Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, Section 1315, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

Paperwork Reduction Act. This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

- 1. The authority citation for part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§ 64.6 [Amended]

- 2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map Date	Date certain Federal assistance no longer available in SFHAs
Region IV				
North Carolina:				
Charlotte, City of, Mecklenburg County	370159	April 12, 1973, Emerg; August 15, 1978, Reg; November 16, 2018, Susp.	November 16, 2018.	November 16, 2018.
Concord, City of, Cabarrus County	370037	January 16, 1974, Emerg; March 4, 1980, Reg; November 16, 2018, Susp.-do	Do.
Cornelius, Town of, Mecklenburg County.	370498	N/A, Emerg; September 30, 1997, Reg; November 16, 2018, Susp.-do	Do.
Davidson, Town of, Mecklenburg and Iredell Counties.	370503	N/A, Emerg; October 16, 1997, Reg; November 16, 2018, Susp.-do	Do.
Fairview, Town of, Union County	370024	N/A, Emerg; June 9, 2009, Reg; November 16, 2018, Susp.-do	Do.
Harrisburg, Town of, Cabarrus County	370038	June 17, 1975, Emerg; June 30, 1976, Reg; November 16, 2018, Susp.-do	Do.
Huntersville, Town of, Mecklenburg County.	370478	January 11, 1995, Emerg; February 4, 2004, Reg; November 16, 2018, Susp.-do	Do.
Iredell County, Unincorporated Areas ...	370313	July 23, 1976, Emerg; May 15, 1980, Reg; November 16, 2018, Susp.-do	Do.
Kannapolis, City of, Cabarrus and Rowan Counties.	370469	N/A, Emerg; March 25, 1991, Reg; November 16, 2018, Susp.-do	Do.
Locust, City of, Cabarrus and Stanly Counties.	370508	N/A, Emerg; May 29, 2003, Reg; November 16, 2018, Susp.-do	Do.
Mecklenburg County, Unincorporated Areas.	370158	May 17, 1973, Emerg; June 1, 1981, Reg; November 16, 2018, Susp.-do	Do.
Midland, Town of, Cabarrus County	370182	N/A, Emerg; June 1, 2009, Reg; November 16, 2018, Susp.-do	Do.
Mount Pleasant, Town of, Cabarrus County.	370470	N/A, Emerg; February 24, 2012, Reg; November 16, 2018, Susp.-do	Do.
Rowan County, Unincorporated Areas ..	370351	August 23, 1976, Emerg; November 1, 1979, Reg; November 16, 2018, Susp.-do	Do.
Stanfield, Town of, Stanly County	370510	N/A, Emerg; July 15, 2010, Reg; November 16, 2018, Susp.-do	Do.
Region VII				
Iowa:				
Bevington, City of, Madison and Warren Counties.	190273	November 30, 1976, Emerg; May 1, 1987, Reg; November 16, 2018, Susp.	November 16, 2018.	November 16, 2018.
Carlisle, City of, Polk and Warren Counties.	190274	December 17, 1974, Emerg; August 4, 1987, Reg; November 16, 2018, Susp.-do	Do.
Cumming, City of, Warren County	190946	N/A, Emerg; January 24, 2000, Reg; November 16, 2018, Susp.-do	Do.
Des Moines, City of, Polk and Warren Counties.	190227	September 6, 1974, Emerg; February 4, 1981, Reg; November 16, 2018, Susp.-do	Do.
Hartford, City of, Warren County	190589	N/A, Emerg; October 7, 2008, Reg; November 16, 2018, Susp.-do	Do.
Indianola, City of, Warren County	190275	June 1, 1977, Emerg; July 31, 1979, Reg; November 16, 2018, Susp.-do	Do.
Lacona, City of, Warren County	190752	December 6, 1976, Emerg; July 1, 1987, Reg; November 16, 2018, Susp.-do	Do.
Martensdale, City of, Warren County	190524	April 28, 1994, Emerg; September 1, 1996, Reg; November 16, 2018, Susp.-do	Do.
Norwalk, City of, Warren County	190631	March 3, 1993, Emerg; November 20, 1998, Reg; November 16, 2018, Susp.-do	Do.
Spring Hill, City of, Warren County	190949	N/A, Emerg; May 26, 1998, Reg; November 16, 2018, Susp.-do	Do.
Warren County, Unincorporated Areas	190912	November 19, 1990, Emerg; July 1, 1991, Reg; November 16, 2018, Susp.-do	Do.
Region VIII				
Colorado:				
Breckenridge, Town of, Summit County	080172	July 25, 1975, Emerg; June 4, 1980, Reg; November 16, 2018, Susp.-do	Do.
Silverthorne, Town of, Summit County	080201	July 16, 1975, Emerg; May 1, 1980, Reg; November 16, 2018, Susp.-do	Do.
Summit County, Unincorporated Areas	080290	November 26, 1976, Emerg; December 16, 1980, Reg; November 16, 2018, Susp.-do	Do.
Region X				
Oregon:				
Brookings, City of, Curry County	410053	July 8, 1975, Emerg; September 18, 1985, Reg; November 16, 2018, Susp.-do	Do.

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map Date	Date certain Federal assistance no longer available in SFHAs
Curry County, Unincorporated Areas	410052	March 19, 1971, Emerg; April 3, 1978, Reg; November 16, 2018, Susp.	November 16, 2018.	November 16, 2018.
Gold Beach, City of, Curry County	410054	November 11, 1974, Emerg; November 15, 1985, Reg; November 16, 2018, Susp.-do-	Do.

-do- = Ditto.
Code for reading third column: Emerg. —Emergency; Reg. —Regular; Susp.—Suspension.

Dated: October 30, 2018.
Katherine B. Fox,
*Assistant Administrator for Mitigation,
Federal Insurance and Mitigation
Administration—FEMA Resilience,
Department of Homeland Security, Federal
Emergency Management Agency.*
[FR Doc. 2018–24692 Filed 11–9–18; 8:45 am]
BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 35

[Docket No. USCG–2015–0926]

RIN 1625–AC27

Tankers—Automatic Pilot Systems; Correction

AGENCY: Coast Guard, DHS.

ACTION: Final rule; correction.

SUMMARY: The Coast Guard is correcting a final rule that appeared in the **Federal Register** on November 5, 2018. The document issued a final rule that permitted tankers with automatic pilot systems that meet certain international standards to operate using those systems in shipping safety fairways and traffic separation schemes specified in 33 CFR parts 166 and 167, respectively.

DATES: Effective December 5, 2018.

ADDRESSES: You may view comments and related material identified by docket number USCG–2015–0926 using the Federal eRulemaking Portal at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: For information about this document or to view material incorporated by reference call or email LCDR Matthew J. Walter, CG–NAV–2, U.S. Coast Guard;

telephone 202–372–1565, email cgnav@uscg.mil.

SUPPLEMENTARY INFORMATION: In FR Doc. 2018–24127 appearing on page 55272 in the **Federal Register** of Monday November 5, 2018, the following corrections are made:

§ 35.20–45 [Corrected]

- 1. On page 55281, in the third column, in § 35.20–45, the heading of the section “§ 35.20–40 Use of Auto Pilot—T/ALL.” is corrected to read “§ 35.20–45 Use of Auto Pilot—T/ALL.”

Dated: November 6, 2018.

Rebecca Orban,
Acting Office Chief, Office of Regulations and Administrative Law, U.S. Coast Guard.
[FR Doc. 2018–24619 Filed 11–9–18; 8:45 am]
BILLING CODE 9110–04–P

Proposed Rules

Federal Register

Vol. 83, No. 219

Tuesday, November 13, 2018

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

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 10

[Docket No. USCG–2018–0041]

Draft Merchant Mariner Medical Manual

AGENCY: Coast Guard, DHS.

ACTION: Notification of availability and request for comments.

SUMMARY: The Coast Guard is seeking public comment regarding the draft Merchant Mariner Medical Manual. The guidance in this Manual should assist medical practitioners, the maritime industry, individual mariners, and Coast Guard personnel in evaluating a mariner applicant's physical and medical status to meet the requirements of the merchant mariner medical certificate. This draft Commandant Instruction Manual incorporates and consolidates prior guidance on the medical evaluation of merchant mariners contained in several Coast Guard documents. The Manual includes guidance on the medical certificate and related processes, including procedures for application, issuance, and cancellation of the medical certificate.

DATES: Comments must be submitted to the online docket, via <http://www.regulations.gov>, on or before January 14, 2019.

ADDRESSES: You may submit comments identified by docket number USCG–2018–0041 using the Federal eRulemaking Portal at <http://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: For information about this document call or email Adrienne Buggs, M.D., United States Coast Guard, Office of Merchant Mariner Credentialing; telephone: 202–372–2357, email: MMCPolicy@uscg.mil.

SUPPLEMENTARY INFORMATION:

Public Participation and Comments

We encourage you to submit comments (or related material) on the draft Merchant Mariner Medical Manual. We will consider all submissions and may adjust our final action based on your comments. If you submit a comment, please include the docket number for this document, 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 <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notification, and all public comments, will be posted in our online docket at <http://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 the Coast Guard publishes any additional documents related to this notification of availability.

We accept anonymous comments. All comments received will be posted without change to <http://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>.

Background and Discussion of Draft Manual

The Coast Guard provided guidance on the medical and physical requirements for merchant mariners in the Medical and Physical Evaluation Guidelines for Merchant Mariner Credentials, Navigation and Inspection Circular (NVIC) 04–08, Commandant Publication (COMDTPUB) 16700.4; and in Part A of the Marine Safety Manual, Volume III, Marine Industry Personnel, COMDTINST M16000.8 (Series) [MSM]. In the years since publication of NVIC 04–08, information received from public comment, medical appeals, and federal advisory committee recommendations highlighted the need for additional specificity and clarity in the medical

guidance document. It also underscored the potential for confusion caused by having medical evaluation guidance contained in multiple guidance documents. For example, Part A of the MSM, Volume III, which has not been updated since 1999, may contain some information that conflicts with the guidance in NVIC 04–08. In response to these concerns, the Coast Guard began a series of revisions to the medical evaluation guidelines, published as Change 1 to NVIC 04–08, in June 2013, and Change 2 to NVIC 04–08, in April 2016.

In addition to the revisions needed for improved clarity and specificity, the medical guidance also required new policy following publication of the Coast Guard's final rule on the Implementation of the Amendments to the International Convention on Standards for Training, Certification and Watchkeeping for Seafarers, 1978, and Changes to National Endorsements (78 FR 77795, Dec. 24, 2013). Specifically, the Coast Guard needed to develop new guidance to address the medical certificate and related processes required by these regulations. The Coast Guard provided this new guidance through a separate document, titled NVIC 01–14, Guidance on the Issuance of Medical Certificates. With the experience gained since the publication of NVIC 01–14, the Coast Guard has identified areas of the medical certificate policy that are in need of clarification, particularly with respect to some entry-level mariners, and procedures related to mariners who become unfit while in possession of a valid medical certificate. Rather than issuing a change to NVIC 01–14, the Coast Guard will include the revised medical certificate guidance with the medical evaluation guidance in a new policy document called the Merchant Mariner Medical Manual, also known as Commandant Instruction M16721.48.

The draft Merchant Mariner Medical Manual revises, updates and combines the medical evaluation guidance previously published in NVIC 04–08, Part A of the MSM, Volume III, and NVIC 01–14. The Coast Guard developed the draft Manual in consultation with experienced maritime community medical practitioners and industry stakeholders serving on the Merchant Mariner Medical Advisory Committee (MEDMAC) and the

Merchant Marine Personnel Advisory Committee (MERPAC). The draft Manual reflects a synthesis of their recommendations and the medical requirements of Title 46 Code of Federal Regulations (CFR) part 10, subpart C. Members of the public participated in the development of medical policy by providing comment and serving on working groups at the public meetings of MEDMAC and MERPAC. Additionally, the public had the opportunity to comment on drafts of policies contained in this Manual, and its predecessor, NVIC 04–08. See requests for comment on proposed policies regarding: Diabetes, cardiomyopathy, and sleep disorders (80 FR 8586, Feb. 18, 2015); Medications (80 FR 4582, Jan. 28, 2015); Seizures (78 FR 17917, Mar. 25, 2013); and Implantable cardioverter defibrillators (77 FR 55174, Sep. 7, 2012). The Coast Guard considered these public comments when developing this draft Manual.

Changes made in this draft Manual seek to improve ease of use, clarify and update prior guidance, and provide more transparency to the regulated community. Major changes include (1) use of a single manual format; (2) clarification of medical certificate requirements for certain entry-level mariners; and (3) the proposed medical certificate cancellation policy.

Manual Format: The Coast Guard reorganized the material into a manual format instead of a NVIC to improve utility and ease of use for the regulated community and others who reference the document. Additionally, in issuing a Commandant Instruction Manual, the name and number of the document will not change with every future issuance of the document, reducing the risk of confusion.

Entry-level Mariners: This draft adds provisions that clarify confusion between 46 CFR 15.401(c), which requires a medical certificate in order to serve in a position requiring a merchant mariner credential (MMC), and other provisions in 46 CFR part 10 that indicate entry-level mariners do not require a medical examination except in certain circumstances (see, e.g., Table 1 to 46 CFR 10.239, which marks entry-

level ratings “N/A” as to medical and physical exam requirements, and Table 1 to 46 CFR 10.302(a), which is silent as to medical requirements for certain entry-level mariners). The draft Manual will clarify that the Coast Guard does not require medical certificates for entry-level mariners on vessels not subject to the International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978, as amended, who do not serve as food handlers.

Medical Certificate Cancellation Policy: The guidance now includes the process to be followed when the Coast Guard receives information indicating that a medical certificate holder has developed a medical condition that poses significant risk of sudden incapacitation, or is taking medication that poses significant risk of impairment. This process includes procedures for cancelling medical certificates, rather than merchant mariner credentials (MMCs), for mariners who no longer meet medical certification criteria.

The Coast Guard began issuing medical certificates in January 2014. The medical certificate is a certificate issued by the Coast Guard under 46 CFR part 10, subpart C, that serves as proof that the seafarer meets the medical and physical standards for merchant mariners. The medical certificate is not a credential (see definitions of medical certificate and credential in 46 CFR 10.107). Prior to the establishment of the medical certificate, a merchant mariner’s certification of medical and physical fitness was embedded in the MMC. Under that system, if the Coast Guard received credible information that a mariner no longer met the medical and physical standards, the Coast Guard’s only option was to declare the mariner medically incompetent and take suspension and revocation action against the MMC, the mariner’s professional credential.

However, not all medical concerns require revocation of the professional credential. In most cases, once it is determined that a medical certificate holder no longer meets the standards for medical certification, it is more appropriate for the agency to take action

against the certificate that serves as proof of the mariner’s medical fitness. The proposed medical certificate cancellation policy describes the procedures that the Coast Guard would use to cancel a medical certificate if it receives credible information that a medical certificate holder no longer meets the standards for medical fitness. The process involves providing notice to the involved mariner about the information received, and allowing them the opportunity to respond and provide additional information. The proposed policy preserves the mariner’s right to reconsideration and appeal under 46 CFR 1.03–15, and, allows the involved mariner to continue to work until final agency action, except in cases where there is evidence of compelling and substantial risk of imminent harm. Furthermore, the policy allows the mariner to retain their MMC, simplifying their return to work when their medical condition improves and allowing them to continue to work in the industry in positions that do not require a medical certificate.

Questions for Public Comment

The Coast Guard requests public comment on the draft Medical Manual, with emphasis on its readability, clarity, and ease of use. We welcome suggestions on how the Manual can be improved.

We are particularly interested in whether the draft Manual adequately addresses safety concerns in situations where the Coast Guard receives information indicating that a medical certificate holder has developed a medical condition that poses a significant risk of sudden incapacitation, or is taking a medication that poses a significant risk of impairment.

This document is issued under the authority of 5 U.S.C. 552(a), 46 U.S.C. 7101, and 46 U.S.C. 7302.

Dated: November 5, 2018.

J.G. Lantz,

Director, Commercial Regulations and Standards, U.S. Coast Guard.

[FR Doc. 2018–24502 Filed 11–9–18; 8:45 am]

BILLING CODE 9110–04–P

Notices

Federal Register

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Tuesday, November 13, 2018

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

November 7, 2018.

The Department of Agriculture will submit the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13 on or after the date of publication of this notice. Comments are requested regarding: (1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, Washington, DC; New Executive Office Building, 725 17th Street NW, Washington, DC 20503. Commenters are encouraged to submit their comments to OMB via email to: OIRA_Submission@omb.eop.gov or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602.

Comments regarding these information collections are best assured of having their full effect if received by December 13, 2018. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

National Agricultural Statistics Service

Title: Mink Survey.

OMB Control Number: 0535–0212.

Summary of Collection: The primary function of the National Agricultural Statistics Service (NASS) is to prepare and issue current official State and national estimates of crop and livestock production. The mink program consists of two surveys: An annual census of all known mink producers in the 50 states (the Mink Survey) and an annual survey of two prominent mink pelt auction houses (the Mink Price Survey). Statistics on mink production are published for the 12 major states that account for over 90 percent of the total U.S. pelt production. There is no other source for this type of information. General authority for these data collection activities is granted under U.S. Code Title 7, Section 2204.

Need and Use of the Information: NASS collects information on mink pelts produced by color, number of females bred to produce kits the following year, number of mink farms, average marketing price, and the value of pelts produced. The data is disseminated by NASS in the Mink Report and is used by the U.S. government and other groups.

Description of Respondents: Farms.

Number of Respondents: 352.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 87.

National Agricultural Statistics Service

Title: Cost of Pollination Survey.

OMB Control Number: 0535–0258.

Summary of Collection: The primary objectives of the National Agricultural Statistics Service (NASS) are to prepare and issue official State and national estimates of crop and livestock production, disposition and prices, economic statistics, and environmental statistics related to agriculture and to conduct the Census of Agriculture and its follow-on surveys. Pollinators

(honeybees) are vital to the agricultural industry for producing food for the world's population. NASS' primary focus will center on costs associated with honey bee pollination, but will also collect some basic information relating to other forms of pollination. General authority for these data collection activities is granted under U.S.C. Title 7, Section 2204.

Need and Use of the Information: NASS plans to collect economic data under this new collection using the "Cost of Pollination Inquiry" survey. Data relating to the targeted crops (fruits, nuts, vegetables and specialty crops) will be collected for the total number of acres that rely on honey bee pollination, the number of honey bee colonies that were used on those acres, and any cash fees associated with honey bee pollination. By publishing both regional and crop specific pollination costs, both, crop farmers and beekeepers will be able to benefit from this additional data.

Description of Respondents: Farmers.

Number of Respondents: 18,000.

Frequency of Responses: Reporting: Once a year.

Total Burden Hours: 5,340.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2018–24699 Filed 11–9–18; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

Farm Service Agency

Information Collection Request; Servicing Minor Program Loans

AGENCY: Farm Service Agency, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Farm Service Agency (FSA) is requesting comments from all interested individuals and organizations on an extension of a currently approved information collection to support the Servicing Minor Program Loans.

DATES: We will consider comments that we receive by January 14, 2019.

ADDRESSES: We invite you to submit comments on this notice. In your comments, include the date, volume,

and page number of this issue of the **Federal Register**, the OMB control number and the title of the information collection. You may submit comments by any of the following methods:

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- **Mail:** Cindy Pawlikowski, Loan Servicing and Properties Management Division, USDA, FSA, Farm Loan Programs, 1400 Independence Ave. SW, Mail Stop 0523, Washington, DC 20250-00523.

You may also send comments to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Cindy Pawlikowski, (202) 720-0900.

SUPPLEMENTARY INFORMATION:

Title: Servicing Minor Program Loans.

OMB Control Number: 0560-0230.

Expiration Date: April 30, 2019.

Type of Request: Extension.

Abstract: Section 331(b) of the Consolidated Farm and Rural Development Act (CONTACT, 7 U.S.C. 1981(b)), in part, authorizes the Secretary of Agriculture to modify, subordinate and release terms of security instruments, leases, contracts, and agreements entered by FSA. That section also authorizes transfers of security property, as the Secretary deems necessary, to carry out the purpose of the loan or protect the Government's financial interest. Section 335 of the CONTACT (7 U.S.C. 1985) provides servicing authority for real estate security; operation or lease of realty; disposition of property; conveyance of real property interest of the United States; easements; and condemnations.

The information collection relates to a program benefit recipient or loan borrower requesting action on security they own, which was purchased with FSA loan funds, improved with FSA loan funds or has otherwise been mortgaged to FSA to secure a Government loan. The information collected is primarily financial data not already on file, such as borrower asset values, current financial information and public use and employment data. There are no changes to the burden hours since the last OMB approval.

For the following estimated total annual burden on respondents, the formula used to calculate the total burden hour is the estimated average time per responses hours multiplied by the estimated total annual responses.

Estimate of Annual Burden: Public reporting burden for this collection of

information is estimated to average .64 hours per response.

Type of Respondents: Individuals, associations, partnerships, or corporations.

Estimated Number of Respondents: 58.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Total Annual of Responses: 58.

Estimated Average Time per Responses: 0.64 hours.

Estimated Total Annual Burden on Respondents: 37 hours.

We are requesting comments on all aspects of this information collection to help us:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the collection of information including the validity of the methodology and assumptions used;

(3) Evaluate the quality, utility, and clarity of the information technology; and

(4) Minimize the burden of the information collection on those who respond through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses where provided, will be made a matter of public record. Comments will be summarized and included in the request for OMB approval of the information collection.

Richard Fordyce,

Administrator, Farm Service Agency.

[FR Doc. 2018-24641 Filed 11-9-18; 8:45 am]

BILLING CODE 3410-05-P

BROADCASTING BOARD OF GOVERNORS

Government in the Sunshine Act Meeting Notice

DATE AND TIME: Wednesday, November 14, 2018, 10:00 a.m. ET.

PLACE: Middle East Broadcasting Networks, Suite D, 7600 Boston Blvd, Springfield, VA 22153.

SUBJECT: Notice of meeting of the Broadcasting Board of Governors.

SUMMARY: The Broadcasting Board of Governors (Board) will be meeting at the

time and location listed above. The Board will vote on a consent agenda consisting of the minutes of its September 5, 2018 meeting, a resolution honoring the 20th anniversary of Radio Free Europe/Radio Liberty broadcasting in the Persian language, and a proposed Board meeting dates in 2019. The Board will receive a report from the Chief Executive Officer and Director of U.S. Agency for Global Media (USAGM).

This meeting will be available for public observation via streamed webcast, both live and on-demand, on the agency's public website at www.bbg.gov. Information regarding this meeting, including any updates or adjustments to its starting time, can also be found on the agency's public website.

The public may also attend this meeting in person at the address listed above as seating capacity permits. Members of the public seeking to attend the meeting in person must register at <https://bbgboardmeeting-november2018.eventbrite.com> by 12:00 p.m. (ET) on November 13.

For more information, please contact USAGM Public Affairs at (202) 203-4400 or by email at pubaff@usagm.gov.

CONTACT PERSON FOR MORE INFORMATION: Persons interested in obtaining more information should contact Oanh Tran at (202) 203-4545.

Oanh Tran,

Managing Director.

[FR Doc. 2018-24827 Filed 11-8-18; 4:15 pm]

BILLING CODE 8610-01-P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Indiana Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Indiana Advisory Committee (Committee) will hold a meeting on Thursday September 27, 2018, from 3-4 p.m. EDT for the purpose of discussing a draft op-ed regarding voting rights in the state.

DATES: The meeting will be held on Thursday December 6, 2018, from 3-4 p.m. EDT.

ADDRESSES: *Public call information:* Dial: 855-719-5012; Conference ID: 2724005.

FOR FURTHER INFORMATION CONTACT:

Melissa Wojnaroski, DFO, at mwojnaroski@usccr.gov or 312-353-8311.

SUPPLEMENTARY INFORMATION: This meeting is free and open to the public. Members of the public may join through the above listed toll free call in number. Members of the public will be invited to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1-800-877-8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Regional Programs Unit Office, U.S. Commission on Civil Rights, 230 S Dearborn, Suite 2120, Chicago, IL 60604. They may also be faxed to the Commission at (312) 353-8324, or emailed to Carolyn Allen at callen@usccr.gov. Persons who desire additional information may contact the Regional Programs Unit Office at (312) 353-8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via www.facadatabase.gov under the Commission on Civil Rights, Indiana Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, <http://www.usccr.gov>, or may contact the Regional Programs Unit Office at the above email or street address.

Agenda

Welcome and Introductions
Discussion: Civil Rights in Indiana
Public Comment
Adjournment

Dated: November 7, 2018.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2018-24646 Filed 11-9-18; 8:45 am]

BILLING CODE 6335-01-P

COMMISSION ON CIVIL RIGHTS**Notice of Public Meetings of the Mississippi Advisory Committee to the U.S. Commission on Civil Rights**

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Mississippi Advisory Committee (Committee) will hold a meeting on Monday December 3, 2018 at 2:30 p.m. Central time. The Committee will review a draft project proposal and discuss next steps in their study of prosecutorial discretion in the state.

DATES: The meeting will take place on Monday, December 3, 2018 at 2:30 p.m. Central Time.

FOR FURTHER INFORMATION CONTACT:

Melissa Wojnaroski, DFO, at mwojnaroski@usccr.gov or (312) 353-8311.

SUPPLEMENTARY INFORMATION: *Public Call Information:* Dial: 855-719-5012, Conference ID: 5202137.

Members of the public may listen to this discussion through the above call in number. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1-800-877-8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be

mailed to the Regional Programs Unit, U.S. Commission on Civil Rights, 230 S. Dearborn, Suite 2120, Chicago, IL 60604. They may also be faxed to the Commission at (312) 353-8324, or emailed to Corrine Sanders at csanders@usccr.gov. Persons who desire additional information may contact the Regional Programs Unit at (312) 353-8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via www.facadatabase.gov under the Commission on Civil Rights, Mississippi Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, <http://www.usccr.gov>, or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome and roll call
II. Discussion: Project Proposal, Prosecutorial Discretion in Mississippi
III. Public comment
IV. Vote on proposal
V. Next steps
VI. Adjournment

Dated: November 7, 2018.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2018-24645 Filed 11-9-18; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS**Notice of Public Meeting of the Georgia Advisory Committee to the U.S. Commission on Civil Rights**

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Georgia Advisory Committee (Committee) will hold a meeting via teleconference on Monday December 17, 2018, at 12:00 p.m. EST for the purpose of reviewing testimony regarding Civil Rights and The Olmstead Act (Disability Rights). The Committee will also discuss next steps in their study of this topic.

DATES: The meeting will be held on Monday December 17, 2018, at 12:00 p.m. EST.

ADDRESSES: Public call information: Dial: 855-719-5012, Conference ID: 6973191.

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, DFO, at mwojnaroski@uscrr.gov or 312-353-8311.

SUPPLEMENTARY INFORMATION: Members of the public can listen to the discussion. This meeting is available to the public through the above listed toll free number. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1-800-877-8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Regional Programs Unit Office, U.S. Commission on Civil Rights, 230 S. Dearborn, Suite 2120, Chicago, IL 60604. They may also be faxed to the Commission at (312) 353-8324, or emailed to Carolyn Allen at callen@uscrr.gov. Persons who desire additional information may contact the Regional Programs Unit Office at (312) 353-8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via www.facadatabase.gov under the Commission on Civil Rights, Georgia Advisory Committee link. Persons interested in the work of this Committee are also directed to the Commission's website, <http://www.uscrr.gov>, or may contact the Regional Programs Unit office at the above email or street address.

Agenda

Welcome and Roll Call
Discussion

Civil Rights in Georgia: The Olmstead Act (Disability Rights)

Public Comment
Adjournment

Dated: November 7, 2018.

David Mussatt,
Supervisory Chief, Regional Programs Unit.
[FR Doc. 2018-24647 Filed 11-9-18; 8:45 am]
BILLING CODE P

DEPARTMENT OF COMMERCE

Bureau of the Census

[Docket Number 180927898-8898-01]

Census Tracts for the 2020 Census— Final Criteria

AGENCY: Bureau of the Census, Commerce.

ACTION: Notice of final criteria and program implementation.

SUMMARY: Census tracts are relatively permanent small-area geographic divisions of a county or statistically equivalent entity defined for the tabulation and presentation of data from the decennial census and selected other statistical programs. The Census Bureau is publishing this notice in the **Federal Register** to announce final criteria for defining census tracts for the 2020 Census. Census tracts defined by these criteria will also be used to tabulate and publish estimates from the American Community Survey (ACS) and potentially data from other Bureau of the Census (Census Bureau) censuses and surveys. In addition to census tracts, the Participant Statistical Areas Program (PSAP) encompasses the review and update of census block groups, census designated places, and census county divisions.

DATES: This notice's final criteria will be applicable on December 13, 2018.

FOR FURTHER INFORMATION CONTACT: Requests for additional information on this proposed program should be directed to Vincent Osier at the Geographic Standards, Criteria, and Quality Branch, Geography Division, U.S. Census Bureau, via email at geo.psap.list@census.gov or telephone at 301-763-3056.

SUPPLEMENTARY INFORMATION:

Background

Census tracts are relatively permanent small-area geographic divisions of a county or statistically equivalent entity ¹

¹For the Census Bureau's purposes, the term "county" includes parishes in Louisiana; boroughs, city and boroughs, municipalities, and census areas in Alaska; independent cities in Maryland, Missouri, Nevada, and Virginia; districts and islands in American Samoa; districts in the U.S. Virgin Islands; municipalities in the

defined for the tabulation and presentation of data from the decennial census and selected other statistical programs. The Census Bureau is publishing this notice in the **Federal Register** to announce final criteria for defining census tracts for the 2020 Census. Census tracts defined by these criteria will also be used to tabulate and publish estimates from the American Community Survey (ACS) ² and potentially data from other Census Bureau censuses and surveys.

In addition to providing final criteria for census tracts, this notice contains a summary of comments received in response to proposed criteria published in the **Federal Register** on February 15, 2018 (83 FR 6941) as well as the Census Bureau's response to those comments. After publication of final criteria in the **Federal Register**, the Census Bureau will offer designated governments or organizations an opportunity to review and, if necessary, suggest updates to the boundaries and attributes of the census tracts in their geographic area through the Participant Statistical Areas Program (PSAP). The program also encompasses the review and update of census block groups, census designated places, and census county divisions.

I. History of Census Tracts

In 1905, Dr. Walter Laidlaw originated the concept of permanent, small geographic areas as a framework for studying change from one decennial census to another in neighborhoods within New York City. For the 1910 Census, eight cities—New York, Baltimore, Boston, Chicago, Cleveland, Philadelphia, Pittsburgh, and St. Louis—delineated census tracts (then termed "districts") for the first time. No additional jurisdictions delineated census tracts until just prior to the 1930 Census, when an additional ten cities chose to do so. The increased interest in census tracts for the 1930 Census is attributed to the promotional efforts of Howard Whipple Green, who was a statistician in Cleveland, Ohio, and later the chairman of the American Statistical Association's Committee on Census Enumeration Areas. For more than twenty-five years, Mr. Green strongly encouraged local citizens, via committees, to establish census tracts

Commonwealth of the Northern Mariana Islands; municipios in Puerto Rico; and the areas constituting the District of Columbia and Guam. This notice will refer to all these entities collectively as "counties".

²The ACS is conducted in the United States and in Puerto Rico. In Puerto Rico the survey is called the Puerto Rico Community Survey. For ease of discussion, throughout this document the term ACS is used to represent the surveys conducted in the United States and in Puerto Rico.

and other census statistical geographic areas. The committees created by local citizens were known as Census Tract Committees, later called Census Statistical Areas Committees.

After 1930, the Census Bureau saw the need to standardize the delineation, review, and updating of census tracts and published the first set of census tract criteria in 1934. The goal of the criteria has remained unchanged; they assure comparability and data reliability through the standardization of the population thresholds for census tracts, as well as requiring that tracts' boundaries follow specific types of geographic features that do not change frequently. The Census Bureau began publishing census tract data as part of its standard tabulations beginning with the 1940 Census. Prior to that time, census tract data were published as special tabulations.

For the 1940 Census, the Census Bureau began publishing census block³ data for all cities with 50,000 or more people. Census block numbers were assigned, where possible, by census tract, but for those cities that had not yet delineated census tracts, "block areas," called "block numbering areas" (BNAs) in later censuses, were created to assign census block numbers.

Starting with the 1960 Census, the Census Bureau assumed a greater role in promoting and coordinating the delineation, review, and update of census tracts. For the 1980 Census, criteria for BNAs were changed to make them more comparable in size and shape to census tracts. For the 1990 Census, all counties contained either census tracts or BNAs.

Census 2000 was the first decade in which census tracts were defined in all counties. In addition, the Census Bureau increased the number of geographic areas whose boundaries could be used as census tract boundaries. It also allowed tribal governments of federally recognized American Indian tribes with a reservation and/or off-reservation trust lands to delineate tracts without regard to state and/or county boundaries, provided the tribe had a 1990 Census population of at least 1,000.

For the 2010 Census, the Census Bureau adopted changes to census tract criteria that recognized their utility as a framework of small geographic areas for presenting and analyzing statistical and

other data for a variety of communities, settlement patterns, and landscapes. The Census Bureau augmented its minimum, maximum, and optimum population threshold with housing unit thresholds for use in defining census tracts for seasonal communities that have no or low population on census day (April 1). The Census Bureau formalized criteria for census tracts defined for employment centers, airports, parks, large water bodies, and other special land uses that had been permitted in previous decades, but never specified within the criteria. The Census Bureau also established tribal census tracts as a geographic framework defined within federally recognized American Indian reservations and off-reservation trust lands that is fully separate from the standard census tracts defined within counties.

II. Summary of Comments Received in Response to the Proposed Criteria

The **Federal Register** published on February 15, 2018 (83 FR 6941) requested comment on the proposed census tract criteria for the 2020 Census. The proposed criteria were unchanged from the final criteria adopted for the 2010 Census.

The Census Bureau received comments from 16 individuals or groups of individuals on topics related to (1) use of non-visible political boundaries when defining census tracts; (2) use of employment data to define census tracts encompassing areas with substantial amounts of commercial, industrial, or other non-residential activity for the purpose of transportation planning; (3) maintaining historical comparability; and (4) accounting for statistical data reliability and quality when developing census tract criteria and defining individual census tracts. Commenters represented state and local government agencies, regional planning organizations and councils of governments, state data centers, non-governmental organizations, and academic researchers. Comments received by the Census Bureau are summarized below, as well as the Census Bureau's response to these comments.

1. Using Non-Visible Minor Civil Division Boundaries in Michigan as Census Tract Boundaries

The Census Bureau received three comments from individuals in Michigan noting that non-visible minor civil division (MCD) boundaries in Michigan should be permitted to be census tract boundaries for the 2020 Census as was the case in the past. The commenters correctly noted that in Table 1,

Acceptable Minor Civil Division and Incorporated Place Boundaries, the proposed criteria were in error with regard to Michigan. The Census Bureau has corrected the table in the final criteria.

2. Defining Census Tracts on the Basis of Employment and Jobs

The Census Bureau received 14 comments related to defining census tracts encompassing areas with concentrations of employment and jobs or other types of non-residential uses to improve the utility of census tracts for transportation and journey-to-work analysis and planning. Eleven commenters suggested adoption of a minimum threshold of 1,200 workers/jobs (and no maximum or optimum thresholds) to be applied as an alternative to the existing minimum population or housing unit threshold or in combination with population or housing unit thresholds. One commenter supported the use of worker/job counts when defining census tracts, but did not specify a minimum threshold. Two commenters expressed support for modifying criteria for special use census tracts primarily to improve identification of census tracts encompassing areas with concentrations of employment. One commenter noted that applying employment thresholds was not necessary as the sample design for the American Community Survey (which is the source for much of the demographic data used in journey-to-work analysis) focused on residential population concentrations rather than employment concentrations. This commenter suggested that changes to the special use census tract land area criteria could achieve the result desired by commenters proposing employment thresholds and could provide greater flexibility when defining census tracts.

Based on consideration of the comments received on this topic and further discussion with stakeholders in the transportation community, the Census Bureau will change its criteria for defining special use census tracts to no longer specify minimum land area requirements. Special use census tracts should be comparable in land area size to surrounding census tracts to assure data reliability and quality when reporting on workplace-related data and to avoid data disclosure issues. The Census Bureau also recommends that, when defining special use census tracts encompassing employment centers and areas with concentrations of jobs, PSAP participants should strive for a minimum threshold of 1,200 workers/jobs.

³ Census blocks are statistical areas bounded by visible features, such as streets, roads, streams, and railroad tracks, and by non-visible boundaries, such as selected property lines and city, township, school district, and county limits and short line-of-sight extensions of streets and roads. Census blocks cover the entire territory of the United States, Puerto Rico, and the Island Areas.

3. Maintaining Historical Comparability

One commenter noted the importance of maintaining historical boundaries of census tracts for chronicling change in the sociodemographic characteristics of neighborhoods. The commenter noted that, while adherence to specified population thresholds (particularly the optimum and maximum population thresholds, which factor in decisions to split census tracts) is an important characteristic of census tracts, comparability over time also is a critical characteristic. Further, allowing census tracts to exceed the optimum and maximum thresholds will help mitigate issues related to the large sampling error associated with small geographic areas. The commenter suggested that by leaving census tract boundaries unchanged (*i.e.*, by not splitting census tracts), local governments will be able to aggregate census tracts more easily to the neighborhood level, allowing for comparability over time as well as more reliable data. The commenter further suggested that if census tracts must be merged in order to meet the minimum population threshold, then an effort should be made to align the boundaries for block groups within the new census tract with the boundaries of the former census tracts.

The Census Bureau agrees with the sentiments expressed by this commenter and will continue to allow individual PSAP participants to avoid splitting census tracts if they are more concerned about historical comparability or statistical data reliability or both. We also agree with the suggestion to align block group boundaries with the boundaries of former census tracts in those instances in which census tracts have been merged and will update the final criteria accordingly.

4. Data Quality as an Explicit Criterion for Census Tracts

One comment, submitted by a team of researchers, centered around the quality and reliability of statistical data for census tracts and other small geographic areas. Their concern was that the current methodology for updating and defining census tracts, with its focus on maintaining historical comparability as well as adherence to the optimum threshold of 4,000 persons, results in a framework of small geographic areas that may not meet current analytical and policy development needs for statistically reliable data. Similar to the sentiment expressed by the comment discussed above, this group of commenters suggested that in some places and contexts, the population size of census tracts should be allowed to

increase beyond the maximum threshold, adding that these larger units would provide higher quality data because they would contain more responses from sample-based surveys. However, in their suggestion regarding adoption of explicit statistical data quality criteria, the commenters are proposing a fundamental change in the process for defining census tracts for data dissemination purposes; that is, if a census tract does not achieve the quality criterion for a given data release, it would be combined with an adjacent tract. The commenters suggest that through this combination, the margins of error on the estimates will be reduced, and data users will be able to obtain a more reliable estimate for a new larger “census tract” (encompassing multiple “sub-tracts”).

While this is an intriguing idea, the Census Bureau cannot implement it at this time. Through the 2020 PSAP, the Census Bureau works with participants to update census tract boundaries prior to the 2020 Census to define a stable geographic framework for tabulating and presenting decennial census and ACS data. As we understand it, the commenters’ proposal would result in a framework of “preliminary” census tracts that would be combined, as necessary, to meet statistical data reliability criteria after data have been tabulated, but prior to final release. The Census Bureau needs more time than is available prior to the start of the 2020 PSAP delineation process to research this proposal and consider any potential data tabulation, data disclosure, and analytical implications, particularly if census tracts were combined in different ways depending on the specific mix of variables presented in a particular data tabulation.

III. General Principles and Criteria for Census Tracts for the 2020 Census

A. General Principles

1. The primary goal of the census tract is to provide a set of nationally consistent small, statistical geographic units, with stable boundaries, that facilitate analysis of data across time. A century of census tract use, along with ACS and the averaging of sample data for tracts over a five-year span, has shown that continuity and comparability in tracts and their boundaries over time are of considerable importance to data users. Pursuant to this goal, the Census Bureau requests that where a census tract must be updated, for example to meet the minimum or maximum population or housing unit thresholds, that the outer boundaries of the tract not be changed,

but rather that a tract be split into two or more tracts, or merged with an adjacent tract. The Census Bureau discourages changes to tract boundaries (that is, “retracting”), except in specified circumstances, which the Census Bureau will review on a case-by-case basis.

2. In order to ensure a minimal level of reliability in sample data and minimize potential disclosures of sensitive information, a census tract should contain at least 1,200 people or at least 480 housing units at minimum, and 8,000 people or 3,200 housing units at maximum. PSAP participants should aim to create census tracts that meet the optimal population of 4,000 or 1,600 housing units and maintain the minimum thresholds unless it is flagged as a special use tract (discussed below), or is coextensive with a county with fewer than 1,200 people. The housing unit criterion is used to accommodate areas that are occupied seasonally and may otherwise show a discrepancy between decennial and ACS figures.⁴

3. The Census Bureau recognizes that there are significant geographic areas that are characterized by unique populations (*e.g.*, prisons or universities) or not characterized by residential populations at all (*e.g.*, National Parks, large bodies of water, or employment centers) which local participants may wish to exclude from populated census tracts for either analytical or cartographic purposes. These areas may be designated as special use census tracts to distinguish them from standard populated census tracts. Special land and/or water use census tracts are not required, but if delineated they must be designated as a specific type of special use (discussed below), have an official name, ideally have no residential population or housing units or at least meet all minimum population or housing thresholds mention above, and must not create noncontiguous census tracts. While there are no longer minimum land area measurement thresholds for special use tracts in urban or rural areas, such census tracts should be comparable in size to surrounding census tracts, particularly if defined to encompass employment centers or other areas containing a greater concentration of jobs than residents. The Census Bureau recognizes that some special use areas not intended for residential

⁴ “Occupied seasonally” refers to seasonal communities in which residents often are not present on the date of the decennial census, but will be present at other times of the year and for which estimates may be reflected in the ACS. The ACS is designed to produce local area data as of a 12-month period estimate (or an average).

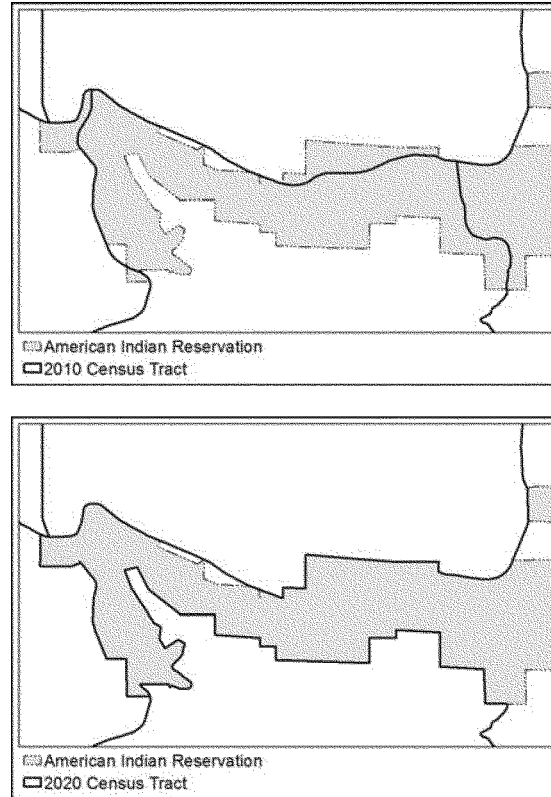
population, such as parks, may contain some minimal population, such as caretakers or those experiencing homelessness. Since the primary purpose of census tracts is to help provide high-quality statistical data about the population, the participant and the Census Bureau must decide if

a special use tract would be useful in such a situation.

4. To facilitate the analysis of data for American Indian tribes, and to recognize their unique governmental status, program participants are encouraged to merge, split, or redefine census tracts to avoid unnecessarily splitting American Indian reservations

(AIRs) and off-reservation trust lands (ORTLs). Each contiguous AIR and/or ORTL should be included, along with any necessary territory outside the AIR and/or ORTL, within a single census tract or as few census tracts as possible for the 2020 Census. This is the only situation in which retracting is encouraged (Figure 1).

Figure 1. – Retracting for American Indian Reservations (AIRs)



B. Criteria

The criteria herein apply to the United States, including federally recognized AIRs and ORTLs, Puerto Rico, and the Island Areas.⁵ The Census Bureau may modify and, if necessary, reject any proposals for census tracts that do not meet the published criteria. In addition, the Census Bureau reserves the right to modify the boundaries and attributes of census tracts as needed to meet the published criteria and/or maintain geographic relationships

⁵ For Census Bureau purposes, the United States typically refers to only the fifty states and the District of Columbia, and does not include the U.S. territories (Puerto Rico, the Island Areas, and the U.S. Minor Outlying Islands). The Island Areas includes American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, and the U.S. Virgin Islands. The U.S. Minor Outlying Islands are an aggregation of nine U.S. territories: Baker Island, Howland Island, Jarvis Island, Johnston Atoll, Kingman Reef, Midway Islands, Navassa Island, Palmyra Atoll, and Wake Island.

before or after the final tabulation geography is set for the 2020 Census.

The Census Bureau sets forth the following criteria for use in reviewing, updating, and delineating 2020 Census tracts:

5. Census tracts must not cross county or state boundaries.

This criterion takes precedence over all other criteria or requirements (except for tribal tracts on federally recognized AIRs and/or ORTLs).

6. Census tracts must cover the entire land and water area of a county.

7. Census tracts must comprise a reasonably compact and contiguous land area.

Noncontiguous boundaries are permitted only where a contiguous area or inaccessible area would not meet population or housing unit count requirements for a separate census tract, in which case the noncontiguous or inaccessible area must be combined within an adjacent or proximate tract.

For example, an island that does not meet the minimum population threshold for recognition as a separate census tract should be combined with other proximate land to form a single, contiguous census tract. Each case will be reviewed and accepted at the Census Bureau's discretion.

8. Census tract boundaries should follow visible and identifiable features.

To make the location of census tract boundaries less ambiguous, wherever possible, tract boundaries should follow significant, visible, easily identifiable features. The use of visible features facilitates the location and identification of census tract boundaries in the field, both on the ground and in imagery. The selection of permanent physical features also increases the stability of the boundaries over time, as the locations of many visible features in the landscape tend to change infrequently. If census tract boundaries are changed, they should not be moved from a more

significant feature (e.g., a highway or a major river) to a less significant feature (e.g., a neighborhood road or a small tributary stream). By definition, state and county boundaries must be used as census tract boundaries. The Census Bureau also permits the use of incorporated place and minor civil division (MCD) boundaries in states where those boundaries tend to remain unchanged over time (see Table 1).

The following features are preferred as census tract boundaries for the 2020 Census:

- a. State and county boundaries must always be census tract boundaries. This criterion takes precedence over all other boundary criteria or requirements.
- b. AIR and ORTL boundaries.
- c. Visible, perennial, stable, relatively permanent natural and constructed features, such as roads, shorelines, rivers, perennial streams and canals, railroad tracks, or above-ground high-tension power lines.

d. Boundaries of legal and administrative entities in selected states. Table 1 identifies by state which MCD and incorporated place boundaries may be used as census tract boundaries.

e. Additionally, the following legally defined, administrative boundaries would be permitted as census tract boundaries:

- i. Barrio, barrio-pueblo, and sub-barrio boundaries in Puerto Rico;
- ii. Census subdistrict and estate boundaries in the U.S. Virgin Islands;
- iii. County and island boundaries (both MCD equivalents) in American Samoa;
- iv. Election district boundaries in Guam;
- v. Municipal district boundaries in the Commonwealth of the Northern Mariana Islands; and,
- vi. Alaska Native Regional Corporation boundaries in Alaska, at the discretion of the Census Bureau, insofar as such boundaries are unambiguous for

allocating living quarters as part of 2020 Census activities.

f. The boundaries of large parks, forests, airports, penitentiaries/prisons, and/or military installations, provided the boundaries are clearly marked or easily recognized in the field, in imagery, and on the ground.

g. When acceptable visible and governmental boundary features are not available for use as census tract boundaries, the Census Bureau may, at its discretion, approve other nonstandard visible features, such as major ridgelines, above-ground pipelines, intermittent streams, or fence lines. The Census Bureau may also accept, on a case-by-case basis, relatively short stretches of boundaries of selected nonstandard and potentially nonvisible features, such as cadastral and parcel boundaries or the straight-line extensions or other lines-of-sight between acceptable visible features.

TABLE 1—ACCEPTABLE MINOR CIVIL DIVISION (MCD) AND INCORPORATED PLACE BOUNDARIES

State	All MCD boundaries	Boundaries of MCDs not co-incident with the boundaries of incorporated places that themselves are MCDs	All incorporated place boundaries	Only conjoint incorporated place boundaries
Alabama				X
Alaska				X
Arizona				X
Arkansas				X
California				X
Colorado				X
Connecticut	X		X	
Delaware				X
Florida				X
Georgia				X
Hawaii				
Idaho				X
Illinois		X ^a		X
Indiana	X			X
Iowa		X		X
Kansas		X		X
Kentucky				X
Louisiana				X
Maine	X		X	
Maryland				X
Massachusetts	X		X	
Michigan		X		X
Minnesota		X		X
Mississippi				X
Missouri		X ^b		X
Montana				X
Nebraska		X ^a		X
Nevada				X
New Hampshire	X		X	
New Jersey	X		X	
New Mexico				X
New York	X		X	
North Carolina				X
North Dakota		X		X
Ohio		X		X
Oklahoma				X
Oregon				X

TABLE 1—ACCEPTABLE MINOR CIVIL DIVISION (MCD) AND INCORPORATED PLACE BOUNDARIES—Continued

State	All MCD boundaries	Boundaries of MCDs not co-incident with the boundaries of incorporated places that themselves are MCDs	All incorporated place boundaries	Only conjoint incorporated place boundaries
Pennsylvania	X	X
Rhode Island	X	X
South Carolina	X
South Dakota	X	X
Tennessee	X
Texas	X
Utah	X
Vermont	X	X
Virginia	X
Washington	X
West Virginia	X
Wisconsin	X	X
Wyoming	X

^a Townships only.

^b Governmental townships only.

9. Population, Housing Unit, and Area Measurement Thresholds

The following are the population, housing unit, and area measurement

threshold criteria for census tracts (as summarized in Table 2). The same population and housing unit thresholds apply to all types of non-special use census tracts, including census tracts

delimited for AIRs and ORTLs, the Island Areas, and encompassing group quarters, military installations, and institutions.

TABLE 2—CENSUS TRACT THRESHOLDS

Census tract type	Threshold type	Optimum	Minimum	Maximum
Standard & tribal census tracts. Special use census tracts	Population threshold	4,000	1,200	8,000.
	Housing unit threshold	1,600	480	3,200.
	Area measurement	At least comparable in land area size to surrounding census tracts.	At least comparable in land area size to surrounding census tracts.	At least comparable in land area size to surrounding census tracts.
	Employment threshold (suggested).	Suggested minimum of 1,200 workers or jobs.		

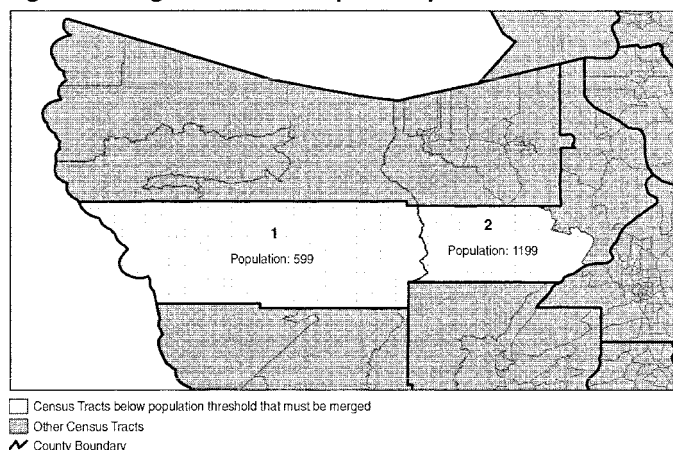
a. 2010 Census population counts should be used in census tract review in most cases. Housing unit counts should be used for census tracts in seasonal communities that have little or no population on Census Day (April 1). Locally produced population and housing unit estimates can be used when reviewing and updating census tracts, especially in areas that have experienced considerable growth since the 2010 Census.

b. The housing unit thresholds are based on a national average of 2.5 persons per household. The Census Bureau recognizes that there are local and regional variations to this average, and will take this into consideration when reviewing all census tract proposals.

c. Any census tract with a population or housing unit count less than the minimum threshold should be merged with an adjacent census tract to form a single tract with at least 1,200 people or at least 480 housing units (Figure 2). The Census Bureau recognizes the complexity that exists between meeting the optimum population or housing unit threshold in a census tract and maintaining census tract comparability over time. For example, if the population or housing unit count based on 2010 Census data was below the minimum thresholds, but significant growth has occurred since 2010 or is expected before 2020 for a census tract, the census tract should not be merged with another census tract. Supporting evidence may be requested by the

Census Bureau. However, if the census tract's population does not increase as expected and does not meet either the minimum population or housing unit thresholds for 2020, this may adversely affect the reliability and availability of any sample estimates for that census tract. For this reason, the Census Bureau suggests merging the census tract with another adjacent census tract if there is a possibility that anticipated growth will not be sufficient to meet minimum thresholds. When merging census tracts, the Census Bureau suggests retaining the former census tract boundaries as boundaries for block groups within the newly defined census tract to facilitate historical analysis.

Figure 2. Merge Tracts for Comparability



d. For the 2020 Census, the Census Bureau will allow the delineation of special use census tracts, but they are not required. A special use census tract must be designated as a specific use type (e.g., state park), must have an official name (e.g., Jay Cooke State Park), have no (or very little) residential population or meet population or housing unit thresholds, and must not create a noncontiguous census tract. In some instances, multiple areas can be combined to form a single special use census tract if the land use or land management characteristics are similar, such as a special use census tract comprising an area with a concentration of employment or adjacent federal and state parks. Any resulting special use census tract should be at least as large

in area as the surrounding standard, populated census tracts.

10. Identification of Census Tracts

a. A census tract has a basic census tract identifier composed of no more than four digits and may have a two-digit decimal suffix.

b. The range of acceptable basic census tract identifiers for the 2020 Census is from 1 to 9989 (see 6.c. below for exceptions); special use census tracts delineated specifically to complete coverage of large water bodies will be numbered from 9950 to 9989 in each county.

c. Census tracts delineated within or to primarily encompass AIRs and/or ORTLs should be numbered from 9400 to 9499.

d. Census tract identifiers must be unique within each county.

e. Once used, census tract identifiers cannot be reused in a subsequent census to reference a completely different area within a county. If a census tract is split, each portion may keep the same basic 4-digit identifier, but each portion must be given a unique suffix. If a census tract that was suffixed for 2010 Census is split, each portion must be given a new suffix.

f. The range of acceptable census tract suffixes is .01 to .98.

11. Census Tract Types

Table 3 provides a summary of the types of census tracts (with their respective population, housing unit, and area measurement thresholds) that the Census Bureau will use for the 2020 Census.

TABLE 3—SUMMARY OF CENSUS TRACT TYPES

Census tract type	Distinction from standard census tract	Population thresholds	Housing unit thresholds	Area measurement thresholds
Standard census tract	Optimum: 4,000; Min: 1,200; Max: 8,000.	Optimum: 1,600; Min: 480; Max: 3,200.	None.
Tribal census tract	Tribal census tracts are conceptually similar and equivalent to census tracts defined within the standard state-county-tract geographic hierarchy used for tabulating and publishing statistical data.	Optimum: 4,000; Min: 1,200; Max: 8,000.	Optimum: 1,600; Min: 480; Max: 3,200.	None.
Special use census tract	A census tract encompassing an employment center, large airport, public park, public forest, or large water body with no (or very little) population or housing units.	None (or very little) or within the standard census tract threshold.	None (or very little) or within the standard census tract threshold.	At least comparable in size to surrounding standard census tracts.

B. Tribal Census Tracts

Tribal census tracts are statistical geographic entities defined by the Census Bureau in cooperation with tribal officials to provide meaningful, relevant, and reliable data for small

geographic areas within the boundaries of federally recognized AIRs and/or ORTLs. As such, they recognize the unique statistical data needs of federally recognized American Indian tribes. The delineation of tribal census tracts allows for an unambiguous presentation of

census tract-level data specific to the federally recognized AIR and/or ORTL without the imposition of state or county boundaries, which might artificially separate American Indian populations located within a single AIR and/or ORTL. To this end, the American

Indian tribal participant may define tribal census tracts that cross county or state boundaries, or both. For federally recognized American Indian tribes with AIRs and/or ORTLs that have more than 2,400 residents, the Census Bureau will offer the tribal government the opportunity to delineate tribal census tracts and other tribal statistical geography on their AIR and/or ORTL. For federally recognized tribes with an AIR and/or ORTL with fewer than 2,400 residents, the Census Bureau will define one tribal census tract coextensive with the AIR and/or ORTL. Tribal census tracts must be delineated to meet all other census tract criteria, and must be identified uniquely to clearly distinguish them from county-based census tracts. Tribal census tracts are conceptually similar and equivalent to census tracts defined within the standard state-county-tract geographic hierarchy used for tabulating and publishing statistical data.

In order to provide meaningful statistical geographic areas within the AIR and/or ORTL, as well as make meaningful and reliable data available for these areas and their populations, tribal census tract geography is maintained separately from standard county-based census tracts. This change was first introduced for the 2010 Census, creating standard, county-based census tracts nationwide and maintaining tribal census tracts as a completely separate set of geography from standard census tracts for both geographic and data presentation purposes. The change eliminated, in part, the reliability and availability data issues for the tribal census tracts and the derived standard census tracts that were present in Census 2000.⁶

As with standard census tracts submitted through this program, the tribal census tracts are submitted to the Census Bureau, and are subject to review to ensure compliance with the published criteria. Detailed criteria pertaining to tribal census tracts will be published in a separate **Federal Register** notice pertaining to all American Indian areas, including statistical areas defined through the PSAP.

⁶ For Census 2000, tribal tracts were defined for federally recognized AIRs and/or ORTLs and standard census tracts were identified by superimposing county and state boundaries onto the tribal tracts. For Census 2000 products in which data were presented by state and county, the standard state-county-census tract hierarchy was maintained, even for territory contained within an AIR and/or ORTL. In such instances, the state-county portions of a tribal tract were identified as individual census tracts. These standard census tracts may not have met the minimum population thresholds, potentially limiting sample data reliability or availability for both the tribal tract and the derived standard census tracts.

IV. Definitions of Key Terms

Alaska Native Regional Corporation (ANRC)—A corporate geographic area established under the Alaska Native Claims Settlement Act (Pub. L. 92–203, 85 Stat. 688 (1971)) to conduct both the business and nonprofit affairs of Alaska Natives. Twelve ANRCs cover the entire state of Alaska except for the Annette Island Reserve.

American Indian off-reservation trust land (ORTL)—An area of land located outside the boundaries of an AIR, whose boundaries are established by deed, and which are held in trust by the U.S. federal government for a federally recognized American Indian tribe or members of that tribe.

American Indian reservation (AIR)—An area of land with boundaries established by final treaty, statute, executive order, and/or court order and over which a federally recognized American Indian tribal government has governmental authority. Along with “reservation,” designations such as colonies, communities, pueblos, rancherías, and reserves apply to AIRs.

Census block—Census blocks are statistical areas bounded by visible features, such as streets, roads, streams, and railroad tracks, and by non-visible boundaries, such as selected property lines and city, township, school district, and county limits and short line-of-sight extensions of streets and roads. Census blocks cover the entire territory of the United States, Puerto Rico, and the Island Areas.

Conjoint—A description of a boundary line shared by two adjacent geographic entities.

Contiguous—A description of areas sharing common boundary lines, more than a single point, such that the areas, when combined, form a single piece of territory. Noncontiguous areas form disjoint pieces.

Group quarters—A location where people live or stay, in a group living arrangement, that is owned or managed by an entity or organization providing housing and/or services for the residents. This is not a typical household-type living arrangement. These services may include custodial or medical care as well as other types of assistance, and residency is commonly restricted to those receiving these services. People living in group quarters are usually not related to each other. Group quarters include such places as college residence halls, residential treatment centers, skilled nursing facilities, group homes, military barracks, correctional facilities, and workers’ dormitories.

Incorporated place—A type of governmental unit, incorporated under

state law as a city, town (except in New England, New York, and Wisconsin), borough (except in Alaska and New York), or village, generally to provide governmental services for a concentration of people within legally prescribed boundaries.

Minor civil division (MCD)—The primary governmental or administrative division of a county in 28 states and the Island Areas having legal boundaries, names, and descriptions. The MCDs represent many different types of legal entities with a wide variety of characteristics, powers, and functions depending on the state and type of MCD. In some states, some or all of the incorporated places also constitute MCDs.

Nonvisible feature—A map feature that is not visible on the ground such as a city or county boundary through space, a property line, or line-of-sight extension of a road.

Retracting—Substantially changing the boundaries of a census tract so that comparability over time is not maintained.

Special use census tract—Type of census tract that must be designated as a specific use type (e.g., state park or large lake) and have an official name (e.g., Jay Cooke State Park or Lake Minnetonka), should have no (or very little) population or housing units, and must not create a noncontiguous census tract. If delineated in a densely populated, urban area, a special use census tract must have an area of at least one square mile. If delineated completely outside an urban area, a special use census tract must have an area of at least 10 square miles.

Visible feature—A map feature that can be seen on the ground and in imagery, such as a road, railroad track, major above-ground transmission line or pipeline, river, stream, shoreline, fence, sharply defined mountain ridge, or cliff. A nonstandard visible feature is a feature that may not be clearly defined on the ground (such as a ridge), may be seasonal (such as an intermittent stream), or may be relatively impermanent (such as a fence). The Census Bureau generally requests verification that nonstandard features used as boundaries for the PSAP geographic areas pose no problem in their location during field work.

Dated: October 30, 2018.

Ron S. Jarmin,

Deputy Director, Performing the Non-Exclusive Functions and Duties of the Director, Bureau of the Census.

[FR Doc. 2018–24567 Filed 11–9–18; 8:45 am]

BILLING CODE 3510-07-P

DEPARTMENT OF COMMERCE**Bureau of the Census**

[Docket Number 180926887–8887–01]

Census County Divisions (CCDs) and Equivalent Entities for the 2020 Census—Final Criteria**AGENCY:** Bureau of the Census, Commerce.**ACTION:** Notice of final criteria and program implementation.

SUMMARY: Census county divisions (CCDs) and equivalent entities are statistical geographic entities established cooperatively by the Census Bureau and officials of state and local governments in 21 states where minor civil divisions (MCDs) either do not exist or have been unsatisfactory for reporting statistical data. The primary goal of the CCD program has been to establish and maintain a set of subcounty units that have stable boundaries and recognizable names. The Census Bureau is publishing this notice in the **Federal Register** to announce final criteria and program implementation for defining CCDs for the 2020 Census. In addition to CCDs, the program also encompasses the review and update of census tracts, block groups, and census designated places (CDPs).

DATES: This notice's final criteria will be effective on December 13, 2018.

FOR FURTHER INFORMATION CONTACT: Requests for additional information on this program should be directed to the Geographic Standards, Criteria, and Quality Branch, Geography Division, U.S. Census Bureau, via email at geo.psap.list@census.gov or telephone at 301–763–3056.

SUPPLEMENTARY INFORMATION:**Background**

Census county divisions (CCDs) and equivalent entities are statistical geographic entities established cooperatively by the Census Bureau and officials of state and local governments in 21 states¹ where minor civil divisions (MCDs) either do not exist or have been unsatisfactory for reporting statistical data. The primary goal of the CCD program has been to establish and maintain a set of subcounty² units that

have stable boundaries and recognizable names.

The Census Bureau is publishing this notice in the **Federal Register** to announce final criteria for defining CCDs for the 2020 Census. The Census Bureau did not receive any comments in response to proposed criteria published in the **Federal Register** on February 15, 2018 (83 FR 6932). After publication of final criteria in the **Federal Register**, the Census Bureau will offer designated governments or organizations an opportunity to review and, if necessary, suggest updates to the boundaries and attributes of CCDs in their geographic area under the Participant Statistical Areas Program (PSAP). In addition to CCDs, the program also encompasses the review and update of census tracts, block groups, and census designated places (CDPs).

I. History

When CCDs were introduced prior to the 1950 Census, few alternatives were available for the provision of statistical data related to relatively stable, subcounty geographic units. Census tracts were defined in only a subset of metropolitan area counties. MCDs existed in all counties, but in some states MCD boundaries changed frequently enough that they were not useful for comparing statistical data from one decade to another.

For much of the period from the 1950 Census through the 1980 Census, county subdivisions (MCDs and CCDs) provided the only subcounty unit of geography at which data users could obtain statistical data for complete coverage of counties nationwide. The introduction of block numbering areas (BNAs) in counties without census tracts for the 1990 Census offered an alternate subcounty entity for which data could be tabulated. For Census 2000, the Census Bureau introduced census tracts nationwide (in many counties, BNAs were simply relabeled as “census tracts”), increasing the dissemination of, and ability to analyze, data at the census tract level, and providing an alternative set of subcounty statistical geographic areas in each county in addition to MCDs and CCDs. Nevertheless, CCDs and MCDs remain useful for presenting subcounty statistics and, in less populous counties containing only one or two census tracts, can provide greater spatial

islands in American Samoa; districts in the U.S. Virgin Islands; municipalities in the Commonwealth of the Northern Mariana Islands; municipios in Puerto Rico; and the areas constituting the District of Columbia and Guam. This notice will refer to all these entities collectively as “counties”.

resolution when analyzing the distribution of population and characteristics.

II. Summary of Comments Received in Response to the Proposed Criteria

The Census Bureau's proposed criteria for the 2020 Census were unchanged from the final criteria used to delineate CCDs for the 2010 Census. The Census Bureau did not receive any comments in response to the proposed criteria published in the **Federal Register** published on February 15, 2018 (83 FR 6932). As a result, the proposed criteria are adopted as final criteria with only minor clarifying changes and an update for a population figure used as an example.

III. General Principles and Criteria for CCDs for the 2020 Census

The criteria outlined herein apply to the United States,³ Puerto Rico, and the Island Areas.⁴

A. General Principles

1. The primary goal of the CCD program is to establish and maintain a set of subcounty units that have stable boundaries and recognizable names. The boundaries of CCDs usually coincide with visible features or stable, significant legal boundaries, such as the boundary of an American Indian reservation (AIR), federally managed land, or conjoint incorporated places. CCDs have no legal status as statistical geographic entities and are defined only for the tabulation and presentation of statistical data.

2. A CCD usually represents a single contiguous area consisting of one or more communities, economic centers, or, in some instances, major land uses that are relatively compact in shape.

3. A CCD should have a relationship to existing census tracts, either encompassing one or more census tracts or having two or more CCDs nest within a single census tract. The boundaries of a CCD, or combination of nested CCDs, align with census tract boundaries. Note that a county with a population less than the optimum population for a census tract (less than 4,000 people) may contain more CCDs than census tracts. For example, McCone County, Montana, which has a 2017 estimated population of 1,718, contains only one

³ For Census Bureau purposes, the United States typically refers to only the fifty states and the District of Columbia, and does not include the U.S. territories (Puerto Rico, the Island Areas, and the U.S. Minor Outlying Islands).

⁴ The Island Areas include the U.S. territories American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, and the U.S. Virgin Islands.

¹ In Alaska, census subareas are county subdivisions equivalent to CCDs. For purposes of this notice, the term CCD also refers to census subareas in Alaska.

² For the Census Bureau's purposes, the term “county” includes parishes in Louisiana; boroughs, city and boroughs, municipalities, and census areas in Alaska; independent cities in Maryland, Missouri, Nevada, and Virginia; districts and

census tract, but is divided into two CCDs.

4. Since the 1950s, the Census Bureau has worked with state and local officials to replace MCDs with CCDs for the collection, presentation, and analysis of Census Bureau data, particularly in states in which MCDs do not provide governmental services and functions, and in which MCD boundaries tend to change between decennial censuses. For the 2020 Census, CCDs are defined in 21 states: Alabama, Alaska, Arizona, California, Colorado, Delaware, Florida, Georgia, Hawaii, Idaho, Kentucky, Montana, Nevada, New Mexico, Oklahoma, Oregon, South Carolina, Texas, Utah, Washington, and Wyoming. North Dakota adopted CCDs for use in tabulating and presenting data from the 1970 Census. Following the 1970 Census, North Dakota requested that the Census Bureau again use MCDs to tabulate and present statistical data. For the 2010 Census, Tennessee requested that the Census Bureau replace its CCDs with county commissioner districts, a type of legal, administrative MCD.

B. Criteria

CCDs should (1) have community orientation, (2) have visible and/or stable boundaries, (3) maintain relationships with census tract boundaries, and (4) have recognizable names.

1. Community Orientation

Each CCD should center on one or more places and encompass additional surrounding territory that together form a cohesive community area. The definition of community should take into account factors, such as production, marketing, consumption, and the integrating factor of local institutions.

The locality on which a CCD is centered usually is an incorporated place or an unincorporated community, which might be identified as a CDP. In some cases, the CCD may center on a major area of significantly different topography, land use, or ownership, such as a large military installation or AIR. A CCD should always comprise a reasonably compact, continuous land area, generally with road access to all areas within the CCD.

2. Visible and/or Stable Boundaries

To make the location of CCD boundaries less ambiguous, the boundaries should follow, wherever possible, visible and identifiable features. The use of visible features makes it easier to locate and identify CCD boundaries over time, as the locations of most visible features in the

landscape change infrequently, making data collection easier and more reliable, while reducing the possibility for data allocation errors. The Census Bureau requires that CCDs follow state and county boundaries, conform to census tract boundaries, and allows CCDs to follow the boundaries of federally recognized AIRs, and federal, state, or locally managed land.

The following features are acceptable:

- a. County boundaries (always a CCD boundary);
- b. Census tract boundaries, which usually follow visible, perennial, natural, and cultural features, such as roads, rivers, canals, railroads, or above-ground, high-tension power lines;
- c. Legally defined, federally recognized AIR boundaries;
- d. The boundaries of federal, state, or locally managed land, such as national parks, national monuments, national forests, other types of large parks or forests, airports, marine ports, prisons, military installations, or other large facilities;
- e. Conjoint city limits (in certain situations, such as city limits that change infrequently); and,
- f. When the above types of features are not available for use as CCD boundaries, the Census Bureau may, at its discretion, approve other nonstandard, visible features, such as ridge lines, above-ground pipelines, streams, or fence lines. The Census Bureau may also accept, on a case-by-case basis, the boundaries of selected nonstandard and potentially nonvisible features, such as the boundaries of cemeteries, golf courses, glaciers, or the straight-line extensions of visible features and other lines-of-sight.

3. Census Tract Boundaries and Population Size

Whenever possible, a CCD should encompass one or more contiguous census tracts, or multiple CCDs should constitute a single census tract. Therefore, CCD boundaries should be consistent with census tract boundaries. Population size is not as important a consideration with CCDs as it is with census tracts. For CCDs that do not meet the thresholds for a census tract, the Census Bureau encourages creating one or more block groups within a census tract that encompass a CCD. Historically, CCDs have ranged from a few hundred people (in selected situations) to more than one million. However, data quality and availability may be factors that local governments and planners should consider in defining statistical geographic areas. As a general rule, period estimates of demographic characteristics of small

population areas from the American Community Survey will be subject to higher variances than comparable period estimates for areas with larger populations. In addition, the Census Bureau's disclosure rules may have the effect of restricting the availability and amount of data for areas with small populations.

4. Name Identification

a. The names of existing CCDs shall not be changed unless a compelling reason is provided, such as when the name from which the CCD was derived has changed, as in the case of Bainbridge Island, Washington, when the name of the city (Winslow) changed;

b. A new CCD usually is named after the largest population center or historically central place within it (*e.g.*, Taos, Hobbs, or Zuni Pueblo, New Mexico);

c. Where a CCD contains multiple centers with relatively equal importance, a CCD name may represent the two or three centers (*e.g.*, Mount Pleasant-Moroni, Utah);

d. A CCD may be named after the AIR (*e.g.*, Hualapai, Arizona or Nez Perce, Idaho) or a prominent land use area (*e.g.*, Federal Reservation, Washington or Yellowstone National Park, Wyoming) in which it is significantly or wholly located;

e. A CCD may be named after a prominent physical feature (*e.g.*, Mount Rainier, Washington) or a distinctive region within the county (*e.g.*, Death Valley, California; Everglades or Lower Keys, Florida); and,

f. If there is no clear cultural focus or topographic name that can be applied, a CCD name shall consist of the county name and a compass direction to indicate the portion of the county in the CCD or a place name and a compass direction to give the CCD location relative to the place. The directional indicator precedes a county name (*e.g.*, Northeast Cobb, Georgia). If a place name is used, the directional indicator follows it (*e.g.*, Del Rio Northwest, Texas).

In all cases, the objective is to clearly identify the extent of the CCD by means of an area name since CCD names always should be meaningful to data users. Any name used as a CCD name must also be recognized by the Board on Geographic Names for federal use and appear in the Geographic Names Information System maintained by the U.S. Geological Survey. This includes any individual names combined to make a hyphenated CCD name.

III. Definitions of Key Terms

American Indian reservation (AIR)—An area of land with boundaries established by final treaty, statute, executive order, and/or court order and over which a federally recognized American Indian tribal government has governmental authority. Along with “reservation,” designations such as colonies, communities, pueblos, rancherias, and reserves apply to AIRs.

Block group—A statistical subdivision of a census tract consisting of all census blocks whose numbers begin with the same digit in a census tract. A block group is the smallest geographic entity for which the Census Bureau normally tabulates sample data.

Census block—A geographic area bounded by visible and/or invisible features shown on a map prepared by the Census Bureau. A block is the smallest geographic entity for which the Census Bureau tabulates and publishes decennial census data.

Census county division (CCD)—Areas delineated by the Census Bureau in cooperation with state, tribal, and local officials for statistical purposes. CCDs have no legal function and are not governmental units. CCD boundaries usually follow visible features and usually coincide with census tract boundaries. The name of each CCD is based on a place, country, or well-known local name that identify its location.

Census designated place (CDP)—A statistical geographic entity equivalent to an incorporated place with a concentration of population, housing, and commercial and nonresidential structures that is identifiable by name, but is not within an incorporated place.

Census tract—A small, relatively permanent statistical geographic division of a county defined for the tabulation and publication of Census Bureau data. The primary goal of census tracts is to provide a set of nationally consistent, relatively small, statistical geographic units, with stable boundaries that facilitate analysis of data across time and between decennial censuses.

Conjoint—A description of a boundary line shared by two adjacent geographic entities.

Contiguous—A description of areas sharing common boundary lines, more than a single point, such that the areas, when combined, form a single piece of territory. Noncontiguous areas form disjoint pieces.

Federally managed land—Territory that is federally owned and/or administered by an agency of the U.S. federal government, such as the National Park Service, Bureau of Land Management, or Department of Defense.

Incorporated place—A type of governmental unit, incorporated under state law as a city, town (except in New England, New York, and Wisconsin), borough (except in Alaska and New York), or village, generally to provide governmental services for a concentration of people within legally prescribed boundaries.

Minor civil division (MCD)—The primary governmental or administrative division of a county in 28 states and the Island Areas having legal boundaries, names, and descriptions. The MCDs represent many different types of legal entities with a wide variety of characteristics, powers, and functions depending on the state and type of MCD. In some states, some or all of the incorporated places also constitute MCDs.

Nonvisible feature—A map feature that is not visible on the ground and in imagery such as a city or county boundary through space, a property line, or line-of-sight extension of a road.

Visible feature—A map feature that can be seen on the ground and in imagery, such as a road, railroad track, major above-ground transmission line or pipeline, river, stream, shoreline, fence, sharply defined mountain ridge, or cliff. A nonstandard visible feature is a feature that may not be clearly defined on the ground (such as a ridge), may be seasonal (such as an intermittent stream), or may be relatively impermanent (such as a fence). The Census Bureau generally requests verification that nonstandard features used as boundaries for the PSAP geographic areas pose no problem in their location during field work.

Dated: October 30, 2018.

Ron S. Jarmin,

Deputy Director, Performing the Non-Exclusive Functions and Duties of the Director, Bureau of the Census.

[FR Doc. 2018–24566 Filed 11–9–18; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Census Bureau

Proposed Information Collection; Comment Request; National Survey of Children’s Health

AGENCY: U.S. Census Bureau, Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to

take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: To ensure consideration, written comments must be submitted on or before January 14, 2019.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW, Washington, DC 20230 (or via the internet at docpra@doc.gov). You may also submit comments, identified by Docket Number USBC–2018–0016 to the Federal e-Rulemaking Portal: <http://www.regulations.gov>. All comments received are part of the public record. No comments will be posted to <http://www.regulations.gov> for public viewing until after the comment period has closed. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Leah Meyer, U.S. Census Bureau, ADDP, HQ–7H157, 4600 Silver Hill Road, Washington, DC 20233–0001 (301–763–7174 or via email at Leah.Meyer@census.gov).

SUPPLEMENTARY INFORMATION:

I. Abstract

Sponsored primarily by the U.S. Department of Health and Human Services’ (HHS) Health Resources Services Administration’s Maternal and Child Health Bureau (HRSA MCHB), the National Survey of Children’s Health (NSCH) is designed to produce data on the physical and emotional health of children under 18 years of age who live in the United States. The United States Department of Agriculture (USDA), Environmental Protection Agency (EPA), and United States Department of Health and Human Services’ Center for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities (HHS/CDC/NCBDDD) sponsor supplemental questions on the NSCH. The NSCH collects information on factors related to the well-being of children, including access to health care, in-home medical

care, family interactions, parental health, school and after-school experiences, and neighborhood characteristics. The goal of the 2019 NSCH is to provide HRSA MCHB with the necessary data to support the production of national estimates yearly and state-based estimates with pooled samples on the health and well-being of children, their families, and their communities as well as estimates of the prevalence and impact of children with special health care needs.

Treatment Groups and Experiments

We have made minor content revisions for the 2019 NSCH. We also plan to monitor the continued effectiveness of unconditional incentives (the relative benefit for reducing survey non-response by providing a \$0, \$1, \$2, or \$5 incentive as a token of appreciation) and modifications to data collection strategies based on modeled information about paper or internet response preference. We will test an envelope overprint, a short message and simple image printed to the outside of the invitation envelope, designed to encourage respondents to open and read the invitation and a modified design for the screener invitation letter. We will also conduct a small test of a new screener card, a mechanism to more efficiently screen address eligibility. We will select approximately 184,000 addresses as the 2019 NSCH sample; around 4,000 of those addresses will be randomly assigned to the screener card test. Results from prior year surveys were used to inform the decisions made regarding this 2019 survey project.

Based on the results from prior survey cycles and available funds, an unconditional cash incentive will be included with the initial mailing. Survey research indicates that incentives are a necessary and cost-effective expense for achieving a response rate that minimizes nonresponse bias¹. Our testing to date is consistent with this research. Evaluation of previous NSCH cycles showed that there was a statistically significant difference in the response rates when respondents received an incentive compared to those who were part of the control group that did not receive an incentive. The effect of the

incentive was proportionately larger for household types that were less likely to respond in previous years, reducing nonresponse bias. There was a larger increase in response for households mailed a \$5 incentive compared to those mailed a \$2 incentive with their initial survey invite; both treatments proved effective at encouraging response and reducing nonresponse bias in 2018. We will continue to use \$2 and \$5 cash incentives going forward, and will include a test of a \$1 cash incentive. A small group (20% or less) receiving no incentive will be included to monitor the effectiveness of the incentive in the initial mailing. For respondents who answer a paper screener interview and are mailed their first paper topical questionnaire, a \$5 incentive will be used to reduce bias and gain cooperation for this critical second stage of paper questionnaire data collection.

In addition to testing incentives and developing materials, the 2019 NSCH will continue to serve as a platform to evaluate different nonresponse follow-up mailing strategies based on a household's likelihood to respond using a paper questionnaire. We assign a paper-preference probability to every address using American Community Survey (ACS) response mode choices, previous NSCH response mode choices, and small area geographic characteristics. The 30% of addresses with the highest paper-preference probability are assigned to the "High Paper" group and receive a paper questionnaire with the initial invitation. The other 70% of addresses are assigned to the "High Web" group and receive their first paper questionnaires in the second nonresponse follow-up screener invitation.

Since there continues to be a significant potential for cost savings for web data collection over paper data collection, we are working to refine and retest an internet response indicator for future NSCH production cycles based on the results from prior data collection efforts.

In 2019 and beyond, we will continue the use of a pressure-sealed reminder postcard. The reminder postcard will be mailed approximately one week after the initial survey invite mailing and the first nonresponse follow-up. We originally implemented this strategy because the time gap between mailings during the 2016 NSCH proved too long, and a significant dip in response flow was observed between mailings. The pressure-sealed postcard reminder proved effective in 2017 and 2018 at boosting response from the initial mailing and, in 2018, the first nonresponse follow-up. The ability to

send reminders enclosed with a pressure-seal system allows us to include login information for the Centurion web instrument as well as specific information about the survey. The postcard also allows us to include a paragraph in Spanish that will direct the respondent to the Spanish web survey or the Telephone Questionnaire Assistance (TQA) line for assistance.

As in prior administration of the NSCH, the 2019 NSCH will have a TQA line available to respondents who experience technical problems with the web instrument, have questions about the survey, or need other forms of assistance. TQA staff will be able to answer respondent questions and concerns, and also collect survey responses over the phone—if the respondent calls in and would like to have interviewer assistance in completing the interview. Also, respondents can submit questions by email. Email Questionnaire Assistance (EQA) agents will monitor the email account inbox and respond promptly.

The 2018 NSCH tested a certified mail sticker, designed to encourage respondents to open the invitation envelope and respond to the NSCH. The sticker significantly increased response, but did not reduce nonresponse bias. The sticker also introduced logistical challenges that make current use as a treatment option untenable. Instead, we will test an envelope overprint, which is a short message on the outside of the envelope that can potentially encourage response and reduce nonresponse bias. Half of addresses (approximately 90,000) will receive the screener invitation in an envelope with the overprint; the other half of addresses will receive our standard white envelope. Packages can also include a modified version of the invitation letter designed to make the text more accessible, such as relocating some necessary information to a text box with a boundary.

In both internet and paper collection modes, the survey design for the 2019 NSCH focuses on first collecting information about the children in the household and basic special health care needs, and then selecting a child from the household for follow-up to collect additional detailed topical information. If there is more than one eligible child in a household, a single child will be selected based on a sampling algorithm that considers the age and number of children as well as the presence of children with special health care needs. We estimate that, from the original 180,000 selected addresses that are assigned to the primary production cycle (excluding the 4,000 addresses

¹Brick JM, Williams D, Montaquila JM. 2011. "Address-Based Sampling for Subpopulation Surveys". *Public Opinion Quarterly*, 75(3): 409–28; Foster EB, Frasier AM, Morrison HM, O'Connor KS, Blumberg SJ. 2010. "All Things Incentive: Exploring the Best Combination of Incentive Conditions". Paper presented at the American Association for Public Opinion Research annual conference, Chicago, IL.

assigned to the screener card test), our target screener return rate of 40.5% will yield approximately 72,900 responses to the screener. We then estimate that 50% of households from the first phase of the screener will be eligible to receive a topical questionnaire (households with children), and 70% of these households with children will return the topical questionnaire, resulting in approximately 25,515 completed topical interviews.² A household could be selected for one of three age-based topical surveys: 0-to-5-year-old children, 6-to-11-year-old children, or 12-to-17-year-old children.

For the 4,000 screener card test addresses, we anticipate that 50% (2,000 addresses) will return the screener card and 10% (400 addresses) will use the web instrument.

Census staff have developed a plan to select a production sample of approximately 184,000 households (addresses) from a Master Address File (MAF)-based sampling frame, with split panels to test mode of administration (*i.e.*, high-web and low-web), and improvements to contact materials and strategies. Based on results of the prior NSCH incentive experiments, we plan to use small, unconditional cash incentives with a control group receiving no incentive to monitor the effectiveness of the incentive expenditures. For respondents who answer the paper screener and are mailed a paper topical questionnaire, an additional incentive is expected for that mailing. The recommendation for the amount of this secondary incentive will be based on the results of the 2016 NSCH and available funding. From prior cycles of the NSCH, using American Association for Public Opinion Research (AAPOR) definitions of response, we can expect an overall screener completion rate for the 2019 NSCH to be about 45% and a 31% overall topical completion rate.³ This is different from

² The topical return rate was calculated using an average of the web topical return rate (95%) and the paper topical return rate (45%). The return rate includes fully complete topicals and sufficient partial topicals out of all completed screeners. The completion rate (31% for topicals) and response rate (40.4%) calculations on the following page additionally includes households in the denominator that are estimated to have eligible children, but who did not complete screeners.

³ Screener Completion Rate is the proportion of screener-eligible households (*i.e.*, occupied residences) that completed a screener. It is equal to $(S+X)/(S+X+R+e(UR+UO))$, where S is the count of completed screeners with children, X is completed screeners without children, R, is screener refusals, and e(UR+UO) is the estimated count of screener-eligible households among nonresponding addresses.

The Topical Completion Rate is the proportion of topical-eligible households (*i.e.*, occupied residences with children present) that completed a

the total overall response rate, which we expect to be about 40.4%.⁴

II. Method of Collection

Web Push

The production 2019 NSCH plan for the web push data collection design includes 70% of the estimated 180,000 primary production addresses receiving an initial invite with instructions on how to complete an English or Spanish-language screening questionnaire via the web. Households that decide to complete the web-based survey will be taken through the screening questionnaire to determine if they screen into one of the three topical instruments. Households that list at least one child who is 0 to 17 years old in the screener are directed into a topical questionnaire immediately after the last screener question. If a household in the web push treatment group decides to complete the paper screener, the household may have a chance to receive an additional topical questionnaire incentive.

Mixed-Mode

The production 2019 NSCH plan for the mixed-mode data collection design includes approximately 30% of the 180,000 primary production addresses receiving both an initial invite with a paper screening questionnaire and instructions on how to complete an English or Spanish language screening questionnaire via the web. Households that decide to complete the web-based survey will follow the same screening and topical selection path as the web push. Households that choose to complete the paper screener questionnaire rather than completing the survey on the internet and that have eligible children will be mailed a paper topical questionnaire upon receipt of their completed paper screener at the Census Bureau's National Processing Center. If a household in the mixed-mode group chooses to complete the paper screener instead of completing by internet, then the household may receive an additional topical questionnaire incentive.

topical questionnaire. It is equal to I/HCT , where I is the count of completed topicals and HCT is the estimated count of households with children in the sample or $S+R+(S+R)/(S+X+R)*e(UR+UO)$.

⁴ Total Response Rate is the proportion of screener-eligible households that completed a screener or topical questionnaire. It is equal to $(X+I+P)/(X+I+P+RS+eUS)$, where I is the count of completed topicals, P is the count of sufficient partial completed topicals, RS is screener refusals, and eUS is the estimated count of screener-eligible households among nonresponding addresses.

Follow-Up Reminder Design

Prior to Census administration of the survey, the NSCH was conducted by the Health Services Resources Administration's Maternal and Child Health Bureau and the National Center for Health Statistics. As such, the survey information was sent to respondents under letterhead from the Department of Health and Human Services and the Centers for Disease Control and Prevention, with the Director of NCHS signing the letters to the respondent.

In the 2016 NSCH, we tested both standard contact branding utilized for Census Bureau surveys, which included Census Bureau letterhead and the Census Director's signature, and an alternative sent with HRSA MCHB branding. The first follow-up mailing, sent to non-responding households approximately three-weeks after their initial invitation to respond to the survey by web, was split into two groups. The first group was sent a reminder to participate with their web login and password under standard Census Bureau letterhead. Response was higher from those addresses receiving the standard Census branding.

Non-Response Follow-Up for the "High Web" Group and "High Paper" Group

The "High Web" group will receive two web survey invitation letters requesting their participation in the survey prior to receiving their first paper screener questionnaire in the second follow-up mailing. The "High Paper" group will receive both a web survey invitation letter along with a mailed paper screener questionnaire with the initial invitation and each follow-up mailing. Once a household in the "High Web" group receives a paper screener questionnaire, it will then have the option to either complete the web-based survey or complete the mailed paper screener, similar to the "High Paper" group. If the household chooses to complete the mailed paper questionnaire, then they would then be considered part of the mailout/mailback paper-and-pencil interviewing treatment group. The paper-and-pencil treatment group receives a paper topical questionnaire, if there is at least one eligible child who is 0 to 17 years old listed on the screener. Nonresponse follow-up for the topical questionnaire will include up to one pressure-sealed postcard and up to three mailings including the paper topical questionnaire.

The 2019 NSCH will also include a small screener card test. The screener card is a single-page instrument designed to screen household eligibility

for the NSCH. An additional 4,000 addresses will receive the screener card in place of the traditional screener instrument. They will have the option to report only if there are children present at the address or not. Respondents will also have the option to report using the web instrument. We anticipate that the screener card instrument will reduce respondent burden for households without children and allow us to more efficiently identify households with children.

III. Data

OMB Control Number: 0607–0990.

Form Number(s): NSCH–S1 (English Screener), NSCH–T1 (English Topical for 0- to 5-year-old children), NSCH–T2 (English Topical for 6- to 11-year-old children), NSCH–T3 (English Topical for 12- to 17-year-old children), NSCH–S–S1 (Spanish Screener), NSCH–S–T1 (Spanish Topical for 0- to 5-year-old children), NSCH–S–T2 (Spanish Topical for 6- to 11-year-old children), NSCH–S–T3 (Spanish Topical for 12- to 17-year-old children), and NSCH–SC1 (Screener Card—perforated).

Type of Review: Regular submission.

Affected Public: Parents, researchers, policymakers, and family advocates.

Estimated Number of Respondents: 72,900 for the screener, 25,515 for the topical, 2,000 for the screener card, and 400 screener card respondents using the web instrument.

Estimated Time per Response: 5 minutes per screener response, 33 minutes per topical response, 2 minutes per screener card response, and 38 minutes per screener card response using the web instrument.

Estimated Total Annual Burden Hours: 20,428 hours.

Estimated Total Annual Cost to Public: \$0 (This is not the cost of respondents' time, but the indirect costs respondents may incur for such things as purchases of specialized software or hardware needed to report, or expenditures for accounting or records maintenance services required specifically by the collection.)

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C. Section 8(b); 42 U.S.C. 701; 1769d(a)(4)(B); 42 U.S.C. 241; 7 U.S.C. 136r(a); and 15 U.S.C. 2609.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c)

ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer.

[FR Doc. 2018–24681 Filed 11–9–18; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Bureau of the Census

[Docket Number 180927893–8893–01]

Census Designated Places (CDPs) for the 2020 Census—Final Criteria

AGENCY: Bureau of the Census, Commerce.

ACTION: Notice of final criteria and program implementation.

SUMMARY: Census designated places (CDPs) are statistical geographic entities representing closely settled, unincorporated communities that are locally recognized and identified by name. They are the statistical equivalents of incorporated places, with the primary differences being the lack of a legally defined boundary and an active, functioning governmental structure, chartered by the state and administered by elected officials. CDPs defined for the 2020 Census will also be used to tabulate American Community Survey, Puerto Rico Community Survey, and Economic Census data after 2020, and potentially data from other Bureau of the Census (Census Bureau) censuses and surveys. The Census Bureau is publishing this notice in the **Federal Register** to announce final criteria for defining CDPs for the 2020 Census. In addition to CDPs, the program also encompasses the review and update of census tracts, block groups, and census county divisions.

DATES: This notice's final criteria will be applicable on December 13, 2018.

FOR FURTHER INFORMATION CONTACT: Requests for additional information on this program should be directed to Vincent Osier, Geographic Standards, Criteria, and Quality Branch, Geography Division, U.S. Census Bureau, via email

at geo.psap.list@census.gov or telephone at 301–763–3056.

SUPPLEMENTARY INFORMATION:

Background

Census designated places (CDPs)¹ are statistical geographic entities representing closely settled, unincorporated communities that are locally recognized and identified by name. They are the statistical equivalents of incorporated places, with the primary differences being the lack of a legally defined boundary and an active, functioning governmental structure, chartered by the state and administered by elected officials. CDPs defined for the 2020 Census will also be used to tabulate American Community Survey, Puerto Rico Community Survey, and Economic Census data after 2020, and potentially data from other Census Bureau censuses and surveys.

The Census Bureau is publishing this notice in the **Federal Register** to announce final criteria for defining CDPs for the 2020 Census. The Census Bureau did not receive any comments in response to proposed criteria published in the **Federal Register** on February 15, 2018 (83 FR 6934). After publication of final criteria in the **Federal Register**, the Census Bureau will offer designated governments or organizations an opportunity to review and, if necessary, suggest updates to the boundaries and attributes of the CDPs in their geographic area under the Participant Statistical Areas Program (PSAP). In addition to CDPs, the program also encompasses the review and update of census tracts, block groups, and census county divisions.

I. History

The CDP concept and delineation criteria have evolved over the past seven decades in response to data user needs for place-level data. This evolution has taken into account differences in the way in which places were perceived, and the propensity for places to incorporate in various states. The result, over time, has been an increase in the number and types of unincorporated communities identified as CDPs. This also results in an increasing consistency in the relationship between the CDP concept and the kinds of places encompassed by the incorporated place category, or a compromise between localized perceptions of place and a concept that would be familiar to data

¹ The term CDP includes *comunidades and zonas urbanas* in Puerto Rico.

users throughout the United States,² Puerto Rico, and the Island Areas.³

Although not as numerous as incorporated places or municipalities,⁴ CDPs have been important geographic entities since their introduction for the 1950 Census (CDPs were referred to as “unincorporated places” from 1950 through the 1970 decennial censuses). For the 1950 Census, CDPs were defined only outside urbanized areas and were required to have at least 1,000 residents. For the 1960 Census, CDPs could also be identified inside urbanized areas outside of New England, but these were required to have at least 10,000 residents. The Census Bureau modified the population threshold within urbanized areas to 5,000 residents in 1970, allowed for CDPs in urbanized areas in New England in 1980, and lowered the threshold for CDPs within urbanized areas to 2,500 in 1990. In time, other population thresholds were adopted for identification of CDPs in Alaska, Puerto Rico, the Island Areas, and on American Indian reservations (AIRs). The Census Bureau eliminated all population threshold requirements for Census 2000, achieving consistency between CDPs and incorporated places, for which the Census Bureau historically has published data without regard to population size.

According to the 2010 Census, more than 38.7 million people in the United States, Puerto Rico, and the Island Areas lived in CDPs. The relative importance of CDPs varies from state to state depending on laws governing municipal incorporation and annexation, but also depending on local preferences and attitudes regarding the identification of places.

II. Summary of Comments Received in Response to Proposed Criteria

The Census Bureau’s proposed criteria for the 2020 Census were unchanged from the final criteria used to delineate CDPs for the 2010 Census. The Census Bureau did not receive any comments in response to the proposed criteria published in the **Federal**

Register on February 15, 2018 (83 FR 6934). As a result, the proposed criteria are adopted as final criteria without change.

III. CDP Criteria and Guidelines for the 2020 Census

The criteria outlined herein apply to the United States, including AIRs and off-reservation trust lands, Puerto Rico, and the Island Areas. In accordance with the final criteria, the Census Bureau may modify and, if necessary, reject any proposals for CDPs that do not meet the established criteria. In addition, the Census Bureau reserves the right to modify the boundaries and attributes of CDPs as needed to maintain geographic relationships before the final tabulation geography is set for the 2020 Census.

The Census Bureau proposes the following criteria and guidelines for use in identifying the areas that will qualify for designation as CDPs for use in tabulating data from the 2020 Census, the American Community Survey, the Puerto Rico Community Survey, the Economic Census, and potentially other Census Bureau censuses and surveys.

1. A CDP constitutes a single, closely settled center of population that is named. To the extent possible, individual unincorporated communities should be identified as separate CDPs. Similarly, a single community should be defined as a single CDP rather than multiple CDPs with each part referencing the community name and a directional term (*i.e.*, north, south, east, or west). Since a CDP is defined to provide data for a single, named locality, the Census Bureau generally will not accept combinations of places and hyphenated place names defined as a CDP. In the past, communities were often combined as a single CDP in order to comply with the Census Bureau’s former minimum population requirements. The Census Bureau’s elimination of population threshold criteria starting with Census 2000 made such combinations unnecessary. Other communities were combined because visible features were not available for use as boundaries for separate CDPs. The Census Bureau’s policy to allow the use of some nonvisible boundaries so that participants can separate individual communities has dispensed with the need to have multi-place CDPs.

Multiple communities may only be combined to form a single CDP when the identities of these communities have become so intertwined that the communities are commonly perceived and referenced as a single place. For example, the communities of Arden and Arcade in California have grown

together over time and residents commonly use the place name Arden-Arcade. Further, because of the intertwined identity, residents would have difficulty identifying a boundary between the separate, historical communities of Arden and Arcade. Multiple communities may also be defined as a single CDP when there are no distinguishable or suitable features in the landscape that can be used as a boundary between the communities, even if the two communities still have separate identities. For example, the CDP of Ashton-Sandy Spring in Maryland encompasses two communities that still maintain separate identities in common, daily usage. The two communities, however, have grown together to such an extent that a clear break between the two communities is no longer identifiable in the landscape. In general, when considering whether to combine multiple communities as a single CDP, the following questions should be taken into account:

- Do residents commonly perceive and refer to the communities as a single entity?
- Are there landscape elements, such as signs, that use a hyphenated name for the community?
- Can residents or other knowledgeable individuals identify clear, commonly accepted boundaries for the individual communities?

2. A CDP generally consists of a contiguous cluster of census blocks comprising a single piece of territory and containing a mix of residential, nonresidential, and commercial uses similar to that of an incorporated place of similar size. Some CDPs, however, may be predominantly residential; such places should represent recognizably distinct, locally known communities, but not typical suburban subdivisions. Examples of such predominantly residential communities that can be recognized as CDPs are colonias, small rural communities, and unincorporated resort and retirement communities.

3. A CDP may not be located, either partially or entirely, within an incorporated place or another CDP.

4. A CDP may be located in more than one county but must not cross state boundaries. It is important to note, however, that since county boundaries provide important demarcations for communities, CDPs that cross county lines should be kept to a minimum and identified only when the community clearly sees itself existing on both sides of a county boundary.

5. There are no minimum population or housing unit thresholds for defining CDPs; however, a CDP must contain some population or housing units or

²For Census Bureau purposes, the United States typically refers to only the fifty states and the District of Columbia, and does not include the U.S. territories (Puerto Rico, the Island Areas, and the U.S. Minor Outlying Islands).

³The Island Areas include the U.S. territories American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, and the U.S. Virgin Islands. There are no CDPs in American Samoa or the Commonwealth of the Northern Mariana Islands because villages are considered incorporated places and cover the entire territory and population in each territory.

⁴Known by various terms throughout the United States: Cities, towns (except in the six New England states, New York, and Wisconsin), villages, and boroughs (except in New York and Alaska).

both. For the 2020 Census, the Census Bureau will not accept a CDP delineated with zero population and zero housing units. The Census Bureau recognizes that some communities, such as a resort or other kinds of seasonal communities, may lack population at certain times of the year. Nevertheless, there should be some evidence, generally in the form of houses, barracks, dormitories, commercial buildings and/or other nonresidential structures, providing the basis for local perception of the place's existence. The Census Bureau will review the number of housing units within the place, as reported in the previous decennial census or as seen in imagery, and consider whether additional information is needed before recognizing the CDP. Participants submitting boundaries for places with less than ten housing units may be asked to provide additional information attesting to the existence of the CDP.

6. CDP boundaries should follow visible features, except in those circumstances when a CDP's boundary is coincident with the nonvisible boundary of a state, county, minor civil division (in the six New England states, Michigan, Minnesota, New Jersey, New York, Pennsylvania, and Wisconsin), or incorporated place. CDP boundaries may follow other nonvisible features in instances where reliance upon visible features would result in overbounding of the CDP in order to include housing units on both sides of a road or street feature. Such boundaries might include parcel boundaries and public land survey system lines; fence lines; national, state, or local park boundaries; ridgelines; or drainage ditches.

7. The CDP name should be one that is recognized and used in daily communication by the residents of the community. Because unincorporated communities generally lack legally defined boundaries, a commonly used community name and the geographic extent of its use by local residents is often the best identifier of the extent of a place, the assumption being that if residents associate with a particular name and use it to identify the place in which they live, then the CDP's boundaries can be mapped based on the use of the name. There should be features in the landscape that use the name, such that a non-resident would have a general sense of the location or extent of the community; for example, signs indicating when one is entering the community; highway exit signs that use the name; or businesses, schools, or other buildings that make use of the name. It should not be a name developed solely for planning or other purposes (including simply to obtain

data from the Census Bureau) that is not in regular daily use by the local residents and business establishments.

8. A CDP may not have the same name as an adjacent or nearby incorporated place. If the community does not have a name that distinguishes it from other nearby communities, then the community is not a distinct place. The use of directional terms ("north", "south", "east", "west", and so forth) to merely differentiate the name of a CDP from a nearby municipality where this name is not in local use is not acceptable. For example, the name "North Laurel" would be permitted if this name were in local use. The name "Laurel North" would not be permitted if it were not in local use. Again, this has much to do with the way in which people typically refer to the places in which they live. It is permissible to change the name of a 2010 CDP for the 2020 Census if the new name provides a better identification of the community.

IV. Definitions of Key Terms

American Indian off-reservation trust land—An area of land located outside the boundaries of an AIR, whose boundaries are established by deed, and which are held in trust by the U.S. federal government for a federally recognized American Indian tribe or members of that tribe.

American Indian reservation (AIR)—An area of land with boundaries established by final treaty, statute, executive order, and/or court order and over which a federally recognized American Indian tribal government has governmental authority. Along with "reservation," designations such as colonies, communities, pueblos, rancherias, and reserves apply to AIRs.

Census block—A geographic area bounded by visible and/or invisible features shown on a map prepared by the Census Bureau. A block is the smallest geographic entity for which the Census Bureau tabulates and publishes decennial census data.

Coextensive—A description of two or more geographic entities that cover exactly the same area, with all boundaries shared.

Colonia—A small, generally unincorporated community located in one of the states on the U.S.-Mexico border where residents often build or provide their own housing and that usually lacks utilities, paved roads, and other infrastructure typically found other similarly sized communities.

Comunidad—A CDP in Puerto Rico that is not related to a municipio's seat of government, called an aldea or a ciudad prior to the 1990 Census.

Contiguous—A description of areas sharing common boundary lines, more than a single point, such that the areas, when combined, form a single piece of territory. Noncontiguous areas form disjoint pieces.

Housing unit—A house, an apartment, a mobile home or trailer, or a group of rooms or a single room occupied as a separate living quarter or, if vacant, intended for occupancy as a separate living quarter. Separate living quarters are those in which the occupants live and eat separately from any other residents of the building and which have direct access from outside the building or through a common hall.

Incorporated place—A type of governmental unit, incorporated under state law as a city, town (except in New England, New York, and Wisconsin), borough (except in Alaska and New York), or village, generally to provide governmental services for a concentration of people within legally prescribed boundaries.

Minor civil division (MCD)—The primary governmental or administrative division of a county in 28 states and the Island Areas having legal boundaries, names, and descriptions. The MCDs represent many different types of legal entities with a wide variety of characteristics, powers, and functions depending on the state and type of MCD. In some states, some or all of the incorporated places also constitute MCDs.

Municipio—A type of governmental unit that is the primary legal subdivision of Puerto Rico. The Census Bureau treats the municipio as the statistical equivalent of a county.

Nonvisible feature—A map feature that is not visible on the ground and in imagery such as a city or county boundary through space, a property line, or line-of-sight extension of a road.

Statistical geographic entity—A geographic entity that is specially defined and delineated, such as block group, CDP, or census tract, so that the Census Bureau may tabulate data for it. Designation as a statistical entity neither conveys nor confers legal ownership, entitlement, or jurisdictional authority.

Urbanized area (UA)—An area consisting of a central place(s) and adjacent urban fringe that together have a minimum residential population of at least 50,000 people and generally an overall population density of at least 1,000 people per square mile. The Census Bureau uses published criteria to determine the qualification and boundaries of UAs at the time of each decennial census.

Visible feature—A map feature that can be seen on the ground and in

imagery, such as a road, railroad track, major above-ground transmission line or pipeline, river, stream, shoreline, fence, sharply defined mountain ridge, or cliff. A nonstandard visible feature is a feature that may not be clearly defined on the ground (such as a ridge), may be seasonal (such as an intermittent stream), or may be relatively impermanent (such as a fence). The Census Bureau generally requests verification that nonstandard features used as boundaries for the PSAP geographic areas pose no problem in their location during field work.

Zona urbana—In Puerto Rico, the settled area functioning as the seat of government for a municipio. A zona urbana cannot cross a municipio boundary.

Dated: October 30, 2018.

Ron S. Jarmin,

Deputy Director, Performing the Non-Exclusive Functions and Duties of the Director, Bureau of the Census.

[FR Doc. 2018–24571 Filed 11–9–18; 8:45 am]

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DEPARTMENT OF COMMERCE

Bureau of the Census

[Docket Number 180926886–8886–01]

Block Groups for the 2020 Census— Final Criteria

AGENCY: Bureau of the Census, Commerce.

ACTION: Notice of final criteria and program implementation.

SUMMARY: Block groups are statistical geographic subdivisions of a census tract defined for the tabulation and presentation of data from the decennial census and selected other statistical programs. Block groups also will be used to tabulate and publish estimates from the American Community Survey (ACS) after 2020 and potentially data from other Bureau of the Census (Census Bureau) censuses and surveys. The Census Bureau is publishing this notice in the **Federal Register** to announce final criteria for defining block groups for the 2020 Census Participant Statistical Areas Program (PSAP). In addition to block groups, the program also encompasses the review and update of census tracts, census designated places, and census county divisions.

DATES: This notice's final criteria will be applicable on December 13, 2018.

FOR FURTHER INFORMATION CONTACT: Requests for additional information on this program should be directed to

Vincent Osier at the Geographic Standards, Criteria, and Quality Branch, Geography Division, U.S. Census Bureau, via email at geo.psap.list@census.gov or by telephone at 301–763–3056.

SUPPLEMENTARY INFORMATION:

Background

Block groups are statistical geographic subdivisions of a census tract defined for the tabulation and presentation of data from the decennial census and selected other statistical programs. Block groups also will be used to tabulate and publish estimates from the American Community Survey (ACS)¹ after 2020 and potentially data from other Bureau of the Census (Census Bureau) censuses and surveys.

The Census Bureau is publishing this notice in the **Federal Register** to announce final criteria for defining block groups for the 2020 Census. In addition to providing final criteria for block groups, this notice also contains a summary of comments received in response to proposed criteria published in the **Federal Register** on February 15, 2018 (83 FR 6937), as well as the Census Bureau's response to those comments. After publication of this final criteria in the **Federal Register**, the Census Bureau will offer designated governments or organizations an opportunity to review and, if necessary, suggest updates to the boundaries and attributes of the block groups in their geographic area under the Participant Statistical Areas Program (PSAP). In addition to block groups, the program also encompasses the review and update of census tracts, census designated places, and census county divisions. The Census Bureau published a notice, explaining PSAP process and participation, in the **Federal Register** on November 28, 2017 (82 FR 56208).

I. History of Block Groups

The Census Bureau first delineated block groups as statistical geographic divisions of census tracts for the 1970 Census, comprising contiguous combinations of census blocks for data presentation purposes. At that time, census block groups only existed in urbanized areas in which census blocks were defined. Block groups were defined without regard to political and administrative boundaries, with an average population of 1,000, and to be approximately equal in area.

¹ The ACS is conducted in the United States and in Puerto Rico. In Puerto Rico the survey is called the Puerto Rico Community Survey. For ease of discussion, throughout this document the term ACS is used to represent the surveys conducted in the United States and in Puerto Rico.

As use of census block, block group, and census tract data increased among data users, the Census Bureau expanded these programs to cover additional geographic areas while redefining the population threshold criteria to more adequately suit data users' needs. The 1990 Census was the first in which census blocks and block groups were defined throughout the entirety of the United States, Puerto Rico, and the Island Areas. For the 2000 Census, as with census tracts, the Census Bureau increased the number of geographic areas whose boundaries could be used as block group boundaries, and allowed tribal governments of federally recognized American Indian tribes with a reservation and/or off-reservation trust lands to delineate tribal block groups without regard to state and/or county boundaries, provided the tribe had a 1990 Census population of at least 1,000.

For the 2010 Census, the Census Bureau adopted changes to block group criteria that recognized their utility as a framework of small geographic areas and established tribal block groups as a geographic framework for presenting and analyzing statistical and other data for a variety of communities, settlement patterns, and landscapes. The Census Bureau augmented its minimum and maximum population threshold with housing unit thresholds for use in defining block groups for seasonal communities that have no or low population on census day (April 1). In addition, the Census Bureau formalized criteria for block groups defined for employment centers, airports, parks, large water bodies, and other special land uses that had been permitted in previous decades, but never specified within the criteria. The Census Bureau also established tribal block groups as a geographic framework defined within federally recognized American Indian reservations and off-reservation trust lands that is fully separate from the standard block groups defined within counties.

II. Summary of Comments Received in Response to the Proposed Criteria

The **Federal Register** notice published on February 15, 2018 (83 FR 6937) requested comment on the proposed block group criteria for the 2020 Census. The proposed criteria were unchanged from the final criteria adopted for the 2010 Census.

The Census Bureau received comments from 16 individuals on one or more topics related to (1) use of non-visible political boundaries when defining block groups, (2) use of employment data to define block groups

encompassing areas with substantial amounts of commercial, industrial, or other non-residential activity for the purpose of transportation planning, and (3) defining block groups to align with former census tract boundaries when census tracts are merged. Commenters represented state and local government agencies, regional planning organizations and councils of governments, state data centers, and non-governmental organizations. Comments received by the Census Bureau are summarized below, as well as the Census Bureau's response to these comments.

1. Using Non-Visible Minor Civil Division Boundaries in Michigan as Block Group Boundaries

The Census Bureau received three comments from individuals in Michigan noting that all minor civil division (MCD) boundaries in Michigan should be permitted to be block group boundaries for the 2020 Census as was the case in the past. The commenters correctly noted that in Table 1, Acceptable Minor Civil Division and Incorporated Place Boundaries, the proposed criteria were in error with regard to Michigan. The Census Bureau has corrected the table in the final criteria.

2. Defining Block Groups on the Basis of Employment and Jobs

The Census Bureau received 14 comments related to defining block groups encompassing areas with concentrations of employment and jobs or other types of non-residential uses to improve the utility of block groups for transportation and journey-to-work analysis and planning. Eleven commenters suggested adoption of a minimum threshold of 600 workers/jobs (and no maximum or optimum thresholds) to be applied as an alternative to the existing minimum population or housing unit threshold or in combination with population or housing unit thresholds. One commenter supported the use of worker/job counts when defining block groups, but did not specify a minimum threshold. Two commenters expressed support for modifying criteria for special use block groups primarily to improve identification of block groups encompassing areas with concentrations of employment. One of these commenters noted that applying employment thresholds was not necessary as the sample design for the American Community Survey (which is the source for much of the demographic data used in journey-to-work analysis) focused on residential population

concentrations and not employment concentrations. Changes to the special use block group criteria could achieve the result desired by commenters proposing employment thresholds and could also provide greater flexibility when defining block groups.

Based on consideration of the comments received on this topic and further discussion with stakeholders in the transportation community, the Census Bureau will change its criteria for defining special use block groups to no longer specify minimum land area requirements. Special use block groups should be comparable in land area size to surrounding block groups so as to assure data reliability and quality when reporting on workplace-related data and to avoid data disclosure issues. The Census Bureau also recommends that, when defining special use block groups encompassing employment centers and areas with concentrations of jobs, PSAP participants should strive for a minimum threshold of 600 workers/jobs.

3. Defining Block Groups To Follow Former Census Tract Boundaries

One commenter proposed that, when census tracts are merged, an effort should be made to align the boundaries for block groups within the new census tract with the boundaries of the former census tracts that were merged. The commenter noted that this would facilitate historical comparisons of data, particularly when chronicling change in the sociodemographic characteristics of neighborhoods, allowing data users to use block group data to bridge back to previous decades' census tracts.

The Census Bureau agrees with the sentiments expressed by this commenter. We also agree with the suggestion to align block group boundaries with the boundaries of former census tracts in those instances in which census tracts have been merged and will update both the final block group and final census tract criteria accordingly.

III. General Principles and Criteria for Block Groups for the 2020 Census

A. General Principles

1. Block groups are statistical geographic subdivisions of a census tract and are the smallest geographic areas for which the Census Bureau provides sample data, primarily from the ACS 5-year period estimates.
2. Block groups form the geographic framework within which census blocks are numbered.
3. In order to ensure a minimal level of reliability in sample data and

minimize potential disclosures of sensitive information, a block group should contain either at least 600 people or at least 240 housing units at minimum, and 3,000 people or 1,200 housing units at maximum. The housing unit criterion is used to accommodate areas that are occupied seasonally and may otherwise show a discrepancy between decennial and ACS figures.² For the ACS, block groups are not designed to be used individually, rather they provide a smaller geographic area than census tracts that allow data users to combine them to create larger geographic areas that may be more meaningful for their specific use.

4. The Census Bureau also recognizes that there are significant geographic areas that are characterized by unique populations (e.g., prisons or universities) or not characterized by residential populations at all (e.g., National Parks or large bodies of water) which local participants may wish to exclude from populated block groups for either analytical or cartographic purposes. These areas may be designated as special use block groups to distinguish them from standard populated block groups. Special land and/or water use block groups are not required, but if delineated they must be designated as a specific type of special use (discussed below), have an official name, ideally have no residential population or housing units or at least meet all minimum population or housing thresholds mentioned above, and must not create noncontiguous block groups. While there are no longer minimum land area measurement thresholds for special uses block groups in urban or rural areas, such block groups should be comparable in size to surrounding block groups, particularly if defined to encompass employment centers or other areas containing a greater concentration of jobs than residents. The Census Bureau recognizes that some special use areas not intended for residential population, such as parks, may contain some minimal population, such as caretakers or the homeless, but since the primary purpose of block groups is to help provide high-quality statistical data about the population, the participant and the Census Bureau must decide if a special use block group would be useful in such a situation.

² "Occupied seasonally" refers to seasonal communities in which residents often are not present on the date of the decennial census, but will be present at other times of the year and for which estimates may be reflected in the ACS. The ACS is designed to produce local area data as of a 12-month period estimate (or an average).

B. Criteria

The criteria herein apply to the United States, including federally recognized American Indian reservations (AIRs) and off-reservation trust lands (ORTLs), Puerto Rico, and the Island Areas.³ The Census Bureau may modify and, if necessary, reject any proposals for block groups that do not meet the published criteria. In addition, the Census Bureau reserves the right to modify the boundaries and attributes of block groups as needed to meet the published criteria and/or maintain geographic relationships before or after the final tabulation geography is set for the 2020 Census.

The Census Bureau sets forth the following criteria for use in reviewing, updating, and delineating 2020 Census block groups:

1. Block groups must not cross census tract boundaries.

This criterion takes precedence over all other criteria or requirements. By definition, because census tracts cannot cross county⁴ and state boundaries, neither can block groups. It is only permissible to define a block group with fewer than 600 people in a county that has a population less than 600, coextensive with a special use census tract, or as a special use block group delineated within a standard census tract.

2. Block groups must cover the entire land and water area of each census tract.

³ For Census Bureau purposes, the United States typically refers to only the fifty states and the District of Columbia, and does not include the U.S. territories (Puerto Rico, the Island Areas, and the U.S. Minor Outlying Islands). The Island Areas includes American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, and the U.S. Virgin Islands. The U.S. Minor Outlying Islands are an aggregation of nine U.S. territories: Baker Island, Howland Island, Jarvis Island, Johnston Atoll, Kingman Reef, Midway Islands, Navassa Island, Palmyra Atoll, and Wake Island.

⁴ For the Census Bureau's purposes, the term "county" includes parishes in Louisiana; boroughs, city and boroughs, municipalities, and census areas in Alaska; independent cities in Maryland, Missouri, Nevada, and Virginia; districts and islands in American Samoa; districts in the U.S. Virgin Islands; municipalities in the Commonwealth of the Northern Mariana Islands; municipios in Puerto Rico; and the areas constituting the District of Columbia and Guam. This notice will refer to all these entities collectively as "counties".

Because census tracts must cover the entire area of a county, by definition, block groups also must cover the entire area of each census tract within each county.

3. A block group must comprise a reasonably compact and contiguous land area.

Noncontiguous boundaries are permitted only where a contiguous area or inaccessible area would not meet population or housing unit count requirements for a separate block group, in which case the noncontiguous or inaccessible area must be combined within an adjacent or proximate block group. For example, an island that does not meet the minimum population threshold for recognition as a separate block group should be combined with other proximate land to form a single block group. Each case will be reviewed and accepted at the Census Bureau's discretion.

4. Block group boundaries should follow visible and identifiable features.

To make the location of block group boundaries less ambiguous, wherever possible, block group boundaries should follow significant, visible, easily identifiable features. The use of visible features facilitates the location and identification of block group boundaries in the field, both on the ground and in imagery. The selection of permanent physical features also increases the stability of the boundaries over time, as the locations of many visible features in the landscape tend to change infrequently. If block group boundaries are changed, they should not be moved from a more significant feature (e.g., a highway or a major river) to a less significant feature (e.g., a neighborhood road or a small tributary stream). The Census Bureau also requires the use of state and county boundaries in all states to be used as census tract and block group boundaries. The Census Bureau also permits the use of incorporated place and minor civil division (MCD) boundaries in states where those boundaries tend to remain unchanged over time (see Table 1).

The following features are preferred as block group boundaries for the 2020 Census:

a. State, county, and census tract boundaries must always be block group

boundaries. This criterion takes precedence over all other boundary criteria or requirements.

b. AIR and ORTL boundaries.

c. Visible, perennial, stable, relatively permanent natural and constructed features, such as roads, shorelines, rivers, perennial streams and canals, railroad tracks, or above-ground high-tension power lines.

d. Boundaries of legal and administrative entities in selected states. Table 1 identifies by state which MCD and incorporated place boundaries may be used as block group boundaries.

e. Additionally, the following legally defined, administrative boundaries are permitted as block group boundaries:

i. Barrio, barrio-pueblo, and subbarrio boundaries in Puerto Rico;

ii. Census subdistrict and estate boundaries in the U.S. Virgin Islands;

iii. County and island boundaries (both MCD equivalents) in American Samoa;

iv. Election district boundaries in Guam;

v. Municipal district boundaries in the Commonwealth of the Northern Mariana Islands; and

vi. Alaska Native Regional corporation boundaries in Alaska, at the discretion of the Census Bureau, insofar as such boundaries are unambiguous for allocating living quarters as part of 2020 Census activities.

f. The boundaries of large parks, forests, airports, penitentiaries/prisons, and/or military installations, provided the boundaries are clearly marked or easily recognized in the field in imagery and on the ground.

g. When acceptable visible and governmental boundary features are not available for use as block group boundaries, the Census Bureau may, at its discretion, approve other nonstandard visible features, such as major ridgelines, above-ground pipelines, intermittent streams, or fence lines. The Census Bureau may also accept, on a case-by-case basis, relatively short stretches of boundaries of selected nonstandard and potentially nonvisible features, such as cadastral and parcel boundaries or the straight-line extensions or other lines-of-sight between acceptable visible features.

TABLE 1—ACCEPTABLE MINOR CIVIL DIVISION (MCD) AND INCORPORATED PLACE BOUNDARIES

State	All MCD boundaries	Boundaries of MCDs not coincident with the boundaries of incorporated places that themselves are MCDs	All incorporated place boundaries	Only conjoint incorporated place boundaries
Alabama				X
Alaska				X
Arizona				X
Arkansas				X
California				X
Colorado				X
Connecticut	X		X	
Delaware				X
Florida				X
Georgia				X
Hawaii				
Idaho				X
Illinois		X ^a		X
Indiana	X			X
Iowa		X		X
Kansas		X		X
Kentucky				X
Louisiana				X
Maine	X		X	
Maryland				X
Massachusetts	X		X	
Michigan		X		X
Minnesota		X		X
Mississippi				X
Missouri		X ^b		X
Montana				X
Nebraska		X ^a		X
Nevada				X
New Hampshire	X		X	
New Jersey	X		X	
New Mexico				X
New York	X		X	
North Carolina				X
North Dakota		X		X
Ohio		X		X
Oklahoma				X
Oregon				X
Pennsylvania	X		X	
Rhode Island	X		X	
South Carolina				X
South Dakota		X		X
Tennessee				X
Texas				X
Utah				X
Vermont	X		X	
Virginia				X
Washington				X
West Virginia				X
Wisconsin		X		X
Wyoming				X

^a Townships only.

^b Governmental townships only.

5. Population, Housing Unit, and Area Measurement Thresholds

The following are the population, housing unit, and area measurement

threshold criteria for block groups (as summarized in Table 2). The same population and housing unit thresholds apply to all types of non-special use

block groups, including those delineated for AIRs and ORTLs, the Island Areas, and encompassing group quarters, military installations, and institutions.

TABLE 2—BLOCK GROUP THRESHOLDS

Block group type	Threshold types	Minimum	Maximum
Standard & tribal block groups	Population thresholds	600	3,000
	Housing unit thresholds	240	1,200
Special use block groups	Area measurement	At least comparable in land area size to surrounding block groups.	At least comparable in land area size to surrounding block groups.
	Population thresholds	None (or very little), or must be within the standard block group thresholds.	

a. 2010 Census population counts should be used in census block group review in most cases. Housing unit counts should be used for block groups in seasonal communities that have little or no population on Census Day (April 1). Locally produced population and housing unit estimates can be used when reviewing and updating block groups, especially in areas that have experienced considerable growth since the 2010 Census.

b. The housing unit thresholds are based on a national average of 2.5 people per household. The Census Bureau recognizes that there are regional variations to this average, and will take this into consideration when reviewing all census block group proposals.

c. For the 2020 Census, the Census Bureau will allow the delineation of special use census tracts, and special use block groups will be created

coextensive with these special use census tracts, but they are not required. A special use census tract, and hence a special use block group, must be designated as a specific use type (e.g., state park), must have an official name (e.g., Jay Cooke State Park), have no (or very little) residential population or meet population or housing unit thresholds, and must not create a noncontiguous census tract/block group. In some instances, multiple areas can be combined to form a single special land use census tract/block group if the land management characteristics are similar, such as a special land use census tract/block group comprising an area with a concentration of employment or adjacent federal and state parks. Any resulting special use census tract/block group should be at least as large in area as the surrounding adjacent standard, populated census tracts/block groups.

6. Identification of Block Groups

a. A block group encompasses a cluster of census blocks. Each standard block group is identified using a single-digit number that will correspond to the first digit in the number of each census block encompassed by the block group. For example, block group 3 includes all census blocks numbered in the 3000 range within a single census tract.

b. The range of acceptable standard block group numbers is 1 through 9.

c. Block group numbers must be unique within a census tract.

7. Block Group Types

Table 3 provides a summary of the types of block groups (with their respective population, housing unit, and area measurement thresholds) that the Census Bureau will use for the 2020 Census.

TABLE 3—SUMMARY OF BLOCK GROUP TYPES

Block group types	Distinction from standard block groups	Population thresholds	Housing unit thresholds	Area measurement thresholds
Standard block groups	Min: 600, Max: 3,000	Min: 240, Max: 1,200	None.
Tribal block groups	Tribal block groups are conceptually similar and equivalent to census block groups defined within the standard state-county-tract-block group geographic hierarchy used for tabulating and publishing statistical data.	Min: 600, Max: 3,000	Min: 240, Max: 1,200	None.
Special use block groups.	A block group, usually coextensive with a special census tract, encompassing an employment center, large airport, public park, public forest, or large water body with no (or very little) population or housing units.	None (or very little) or within the standard block group thresholds.	None (or very little) or within the standard block group thresholds.	At least comparable in size to surrounding standard block groups.

C. Tribal Block Groups

Tribal block groups are statistical geographic entities defined by the Census Bureau in cooperation with tribal officials to provide meaningful, relevant, and reliable data for small geographic areas within the boundaries of federally recognized AIRs and/or ORTLs. As such, they recognize the unique statistical data needs of federally recognized American Indian tribes. The delineation of tribal block groups allows for an unambiguous presentation of

statistical data specific to the federally recognized AIR and/or ORTL without the imposition of state or county boundaries, which might artificially separate American Indian populations located within a single AIR and/or ORTL. To this end, the American Indian tribal participant may define tribal block groups that cross county or state boundaries, or both. For federally recognized American Indian tribes with AIRs and/or ORTLs that have fewer than 1,200 residents, the Census Bureau will

define one tribal census tract and one tribal block group coextensive with the AIR and/or ORTL. Tribal block groups must be delineated to meet all other census block group criteria, and must be identified uniquely so as to clearly distinguish them from county-based block groups. The Census Bureau will address the type of identifiers required for tribal block groups in more detail in a separate **Federal Register** notice pertaining to all American Indian areas, including statistical areas defined

through PSAP. Tribal block group boundaries will be held as census block boundaries. Census blocks, however, will be numbered uniquely within county-based block groups, and thus there will not be a direct relationship between a tribal block group identifier and the census block numbers. Tribal block groups are conceptually similar and equivalent to census block groups defined within the standard state-county-tract-block group geographic hierarchy used for tabulating and publishing statistical data.

In order to provide meaningful statistical geographic areas within the AIR and/or ORTL, as well as make meaningful and reliable data available for these areas and their populations, tribal block group geography is maintained separately from standard, county-based block groups. This change was first introduced for the 2010 Census, creating standard block groups nationwide and maintaining tribal block groups as a completely separate set of geography from standard block groups for both geographic and data presentation purposes, and eliminates, in part, the reliability and availability data issues for the tribal block groups and the derived standard block groups that were present in Census 2000.⁵

As with standard block groups submitted through this program, the tribal block groups are submitted to the Census Bureau, and are subject to review to ensure compliance with the published criteria. Detailed criteria pertaining to tribal block groups will be published in a separate **Federal Register** notice pertaining to all American Indian areas, including statistical areas defined through PSAP.

IV. Definitions of Key Terms

Alaska Native Regional Corporation (ANRC)—A corporate geographic area established under the Alaska Native Claims Settlement Act (Pub. L. 92–203, 85 Stat. 688 (1971)) to conduct both the business and nonprofit affairs of Alaska Natives. Twelve ANRCs cover the entire state of Alaska except for the Annette Island Reserve.

⁵ For Census 2000, tribal block groups were defined for federally recognized AIRs and/or ORTLs, and standard block groups were identified by superimposing county and state boundaries onto the Census 2000 tribal block groups. For Census 2000 products in which data were presented by state and county, the standard state-county-tract-block group hierarchy was maintained, even for territory contained within an AIR and/or ORTL. In such instances, the state-county portions of tribal block groups were identified as individual block groups, and these standard block groups may not have met the minimum population or housing unit thresholds, potentially limiting sample data reliability or availability for both the tribal block groups and the derived standard block groups.

American Indian off-reservation trust land (ORTL)—An area of land located outside the boundaries of an AIR, whose boundaries are established by deed, and which are held in trust by the U.S. federal government for a federally recognized American Indian tribe or members of that tribe.

American Indian reservation (AIR)—An area of land with boundaries established by final treaty, statute, executive order, and/or court order and over which a federally recognized American Indian tribal government has governmental authority. Along with “reservation”, designations such as colonies, communities, pueblos, rancherías, and reserves apply to AIRs.

Conjoint—A description of a boundary line shared by two adjacent geographic entities.

Contiguous—A description of areas sharing common boundary lines, more than a single point, such that the areas, when combined, form a single piece of territory. Noncontiguous areas form disjoint pieces.

Group quarters—A location where people live or stay in a group living arrangement that is owned or managed by an entity or organization providing housing and/or services for the residents. This is not a typical household-type living arrangement. These services may include custodial or medical care as well as other types of assistance, and residency is commonly restricted to those receiving these services. People living in group quarters are usually not related to each other. Group quarters include such places as college residence halls, residential treatment centers, skilled nursing facilities, group homes, military barracks, correctional facilities, and workers’ dormitories.

Incorporated place—A type of governmental unit, incorporated under state law as a city, town (except in New England, New York, and Wisconsin), borough (except in Alaska and New York), or village, generally to provide governmental services for a concentration of people within legally prescribed boundaries.

Minor civil division (MCD)—The primary governmental or administrative division of a county in 28 states and the Island Areas having legal boundaries, names, and descriptions. The MCDs represent many different types of legal entities with a wide variety of characteristics, powers, and functions depending on the state and type of MCD. In some states, some or all of the incorporated places also constitute MCDs.

Nonvisible feature—A map feature that is not visible on the ground and in

imagery such as a city or county boundary through space, a property line, or line-of-sight extension of a road.

Retracting—Substantially changing the boundaries of a census tract so that comparability over time is not maintained.

Special use census tract/block group—Type of census tract or block group that must be designated as a specific use type (e.g., state park or large lake) and have an official name (e.g., Jay Cooke State Park or Lake Minnetonka), should have no (or very little) population or housing units, and must not create a noncontiguous census tract/block group. If delineated in a densely populated, urban area, a special use census tract/block group must have an area of at least one square mile. If delineated completely outside an urban area, a special use census tract/block group must have an area of at least 10 square miles.

Statistical geographic entity—A geographic entity that is specially defined and delineated, such as block group, CDP, or census tract, so that the Census Bureau may tabulate data for it. Designation as a statistical entity neither conveys nor confers legal ownership, entitlement, or jurisdictional authority.

Visible feature—A map feature that can be seen on the ground and in imagery, such as a road, railroad track, major above-ground transmission line or pipeline, river, stream, shoreline, fence, sharply defined mountain ridge, or cliff. A nonstandard visible feature is a feature that may not be clearly defined on the ground (such as a ridge), may be seasonal (such as an intermittent stream), or may be relatively impermanent (such as a fence). The Census Bureau generally requests verification that nonstandard features used as boundaries for the PSAP geographic areas pose no problem in their location during field work.

Dated: November 1, 2018.

Ron S. Jarmin,

Deputy Director, Performing the Non-Exclusive Functions and Duties of the Director, Bureau of the Census.

[FR Doc. 2018–24570 Filed 11–9–18; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE**International Trade Administration**

[A-570-071, C-570-072]

Sodium Gluconate, Gluconic Acid, and Derivative Products From the People's Republic of China: Antidumping Duty and Countervailing Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: Based on affirmative final determinations by the Department of Commerce (Commerce) and the International Trade Commission (ITC), Commerce is issuing antidumping duty (AD) and countervailing duty (CVD) orders on sodium gluconate, gluconic acid, and derivative products (GNA Products) from the People's Republic of China (China).

DATES: Applicable November 13, 2018.

FOR FURTHER INFORMATION CONTACT: Magd Zalok (AD) at (202) 482-4162 or Robert Galantucci (CVD) at (202) 482-2923, AD/CVD Operations, Office IV, Enforcement and Compliance, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:**Background**

In accordance with sections 705(d) and 735(d) of the Tariff Act of 1930, as amended (the Act), on September 21, 2018, Commerce published its affirmative final determination of sales at less than fair value (LTFV) and its affirmative final determination that countervailable subsidies are being provided to producers and exporters of GNA Products from China.¹ On October 31, 2018, the ITC notified Commerce of its final affirmative determination that an industry in the United States is materially injured by reason of LTFV imports and subsidized imports of GNA Products from China, within the meaning of sections 705(b)(1)(A)(i) and 735(b)(1)(A)(i) of the Act.²

Scope of the Orders

The scope of the orders covers all grades of sodium gluconate, gluconic acid, liquid gluconate, and glucono delta lactone (GDL) (collectively GNA

Products), regardless of physical form (including, but not limited to substrates; solutions; dry granular form or powders, regardless of particle size; or as a slurry). The scope also includes GNA Products that have been blended or are in solution with other product(s) where the resulting mix contains 35 percent or more of sodium gluconate, gluconic acid, liquid gluconate, and/or GDL by dry weight.

Sodium gluconate has a molecular formula of NaC₆H₁₁O₇. Sodium gluconate has a Chemical Abstract Service (CAS) registry number of 527-07-1, and can also be called "sodium salt of gluconic acid" and/or sodium 2, 3, 4, 5, 6 pentahydroxyhexanoate. Gluconic acid has a molecular formula of C₆H₁₂O₇. Gluconic acid has a CAS registry number of 526-95-4, and can also be called 2, 3, 4, 5, 6 pentahydroxycaproic acid. Liquid gluconate is a blend consisting only of gluconic acid and sodium gluconate in an aqueous solution. Liquid gluconate has CAS registry numbers of 527-07-1, 526-95-4, and 7732-18-5, and can also be called 2, 3, 4, 5, 6-pentahydroxycaproic acid-hexanoate. GDL has a molecular formula of C₆H₁₀O₆. GDL has a CAS registry number of 90-80-2, and can also be called d-glucono-1,5-lactone.

The merchandise covered by the scope of the orders is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 2918.16.1000, 2918.16.5010, and 2932.20.5020. Merchandise covered by the scope may also enter under HTSUS subheadings 2918.16.5050, 3824.99.2890, and 3824.99.9295. Although the HTSUS subheadings and CAS registry numbers are provided for convenience and customs purposes, the written description of the merchandise is dispositive.

Antidumping Duty Order

In accordance with section 735(d) of the Act, the ITC has notified Commerce of its final determination that an industry in the United States is materially injured within the meaning of section 735(b)(1)(A)(i) of the Act by reason of imports of GNA Products that are sold in the United States at LTFV.

Therefore, in accordance with section 735(c)(2) of the Act, we are publishing this antidumping duty order. Because the ITC determined that imports of GNA Products from China are materially injuring a U.S. industry, unliquidated entries of such merchandise from China, entered or withdrawn from warehouse for consumption, are subject to the assessment of antidumping duties.

In accordance with section 736(a)(1) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to assess, upon further instruction by Commerce, antidumping duties equal to the amount by which the normal value of the merchandise exceeds the export price (or constructed export price) of the merchandise, for all relevant entries of GNA Products from China. Antidumping duties will be assessed on unliquidated entries of GNA Products from China entered, or withdrawn from warehouse, for consumption on or after July 10, 2018, the date of publication of the *AD Preliminary Determination*.³

Continuation of Suspension of Liquidation (AD)

In accordance with section 735(c)(1)(B) of the Act, we will instruct CBP to continue to suspend liquidation on entries of subject merchandise from China. These instructions suspending liquidation will remain in effect until further notice.

We will also instruct CBP to require cash deposits equal to the amount indicated below. Accordingly, effective on the date of publication of the ITC's final affirmative injury determination, CBP will require, at the same time as importers would normally deposit estimated duties on this subject merchandise, a cash deposit equal to the estimated weighted-average dumping margins listed below. Commerce has made no adjustments to the antidumping cash deposit rate because Commerce has made no findings in the countervailing duty investigation that any of the programs are export subsidies.⁴

Estimated Weighted-Average Antidumping Duty Margin

The weighted-average antidumping duty margin is as follows:

¹ See *Sodium Gluconate, Gluconic Acid, and Derivative Products from the People's Republic of China: Final Affirmative Determination of Sales at Less Than Fair Value*, 83 FR 47876 (September 21, 2018) (*AD Final Determination*); *Sodium Gluconate, Gluconic Acid and Derivative Products from the People's Republic of China: Final Affirmative Countervailing Duty Determination*, 83 FR 47879 (September 21, 2018) (*CVD Final Determination*).

² See Letter to Honorable Gary Taverman, Acting Assistant Secretary of Commerce for Enforcement and Compliance, from David S. Johanson, Chairman of the U.S. International Trade Commission, regarding antidumping and countervailing duty investigations concerning imports of Sodium Gluconate, Gluconic Acid, and Derivative Products from the People's Republic of China (Investigation

Nos. 701-TA-590 and 731-TA-1397(Final)), dated October 31, 2018 (ITC Letter).

³ See *Sodium Gluconate, Gluconic Acid, and Derivative Products from the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value*, 83 FR 31949 (July 10, 2018).

⁴ See *AD Final Determination*, 83 FR at 47878.

Exporter	Producer	Weighted-average dumping margin (percent)
Anhui Xingzhou Medicine Food Co., Ltd	Xiwang Pharmaceutical Co., Ltd	213.15
Anhui Xingzhou Medicine Food Co., Ltd	Zhucheng Shuguang Biotech Co., Ltd	213.15
	China-wide Entity ⁵	213.15

Countervailing Duty Order

In accordance with section 705(d) of the Act, the ITC notified Commerce of its final determination that the industry in the United States producing GNA Products is materially injured within the meaning of section 705(b)(1)(A)(i) of the Act by reason of subsidized imports of GNA Products from China.⁶ Therefore, in accordance with section 705(c)(2) of the Act, we are publishing this countervailing duty order. Because the ITC determined that imports of GNA Products from China are materially injuring a U.S. industry, unliquidated entries of such merchandise from China, entered or withdrawn from warehouse for consumption, are subject to assessment of countervailing duties.

Commerce directed CBP to assess, upon further instruction by Commerce, countervailing duties on unliquidated entries of GNA Products entered, or withdrawn from warehouse, for consumption on or after May 23, 2018, the date of publication of the *CVD Preliminary Determination*.⁷ However, section 703(d) of the Act states that the suspension of liquidation pursuant to a preliminary determination may not remain in effect for more than 120 days. Therefore, we instructed CBP to terminate the suspension of liquidation and to liquidate, without regard to countervailing duties, unliquidated entries of GNA Products from China entered, or withdrawn from warehouse, for consumption, on or after September 20, 2018, until and through the day preceding the date of publication of the **Federal Register**.

Suspension of Liquidation (CVD)

In accordance with section 706 of the Act, Commerce will instruct CBP to

⁵ The China-wide Entity includes Dezhou Huiyang Biotechnology Co., Ltd., Qingdao Dongxiao Enterprise Co., Ltd., Shandong Fuyang Biotechnology Co., Ltd./Shandong Fuyang Biology Starch Co., Ltd., and Zhejiang Tianyi Food Additives Co., Ltd.

⁶ See ITC Letter.

⁷ See *Sodium Gluconate, Gluconic Acid, and Derivative Products from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination with Final Antidumping Duty Determination*, 83 FR 23888 (May 23, 2018).

suspend liquidation on all entries of GNA Products from China, as further described below. These instructions suspending liquidation will remain in effect until further notice. Commerce will also instruct CBP to require cash deposits equal to the amounts as indicated below. Accordingly, effective on the date of publication of the ITC's final affirmative injury determination, CBP will require, at the same time as importers would normally deposit estimated duties on this subject merchandise, a cash deposit equal to the subsidy rates listed below. The all-others rate applies to all producers or exporters not specifically listed below, as appropriate.

Exporter/producer	Subsidy rate (percent)
Qingdao Dongxiao Enterprise Co., Ltd	194.67
Shandong Fuyang Biotechnology Co	194.67
Shandong Kaison Biochemical Co Ltd	194.67
Tongxiang Hongyu Chemical Co., Ltd	194.67
All-Others	194.67

Notification to Interested Parties

This notice constitutes the AD and CVD orders with respect to GNA Products from China pursuant to sections 736(a) and 706(a) of the Act. Interested parties can find an updated list of orders currently in effect by either visiting <http://enforcement.trade.gov/stats/iastats1.html>.

These orders are published in accordance with sections 706(a), 736(a), and 19 CFR 351.211(b).

Dated: November 2, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2018–24705 Filed 11–9–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–357–820, C–357–821]

Biodiesel From Argentina: Initiation of Changed Circumstances Reviews of the Antidumping and Countervailing Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is initiating changed circumstances reviews (CCR) of the antidumping duty (AD) and countervailing duty (CVD) orders on biodiesel from Argentina.

DATES: Applicable November 13, 2018.

FOR FURTHER INFORMATION CONTACT: Kathryn Wallace, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6251.

SUPPLEMENTARY INFORMATION:

Background

On January 4, 2018, and April 26, 2018, Commerce published the CVD and AD orders on biodiesel from Argentina.¹ On September 21, 2018, the GOA, joined by Vicentin S.A.I.C. (Vicentin) and LDC Argentina (LDC), requested that Commerce initiate a CCR of the AD order, and the GOA requested that Commerce initiate a CCR of the CVD order, in order to adjust the cash deposit rates established in the AD and CVD investigations to reflect changes to Argentina's export tax regime.² On

¹ See *Biodiesel from the Republic of Argentina and the Republic of Indonesia: Countervailing Duty Orders*, 83 FR 522 (January 4, 2018), corrected by *Biodiesel from the Republic of Argentina and the Republic of Indonesia: Countervailing Duty Orders*, 83 FR 3114 (January 23, 2018); see also *Biodiesel from Argentina and Indonesia: Antidumping Duty Orders*, 83 FR 18278 (April 26, 2018) (collectively, *Orders*).

² See GOA's Letter, "Biodiesel from Argentina: Request for Changed Circumstances Review," dated September 21, 2018 and filed on the record of A–357–820; see also GOA's Letter, "Biodiesel from Argentina: Request for Changed Circumstances Review," dated September 21, 2018 and filed on the

October 1, 2018, the National Biodiesel Board Fair Trade Coalition (petitioner) filed comments requesting that Commerce deny the GOA's request.³ On October 11, 2018, the GOA, Vicentin and LDC filed comments responding to the petitioner's October 1, 2018 comments.⁴ On October 15, 2018, the petitioner submitted information and data illustrating the improvements in the domestic industry since the imposition of the orders, and on October 23, 2018, the petitioner submitted further comments opposing the CCRs.⁵ Between September 26, 2018, and October 19, 2018, Commerce met with the GOA and the petitioner to discuss their submissions to the record.⁶

Scope of the Orders

The product covered by the *Orders* is biodiesel from Argentina. For a complete description of the scope of the *Orders*, see the appendix to this notice.

Initiation of Changed Circumstances Reviews

Pursuant to section 751(b)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.216(d), Commerce will conduct a CCR of an AD or CVD order when it receives information concerning, or a request from an interested party which demonstrates, changed circumstances sufficient to warrant such a review. However, section 751(b)(4) of the Act also provides that Commerce may not conduct a CCR of an investigation determination within 24 months of the date of the investigation determination in the absence of "good cause."

In its request for initiation, the GOA explains that there are changed

circumstances sufficient to warrant reconsideration of the AD and CVD final determinations. Regarding changed circumstances, the GOA provided information indicating that, since the *Orders*, there have been changes in the export tax regime, which was a key element in Commerce's analysis of: (1) The soybeans for less than adequate remuneration program in the CVD investigation; and (2) the particular market situation finding concerning the cost of soybean input prices in the AD investigation.⁷ In particular, the GOA attached three legislative decrees effecting changes across its export tax regime, including changes to the export taxes applied to soybeans, soybean oil, soy meal, and biodiesel. Decrees 793/2018 and 486/2018, issued after the investigations were finalized, in May and September 2018, respectively, decreased significantly the export tax on soybeans and other commodities in the soybean value chain (e.g., soybean oil, soy meal), and imposed a new biodiesel export tax. According to the decrees themselves, such changes were "necessary to continue fostering the convergence between the export tax applicable to {soybeans, soybean oil, soy meal} and that applicable to biodiesel,"⁸ and "in order to, among other objectives, implement the monetary, exchange or foreign trade policy, to stabilize internal prices and to address public financial needs."⁹ Additionally, Decree 793/2018, in addition to decreasing the export tax on soybeans, imposes new, temporary taxes on "all products" exported from Argentina. The decree's preamble references an underlying statutory regime, as well as the GOA's 2018 national budget, noting concerns with ensuring "fiscal convergence, an efficient tax policy and the gradual reduction of the tax burden."¹⁰ The GOA suggests that such changes indicate a revised focus on fiscal policy, and not the development of particular industries. The GOA documented that these changes are not merely theoretical or prospective but have been in full

effect as of September 2018. Furthermore, the GOA submitted information to support its claim that, since the imposition of the *Orders*, Argentine exporters have effectively been unable to ship biodiesel to the United States in light of combined AD and CVD cash deposit rates.¹¹ According to the GOA, this alleged inability to ship to the United States prevents the conduct of administrative reviews through which Commerce would typically reexamine findings from investigations.¹²

Additionally, the GOA provided two correlating reasons for satisfying the "good cause" requirement pursuant to section 751(b)(4) of the Act. First, the GOA explained that the changes it has made to its export tax system, discussed above, have virtually eliminated the export tax differential among products in the soybean value chain. Specifically, prior to the issuance of the CVD order, in December 2017, products in the soybean value chain (except biodiesel) were subject to an export tax of 27 to 30 percent, while biodiesel was subject to an export tax rate of zero percent.¹³ As of September 2018, the export tax on soybean products has been reduced to 18 percent, and the export tax on biodiesel has been increased to 15 percent, reducing the export tax differential from approximately 30 percent to 3 percent.¹⁴ The GOA also noted its belief that the remaining three percent differential is offset by the Most-Favored Nation tariff of 4.6 percent applied to U.S. biodiesel imports.¹⁵ Second, the GOA notes that the imposition of the AD and CVD rates (ranging from 60.44 percent to 86.23 percent, and 71.45 percent to 72.28 percent, respectively) has completely closed the U.S. market for Argentine biodiesel, reducing Argentina's biodiesel exports to the United States from approximately \$1.2 billion in 2016 to zero in 2018.¹⁶ The GOA notes the combined AD and CVD rates total at least 130 percent, depending on the producer and exporter.

In considering the GOA's request for a CCR, we note that Commerce has initiated CCRs to address a wide variety of issues, some of which otherwise may or may not be addressed in the context of an annual administrative review.¹⁷

record of C-357-821 (collectively, Requests for CCRs).

³ See Petitioner's Letter, "Biodiesel from Argentina: Petitioner's Opposition to the Government of Argentina's Requests for Changed Circumstances Reviews," dated October 1, 2018.

⁴ See GOA's Letter, "Biodiesel from Argentina: Response to Petitioners' Opposition to the Government of Argentina's Request for Changed Circumstances Review," dated October 11, 2018 (GOA's October 11, 2018 Submission).

⁵ See Petitioner's Letter, "Positive Impact of Orders from Argentina on Domestic Biodiesel Industry," dated October 15, 2018; see also Petitioner's Letter, "Biodiesel from Argentina: Petitioner's Response to Respondents' October 11, 2018 Submission," dated October 23, 2018.

⁶ See Memorandum, "AD/CVD Orders on Biodiesel from Argentina—Requests for Changes Circumstance Reviews," dated September 26, 2018; see also Memorandum, "Antidumping and Countervailing Duty Orders on Biodiesel from Argentina—Requests for Changed Circumstances Reviews: Ex Parte Meeting," dated October 4, 2018; see also Memorandum, "Antidumping and Countervailing Duty Orders on Biodiesel from Argentina—Requests for Changed Circumstances Reviews: Ex Parte Meeting," dated October 19, 2018.

⁷ See Requests for CCRs at 2, 4; see also *Biodiesel from the Republic of Argentina: Final Affirmative Countervailing Duty Determination*, 82 FR 53477 (November 16, 2017) and accompanying Issues and Decision Memorandum (*CVD Final Determination*) and *Biodiesel from Argentina: Final Determination of Sales at Less Than Fair Value and Final Determination of Critical Circumstances, in Part*, 83 FR 8837, and accompanying Issues and Decision Memorandum (*AD Final Determination*), which discussed these aspects of the final determinations.

⁸ Decree 486/2018. See Requests for CCRs at Attachment 3.

⁹ Decree 793/2018. See Requests for CCRs at Attachment 2.

¹⁰ *Id.*

¹¹ See GOA's October 11, 2018 Submission at 8.

¹² *Id.* (citing U.S. Census Data).

¹³ See Requests for CCRs at 3-4, Attachments 1-3.

¹⁴ *Id.*

¹⁵ See Requests for CCRs at 4.

¹⁶ See GOA's October 11, 2018 Submission at 8.

¹⁷ See, e.g., *Aluminum Extrusions from the People's Republic of China: Initiation and*

Here, although the issues raised by the GOA may be considered in the context of an administrative review under section 751(a) of the Act, there have been no shipments which could be the subject of an administrative review. Thus, under Commerce's normal administrative review procedures, we otherwise would not have an opportunity to review the substantial changes that the GOA has made to its export tax regime, which formed the basis for certain of our findings in the *AD Final Determination* and *CVD Final Determination*. These changes, as discussed in greater detail above, include legislative decrees that significantly reduced the export tax on soybeans and other soybean products which were examined in the underlying investigations, and imposed new export taxes on biodiesel and other goods which were not previously in place at the time of the investigations. In light of the above, including the information submitted by the GOA regarding a complete cessation of shipments of biodiesel from Argentina to the United States and the unique nature of the substantial changes to the GOA's export tax regime since the imposition of the *Orders*, we find that there is sufficient information and "good cause" to initiate CCRs.

Therefore, we are initiating CCRs pursuant to sections 751(b)(1) and (4) of the Act and 19 CFR 351.216(c) and (d) to assess the impacts of the GOA's revised export tax regime on the *AD Final Determination* and *CVD Final Determination*, as discussed above.

We intend to publish in the **Federal Register** a notice of preliminary results of the AD and CVD CCRs, in accordance with 19 CFR 351.221(b)(4) and 351.221(c)(3)(i), which will set forth the factual and legal conclusions upon which our preliminary results are based, and a description of any action proposed based on these results. Pursuant to 19 CFR 351.221(b)(4), interested parties will have an opportunity to comment on the preliminary results. We will issue the final results of review no later than 270

Preliminary Results of Expedited Changed Circumstances Review, 83 FR 34548 (July 20, 2018) (finding sufficient information to initiate a CCR to recalculate certain cash deposit rates); *Certain Steel Nails From Malaysia: Initiation of Antidumping Duty Changed Circumstances Review*, 80 FR 71772 (Nov. 17, 2015) (finding sufficient information and "good cause" to initiate a CCR to evaluate whether a company was properly utilizing the correct cash deposit rate); *Initiation of Changed Circumstances Countervailing Duty Administrative Reviews; Pure Magnesium and Alloy Magnesium From Canada*, 57 FR 41473 (Sept. 10, 1992) (finding sufficient information and "good cause" to initiate a CCR to evaluate changes to the major subsidy program at issue in the underlying investigation).

days after publication of this notice of initiation in accordance with 19 CFR 351.216(e).

This notice is published in accordance with section 751(b)(1) and 777(i) of the Act and 19 CFR 351.221(c)(3) of the Act.

Dated: November 5, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

APPENDIX

Scope of the Orders

The product covered by these orders is biodiesel, which is a fuel comprised of mono-alkyl esters of long chain fatty acids derived from vegetable oils or animal fats, including biologically-based waste oils or greases, and other biologically-based oil or fat sources. These orders cover biodiesel in pure form (B100), as well as fuel mixtures containing at least 99 percent biodiesel by volume (B99). For fuel mixtures containing less than 99 percent biodiesel by volume, only the biodiesel component of the mixture is covered by the scope of these order.

Biodiesel is generally produced to American Society for Testing and Materials International (ASTM) D6751 specifications, but it can also be made to other specifications. Biodiesel commonly has one of the following Chemical Abstracts Service (CAS) numbers, generally depending upon the feedstock used: 67784–80–9 (soybean oil methyl esters); 91051–34–2 (palm oil methyl esters); 91051–32–0 (palm kernel oil methyl esters); 73891–99–3 (rapeseed oil methyl esters); 61788–61–2 (tallow methyl esters); 68990–52–3 (vegetable oil methyl esters); 129828–16–6 (canola oil methyl esters); 67762–26–9 (unsaturated alkylcarboxylic acid methyl ester); or 68937–84–8 (fatty acids, C12–C18, methyl ester).

The B100 product subject to the orders is currently classifiable under subheading 3826.00.1000 of the Harmonized Tariff Schedule of the United States (HTSUS), while the B99 product is currently classifiable under HTSUS subheading 3826.00.3000. Although the HTSUS subheadings, ASTM specifications, and CAS numbers are provided for convenience and customs purposes, the written description of the scope is dispositive.

[FR Doc. 2018–24689 Filed 11–9–18; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

National Construction Safety Team Advisory Committee Meeting

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: The National Construction Safety Team (NCST) Advisory Committee (Committee) will hold an open meeting via teleconference on Tuesday, November 27, 2018 from 11:00 a.m. to 2:00 p.m. Eastern Time. The primary purpose of this meeting is to finalize the Committee's annual report to Congress. The agenda may change to accommodate Committee business. The final agenda will be posted on the NIST website at <https://www.nist.gov/topics/disaster-failure-studies/national-construction-safety-team-ncst/advisory-committee>.

DATES: The NCST Advisory Committee will meet on Tuesday, November 27, 2018 from 11:00 a.m. until 2:00 p.m. Eastern Time.

ADDRESSES: The meeting will be held via teleconference. For instructions on how to participate in the meeting, please see the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Melissa Banner, Administrative Office Assistant, Community Resilience Program, Engineering Laboratory, NIST, 100 Bureau Drive, Mail Stop 8615, Gaithersburg, Maryland 20899–8604. Ms. Banner's email address is Melissa.Banner@nist.gov; and her phone number is (301) 975–8912.

SUPPLEMENTARY INFORMATION: The Committee was established pursuant to Section 11 of the NCST Act (Pub. L. 107–231, codified at 15 U.S.C. 7301 *et seq.*). The Committee is currently composed of six members, appointed by the Director of NIST, who were selected on the basis of established records of distinguished service in their professional community and their knowledge of issues affecting the National Construction Safety Teams. The Committee advises the Director of NIST on carrying out the NCST Act; reviews the procedures developed for conducting investigations; and reviews the reports issued documenting investigations. Background information on the NCST Act and information on the NCST Advisory Committee is available at <https://www.nist.gov/topics/disaster-failure-studies/national-construction-safety-team-ncst/advisory-committee>.

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the NCST Advisory Committee will meet on Tuesday, November 27, 2018 from 11:00 a.m. until 2:00 p.m. Eastern Time. The meeting will be open to the public and will be held via teleconference. There will be no central meeting location. Interested members of the public will be

able to participate in the meeting from remote locations by calling into a central phone number. The primary purpose of this meeting is to finalize the Committee's annual report due to Congress. The agenda may change to accommodate Committee business. The final agenda will be posted on the NIST website at <https://www.nist.gov/topics/disaster-failure-studies/national-construction-safety-team-ncst/advisory-committee-meetings>.

Individuals and representatives of organizations who would like to offer comments and suggestions related to items on the Committee's agenda for this meeting are invited to request a place on the agenda. Approximately fifteen minutes will be reserved at the beginning of the meeting for public comments. Speaking times will be assigned on a first-come, first-served basis. The amount of time per speaker will be determined by the number of requests received. Questions from the public will not be considered during this period. All those wishing to speak must submit their request by email to the attention of Melissa Banner Melissa.Banner@nist.gov, by 5:00 p.m. Eastern Time, Friday, November 23, 2018. Speakers who wish to expand upon their oral statements, those who had wished to speak but could not be accommodated on the agenda, and those who were unable to attend are invited to submit written statements to the NCST, National Institute of Standards and Technology, 100 Bureau Drive, MS 8604, Gaithersburg, Maryland 20899-8604, or electronically by email to Benjamin.Davis@nist.gov.

Anyone wishing to participate in this meeting must register by 5:00 p.m. Eastern Time, Friday, November 23, 2018. To register please submit your first and last name, email address, and phone number to Melissa Banner at Melissa.Banner@nist.gov or (301) 975-8912. After registering, participants will be provided with detailed instructions on how to join the meeting remotely.

Kevin A. Kimball,
Chief of Staff.

[FR Doc. 2018-24639 Filed 11-9-18; 8:45 am]

BILLING CODE 3510-13-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XG596

Caribbean Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Caribbean Fishery Management Council will hold its 164th meeting in December to discuss the items contained in the agenda in the **SUPPLEMENTARY INFORMATION.**

DATES: The meetings will be held on December 11-12, 2018, from 9 a.m. to 5 p.m.

ADDRESSES: The meetings will be held at the Condado Vanderbilt Hotel, Ashford Avenue, 1055, San Juan, Puerto Rico 00907.

FOR FURTHER INFORMATION CONTACT: Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico 00918-1903, telephone: (787) 766-5926.

SUPPLEMENTARY INFORMATION:

December 11, 2018, 9 a.m.-5 p.m.

- Call to Order
 - Adoption of Agenda
 - Consideration of 163rd Council Meeting Verbatim Transcriptions
 - Executive Director's Report
 - Island-Based Fishery Management Plans
 - Review of Draft Environmental Impact Statements
 - Puerto Rico
 - St. Thomas/St. John
 - St. Croix
 - Review Action 7 (Accountability Measures) of Draft Environmental Impact Statements and Choose Preferred Alternative(s)
 - Review Other Actions, Additions, or Changes, as Appropriate
 - Council Decision on Publication of DEIS for Public Comment
 - Review Timeline for Completion of IBFMPs
 - Project Events Update—Graciela García-Moliner
 - GIS PR/USVI
 - Connectivity Report
 - EFH 3-Year Review
 - Okeanos Explorer Visit
- Public Comment Period (5-minute presentations)

December 11, 2018, 5 p.m.-6 p.m.

- Administrative Issues

—Closed Session

December 12, 2018, 9 a.m.-5 p.m.

- °Strategic Reorientation of the Western Central Atlantic Fishery Commission (WECAFC)—Ms. Warner Kramer
 - Ecosystem Based Fishery Management (EBFM) Initiative Update
 - Data Compilations and Integrations—Mallory Brooks
 - Risk Assessment Framework and Application to Conceptual Model—Tauna Rankin
 - Request to Council to Convene DAPs and SSC for Risk Analysis Exercise
 - Engagement Strategy—Alida Ortiz
 - Outreach and Education Report—Alida Ortiz
 - USVI Recreational Fishery Data Project Update—Ruth Gomez
 - Exempted Fishing Permit Application Updates
 - Clean Ocean Initiative
 - Puerto Rico DNER
 - NOAA/NMFS Panama City Laboratory
 - Any Other Applications Received Prior to this Meeting
 - Enforcement Issues:
 - Puerto Rico-DNER
 - USVI—DPNR
 - U.S. Coast Guard
 - NMFS/NOAA
 - Meetings Attended by Council Members and Staff
 - Other Business
 - Spiny Lobster Data Collection Project Update—Marcos Hanke
- Public Comment Period—(5-minute presentations)
- °Next Meeting

The order of business may be adjusted as necessary to accommodate the completion of agenda items. The meeting will begin on December 11, 2018 at 9 a.m. Other than the start time, interested parties should be aware that discussions may start earlier or later than indicated. In addition, the meeting may be extended from, or completed prior to the date established in this notice.

Special Accommodations

These meetings are physically accessible to people with disabilities. For more information or request for sign language interpretation and other auxiliary aids, please contact Mr. Miguel A. Rolón, Executive Director, Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico, 00918-1903, telephone: (787) 766-5926, at least 5 days prior to the meeting date.

Dated: November 6, 2018.

Tracey L. Thompson,

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

[FR Doc. 2018-24614 Filed 11-9-18; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Capital Construction Fund Agreement, Certificate Family of Forms and Deposit/Withdrawal Report

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before January 14, 2019.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW, Washington, DC 20230 (or via the internet at pracomments@doc.gov).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Richard VanGorder, NOAA/NMFS/F/MB5, 1315 East-West Highway, Room 13113, Silver Spring, MD 20910, (301) 427-8784, and Richard.VanGorder@noaa.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a currently approved information collection.

Respondents will be commercial fishing industry individuals, partnerships, and corporations which entered into Capital Construction Fund (CCF) agreements with the Secretary of Commerce allowing deferral of Federal taxation on fishing vessel income deposited into the fund for use in the acquisition, construction, or reconstruction of fishing vessels. Deferred taxes are recaptured by reducing an agreement vessel's basis for

depreciation by the amount withdrawn from the fund for its acquisition, construction, or reconstruction. The Capital Construction Fund Agreement and Certificate Family of Forms is required pursuant to 50 CFR part 259.2, 50 CFR part 259.9 and Public Law 115-97 (Tax Cuts and Jobs Act of 2017). The deposit/withdrawal information collected from agreement holders is required pursuant to 50 CFR part 259.7 and Public Law 115-97. The information collected from applicants for the CCF Agreement is used to determine their eligibility to participate in the CCF Program. The information collected from agreement holders for the Certificate Family of Forms is used to identify their program eligible vessels, their program projects and to certify the cost of a project at completion. The information collected on the deposit/withdrawal report form is required to ensure that agreement holders are complying with fund deposit/withdrawal requirements established in program regulations and properly accounting for fund activity on their Federal income tax returns. The information collected on the deposit/withdrawal report must also be reported semi-annually to the Secretary of Treasury in accordance with the Tax Reform Act.

II. Method of Collection

The information will be collected on forms submitted electronically, by mail or by fax.

III. Data

OMB Control Number: 0648-0041.

Form Number(s): NOAA Form 34-82, NOAA Form 88-14.

Type of Review: Regular submission (extension of a current information collection).

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 3,000.

Estimated Time Per Response: NOAA Form 34-82, 20 minutes; NOAA Form 88-14, 3.5 hours for agreements and 1 hour for certificate.

Estimated Total Annual Burden Hours: 2,917.

Estimated Total Annual Cost to Public: \$15,320 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden

(including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: November 6, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018-24611 Filed 11-9-18; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XG133

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Port of Kalama Expansion Project on the Lower Columbia River

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

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that NMFS has issued an Incidental Harassment Authorization (IHA) to the Port of Kalama (POK) for the take of marine mammals, by harassment, incidental to construction activities associated with an expansion project at the Port of Kalama on the Lower Columbia River, Washington.

DATES: This Authorization is in effect from October 18, 2018 to October 18, 2019.

FOR FURTHER INFORMATION CONTACT: Dale Youngkin, 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 by visiting the internet at: www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities. In case of problems accessing

these documents, please call the contact listed 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 monitoring and reporting of such takings.

The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

History of Request

On September 28, 2015, we received a request from the POK for authorization of the taking, by Level B harassment only, of marine mammals incidental to the construction associated with the Port of Kalama Expansion Project, which involved construction of the Kalama Marine Manufacturing and Export Facility including a new marine terminal for the export of methanol, and installation of engineered log jams, restoration of riparian wetlands, and the removal of existing wood piles in a side channel as mitigation activities. The specified activity is expected to result in the take of three species of marine mammals (harbor seals, California sea lions, and Steller sea lions). A final version of the application, which we deemed adequate and complete, was submitted on December 10, 2015. We

published a notice of a proposed IHA and request for comments on March 21, 2016 (81 FR 715064). After the public comment period and before we issued the final IHA, POK requested that we issue the IHA for 2017 instead of the 2016 work season. We subsequently published the final notice of our issuance of the IHA on December 12, 2016 (81 FR 89436), effective from September 1, 2017–August 31, 2018. In-water work associated with the project was expected to be completed within the one-year timeframe of the IHA.

On June 21, 2018, POK informed NMFS that work relevant to the specified activity considered in the MMPA analysis for the 2017–2018 IHA was postponed and would not be completed. POK requested that the IHA be issued to be effective for the period from 2018–2019. In support of that request, POK submitted an application addendum affirming that no change in the proposed activities is anticipated and that no new information regarding the abundance of marine mammals is available that would change the previous analysis and findings. A notice for the proposed incidental take authorization was published on July 25, 2018 (83 FR 35220), and a corrected notice was published on August 14, 2018 (83 FR 40257). Therefore, comments were received until September 13, 2018. Please refer to the Comments and Responses section below for information on the comments received during the comment periods for the proposed IHA.

Description of the Activity

The 2017–2018 IHA covered the incidental take of marine mammals due to construction of a marine terminal and dock/pier for the export of methanol, and associated compensatory mitigation activities for the purposes of offsetting habitat effects from the action. The marine terminal will be approximately 45,000 square feet in size, supported by 320 concrete piles (24-inch precast octagonal piles to be driven by impact hammer) and 16 steel piles (12 × 12-inch and 4 × 18-inch anticipated to be driven by vibratory hammer, and impact hammering will only be done to drive/proof if necessary). The compensatory mitigation includes installation of eight engineered log jams (ELJs), which will be anchored by untreated wooden piles driven by impact hammer at low tides (not in water). The compensatory mitigation also includes removal of approximately 157 untreated wooden piles from an old trestle in a nearby backwater area. The piles will be removed either by direct pull or vibratory extraction. Finally, the

compensatory mitigation includes wetland restoration and enhancement by removal of invasive species and replacement with native wetland species.

Since no changes have been made to the planned activities reflected in the proposed IHA, NMFS refers the reader to the documents related to the 2017–2018 IHA for more detailed description of the project activities. These previous documents include the **Federal Register** notice of the issuance of the 2017–2018 IHA for the POK’s Port of Kalama Expansion Project (81 FR 89436, December 12, 2016), the **Federal Register** notice of the proposed IHA (81 FR 15064, March 21, 2016), POK’s application (and 2018 application addendum), and all associated references, which can be found at www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities.

Comments and Responses

NMFS published a notice of receipt of POK’s updated application addendum and proposed IHA in the **Federal Register** on July 25, 2018 (83 FR 35220), with a comment response date of August 24, 2018. However, during the public review period for this notice, it was noted that instructions for submitting comments were lacking. Therefore, a second notice of the proposed IHA was published on August 14, 2018 (83 FR 40257), which included full instructions for submittal of comments. Comments were accepted on this corrected notice until September 13, 2018. NMFS received two comments during the review of the first notice. One comment was from a private citizen and one comment was received from the Columbia Riverkeeper, stating that instructions for submitting comments was not clear and voicing their concern with the use of a Categorical Exclusion (CE) for our action. During public review of the corrected notice, NMFS received four additional comments. Two of these additional comments were from the same private citizen who commented on the first notice; one was from the Marine Mammal Commission (MMC); and one was from the Center for Biological Diversity (CBD). Copies of the full comments received are available at <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities>. Additionally, all comments received on both notices are summarized and responses are provided below:

Comment: Three comments were received from the same private citizen

(Jean Public) expressing opposition to the project and concern regarding any government authorization to kill birds, seals, and sea lions in the Columbia River. One of these comments also suggested charging the POK (terminal builders) \$100,000 for every seal they kill.

Response: NMFS has issued an IHA to the POK for the incidental take, by Level A and Level B harassment only, of marine mammals due to in-water construction activities associated with the POK expansion project. Mortality is not expected or authorized by the IHA.

Comment: The MMC concurred with NMFS's findings and recommended that NMFS issue the IHA subject to inclusion of the mitigation, monitoring, and reporting measures discussed in the notice of the Proposed IHA.

Response: NMFS thanks the MMC for their comment and concurs with the recommendation. NMFS has issued the IHA to the Port of Kalama subject to the mitigation, monitoring, and reporting measures that were included in the notice of the Proposed IHA.

Comment: The MMC recommended that NMFS revise the Level A harassment zones for harbor seals during impact driving of concrete piles and vibratory driving of steel piles based on eight hours of activities, or eight piles/day, because harbor seals may be present in the project area for longer periods than California or Steller sea lions and therefore accumulate more sound energy.

Response: NMFS agrees that it is possible that harbor seals may be present in the general project area for longer periods than California or Steller sea lions. However, NMFS feels that it is unreasonable to assume that seals would remain within the area for a full eight hours, as they may be transiting between two sites (one approximately one mile upstream and one approximately 3.5 miles downstream) where they are known to forage and/or haul out. In addition, it is not reasonable to assume that pile driving activities would occur for eight consecutive hours daily, and is more likely that these activities would occur for an hour to two hours at a time, and would be broken up by time needed to set up new piles. However, NMFS has determined it is reasonable to assume that seals would be present for double the amount of time as sea lions (assuming a two-hour duration versus a one-hour duration due to the fact that they may be transiting the area twice if they move from one site to the other and return again) results in a Level A harassment threshold distance of 63 m

for impact driving of concrete piles and 26 m for vibratory driving of steel piles.

As noted in the notice for the proposed IHA, Level A harassment takes proposed for authorization did not rely on calculated takes, and were qualitatively proposed for authorization out of an abundance of caution in the event that some seals may be undetected before entering the Level A harassment zone. Therefore, the amount of Level A harassment takes authorized has not changed as a result of reconsidering the Level A harassment zone and only results in a revision of the Level A harassment monitoring area. Therefore, the requirement for monitoring and shut down distance to avoid Level A harassment take has been revised to 63 m and 26 m to correspond to a two-hour duration for impact driving of concrete piles and vibratory driving of steel piles, respectively.

Comment: The MMC recommended that NMFS further investigate appropriate timeframes over which sound exposure levels should be accumulated when estimating Level A harassment zones, and recommended that NMFS make this a priority to resolve in the near future. MMC further recommended that NMFS consult with its own and external scientists and acousticians to determine appropriate accumulation times.

Response: NMFS considers this a priority and has recently formed a group to work on the issue of accumulation time.

Comment: The Commission expressed continuing concern with NMFS's notice that one-year renewals could be issued in certain circumstances without additional public notice and comment requirements. The Commission also suggested that NMFS should discuss the possibility of renewals through a more general route, such as abbreviated notices such as was done in this instance. The Commission further recommended that if NMFS did not pursue renewals solely using abbreviated notices, that the agency provide a legal analysis supporting our conclusion that this process is consistent with the requirements of section 101(a)(5)(D) of the MMPA.

Response: As stated in previous responses to this comment from the Commission, the process of issuing a renewal IHA does not bypass the public notice and comment requirements of the MMPA. The **Federal Register** notice of the proposed IHA expressly notified the public that under certain, limited conditions an applicant could seek a renewal IHA for an additional year. The notice describes the conditions under which such a renewal request could be

considered and seeks public comment on those circumstances. Importantly, such renewals would be limited to circumstances where: The activities are identical or nearly identical to those analyzed in the proposed IHA or the activities would not be completed by the time the IHA expires and renewal would allow completion of the activities beyond that described in the Dates and Duration section; monitoring does not indicate impacts that were not previously analyzed and authorized; and the mitigation and monitoring requirements remain the same, all of which allow the public to comment on the appropriateness and effects of a renewal at the same time the public provides comments on the initial proposed IHA. NMFS has, however, modified the language to clarify that all IHAs, including renewal IHAs, are valid for no more than one year and that the agency would consider only one renewal for a project at this time. In addition, notice of issuance or denial of a renewal IHA would be published in the **Federal Register**, as they are for all IHAs. The option for issuing renewal IHAs has been in NMFS's implementing regulations for the incidental take provisions of the MMPA (Section 101(a)(5)(A) and (D)) since 1996.

Comment: The Columbia Riverkeeper (Riverkeeper) submitted a comment expressing concern with NMFS's use of a CE for purposes of the National Environmental Policy Act (NEPA) for the issuance of our IHA to the POK for incidental take of marine mammals from construction activities associated with the POK expansion project. The Riverkeeper stated that use of the CE would be counter to NOAA's NEPA guidance, citing language in the Companion Manual to NOAA Administrative Order 216-6A that says a CE may only be applied when the proposed action is not part of a larger action and can therefore be reviewed independently from other actions under NEPA. In addition, the Riverkeeper asserted that use of the CE would be a waste of agency time and resources since the US Army Corps of Engineers (USACE) is currently preparing an Environmental Assessment (EA) for the overall construction project. The Riverkeeper suggested that NMFS should participate in USACE's ongoing NEPA process and base its IHA decision on the USACE NEPA document. In addition, the Center for Biological Diversity (CBD) submitted a comment stating they were in agreement with the Riverkeeper comment.

Response: The application of a CE for NMFS's action (issuance of an IHA) is entirely consistent with NOAA's NEPA

guidance and practices. The issuance of an IHA is not part of a larger NMFS action that would be segmented for the purposes of NEPA (*i.e.*, NMFS's action would not be segmented for purposes of NEPA such that several CEs would be required for a larger project, as the only action NMFS has would be the issuance or denial of the IHA for the incidental take of marine mammals due to in-water construction work associated with the POK expansion). Further, as stated in the notice of the proposed IHA, NMFS had previously prepared its own EA for the issuance of the previous IHA, which resulted in a Finding of No Significant Impact (FONSI). Based on this past analysis, as well as an Administrative Record justifying the use of the CE (CE B4) for similar types of activities, NMFS has determined that the use of the CE for this action is well supported. While we appreciate that the USACE must prepare a NEPA document for its own action (issuance of a permit, or permits, for the larger construction project), relying on the NEPA analysis for this larger project would be of no benefit for NMFS's purposes due to the fact that the majority of the larger project construction activities would be associated with upland areas with no potential for the incidental take of marine mammals associated with NMFS's action.

Comment: The CBD commented that their primary concern is that the scope of the authorization is arbitrarily narrow in light of the Project's recognized impacts on marine mammals. More specifically, the CBD states that NMFS previously considered the Project and concluded in its biological opinion that the Project would adversely affect blue, humpback, fin, and sperm whales, yet none of these species are considered in the applicant's request. The Biological Opinion also concluded the Project would adversely affect several species of Chinook salmon and critical habitat, yet the applicant did not consider the resulting impacts to the critically

endangered Southern Resident killer whales that feed on those salmon.

Response: The two statutes (Endangered Species Act (ESA) and MMPA) are different both substantively and procedurally, with different analyses and potentially involving different scopes. The Biological Opinion was prepared pursuant to section 7(a)(2) of the ESA due to the requirement for consultation on the effects of the proposed action by a federal action agency, in this case the USACE, to issue permits for the construction of the Kalama Manufacturing and Marine Export Facility on the Columbia River and to Northwest Pipeline LLC for construction of the Kalama Lateral Project.¹ The Biological Opinion evaluates the effects of the USACE issuance of permits that would authorize the construction project for the marine export facility, which is a component of the overall Kalama Manufacturing and Marine Export Facility project. The ESA consultation (Biological Opinion) evaluates the direct and indirect effects of the proposed action, together with interrelated and interdependent actions such as the manufacturing/production facility, into the reasonably foreseeable future. Therefore, the ESA consultation broadly evaluated the effects of the agency action. The Biological Opinion determined that the project is likely to indirectly affect several species of marine mammals including blue, humpback, fin, and sperm whales, based on increased vessel traffic (including increased potential for ship strike and noise associated with OGVs and supertankers) from the long-term operation of the facility.

The Biological Opinion does not identify potential effects of pile driving/in-water construction in regard to any ESA-listed marine mammal species, as none are anticipated to be present in the area of pile driving activities. The Biological Opinion did determine adverse effects to salmon as a result of in-water construction/pile driving but

also concluded that the proposed action is not likely to adversely affect southern resident killer whales.

The IHA was issued pursuant to section 101(a)(5)(D) of the MMPA, which requires NMFS to authorize the incidental (but not intentional) take from a specified activity (in this case, in-water construction work associated with the Kalama Manufacturing and Marine Export Facility) in a specified geographic region for a one-year period if the relevant statutory standards are satisfied. The applicant for an IHA describes the specified activity for which the IHA is requested, and need not be a federal action agency. The IHA does not evaluate interrelated and interdependent activities of the specified activity. As Steller sea lions, California sea lions, and harbor seals are the only marine mammal species anticipated to occur in the specified area, these are the appropriate species considered for the IHA.

Description of Marine Mammals

A description of the marine mammals in the area of the activities is found in the previous documents referenced above, which remain applicable to this IHA as well. In addition, NMFS has reviewed recent Stock Assessment Reports, information on relevant Unusual Mortality Events, and recent scientific literature. Since the submittal of the 2015 IHA application, the USACE has published updated data on pinniped presence at the Bonneville Dam (Tidwell *et al.*, 2017). This information reveals that in both 2016 and 2017 the numbers of pinnipeds present at Bonneville Dam were within the range of historical variability. The latest USACE data does not suggest a trend that would require a modification to the take estimates or to the effects analysis (see Table 1 below for a summary of monitoring data by year from Tidwell *et al.*, 2017). Therefore, NMFS has determined that the updated information does not affect our analysis of impacts for the 2018–2019 IHA.

TABLE 1—MINIMUM ESTIMATED NUMBER OF INDIVIDUAL PINNIPEDS OBSERVED AT BONNEVILLE DAM TAILRACE AREAS AND THE HOURS OF OBSERVATION DURING THE FOCAL SAMPLING PERIOD, 2002 TO 2017

[From Tidwell *et al.*, 2017]

Year	Total hours observed	California sea lions	Steller sea lions	Harbor seals	Total pinnipeds
2002	662	30	0	1	31
2003	1,356	104	3	2	109
2004	516	99	3	2	104
2005*	1,109	81	4	1	86

¹ The U.S. Department of Energy is also identified as an action agency because of its consideration of whether to issue a loan guarantee for the project.

TABLE 1—MINIMUM ESTIMATED NUMBER OF INDIVIDUAL PINNIPEDS OBSERVED AT BONNEVILLE DAM TAILRACE AREAS AND THE HOURS OF OBSERVATION DURING THE FOCAL SAMPLING PERIOD, 2002 TO 2017—Continued

[From Tidwell *et al.*, 2017]

Year	Total hours observed	California sea lions	Steller sea lions	Harbor seals	Total pinnipeds
2006	3,650	72	11	3	86
2007	4,433	71	9	2	82
2008	5,131	82	39	2	123
2009	3,455	54	26	2	82
2010	3,609	89	75	2	166
2011	3,315	54	89	1	144
2012	3,404	39	73	0	112
2013	3,247	56	80	0	136
2014	2,947	71	65	1	137
2015	2,995	195	^a 69	0	264
2016	1,974	149	^a 54	0	203
2017	1,142	92	^a 63	1	156

* Observations did not begin until March 18 in 2005.

^a In 2015, 2016, and 2017 the minimum estimated number of Steller sea lions was 55, 41, and 32, respectively. These counts were less than the maximum number of Steller sea lions observed on one day, so Tidwell *et al.* (2017) used the maximum number observed on one day as the minimum number. This difference was driven by a focus on California sea lions and lack of branding or unique markers on Steller sea lions.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

A description of the potential effects of the specified activities on marine mammals and their habitat is found in the previous documents referenced above, and remain applicable to this proposed IHA. There is no new information on potential effects that would change our analyses or determinations under the 2018–2019 IHA.

Estimated Take

A description of the methods and inputs used to estimate take anticipated to occur and, ultimately, the take that was authorized is found in the previous documents referenced above. The methods of estimating take for this IHA are identical to those used in the 2017–2018 IHA, as is the density of marine mammals. The source levels, also

remain unchanged from the 2017–2018 IHA, and NMFS’s 2016 Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (NMFS 2016) was used to address new acoustic thresholds in the notice of issuance of the 2017–2018 IHA (see Table 2 for NMFS User Spreadsheet inputs). As stated above, since the submittal of the application for the 2017–2018 IHA (in effect from September 1, 2017 through August 31, 2018), the USACE has published updated data on pinniped presence at the Bonneville Dam, and this data does not suggest a trend that would require a modification to the take estimates or effects analysis. Consequently, the authorized Level B harassment take for this 2018–2019 IHA is identical to the 2017–2018 IHA, as presented in Table 3 below. However, the originally issued IHA did not authorize any Level A

harassment take. As harbor seals are smaller and may be more difficult to detect at larger Level A harassment zones, and to account for the potential that they may be unseen or linger longer than expected, a small number of takes by Level A harassment is now authorized. Finally, the pile driving duration informing the calculation of Level A harassment zone sizes has changed from the notice of the proposed IHA as a result of a public comment received. As seals are not transiting to the Bonneville Dam similar to sea lions, and may spend more time in the project vicinity, the duration has been doubled for these species for impact driving of concrete piles and for vibratory driving of steel piles. For impact driving of steel piles, the duration was kept at the original one hour due to the fact that impact driving of these piles would only occur briefly (for proofing) if at all.

TABLE 2—INPUTS FOR NMFS USER SPREADSHEET

Input parameter	Vibratory pile driving (steel)	Impact pile driving (steel)	Impact pile driving (concrete)
Weighting Factor Adjustment ¹	2.5	2	2
Source Level (SL) ²	170	178	166
Duration ³	2 hours	1 hour	2 hours
Strikes per pile		1,025	1,025
Piles per day ³	1 (1 hour duration)	(1 pile/hour)	(1 pile/hour)
Propagation (xlogR)	15	15	15
Distance from SL measurement	10	10	10

¹ In instances where full auditory weighting functions associated with the SEL_{cum} metric cannot be applied, NMFS has recommended the default, single frequency weighting factor adjustments (WFAs) provided here. As described in Appendix D of NMFS’s Technical Guidance (NMFS, 2016), the intent of the WFA is to broadly account for auditory weighting functions below the 95 frequency contour percentile. Use of single frequency WFA is likely to over-predict Level A harassment distances.

² SLs from CalTrans (2012). SL for all steel piles are based on 18” steel pipe (4 of the piles are 18” and 12 of the piles are 12”).

³ A 1-hour duration was used for California and Steller sea lions, as there are no haul-outs in the project area. Animals are transiting through the project area, and are not anticipated to be present for a full 8-hour day of pile driving activity. POK estimates 6–8 piles/day, or approximately 1 pile/hour. Animals are anticipated to be present for the duration of 1 pile being driven (1 hour) at most. For harbor seals, a two-hour duration was used, as they may be transiting between two sites (one approximately one mile upstream and one approximately 3.5 miles downstream of the project area). Given that these animals may transit back and forth between these two sites, the duration was doubled.

TABLE 3—ESTIMATED TAKE AUTHORIZED AND PROPORTION OF POPULATION POTENTIALLY AFFECTED

	Estimated take by level B harassment	Estimated take by level A harassment	Abundance of stock	Percentage of stock potentially affected	Population trend
Harbor seal	1,530	10	24,732	6.2	Stable.
California sea lion	372	0	153,337	0.2	Stable.
Steller sea lion	372	0	59,968	0.6	Increasing.

Description of Mitigation, Monitoring and Reporting Measures—A description of mitigation, monitoring, and reporting measures is found in the previous documents referenced above, and remain unchanged for this IHA with the exception of a change in the required monitoring distance to avoid Level A harassment takes. In summary, mitigation includes implementation of shut down procedures if any marine mammal approaches or enters the Level A harassment zone for pile driving (26 m (85 feet (ft)) for vibratory pile driving of steel piles; 63 m (207 ft) for impact driving of concrete piles; and 252 m (828 ft) for impact driving of steel piles). For in-water heavy machinery work other than pile driving (e.g. standard barges, barge-mounted cranes, excavators, etc.), if a marine mammal comes within 10 m, operations must cease and vessels must reduce speed to the minimum level required to maintain steerage and safe working conditions. One trained observer must monitor to implement shutdowns and collect information at each active pile driving location (whether vibratory or impact driving of steel or concrete piles).

At least three observers must be on duty during impact driving at all times. As discussed above, one observer must monitor and implement shutdowns and collect information at each pile driving location at all times. In addition, two shore-based observers are required (one upstream of the project and another downstream of the project), whose primary responsibility shall be to record pinnipeds in the Level B harassment zone and to alert the barge-based observer to the presence of pinnipeds, thus creating a redundant alert system for prevention of injurious interaction as well as increasing the probability of detecting pinnipeds in the disturbance zone. At least three observers must be on duty during vibratory pile driving activity for the first two days, and thereafter on every third day to allow for estimation of Level B harassment takes. Similar to requirements for impact driving, the first observer must be positioned on a work platform or barge where the entirety of the shutdown zone can be monitored. Shore based observers must be positioned to observe

the disturbance zone from the bank of the river. Protocols will be implemented to ensure that coordinated communication of sightings occurs between observers in a timely manner.

Pile driving activities may only be conducted during daylight hours. If the shutdown zone is obscured by fog or poor lighting conditions, pile driving will not be initiated until the entire shutdown zone is visible. Work that has been initiated appropriately in conditions of good visibility may continue during poor visibility. The shutdown zone will be monitored for 30 minutes prior to initiating the start of pile driving, during the activity, and for 30 minutes after activities have ceased. If pinnipeds are present within the shutdown zone prior to pile driving, the start will be delayed until the animals leave the shutdown zone of their own volition, or until 15 minutes elapse without re-sighting the animal(s).

Soft start procedures must be implemented at the start of each day's impact pile driving and at any time following cessation of impact driving for a period of thirty minutes or longer. If steel piles require impact installation or proofing, a bubble curtain must be used for sound attenuation. If water velocity is 1.6 ft per second (1.1 miles per hour (mph)) or less for the entire installation period, the pile being driven must be surrounded by a confined or unconfined bubble curtain that will distribute small air bubbles around 100 percent of the pile perimeter for the full depth of the water column. If water velocity is greater than 1.6 feet per second (1.1 mph) at any point during installation, the pile being driven must be surrounded by a confined bubble curtain (e.g., a bubble ring surrounded by a fabric or non-metallic sleeve) that will distribute air bubbles around 100 percent of the pile perimeter for the full depth of the water column.

Determinations

The POK proposes to conduct activities in 2018–2019 that are identical to those covered in the current 2017–2018 IHA. As described above, the number of estimated takes of the same stocks of harbor seals (OR/WA Coast stock), California sea lion (U.S. stock),

and Steller sea lion (Eastern DPS) is the same for this IHA as those authorized in the 2017–2018 IHA, which were found to meet the negligible impact and small numbers standards. The authorized take of 1,540 harbor seals; 372 California sea lions, and 372 Steller sea lions represent 6.2 percent, 0.2 percent, and 0.6 percent of these stocks of marine mammals, respectively. We evaluated the impacts of the additional authorization of 10 Level A harassment takes of harbor seal, and find that consideration of impacts to these 10 individuals accruing a small degree of permanent threshold shift (PTS) does not meaningfully change our analysis, nor does it change our findings/determinations. This IHA includes identical required mitigation, monitoring, and reporting measures as the 2017–2018 IHA, and there is no new information suggesting that our prior analyses or findings should change.

Based on the information contained here and in the referenced documents, NMFS has determined the following: (1) The authorized takes will have a negligible impact on the affected marine mammal species or stocks; (2) the required mitigation measures will effect the least practicable impact on marine mammal species or stocks and their habitat; (3) the authorized takes represent small numbers of marine mammals relative to the affected species or stock abundances; and (4) the POK's activities will not have an unmitigable adverse impact on taking for subsistence purposes, as no relevant subsistence uses of marine mammals are implicated by this action.

National Environmental Policy Act

In compliance with the NEPA of 1969 (42 U.S.C. 4321 *et seq.*), as implemented by the regulations published by the Council on Environmental Quality (40 CFR parts 1500–1508), NMFS prepared an EA to consider the direct, indirect and cumulative effects to the human environment resulting from our previous IHA action (issuance of an IHA for incidental take of marine mammals due to the POK Expansion project). NMFS made the EA available to the public for review and comment in order to assess the impacts to the human environment of issuance of the 2017–

2018 IHA to the POK. Also in compliance with NEPA and the CEQ regulations, as well as NOAA Administrative Order 216–6, NMFS made a FONSI on October 24, 2016, for issuance of the 2017–2018 IHA. These NEPA documents are available at <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities>.

Since this IHA covers the same work covered in the 2017–2018 IHA, NMFS has reviewed our previous EA and FONSI, and has determined that our current action is consistent with categories of activities identified in CE B4 of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has determined that the issuance of the IHA qualifies to be categorically excluded from further NEPA review. We have reviewed all comments submitted in response to this notice prior to concluding our NEPA process and making our final decision on the 2018–2019 IHA request.

Endangered Species Act (ESA)

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species. No incidental take of ESA-listed marine mammal species is expected to result from this activity, and none would be authorized. Therefore, NMFS has determined that consultation under section 7 of the ESA is not required for this action.

Authorization

NMFS has issued an IHA to POK for the incidental take of marine mammals due to in-water construction work associated with the POK Expansion Project for a period of one year, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: November 6, 2018.

Donna S. Wieting,

*Director, Office of Protected Resources,
National Marine Fisheries Service.*

[FR Doc. 2018–24665 Filed 11–9–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Application for Appointment in the NOAA Commissioned Officer Corps

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before January 14, 2019.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW, Washington, DC 20230 (or via the internet at Jjessup@doc.gov).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to LT Jared Halonen—Chief, NOAA Corps Recruiting, or LT Ricardo Rodriguez—NOAA Corps Recruiting Officer; OMAO–CPC–OCMD, 8403 Colesville Road, Suite 500, Silver Spring, MD 20910, ((800)-299–6622), noaacorps.recruiting@noaa.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a currently approved information collection. The NOAA Commissioned Corps is the uniformed component of the National Oceanic and Atmospheric Administration (NOAA), a bureau of the Department of Commerce. Officers serve under Senate-confirmed appointments and Presidential commissions (33 U.S.C. chapter 17, subchapter 1, sections 853 and 854). The NOAA Corps provides a cadre of professionals trained in engineering, earth sciences, oceanography, meteorology, fisheries

science, and other related disciplines, who are dedicated to the service of their country and optimization of NOAA's missions to ensure the economic and physical well-being of the Nation.

NOAA Corps officers serve in assignments throughout NOAA, as well as in each of NOAA's Line Offices (National Environmental Satellite, Data, and Information Service, National Ocean Service, National Weather Service, Office of Oceanic and Atmospheric Research and Office of Planning, Programming and Integration).

Persons wishing to be considered for a NOAA Corps Commission must submit a complete application package, including NOAA Form 56–42, at least three letters of recommendation, and official transcripts. A personal interview must also be conducted. Eligibility requirements include a bachelor's degree with at least 48 credit hours of science, engineering or other disciplines related to NOAA's mission, excellent health, and normal color vision with uncorrected visual acuity no worse than 20/400 in each eye (correctable to 20/20).

II. Method of Collection

Applicants must utilize the E-recruit electronic application process (<https://cpc.oma.noaa.gov/erecruit/login.jsp>) and then submit paper forms via mail. An in-person interview is also required.

III. Data

OMB Control Number: 0648–0047.

Form Number(s): NOAA 56–42 and NOAA 56–42A.

Type of Review: Regular submission (extension of a currently approved information collection).

Affected Public: Individuals or households.

Estimated Number of Respondents: 150.

Estimated Time per Response: Written applications, 5 hours; interviews, 90 minutes; references, 15 minutes.

Estimated Total Annual Burden Hours: 1,088.

Estimated Total Annual Cost to Public: \$10,875 in recordkeeping, recording and travel costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and

clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: November 6, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018-24610 Filed 11-9-18; 8:45 am]

BILLING CODE 3510-12-P

DEPARTMENT OF DEFENSE

Office of the Secretary

Department of Defense Military Family Readiness Council; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, Department of Defense.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The Department of Defense (DoD) is publishing this notice to announce that the following Federal Advisory Committee meeting of the Department of Defense Military Family Readiness Council will take place.

DATES: Open to the public Tuesday, December 11, 2018 from 10:00 a.m. to 12:00 p.m.

ADDRESSES: The address of the open meeting is the Pentagon, 1155 Defense Pentagon PLC2, Pentagon Library and Conference Center, Room B6, Washington, DC 20301.

FOR FURTHER INFORMATION CONTACT: William C. Story, (571) 372-5345 (Voice), (571) 372-0884 (Facsimile), OSD Pentagon OUSD P-R Mailbox Family Readiness Council, osd.pentagon.ousd-p-r.mbx.family-readiness-council@mail.mil (Email). Mailing address is Office of the Deputy Assistant Secretary of Defense (Military Community & Family Policy), Office of Family Readiness Policy, 4800 Mark Center Drive, Alexandria, VA 22350-2300, Room 3G15. Website: <http://www.militaryonesource.mil/those-who-support-mfrc>. The most up-to-date changes to the meeting agenda can be found on the website.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory

Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102-3.140 and 102-3.150.

Purpose of the Meeting: This is the first meeting of the Council for Fiscal Year 2019 (FY2019). During this meeting subject matter experts will present information to the Council concerning the Delivery of Service and Family Member Programs Tailored to Millennials, one of the focus areas chosen by the Council for FY2019.

Agenda: Opening Remarks, Status Updates, Administrative Issues, Review of Written Public Submissions, Effective Digital Communication Strategies to Reach Millennials, Installations of the Future-What Today's Millennials Want on Tomorrow's Installations, Marine Corps Community Services Innovation Effort, Military Community Outreach and Messaging to Millennials and Families, Questions and Answers and Council Member Discussion, Closing Remarks. Note: exact order may vary.

Meeting Accessibility: This meeting is open to the public. Members of the public who are interested in attending this meeting must RSVP online to osd.pentagon.ousd-p-r.mbx.family-readiness-council@mail.mil no later than December 4, 2018. Meeting attendee RSVPs should indicate if an escort is needed to the meeting location (non-CAC Card holders need an escort) and if handicapped accessible transportation is needed. All visitors without CAC cards that are attending the MFRC must pre-register prior to entering the Pentagon. RSVPs to the MFRC mailbox needing escort to the meeting will be contacted by email from the Pentagon Force Protection Agency (PFPA) with instructions for registration. Please follow these instructions carefully. Otherwise, members of the public may be denied access to the Pentagon on the day of the meeting. Members of the public who are approved for Pentagon access should arrive at the Pentagon Visitors Center waiting area (Pentagon Metro Entrance) no later than 9:00 a.m. on the day of the meeting to allow time to pass through security check points and to be escorted to the meeting location. Contact Eddy Mentzer, (571) 372-0857 (Voice), (571) 372-0884, (Facsimile) if you have any questions about your RSVP.

Written Statements: Persons interested in providing a written statement for review and consideration by Council members attending the December 11, 2018 meeting must do so no later than close of business Tuesday, November 27, 2018, through the Council mailbox at [\[r.mbx.family-readiness-council@mail.mil\]\(mailto:r.mbx.family-readiness-council@mail.mil\). Written statements received after this date will be provided to Council members in preparation for the second MFRC meeting of FY2019. The Designated Federal Officer \(DFO\) will review all timely submissions and ensure submitted written statements are provided to Council members prior to the meeting that is subject to this notice. Written statements must not be longer than two type-written pages and should address the following details: Issue or concern, discussion, and a recommended course of action. Those who make submissions are requested to avoid including personally identifiable information \(PII\) such as names of adults and children, phone numbers, addresses, social security numbers and other contact information within the body of the written statement. Links or supporting documentation may also be included, if necessary, to provide brief appropriate historical context and background information.](mailto:osd.pentagon.ousd-p-</p>
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Dated: November 6, 2018.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018-24640 Filed 11-9-18; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

Board of Regents, Uniformed Services University of the Health Sciences; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the Board of Regents ("the Board"), Uniformed Services University of the Health Sciences (USU) will take place.

DATES: Tuesday, November 6, 2018, open to the public from 8:00 a.m. to approximately 11:15 a.m. Closed session will occur from approximately 11:20 a.m. to 11:50 a.m.

ADDRESSES: Uniformed Services University of the Health Sciences, 4301 Jones Bridge Road, Everett Alvarez Jr. Board of Regents Room (D3001), Bethesda, Maryland 20814.

FOR FURTHER INFORMATION CONTACT: Joshua Barricklow, 301-295-9805 (Voice), 301-295-1960 (Facsimile), joshua.barricklow@usuhs.edu (Email).

Mailing address is 4301 Jones Bridge Road, A1020, Bethesda, Maryland 20814. Website: <https://www.usuhs.edu/vpe/bor>.

SUPPLEMENTARY INFORMATION: Due to circumstances beyond the control of the Department of Defense (DoD) and the Designated Federal Officer, the Board of Regents, Uniformed Services University of the Health Sciences was unable to provide public notification required by 41 CFR 102–3.150(a) concerning the meeting on November 6, 2018 of the Board of Regents, Uniformed Services University of the Health Sciences. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) (5 U.S.C., Appendix), the Government in the Sunshine Act (5 U.S.C. 552b), and 41 CFR 102–3.140 and 102–3.150.

Purpose of the Meeting: The purpose of the meeting is to provide advice and recommendations to the Secretary of Defense, through the Under Secretary of Defense for Personnel and Readiness, on academic and administrative matters critical to the full accreditation and successful operation of USU. These actions are necessary for USU to pursue its mission, which is to educate, train and comprehensively prepare uniformed services health professionals, officers, scientists and leaders to support the Military and Public Health Systems, the National Security and National Defense Strategies of the United States, and the readiness of our Uniformed Services.

Agenda: The actions scheduled to occur include recommendations regarding the awarding of associate, baccalaureate and graduate degrees; recommendations regarding the approval of faculty appointments and promotions; and recommendations regarding award nominations. The USU President will provide a report on recent actions affecting academic and operational aspects of USU. Member reports will include an Academics Summary consisting of reports from the Armed Forces Radiobiology Research Institute; the Registrar; the Assistant Vice President for Accreditation and Organizational Assessment; and the Faculty Senate. Member Reports will also include a Finance and Administration Summary consisting of reports from the Senior Vice President, Southern Region; the Senior Vice President, Western Region; the Vice President for Finance and

Administration; and the Henry M. Jackson Foundation for the Advancement of Military Medicine. There will be reports from each of the deans from the F. Edward Hebert School of Medicine, the Daniel K. Inouye Graduate School of Nursing, the Postgraduate Dental College, and the College of Allied Health Sciences. A closed session will be held, immediately following the open session, to discuss active investigations and personnel actions.

Meeting Accessibility: Pursuant to Federal statutes and regulations (5 U.S.C., Appendix, 5 U.S.C. 552b, and 41 CFR 102–3.140 through 102–3.165) and the availability of space, the meeting is open to the public from 8:00 a.m. to approximately 11:15 a.m. Seating is on a first-come basis. Members of the public wishing to attend the meeting should contact Joshua Barricklow at the address and phone number noted in the **FOR FURTHER INFORMATION CONTACT** section. Pursuant to 5 U.S.C. 552b(c)(2, 5–7), the DoD has determined that the portion of the meeting from 11:20 a.m. to 11:50 a.m. shall be closed to the public. The Under Secretary of Defense (Personnel and Readiness), in consultation with the Department of Defense Office of General Counsel, has determined in writing that this portion of the Board's meeting will be closed as the discussion will disclose sensitive personnel information, will include matters that relate solely to the internal personnel rules and practices of the agency, will involve allegations of a person having committed a crime or censuring an individual, and may disclose investigatory records compiled for law enforcement purposes.

Written Statements: Pursuant to section 10(a)(3) of the Federal Advisory Committee Act and 41 CFR 102–3.140, the public or interested organizations may submit written comments to the Board about its approved agenda pertaining to this meeting or at any time regarding the Board's mission. Individuals submitting a written statement must submit their statement to the Designated Federal Officer at the address listed in the **FOR FURTHER INFORMATION CONTACT** section. Written statements that do not pertain to a scheduled meeting of the Board may be submitted at any time. However, if individual comments pertain to a specific topic being discussed at the planned meeting, then these statements must be received prior to the meeting, otherwise, the comments may not be provided to or considered by the Board until a later date. The Designated Federal Officer will compile all timely submissions with the Board's Chair and

ensure such submissions are provided to Board Members before the meeting.

Dated: November 6, 2018.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018–24634 Filed 11–9–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Availability of Government-Owned Inventions; Available for Licensing

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The Department of the Navy (DoN) announces the availability of the inventions listed below, assigned to the United States Government, as represented by the Secretary of the Navy, for domestic and foreign licensing by the Department of the Navy.

ADDRESSES: Requests for copies of the patents cited should be directed to Naval Surface Warfare Center, Crane Div., Code OOL, Bldg. 2, 300 Highway 361, Crane, IN 47522–5001.

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Monsey, Naval Surface Warfare Center, Crane Div., Code OOL, Bldg. 2, 300 Highway 361, Crane, IN 47522–5001, email Christopher.Monsey@navy.mil, 812–854–2777.

SUPPLEMENTARY INFORMATION: The following patents are available for licensing: Patent No. 10,101,125 (Navy Case No. 200366): PRECISION ENGAGEMENT SYSTEM//Patent No. 10,106,880 (Navy Case No. 200332): MODIFYING THE SURFACE CHEMISTRY OF A MATERIAL//Patent No. 10,109,915 (Navy Case No. 103078): PLANAR NEAR-FIELD CALIBRATION OF DIGITAL ARRAYS USING ELEMENT PLANE WAVE SPECTRA//Patent No. 10,091,664 (Navy Case No. 200240): SYSTEM AND METHODS FOR UNOBTRUSIVELY AND RELOCATEABLY EXTENDING COMMUNICATION COVERAGE AND SUPPORTING UNMANNED AERIAL VEHICLE (UAV) ACTIVITIES//Patent No. 10,094,866 (Navy Case No. 103206): PORTABLE MULTI-FUNCTION CABLE TESTER//Patent No. 10,095,193 (Navy Case No. 200284): HIGH SPEED, HIGH VOLTAGE (HV) CAPACITOR SYSTEM (HVCS) CONTROL SYSTEMS AND RELATED METHODS FOR HVCS CHARGE/DISCHARGE UPON ACTIVATION/DEACTIVATION OF A HV MAIN POWER SYSTEM (MPS) OR

SYSTEM FAULT EVENT INCLUDING A FIRST AND SECOND TIMING SEQUENCE FOR MPS MAIN RELAY(S) AND HVCS RELAY(S) OPERATION// Patent No. 10,101,106 (Navy Case No. 200388); PORTABLE PART OR CONSUMABLE ITEM CARRIER WITH ANTI-JAM FEED SYSTEM WITH EXEMPLARY CONSUMING ITEM SYSTEMS//Patent No. 10,107,858 (Navy Case No. 200360); DIGITAL TEST SYSTEM//Patent No. 10,109,924 (Navy Case No. 200393); METHOD FOR ASSEMBLING A MULTI-ELEMENT APPARATUS USING A RECONFIGURABLE ASSEMBLY APPARATUS//and Patent No. 10,114,127 (Navy Case No. 200238); AUGMENTED REALITY VISUALIZATION SYSTEM.

Authority: 35 U.S.C. 207, 37 CFR part 404.

Dated: November 5, 2018.

Meredith Steingold Werner,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2018-24644 Filed 11-9-18; 8:45 am]

BILLING CODE 3810-FF-P

ELECTION ASSISTANCE COMMISSION

Meeting Notice

AGENCY: U.S. Election Assistance Commission.

ACTION: Notice of Public Quarterly Conference Call for EAC Board of Advisors.

DATES: Monday, November 26, 2018, 2:00–4:00 p.m. (EDT).

ADDRESSES: EAC Board of Advisors Quarterly Conference Call.

To listen and monitor the event as an attendee:

1. Go to: <https://eacevents.webex.com/eacevents/onstage/g.php?MTID=e510ecfadd5368d5dd1ccb09b121792fa>.

2. Click "Join Now".

To join the audio conference only:

1. To receive a call back, provide your phone number when you join the event, or

2. call the number below and enter the access code.

U.S. Toll Free: +1-855-892-3345

U.S. TOLL: +1-415-527-5035

Access code: 905 062 514

(See toll-free dialing restrictions at https://www.webex.com/pdf/tollfree_restrictions.pdf).

For assistance: Contact the host, Mark Abbott at mabbott@eac.gov.

FOR FURTHER INFORMATION CONTACT: Bryan Whitener; Telephone: (301) 563-3961.

Purpose: In accordance with the Federal Advisory Committee Act

(FACA), Public Law 92-463, as amended (5 U.S.C. Appendix 2), the U.S. Election Assistance Commission (EAC) Board of Advisors will conduct a conference call to discuss current EAC activities.

Agenda: The Board of Advisors (BOA) will receive updates from EAC staff and BOA officers regarding EAC activities; the 2019 BOA Conference; Election Day Activities; Post-Election Day Activities; and BOA Committee/Sub-Committee Updates. The Board of Advisors will receive updates from the following BOA Committees: Resolutions; Voluntary Voting System Guidelines (VVSG); By-Laws; and Strategic Planning. The Board of Advisors will discuss the next Quarterly BOA Conference Call. There will be no votes conducted on this call.

SUPPLEMENTARY INFORMATION: Members of the public may submit relevant written statements to the Board of Advisors with respect to the meeting no later than 5:00 p.m. EDT on Friday, November 23, 2018. Statements may be sent via email at facboards@eac.gov, via standard mail addressed to the U.S. Election Assistance Commission, 1335 East-West Highway, Suite 4300, Silver Spring, MD 20910, or by fax at 301-734-3108.

This conference call will be open to the public.

Bryan Whitener,

Director, National Clearinghouse on Elections, U.S. Election Assistance Commission.

[FR Doc. 2018-24631 Filed 11-9-18; 8:45 am]

BILLING CODE 6820-KF-P

DEPARTMENT OF ENERGY

Extension of a Currently Approved Information Collection for the Weatherization Assistance Program

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

ACTION: Notice and request for comments.

SUMMARY: The Department of Energy (DOE), pursuant to the Paperwork Reduction Act of 1995, intends to extend for three years, an information collection request with the Office of Management and Budget (OMB). The information collection request, Historic Preservation for Energy Efficiency Programs, was initially approved on December 1, 2010 under OMB Control No. 1910-5155 and expired on September 30, 2015. The reinstatement will allow DOE to continue data collection on the status of the

Weatherization Assistance Program (WAP), the State Energy Program (SEP), and the Energy Efficiency and Conservation Block Grant (EECBG) program

DATES: Comments regarding this propose information collection must be received on or before January 14, 2019. If you anticipate difficulty in submitting comments within that period, contact the person listed below as soon as possible.

ADDRESSES: Written comments may be sent to: Christine Askew, EE-5W, U.S. Department of Energy, 1000 Independence Ave. SW, Washington, DC 20585, Email: Christine.Askew@ee.doe.gov.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the information collection instrument and instructions should be directed to: Christine Askew, EE-5W, U.S. Department of Energy, 1000 Independence Ave. SW, Washington, DC 20585-1290, Phone: (202) 586-8224, Fax: (202) 287-1992, Email: Christine.Askew@ee.doe.gov.

Additional information and reporting guidance concerning the Historic Preservation reporting requirement for the WAP, SEP, and EECBG programs are available for review at: <https://www.energy.gov/eere/wipo/downloads/wpn-10-12-historic-preservation-implementation>.

SUPPLEMENTARY INFORMATION: Program activities will ensure compliance the National Historic Preservation Act (NHPA). Comments are invited on: (a) Whether the extended collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. This information collection request contains: (1) *OMB No.:* 1910-5155; (2) *Information Collection Request Title:* "Historic Preservation for Energy Efficiency Programs"; (3) *Type of Review:* Extension of a Currently Approved Information Collection; (4) *Purpose:* To collect information on the status of Weatherization Assistance Program, State Energy Program, and Energy Efficiency and Conservation

Block Grant Program activities; (5) *Annual Estimated Number of Respondents*: 275; (6) *Annual Estimated Number of Total Responses*: 275; (7) *Annual Estimated Number of Burden Hours*: 662; (8) *Annual Estimated Reporting and Recordkeeping Cost Burden*: \$0.

Statutory Authority: Title V, National Historic Preservation Act of 1966, Public Law 89–665 as amended (16 U.S.C. 470 *et seq.*).

Signed in Washington, DC, on October 30, 2018.

James R. Carlisle,

Operations Supervisor, Weatherization and Intergovernmental Programs, U.S. Department of Energy.

[FR Doc. 2018–24695 Filed 11–9–18; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC19–23–000.

Applicants: sPower OpCo A, LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act, et al. of sPower OpCo A, LLC.

Filed Date: 11/6/18.

Accession Number: 20181106–5096.

Comments Due: 5 p.m. ET 11/27/18.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER18–1648–002.

Applicants: Midcontinent

Independent System Operator, Inc.

Description: Compliance filing: 2018–11–06 Time Bar Compliance Filing to be effective 11/1/2018.

Filed Date: 11/6/18.

Accession Number: 20181106–5051.

Comments Due: 5 p.m. ET 11/27/18.

Docket Numbers: ER18–2440–001.

Applicants: Southern California

Edison Company.

Description: Tariff Amendment: SCE's Response to Deficiency re Revised Formula Rate TO Tariff TCJA to be effective 11/16/2018.

Filed Date: 11/6/18.

Accession Number: 20181106–5104.

Comments Due: 5 p.m. ET 11/27/18.

Docket Numbers: ER18–2465–000.

Applicants: Potter Road Powerhouse LLC.

Description: Supplement to September 24, 2018 Potter Road Powerhouse LLC tariff filing.

Filed Date: 11/6/18.

Accession Number: 20181106–5067.

Comments Due: 5 p.m. ET 11/27/18.

Docket Numbers: ER18–2466–000.

Applicants: Federal Way Powerhouse LLC.

Description: Supplement to September 24, 2018 Federal Way Powerhouse LLC tariff filing.

Filed Date: 11/6/18.

Accession Number: 20181106–5066.

Comments Due: 5 p.m. ET 11/27/18.

Docket Numbers: ER19–292–000.

Applicants: Alabama Power Company.

Description: Tariff Cancellation: Clay Solar LGIA Termination Filing to be effective 10/10/2018.

Filed Date: 11/6/18.

Accession Number: 20181106–5055.

Comments Due: 5 p.m. ET 11/27/18.

Docket Numbers: ER19–293–000.

Applicants: Midcontinent Independent System Operator, Inc., ALLETE, Inc.

Description: § 205(d) Rate Filing: 2018–11–06 SA 3202 MP–GRE IA (Clover Valley) to be effective 11/7/2018.

Filed Date: 11/6/18.

Accession Number: 20181106–5079.

Comments Due: 5 p.m. ET 11/27/18.

Docket Numbers: ER19–294–000.

Applicants: GE Oleander LLC.

Description: Baseline eTariff Filing: Application for Market Based Rate Authority to be effective 11/7/2018.

Filed Date: 11/6/18.

Accession Number: 20181106–5082.

Comments Due: 5 p.m. ET 11/27/18.

Docket Numbers: ER19–295–000.

Applicants: ISO New England Inc.

Description: ISO New England Inc. submits informational filing for Qualification in the Forward Capacity Market.

Filed Date: 11/6/18.

Accession Number: 20181106–5083.

Comments Due: 5 p.m. ET 11/21/18.

Docket Numbers: ER19–296–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amendment to WMPA, SA No. 4794; Queue No. AC1–116 (consent and amend) to be effective 8/22/2017.

Filed Date: 11/6/18.

Accession Number: 20181106–5107.

Comments Due: 5 p.m. ET 11/27/18.

Docket Numbers: ER19–297–000.

Applicants: Mid-Atlantic Interstate Transmission, LLC, West Penn Power Company.

Description: PJM RTEP Generator Deactivation Project, Incentive Rate Application, et al. of Mid-Atlantic Interstate Transmission, LLC, et al.

Filed Date: 11/6/18.

Accession Number: 20181106–5109.

Comments Due: 5 p.m. ET 11/27/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 6, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–24669 Filed 11–9–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC19–22–000.

Applicants: Dominion Bridgeport Fuel Cell, LLC, FuelCell Energy Finance, LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act, et al. of Dominion Bridgeport Fuel Cell, LLC, et al.

Filed Date: 11/5/18.

Accession Number: 20181105–5209.

Comments Due: 5 p.m. ET 11/26/18.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1533–018.

Applicants: Macquarie Energy LLC.

Description: Notice of Non-Material Change in Status of Macquarie Energy LLC.

Filed Date: 11/5/18.

Accession Number: 20181105–5199.

Comments Due: 5 p.m. ET 11/26/18.

Docket Numbers: ER17–2219–001.

Applicants: System Energy Resources, Inc.

Description: Report Filing: SERI Refund Report to be effective N/A.

Filed Date: 11/5/18.

Accession Number: 20181105–5197.

Comments Due: 5 p.m. ET 11/26/18.

Docket Numbers: ER18–2324–000.

Applicants: NorthWestern Corporation.

Description: Supplement (Diagram) to August 27, 2018 Request for Limited Waiver of Filed Tariff of NorthWestern Corporation.

Filed Date: 11/2/18.

Accession Number: 20181102–5259.

Comments Due: 5 p.m. ET 11/9/18.

Docket Numbers: ER19–286–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 3101R2 Heartland Consumers Power District NITSA and NOA to be effective 4/22/2018.

Filed Date: 11/5/18.

Accession Number: 20181105–5063.

Comments Due: 5 p.m. ET 11/26/18.

Docket Numbers: ER19–287–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original ISA SA No. 5227; Queue No. AB2–158 to be effective 10/8/2018.

Filed Date: 11/5/18.

Accession Number: 20181105–5064.

Comments Due: 5 p.m. ET 11/26/18.

Docket Numbers: ER19–288–000.

Applicants: Carson Hybrid Energy Storage LLC.

Description: Baseline eTariff Filing: Application for Market Based Rate to be effective 12/1/2018.

Filed Date: 11/5/18.

Accession Number: 20181105–5076.

Comments Due: 5 p.m. ET 11/26/18.

Docket Numbers: ER19–289–000.

Applicants: Cleco Cajun LLC.

Description: Baseline eTariff Filing: Baseline new to be effective 1/5/2019.

Filed Date: 11/5/18.

Accession Number: 20181105–5181.

Comments Due: 5 p.m. ET 11/26/18.

Docket Numbers: ER19–290–000.

Applicants: Pacific Gas and Electric Company.

Description: § 205(d) Rate Filing: Revisions to Appendix A to the US DOE Berkeley Site Office IA (SA 63) to be effective 11/6/2018.

Filed Date: 11/5/18.

Accession Number: 20181105–5198.

Comments Due: 5 p.m. ET 11/26/18.

Docket Numbers: ER19–291–000.

Applicants: ISO New England Inc., New England Power Pool.

Description: ISO New England Inc., et al. submits Installed Capacity Requirement, Hydro Quebec Interconnection Capability Credits and Related Values for the 2022/2023 Capacity Commitment Period.

Filed Date: 11/6/18.

Accession Number: 20181106–5025.

Comments Due: 5 p.m. ET 11/27/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date.

Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 6, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–24671 Filed 11–9–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2788–017]

Goodyear Lake Hydro, LLC; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed the application for a subsequent license for the Colliersville Hydroelectric Project, located on the Susquehanna River, in the Town of Milford, Otsego County, New York, and has prepared an Environmental Assessment (EA) for the project.

The EA contains staff's analysis of the potential environmental impacts of the project and concludes that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

A copy of the EA is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website at <http://www.ferc.gov> using the "eLibrary" link.

Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov, (866) 208–3676 (toll free), or (202) 502–8659 (TTY).

You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 30 days from the date of this notice.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–2788–017.

For further information, contact Emily Carter at (202) 502–6512 or by email at emily.carter@ferc.gov.

Dated: November 6, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–24703 Filed 11–9–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 11426–000]

T.A. Keck, III and H.S. Keck; Notice of Existing Licensee's Failure To File a Notice of Intent To File a Subsequent License Application, and Soliciting Notices of Intent To File a License Application and Pre-Application Documents

The current license for T.A. Keck, III and H.S. Keck's (the Kecks') Blackstone Mill Hydroelectric Project No. 11426 (Blackstone Mill Project) was issued on November 18, 1993, for a term of 30 years, ending October 31, 2023.¹ The 65-

¹ See *T.A. Keck, III and H.S. Keck*, 65 FERC ¶ 62,149 (1993).

kilowatt (kW) project is located on East Mahantango Creek, a tributary of the Susquehanna River near the Town of Pillow, in Dauphin County, Pennsylvania.

The principal project works consist of: (1) A 102-foot-long, approximately 2.5-foot-high dam; (2) a reservoir with a surface area of about 3 acres and a total volume of about 7 acre-feet at the normal water surface elevation of approximately 470 feet mean sea level; (3) a headrace or power canal about 3,200 feet long by 20 feet wide by 5 feet deep; (4) a stone-masonry powerhouse containing two generating units rated at 50 kW and 15 kW for a total installed capacity of 65 kW; (5) an overhead 240-volt transmission line about 60 feet long; and (6) appurtenant equipment and facilities.

At least five years before the expiration of a license for a minor water power project in which sections 14 and 15 of the Federal Power Act were waived, the Commission's regulations require the licensee to file with the Commission a notice of intent (NOI) that contains an unequivocal statement of the licensee's intention to file or not to file an application for a subsequent license, details on the principal project works and installed plant capacity, and other information.²

If such a licensee does not inform the Commission that it intends to file an application for, in this case, a subsequent license for the project, the licensee may not file an application for a subsequent license, either individually or in conjunction with an entity or entities that are not currently licensees of the project.³

Because the existing license expires on October 31, 2023, the NOI was due to be filed no later than the close of business on October 31, 2018. The Kecks, the existing licensee for the Blackstone Mill Project, failed to file an NOI by this date.

Any party interested in filing a license application for the Blackstone Mill Project No. 11426 must first file a Notice of Intent (NOI)⁴ and pre-application document (PAD)⁵ pursuant to Part 5 of the Commission's regulations. Although the integrated licensing process (ILP) is the default pre-filing process, section 5.3(b) of the Commission's regulations allows a potential license applicant to request to use alternative licensing procedures when it files its NOI.⁶

This notice sets a deadline of 120 days from the date of this notice for interested applicants, other than the existing licensee, to file NOIs, PADs, and requests to use an alternative licensing process.

Applications for a subsequent license from potential (non-licensee) applicants must be filed with the Commission at least 24 months prior to the expiration of the existing license.⁷ Because the existing license expires on October 31, 2023, applications for license for this project must be filed by October 31, 2021.⁸

Questions concerning this notice should be directed to Andy Bernick at (202) 502-8660 or andrew.bernick@ferc.gov.

Dated: November 6, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018-24701 Filed 11-9-18; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER19-288-000]

Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization: Carson Hybrid Energy Storage LLC

This is a supplemental notice in the above-referenced proceeding of Carson Hybrid Energy Storage 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 November 26, 2018.

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: November 6, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018-24670 Filed 11-9-18; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL19-11-000]

American Wind Energy Association, The Wind Coalition v. Southwest Power Pool, Inc.; Notice of Complaint

Take notice that on November 2, 2018, pursuant to sections 206, 306, and 309 of the Federal Power Act, 16 U.S.C. 824e, 825e, and 825h, and section 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206 (2018), the American Wind Energy Association and The Wind Coalition (collectively, Complainants) filed a formal complaint (complaint) against Southwest Power Pool, Inc.

² 18 CFR 16.19(b) (2018) (citing 18 CFR 16.6(b)). Section 16.19(b) applies to licenses not subject to Parts 14 and 15 of the Federal Power Act.

³ 18 CFR 16.24(b) (2018).

⁴ 18 CFR 5.5 (2018).

⁵ 18 CFR 5.6 (2018).

⁶ 18 CFR 5.3(b) (2018).

⁷ 18 CFR 16.20 (2018).

⁸ To the extent an interested applicant files an NOI and PAD and elects or is required to use the Commission's ILP, a process plan will be issued within 180 days of this notice, which accelerates the steps of the ILP to allow for filing a subsequent license application by the October 31, 2021 deadline.

(Respondent) requesting that the Commission find that sections of the Respondent's Financial Obligations of Withdrawing Members Bylaws and Membership Agreement, as applied to Independent Power Producer and other similarly situated non-transmission owners and non-load-serving entities, are unlawful, unjust and unreasonable, and unduly discriminatory, as more fully explained in the complaint.

Complainants certify that a copy of the complaint has been served on the contacts for the Respondent as listed on the Commission's website in the list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

This filing is accessible on-line at <http://www.ferc.gov>, using the "eLibrary" link and is available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email FERCOnlineSupport@ferc.gov, or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Comment Date: 5:00 p.m. Eastern Time on November 23, 2018.

Dated: November 6, 2018.

Kimberly D. Bose,
Secretary.

[FR Doc. 2018-24702 Filed 11-9-18; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AC19-19-000]

Notice of Filing; Southern California Edison Company, Appalachian Power Company, Arizona Public Service, Indiana Michigan Power Company, Kentucky Power Company, Pacific Gas and Electric Company, PNM Resources, Public Service Company of Colorado, Puget Sound Energy, San Diego Gas & Electric Company, South Carolina Electric & Gas Company, Southwestern Electric Power Company, Southwestern Public Service Company, Wheeling Power Company

Take notice that on November 5, 2018, Southern California Edison Company, Appalachian Power Company, Arizona Public Service, Indiana Michigan Power Company, Kentucky Power Company, Pacific Gas and Electric Company, PNM Resources, Public Service Company of Colorado, Puget Sound Energy, San Diego Gas & Electric Company, South Carolina Electric & Gas Company, Southwestern Electric Power Company, Southwestern Public Service Company, and Wheeling Power Company (collectively, the Joint Requesters), filed a request for approval to use Account 439, authorized by the Financial Accounting Standards Board.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

This filing is accessible on-line at <http://www.ferc.gov>, using the "eLibrary" link and is available for review in the Commission's Public

Reference Room in Washington, DC. There is an "eSubscription" link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email FERCOnlineSupport@ferc.gov, or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Comments: 5:00 p.m. Eastern Time on November 26, 2018.

Dated: November 6, 2018.

Kimberly D. Bose,
Secretary.

[FR Doc. 2018-24706 Filed 11-9-18; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OECA-2011-0256; FRL-9986-00-OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Emission Guidelines for Existing Other Solid Waste Incineration Units (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Emission Guidelines for Existing Other Solid Waste Incineration Units (EPA ICR No. 2164.06, OMB Control No. 2060-0562), to the Office of Management and Budget (OMB), for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through November 30, 2018. Public comments were previously requested, via the **Federal Register** on June 29, 2017, during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before December 13, 2018.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA-HQ-OECA-2011-0256, to: (1) EPA online using www.regulations.gov (our

preferred method), or by email to docket.oeca@epa.gov, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460; and (2) OMB via email to oira_submission@omb.eop.gov. Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT:

Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564-2970; fax number: (202) 564-0050; email address: yellin.patrick@epa.gov.

SUPPLEMENTARY INFORMATION:

Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit: <http://www.epa.gov/dockets>.

Abstract: The Emission Guidelines for Existing Other Solid Waste Incineration (OSWI) Units (40 CFR part 60, subpart FFFF) apply to any air quality program in either a state or a United States protectorate with one or more existing OSWI units or air curtain incinerators that commenced construction either on or before December 9, 2004. The affected OSWI units include two subcategories: Very small municipal waste combustion (VSMWC) units that combust less than 35 tons per day of waste and institutional waste incineration (IWI) units. This Subpart does not directly affect incineration unit owners and operators; however, they must comply with the state's plan that was developed by the air quality program administrator to implement the emission guidelines. In general, all emission guidelines require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any

startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance with 40 CFR part 60, subpart FFFF.

Form Numbers: None.

Respondents/affected entities: OSWI units, which include two subcategories—VSMWC units that combust less than 35 tons per day of waste and IWI units.

Respondent's obligation to respond: Mandatory (40 CFR part 60, subpart FFFF).

Estimated number of respondents: 99 (total).

Frequency of response: Initially, occasionally, semiannually, and annually.

Total estimated burden: 70,200 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$8,190,000 (per year), which includes \$495,000 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is no change in the labor hours or cost in this ICR compared to the previous ICR. This is due to two considerations: (1) The regulations have not changed over the past three years, and are not anticipated to change over the next three years; and (2) the growth rate for the industry is very low, negative or non-existent, so there is no significant change in the overall burden.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2018-24654 Filed 11-9-18; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2009-0022; FRL-9983-64-OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Acid Rain Program (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Acid Rain Program (EPA ICR No. 1633.17, OMB Control No. 2060-0258) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed

extension of the ICR, which is currently approved through November 30, 2018. Public comments were previously requested via the **Federal Register** on June 6, 2018 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. 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.

DATES: Additional comments may be submitted on or before December 13, 2018.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA-HQ-OAR-2009-0022, to (1) EPA online using www.regulations.gov (our preferred method), by email to a-and-r-docket@epa.gov, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460, and (2) OMB via email to oira_submission@omb.eop.gov. Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT:

Karen VanSickle, Clean Air Markets Division, Office of Air and Radiation, (6204M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202-343-9220; fax number: 202-343-2361; email address: vansickle.karen@epa.gov.

SUPPLEMENTARY INFORMATION:

Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit <http://www.epa.gov/dockets>.

Abstract: The Acid Rain Program was established under Title IV of the 1990 Clean Air Act Amendments to address acid deposition by reducing emissions of sulfur dioxide (SO₂) and nitrogen oxides (NO_x). This ICR addresses the

burden and costs associated with developing and modifying permits, complying with NO_x permitting requirements, monitoring emissions, transferring allowances, participating in the annual allowance auctions, and participating in the program as an opt-in source.

Form Numbers: Agent Notice of Delegation #5900–172; Certificate of Representation #7610–1; General Account Form #7610–5; Allowance Transfer Form #7610–6; Retired Unit Exemption #7610–20; Allowance Deduction #7620–4; Acid Rain Permit Application #7610–16; Acid Rain NO_x Compliance Plan #7610–28; Acid Rain NO_x Averaging Plan #7610–29; New Unit Exemption #7610–19; Opt-In Permit Application #7610–26; Opt-In Utilization Report #7620–9; Letter of Credit #7610–7A; EPA Allowance Auctions—Additional Information for Certified Checks or Wire Transfers #7610–7; SO₂ Allowance Offer Form #7610–8; Thermal Energy Plan #7610–27; Notification For Distribution of Proceeds From EPA Auctions #7610–11; Opt-In Reduction from Improved Efficiency Confirmation Report #7620–8; Thermal Energy Compliance Report #7620–10.

Respondents/affected entities: Electricity generating plants, industrial sources, and other persons.

Respondents' obligation to respond: Voluntary and mandatory (Clean Air Act sections 403, 407, 408, 410, 412, and 416).

Estimated number of respondents: 1,234 (total); includes 1,184 sources and 50 non-source entities participating in allowance trading activities.

Frequency of response: On occasion, quarterly, and annually.

Total estimated burden: 1,873,880 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: \$276,159,952 (per year), includes \$139,339,770 annualized capital or operation & maintenance costs.

Changes in Estimates: There is a decrease of 249,525 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. The decrease is principally due to source retirements, which have both reduced the estimated overall number of affected sources and shifted the estimated mix of monitoring methodologies used. The other factors contributing to the decrease in burden are reductions in the estimated numbers of allowance transfer and deduction

submissions, expected opt-in sources, and allowance auction bids.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2018–24649 Filed 11–9–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2017–0599; FRL–9985–43–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Renewable Fuel Standard Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Renewable Fuel Standard Program (EPA ICR No. 2546.01, OMB Control No. 2060–NEW) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a request for approval of an ICR that consolidates several existing collections. Public comments were previously requested via the **Federal Register** on December 8, 2017 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below. 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.

DATES: Additional comments may be submitted on or before December 13, 2018.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OAR–2017–0599, to (1) EPA online using www.regulations.gov (our preferred method), by email to a-and-r-docket@epa.gov, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460; and (2) OMB via email to oir_submission@omb.eop.gov. Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other

information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT:

Anne-Marie Pastorkovich, Office of Air and Radiation/Office of Transportation and Air Quality, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, (6405A), Washington, DC 20460; telephone number: 202–343–9623; fax number: 202–343–2800; email address: pastorkovich.anne-marie@epa.gov.

SUPPLEMENTARY INFORMATION:

Supporting documents, which explain in detail the information that EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For information about EPA's public docket, visit <http://www.epa.gov/dockets>.

Abstract: This information collection request (ICR) consolidates and updates recordkeeping and reporting burden and cost estimates related to the Renewable Fuel Standard (RFS) program into one, consistent, and easy-to-understand format. This consolidation will assist interested parties in better understanding all the information collection activities associated with RFS.

Under the RFS program, a certain volume of renewable fuel is required to replace or reduce the quantity of petroleum-based transportation fuel, heating oil or jet fuel. Obligated parties under the RFS program are refiners or importers of gasoline or diesel fuel. Obligated parties, and exporters of renewable fuel, must meet an annual Renewable Volume Obligation (RVO). Parties meet their RVO by blending renewable fuels into transportation fuel or by obtaining credits called Renewable Identification Numbers (RINs). EPA calculates and establishes RVOs every year through rulemaking, based on the CAA volume requirements and projections of gasoline and diesel production for the coming year. The standards are converted into a percentage and obligated parties must demonstrate compliance annually. RINs are used to demonstrate compliance with the standard and are generated by producers and importers of renewable fuels and traded by various parties. To track compliance with the RFS program, various parties involved with the production and blending of renewable fuels, and who generate, trade or use RINs, must register with EPA and submit various types of compliance

reports related to the activity they engage in under the program. Recordkeeping requirements under the RFS program include product transfer documents (PTDs) and retention of records.

Recordkeeping and reporting are based upon the activity the party engages in under the regulations. A party may be registered in more than one activity. For example, a single party may be both an obligated party and a RIN generator. Such a party would register once, but would submit registration information describing both activities they plan to engage in under the program. The party would then submit reports based upon which activities they actually engaged in during the compliance (calendar) year. Basing the recordkeeping and reporting upon a party's activities ensures that parties must sustain only the recordkeeping and reporting burden necessary to implement the RFS program.

This ICR will supersede and replace several existing ICRs, including: RFS2 Voluntary RIN Quality Assurance Program, OMB Control Number 2060-0688; Cellulosic Production Volume Projections and Efficient Producer Reporting, OMB Control Number 2060-0707; Renewable Fuels Standard Program (RFS2-Supplemental), OMB Control Number 2060-0637; Renewable Fuel Standard (RFS2) Program, OMB Control Number 2060-0640; Regulation of Fuel and Fuel Additives: 2011 Renewable Fuel Standards—Petition for International Aggregate Compliance Approach, OMB Control Number 2060-0655; and Production Outlook Report for Unregistered Renewable Fuels Producers, OMB Control Number 2060-0660.

Form Numbers: RFS0104: RFS Activity Report, RFS0303: RFS Annual Compliance Report, RFS0601: RFS Renewable Fuel Producer Supplemental Report, RFS0701: RFS Renewable Fuel Producer Co-Products Report, RFS0801: RFS Renewable Biomass Report, RFS0901: RFS Production Outlook Report, RFS1400: Reporting Fuels under 80.1451(b)(1)(ii)(T), RFS1500: Reporting Fuels under 80.1451(b)(1)(ii)(T)—Finished Fuel Blending, RFS1600: Reporting Fuels under 80.1451(b)(1)(ii)(T)—Blender Contact, RFS2000: Batch Verification, RFS2100: Aggregate RIN Verification, RFS2200: On-Site Audit Report, RFS2300: List of Potentially Invalid RINs, RFS2400: Mass Balance, RFS2500: RFS Efficient Producer Data Report, and RFS2700: RFS Cellulosic Biofuel Producer Questionnaire.

Respondents/affected entities: RIN Generators (producers and importers of renewable fuels), Obligated Parties (refiners and importers of gasoline and diesel transportation fuels), RIN Owners, Renewable Fuel Exporters, QAP Providers, and petitioners under the international aggregate compliance approach.

Respondent's obligation to respond: The RFS program assigns mandatory reporting that is based upon activity.

Estimated number of respondents: 19,542.

Frequency of response: On occasion, quarterly, annual.

Total estimated burden: 566,665 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: \$57,457,330 (per year), which includes \$0 annualized capital or operation & maintenance costs.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2018-24655 Filed 11-9-18; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OECA-2014-0055; FRL-9985-86-OE1]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for the Secondary Lead Smelter Industry (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NESHAP for the Secondary Lead Smelter Industry (EPA ICR No. 1686.11, OMB Control No. 2060-0296), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through November 30, 2018. Public comments were previously requested, via the **Federal Register**, on June 29, 2017 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before December 13, 2018.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA-HQ-OECA-2014-0055, to: (1) EPA online using www.regulations.gov (our preferred method), or by email to docket.oeca@epa.gov, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460; and (2) OMB via email to oir_submission@omb.eop.gov. Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564-2970; fax number: (202) 564-0050; email address: yellin.patrick@epa.gov.

SUPPLEMENTARY INFORMATION:

Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit: <http://www.epa.gov/dockets>.

Abstract: The National Emission Standards for Hazardous Air Pollutants (NESHAP) for the Secondary Lead Smelter Industry apply to existing facilities and new facilities that operate furnaces to reduce scrap lead metal and lead compounds to elemental lead. Specifically, the rule applies to secondary lead smelters that use blast, reverberatory, rotary, or electric smelting furnaces to recover lead metal from scrap lead, primarily from used lead-acid automotive-type batteries. New facilities include those that commenced construction or reconstruction after the date of proposal. In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected

facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance with 40 CFR 63, subpart X.

Form Numbers: None.

Respondents/affected entities: Secondary lead smelters.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart X).

Estimated number of respondents: 12 (total).

Frequency of response: Initially, occasionally, semiannually and annually.

Total estimated burden: 21,700 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$2,630,000 (per year), which includes \$251,000 annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is an increase in the total estimated burden and the number of responses from the most recently approved ICR due to several adjustments: (1) The overall number of sources decreased; and (2) there were several missing burden line items and inaccurate assumptions that were corrected since the previous renewal. In addition, the previous renewal had not accounted for any burden for dioxin/furan testing since that burden occurs every six years, which was added to this renewal. Third, this renewal includes time for each affected facility to review rule requirements each year. There is a decrease in the O&M costs from the most recently approved ICR due to an adjustment in the number of sources.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2018-24650 Filed 11-9-18; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OECA-2014-0033; FRL-9985-27-OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NSPS for Petroleum Refineries (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an

information collection request (ICR), NSPS for Petroleum Refineries (EPA ICR No. 1054.13, OMB Control No. 2060-0022), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through November 30, 2018. Public comments were previously requested, via the **Federal Register**, on June 29, 2017 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before December 13, 2018.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA-HQ-OECA-2014-0033, to: (1) EPA online using www.regulations.gov (our preferred method), or by email to docket.oeca@epa.gov, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460; and (2) OMB via email to oir_submission@omb.eop.gov. Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT:

Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564-2970; fax number: (202) 564-0050; email address: yellin.patrick@epa.gov.

SUPPLEMENTARY INFORMATION:

Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's

public docket, visit: <http://www.epa.gov/dockets>.

Abstract: The New Source Performance Standards (NSPS) for Petroleum Refineries were proposed on June 11, 1973, promulgated on March 8, 1974, and amended on both September 12, 2012 and December 1, 2015. The 2015 amendment finalized technical clarifications to improve consistency and clarity and to address issues related to a 2008 industry petition for reconsideration. The 2012 amendment allowed the option for affected sources to comply with Subpart J by following the applicable provisions in the NSPS Subpart Ja rule. The affected sources are: (1) Fluid catalytic cracking unit (FCCU) catalyst regenerator or fuel gas combustion device (FGCD) other than a flare that commenced construction, reconstruction or modification after June 11, 1973 and on/or before May 14, 2007; (2) FGCD that is also a flare that commenced construction, reconstruction or modification after June 11, 1973 and on/or before June 24, 2008; or (3) any Claus sulfur recovery plant with a design capacity of more than 20 long tons per day sulfur feed which commenced construction, reconstruction or modification after October 4, 1976 and on/or before May 14, 2007.

In general, all NSPS standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance with 40 CFR part 60, subpart J.

Form Numbers: None.

Respondents/affected entities: Petroleum refineries.

Respondent's obligation to respond: Mandatory (40 CFR part 60, subpart J).

Estimated number of respondents: 149 (total).

Frequency of response: Initially, occasionally, and semiannually.

Total estimated burden: 15,800 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$2,500,000 (per year), which includes \$826,000 annualized capital/startup and/or operation & maintenance (O&M) costs.

Changes in the Estimates: There is an increase in labor hours from the most-recently approved ICR due to an adjustment. The total hours include an hour allowance to allow each source to familiarize themselves with the

requirements each year. Finally, there is slight increase in the O&M costs, as costs were adjusted from \$2,005.00 to \$2,016.00 using the *Chemical Engineering Index*.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2018-24652 Filed 11-9-18; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9986-39-OARM]

Senior Executive Service Performance Review Board; Membership

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Notice is hereby given of the membership of the U.S. Environmental Protection Agency Performance Review Board for 2018.

FOR FURTHER INFORMATION CONTACT: Debbi Hart, Director, Policy, Planning & Training Division, 3601M, Office of Human Resources, Office of Administration and Resources Management, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460 (202) 564-2011.

SUPPLEMENTARY INFORMATION: Section 4314(c)(1) through (5) of Title 5, U.S.C., requires each agency to establish in accordance with regulations prescribed by the Office of Personnel Management, one or more SES performance review boards. This board shall review and evaluate the initial appraisal of a senior executive's performance by the supervisor, along with any recommendations to the appointment authority relative to the performance of the senior executive.

Members of the 2018 EPA Performance Review Board are:

Richard Buhl, Assistant Regional Administrator for Technical and Management Services, Region 8
 Sheryl Bilbrey, Director, Office of Environmental Cleanup, Region 10
 David Bloom, Deputy Chief Financial Officer, Office of the Chief Financial Officer
 Wesley Carpenter, (Ex-Officio), Acting Director, Office of Human Resources, Office of Administration and Resources Management
 Katrina Cherry, Director, Office of Management and International Services, Office of International and Tribal Affairs
 Edward Chu, Deputy Regional Administrator, Region 7

Diana Esher, Assistant Regional Administrator for Policy and Management, Region 3
 Lynn Flowers, Associate Director for Science, Office of Science Policy, Office of Research and Development
 Sheila Frace, Deputy Director, Office of Wastewater Management, Office of Water
 Jeanneanne Gettle, Director, Water Protection Division, Region 4
 Peter Grevatt, Director, Office of Ground Water and Drinking Water, Office of Water
 Christopher Grundler, Director, Office of Transportation and Air Quality, Office of Air and Radiation
 Debbi Hart, (Ex-Officio), Director, Policy, Planning and Training Division, Office Administration and Resources Management
 Randy Hill, Director, Enforcement Targeting and Data Division, Office of Enforcement and Compliance Assurance
 Kathleen Johnson, Director, Enforcement Division, Region 9
 Deborah Jordan, Deputy Regional Administrator, Region 9
 Mark Kasman, Director, Office of Regional and Bilateral Affairs, Office of International and Tribal Affairs
 Richard Keigwin, Director, Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention
 Arnold Layne, Deputy Director, Office of Pesticides Programs, Office of Chemical Safety and Pollution Prevention
 Kenneth Lapiere, Assistant Regional Administrator for Policy and Management, Region 4
 Matthew Leopard, Director, Office of Information Management, Office of Environmental Information
 David Lloyd, Director, Office of Brownfields and Land Revitalization, Office of Land and Emergency Management
 Rohit Mathur, Senior Atmospheric Scientist, Office of Research and Development
 James McDonald, Assistant Regional Administrator for Management, Region 6
 Albert McGartland, Director, National Center for Environmental Economics, Office of the Administrator
 Kenneth Moraff, Director, Office of Ecosystem Protection, Region 1
 Ed Nam, Director, Air and Radiation Division, Region 5
 Jennifer Orme-Zaveleta, Deputy Assistant Administrator (Science), Office of Research and Development
 Howard Osborne, Associate Chief Financial Officer, Office of the Chief Financial Officer

Elise Packard, Associate General Counsel, Civil Rights and Finance Law, Office of General Counsel
 Denise Polk, Director, Office of Grants and Debarment, Office of Administration and Resources Management
 Sylvia Quast, Regional Counsel—Region 9, Office of Enforcement and Compliance Assurance
 Mary Ellen Radzikowski, Deputy Director for Management, National Center for Environmental Research, Office of Research and Development
 Robin Richardson, Principal Deputy Associate Administrator, Office of Congressional and Intergovernmental Relations, Office of the Administrator
 Cecil Rodrigues, Deputy Regional Administrator, Region 3
 Gregory Sayles, Director, National Homeland Security Research Center, Office of Research and Development
 Lorie Schmidt, Principal Associate General Counsel, Office of General Counsel
 Nigel Simon, Director, Office of Program Management, Office of Land and Emergency Management
 Vicki Simons, (Ex-Officio), Director, Office of Civil Rights, Office of the Administrator
 Donna J. Vizian, (Ex-Officio), Principal Deputy Assistant Administrator, Office of Administration and Resources Management
 Jeffrey Wells, Director, Office of Customer Advocacy Policy and Portfolio Management, Office of Environmental Information
 Pai-Yei Whung, Senior Research Scientist, Office of Research and Development
 Anahita Williamson, Director, Environmental Science and Assessment Division, Region 2
 Helena Wooden-Aguilar, (Ex-Officio), Acting Deputy Chief of Staff, Office of the Administrator

Dated: November 1, 2018.

Donna J. Vizian,

Principal Deputy Assistant Administrator, Office of Administration and Resources Management.

[FR Doc. 2018-24741 Filed 11-9-18; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9986-43-OAR]

Clean Air Act Advisory Committee; Notice of Charter Renewal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of charter renewal.

Notice is hereby given that the Environmental Protection Agency (EPA) has determined that, in accordance with the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. App.2, the Clean Air Act Advisory Committee (CAAAC) is a necessary committee which is in the public interest. Accordingly, the CAAAC is being reinstated for a two-year period. The purpose of the CAAAC is to provide advice and recommendations to the EPA Administrator on policy issues associated with implementation of the Clean Air Act. Inquiries may be directed to Larry Weinstock, CAAAC Designated Federal Officer, U.S. EPA, 1200 Pennsylvania Avenue NW (Mail Code 6103A), Washington, DC 20460, or by email to weinstock.larry@epa.gov.

Dated: November 5, 2018.

William L. Wehrum,

Assistant Administrator, Office of Air and Radiation.

[FR Doc. 2018-24710 Filed 11-9-18; 8:45 am]

BILLING CODE P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OECA-2014-0091; FRL-9986-10-OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Engine Test Cells/Standards (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NESHAP for Engine Test Cells/Standards (EPA ICR No. 2066.07, OMB Control No. 2060-0483), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through November 30, 2018. Public comments were previously requested, via the **Federal Register** on June 29, 2017, during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before December 13, 2018.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA-HQ-OECA-2014-0091, to: (1) EPA online using www.regulations.gov (our preferred method), or by email to docket.oeca@epa.gov, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460; and (2) OMB via email to oira_submission@omb.eop.gov. Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564-2970; fax number: (202) 564-0050; email address: yellin.patrick@epa.gov.

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov, or in person, at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit: <http://www.epa.gov/dockets>.

Abstract: The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Engine Test Cells/Standards (40 CFR part 63, subpart P) apply to either new or reconstructed engine test cells/stands located at major source facilities that are being used for testing internal combustion engines. An engine test cell/stand is any apparatus used for testing uninstalled stationary or uninstalled mobile (motive) engines. A plant site that is a major source of hazardous air pollutant (HAP) emissions emits or has the potential to emit any single HAP at a rate of 10 tons (9.07 megagrams) or more per year or any combination of HAPs at a rate of 25 tons (22.68 megagrams) or more per year. New facilities include those that commenced construction or

reconstruction after the date of proposal. In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance with 40 CFR part 63, subpart P.

Form Numbers: None.

Respondents/affected entities:

Owners or operators of engine test cells/stands located at major source facilities that are being used for testing internal combustion engines.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart P).

Estimated number of respondents: 19 (total).

Frequency of response: Initially, occasionally, and semiannually.

Total estimated burden: 2,150 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$204,000 (per year), which includes \$6,200 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is an increase in the total estimated burden, number of responses, and Capital and O&M costs from the most-recently approved ICR due to several adjustments. First, based on consultations with internal Agency experts, there is an increase in the estimated number of new sources. This renewal reflects burden for an increase in the total number of sources and incorporates burden for one-time requirements for the new source. Second, this renewal includes time for each affected facility to review rule requirements each year.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2018-24653 Filed 11-9-18; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OECA-2014-0068; FRL-9986-05-OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Primary Lead Smelting (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), NESHAP for Primary Lead Smelting (EPA ICR No. 1856.11, OMB Control No. 2060-0414), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through November 30, 2018. Public comments were previously requested, via the **Federal Register** on June 29, 2017, during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before December 13, 2018.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA-HQ-OECA-2014-0068, to: (1) EPA online using www.regulations.gov (our preferred method), or by email to docket.oeca@epa.gov, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460; and (2) OMB via email to oir_submission@omb.eop.gov. Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564-2970; fax number: (202) 564-0050; email address: yellin.patrick@epa.gov.

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov, or in person at the EPA Docket Center, WJC West, Room

3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit: <http://www.epa.gov/dockets>.

Abstract: The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Primary Lead Smelting apply to existing and new facilities engaged in producing lead metal from ore concentrates. The category includes, but is not limited to, the following smelting processes: Sintering, reduction, preliminary treatment, refining and casting operations, process fugitive sources, and fugitive dust sources. New facilities include those that commenced construction or reconstruction after the date of proposal. In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance with 40 CFR part 63, subpart TTT.

Form Numbers: None.

Respondents/affected entities: Facilities engaged in primary lead processing.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart TTT).

Estimated number of respondents: 1 (total).

Frequency of response: Initially, quarterly and semiannually.

Total estimated burden: 6,270 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$855,000 (per year), which includes \$169,000 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is an adjustment increase of 5 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase is due to rounding of the total estimated burden to three significant digits.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2018-24651 Filed 11-9-18; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

[CC Docket No. 92-237; DA 18-1118]

Next Meeting of the North American Numbering Council

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the Commission released a public notice announcing the meeting of the North American Numbering Council (NANC). At this meeting, the NANC Working Groups will report on their progress in developing recommendations for the NANC's consideration. In addition, the NANC will continue its discussions on how to modernize and foster more efficient number administration in the United States. The NANC meeting is open to the public. The FCC will accommodate as many attendees as possible; however, admittance will be limited to seating availability.

DATES: Tuesday, December 4, 2018, 9:30 a.m.

ADDRESSES: Requests to make an oral statement or provide written comments to the NANC should be sent to Carmell Weathers, Competition Policy Division, Wireline Competition Bureau, Federal Communications Commission, Portals II, 445 12th Street SW, Room 5-C162, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Carmell Weathers at (202) 418-2325 or Carmell.Weathers@fcc.gov. The fax number is: (202) 418-1413. The TTY number is: (202) 418-0484.

SUPPLEMENTARY INFORMATION: The Commission will also provide audio coverage of the meeting. Other reasonable accommodations for people with disabilities are available upon request. Request for such accommodations should be submitted via email to fcc504@fcc.gov or by calling the Consumer and Governmental Affairs Bureau @ (202) 418-0530 (voice) (202) 418-0432 (TTY). Such requests should include a detailed description of the accommodation needed. In addition, please include a way for the FCC to contact the requester if more information is needed to fill the request. Please allow at least five days advance notice for accommodation requests; last minute requests will be accepted but may not be possible to accommodate.

Members of the public may submit comments to the NANC in the FCC's Electronic Comment Filing System, ECFS, at www.fcc.gov/ecfs. Comments to the NANC should be filed in CC Docket No. 92-237.

More information about the NANC is available at <https://www.fcc.gov/about-fcc/advisory-committees/general/north-american-numbering-council>. You may also contact Marilyn Jones, DFO of the NANC, at Marilyn.jones@fcc.gov, or (202) 418-2357; Michelle Sclater, Alternate DFO, at michelle.sclater@fcc.gov, or (202) 418-0388; or Carmell Weathers, Special Assistant to the DFO, at carmell.weathers@fcc.gov, or (202) 418-2325.

This is a summary of the Commission's document in CC Docket No. 92-237, DA 18-1118 released October 31, 2018. The complete text in this document is available for public inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street SW, Room CY-A257, Washington, DC 20554. The document may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street SW, Room CY-B402, Washington, DC 20554, telephone (800) 378-3160 or (202) 863-2893, facsimile (202) 863-2898, or via the internet at <http://www.bcpweb.com>. It is available on the Commission's website at <http://www.fcc.gov>.

* The Agenda may be modified at the discretion of the NANC Chairman with the approval of the Designated Federal Officer (DFO).

Federal Communications Commission.

Marilyn Jones,

Senior Counsel for Number Administration,
Wireline Competition Bureau.

[FR Doc. 2018-24680 Filed 11-9-18; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

TIME AND DATE: Thursday, November 15, 2018 at 10:00 a.m.

PLACE: 1050 First Street NE,
Washington, DC (12th Floor).

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED:

Correction and Approval of Minutes for October 25, 2018

Draft Advisory Opinion 2018-15:
Wyden

Draft Advisory Opinion 2018-13:
OsiaNetwork LLC

Audit Division Recommendation
Memorandum on Friends of Erik
Paulsen (FEP) (A17-06)

Management and Administrative
Matters

CONTACT PERSON FOR MORE INFORMATION:
Judith Ingram, Press Officer, Telephone:
(202) 694-1220.

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Dayna C. Brown, Secretary and Clerk, at (202) 694-1040, at least 72 hours prior to the meeting date.

Dayna C. Brown,

Secretary and Clerk of the Commission.

[FR Doc. 2018-24864 Filed 11-8-18; 4:15 pm]

BILLING CODE 6715-01-P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Federal Trade Commission ("FTC" or "Commission").

ACTION: Notice; request for comments.

SUMMARY: The FTC intends to ask the Office of Management and Budget ("OMB") to extend for an additional three years the current Paperwork Reduction Act ("PRA") clearance for the information collection requirements in the FTC Red Flags, Card Issuers, and Address Discrepancies Rules¹ ("Rules"). That clearance expires on November 30, 2018.

DATES: Comments must be submitted by December 13, 2018.

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write "Red Flags Rule, PRA Comment, Project No. P095406" on your comment. File your comment online at <https://ftcpublishcommentworks.com/ftc/RedFlagsPRA2> by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT:
Requests for additional information

¹ 16 CFR 681.1 (Duties regarding the detection, prevention, and mitigation of identity theft); 16 CFR 681.2 (Duties of card issuers regarding changes of address); 16 CFR 641.1 (Duties of users of consumer reports regarding address discrepancies).

should be addressed to Mark Eichorn, Assistant Director, Division of Privacy and Identity Protection, Bureau of Consumer Protection, (202) 326-3053, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

Title: Red Flags Rule, 16 CFR 681.1; Card Issuers Rule, 16 CFR 681.2; Address Discrepancy Rule, 16 CFR part 641.

OMB Control Number: 3084-0137.

Type of Review: Extension of currently approved collection.

Abstract: The Red Flags Rule requires financial institutions and certain creditors to develop and implement written Identity Theft Prevention Programs. The Card Issuers Rule requires credit and debit card issuers to assess the validity of notifications of address changes under certain circumstances. The Address Discrepancy Rule provides guidance on what covered users of consumer reports must do when they receive a notice of address discrepancy from a nationwide consumer reporting agency. Collectively, these three anti-identity theft provisions are intended to prevent impostors from misusing another person's personal information for a fraudulent purpose.

The Rules implement sections 114 and 315 of the Fair Credit Reporting Act ("FCRA"), 15 U.S.C. 1681 *et seq.*

The Commission received no relevant public comments on the Rules' information collection requirements and FTC staff's associated PRA burden analysis and estimates that appeared in an August 8, 2018 **Federal Register** Notice.² That Notice discusses in greater detail staff's methodology behind the estimates restated here in summary form, while also providing an overview of the Rules and the statutes that underlie them.³

Pursuant to the OMB regulations, 5 CFR part 1320, that implement the PRA,

² 83 FR 39096.

³ This **Federal Register** Notice, however, corrects summary figures that had appeared in the prior Notice at Part II., page 39,097 (inadvertently carried over from the FTC's 2015 published PRA estimates). The corrections are not numerically material, however, and the calculation methodologies that appeared in the prior Notice were as intended. Further, in Part III. C. of the prior Notice, at page 39,099, 1,667 hours then intended to be shown as an estimate for address verification were omitted from the hours subtotal for Section 315 and, by extension, the aggregate estimated burden hours for the Rules. However, given statutory changes that had not then been appropriately considered, those hours had been tied to an overstatement of the relevant population affected, as explained further in footnote 9 here. Accordingly, ultimately the estimated burden related to address verification is de minimis.

44 U.S.C. 3501 *et seq.*, the FTC is providing a second opportunity for the public to comment on:

(1) Whether the disclosure requirements are necessary, including whether the information will be practically useful; (2) the accuracy of our burden estimates, including whether the methodology and assumptions used are valid; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information.

Estimated Annual Burden (1,385,290 hours; \$66,185,200, labor costs)

A. Section 114: Red Flags and Card Issuers Rules:

(1) Red Flags:

(a) Estimated Number of Respondents: 157,585⁴

(i) High-Risk Entities: 94,052⁵

(ii) Low-Risk Entities: 63,533⁶

(b) Estimated Hours Burden:⁷

(i) High-Risk Entities: 1,222,676 hours

(ii) Low-Risk Entities: 39,179 hours

(2) Card Issuers Rule:

(a) Estimated Number of Respondents: 16,742⁸

(b) Estimated Hours Burden: 66,968 hours

(3) Combined Labor Cost Burden: \$65,112,327

B. Section 315—Address Discrepancy Rule:

⁴ This figure comprises 6,278 financial institutions and 151,307 creditors (87,774 high-risk entities, excluding financial institutions + 63,533 low-risk creditors). The total number of financial institutions draws from FTC staff analysis of state credit unions and insurers within the FTC's jurisdiction using 2015 Census Bureau data ("Statistics of U.S. Businesses") and other online industry data. The total number of creditors draws from FTC staff analysis of 2015 Census data and industry data for businesses or organizations that market goods and services to consumers or other businesses or organizations subject to the FTC's jurisdiction, reduced by entities not likely to: (1) Obtain credit reports, report credit transactions, or advance loans; and (2) entities not likely to have covered accounts under the Rule. Currently, no further updated Census data is available online to inform revised estimates. Thus, for instant purposes, the FTC will continue to draw upon the 2015 data.

⁵ High-risk entities include, for example, financial institutions within the FTC's jurisdiction and utilities, motor vehicle dealerships, telecommunications firms, colleges and universities, and hospitals.

⁶ Low-risk entities include, for example, public warehouse and storage firms, nursing and residential care facilities, automotive equipment rental and leasing firms, office supplies and stationery stores, fuel dealers, and financial transaction processing firms.

⁷ See the August 8, 2018 Notice, 83 FR at 39098, for details underlying the Red Flags hours burden estimates.

⁸ FTC staff estimates that the Rule affects as many as 16,742 card issuers within the FTC's jurisdiction. This includes, for example, state credit unions, general retail merchandise stores, colleges and universities, and telecoms.

(1) Estimated Number of Respondents: 121,000⁹

(2) Estimated Hours Burden: 56,467 hours¹⁰

(3) Estimated Labor Cost Burden: \$1,072,873¹¹

C. Capital/Non-Labor Costs for Sections 114 and 315.

FTC staff believes that the Rules impose negligible capital or other non-labor costs, as the affected entities are likely to have the necessary supplies and/or equipment already (*e.g.*, offices and computers) for the information collections described herein.

IV. Request for Comment

You can file a comment online or on paper. For the FTC to consider your comment, we must receive it on or before December 13, 2018. Write "Red Flags Rule, PRA Comment, Project No. P095406" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public FTC website, at <http://www.ftc.gov/os/publiccomments.shtml>.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online, or to send them to the Commission by courier or overnight service. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublic.commentworks.com/ftc/RedFlagsPRA2> by following the instructions on the web-based form. When this Notice appears at <http://www.regulations.gov/#/home>, you also may file a comment through that website.

www.regulations.gov/#/home, you also may file a comment through that website.

If you file your comment on paper, write "Red Flags Rule, PRA Comment, Project No. P095406" on your comment and on the envelope, and mail it to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible FTC website at <https://www.ftc.gov/>, you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential"—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC

⁹ In the August 8, 2018 Notice, the estimated number of businesses that would be required to comply with the Address Discrepancy Rule had been greatly overstated. 83 FR at 39099. The FTC Address Discrepancy Rule covers only users of consumer reports that are motor vehicle dealers described in section 1029(a) of the Dodd-Frank Act and that are predominantly engaged in the sale and servicing of motor vehicles, the leasing and servicing of them, or both. See 77 FR 22200, 22201 (Apr. 13, 2012). The FTC recently estimated that there are approximately 121,000 motor vehicle dealers, determined as follows: 86,442 car dealers per NAICS data (49,905 new car dealers, 36,537 used car dealers) + [3,191 Recreational Vehicle Dealers; 7,185 boat dealers; 24,157 motorcycle, ATV/All Other Motor Vehicle Dealers] = 120,975. 82 FR 12452 (March 3, 2017). By extension, the estimated number of respondents expected to perform address verification, which had always been secondary to the estimates concerning customer verification and very small relative to the overall population subject to this Rule, becomes de minimis with the corrective adjustment to the latter. Thus, the estimates now concern customer verification only.

¹⁰ Based on an estimated average of 28 minutes per respondent. See 83 FR at 39099.

¹¹ Based on an estimated hourly wage of \$19 for administrative support personnel (computer operators; data entry and information processing workers; word processors and typists).

website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from the FTC website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before December 13, 2018. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>. For supporting documentation and other information underlying the PRA discussion in this Notice, see <http://www.reginfo.gov/public/jsp/PRA/pradashboard.jsp>.

Comments on the information collection requirements subject to review under the PRA should additionally be submitted to OMB. If sent by U.S. mail, they should be addressed to Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Federal Trade Commission, New Executive Office Building, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503. Comments sent to OMB by U.S. postal mail, however, are subject to delays due to heightened security precautions. Thus, comments instead can also be sent by email to wliberante@omb.eop.gov.

Heather Hipsley,
Deputy General Counsel.

[FR Doc. 2018-24682 Filed 11-9-18; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2018-0110; NIOSH-224]

Barriers to Participation in the NIOSH Coal Workers Health Surveillance Program

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Request for information.

SUMMARY: The Coal Workers' Health Surveillance Program (CWHSP or Program), administered by CDC's National Institute for Occupational

Safety and Health (NIOSH), is seeking information from coal miners, miner advocates, unions, industry stakeholders, and other interested parties about barriers to participating in health screening offered by the Program to inform efforts to improve participation.

DATES: Comments must be received by January 14, 2019.

ADDRESSES: *Written comments:* Comments may be submitted electronically, through the Federal eRulemaking Portal: <http://www.regulations.gov>, or by sending a hard copy to the NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 1090 Tusculum Avenue, Cincinnati, OH 45226. All written submissions received must include the agency name (Centers for Disease Control and Prevention, HHS) and docket number (CDC-2018-0110; NIOSH-224) for this action. All relevant comments, including any personal information provided, will be posted without change to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Cara N. Halldin, NIOSH Coal Workers' Health Surveillance Program, Respiratory Health Division, 1095 Willowdale Road, MS HG900.2, Morgantown, WV 26505-2888; (304) 285-5754 (this is not a toll-free number); challdin@cdc.gov.

SUPPLEMENTARY INFORMATION:

The NIOSH Coal Workers' Health Surveillance Program was authorized by the Coal Mine Health and Safety Act of 1969, as amended by the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 *et seq.*), to detect dust-induced interstitial lung disease (black lung or coal workers' pneumoconiosis) and prevent its progression in individual miners, and obtain information about temporal and geographic trends across the population of coal miners. Through the Program, coal miners are offered periodic health screenings, including chest x-rays and spirometry examinations, at no cost to them. These screenings can potentially detect early signs of black lung. NIOSH has administered the Program since 1970. Since that time, the prevalence of radiographic evidence of pneumoconiosis among participating coal miners reached its lowest level in the late 1990s, but has steadily increased since 2000 and is now at a 25-year high. In the Appalachian coal mining states of Kentucky, Virginia, and West Virginia, as many as one in five underground coal miners with more than 25 years' tenure are thought to have radiographic evidence of

pneumoconiosis.¹ Participation by coal miners in the CWHSP is voluntary, and about 35 percent of active coal miners participate in health screenings offered by the Program.²

Greater participation in the Program would provide more opportunities for early detection of pneumoconiosis in coal miners, providing those with early disease the ability to take action to reduce the chance for progression to severe lung disease. In order to identify ways to improve participation in the Program, NIOSH is seeking information from all interested parties, especially active coal miners, as well as miner advocates, unions, industry stakeholders, and healthcare providers of screening services for the CWHSP, to learn about the factors that keep miners from participating in the health screening examinations that are available to them.

NIOSH is particularly interested in receiving information about the following questions:

1. Are coal miners aware that periodic health screenings are available, at no cost to them, through the Coal Workers' Health Surveillance Program?

2. Is lack of convenience of the screening—for example, screening locations or hours of availability—a barrier to participation? If yes, please describe those factors that may prevent miners from accessing CWHSP screenings.

3. NIOSH's mobile surveillance unit travels to different locations to provide free black lung screenings, including chest x-rays and spirometry tests.³ Does the mobile unit provide a useful supplement to services offered by approved healthcare facilities engaged by mine operators? If yes, please explain why mobile outreach is a useful supplement. If no, or if mobile outreach could be improved, please provide recommendations on how it could become more useful to the coal mining community.

4. Do coal miners receive encouragement to participate (or discouragement from participating) in the CWHSP screenings from others such as employers, unions, or co-workers? If so, please describe.

5. Are scheduling issues, such as the need to take unpaid time off from work or use vacation hours or non-work hours for health screenings, a barrier to miners' participation in health

¹ Blackley DJ, Halldin CN, Laney AS [2018]. *Continued increase in prevalence of coal workers' pneumoconiosis in the United States, 1970-2017*. *AJPH* 108(9):1220-1222.

² *Id.*

³ See <https://www.cdc.gov/niosh/topics/cwhsp/free-screening/vv.html>.

screenings? If yes, please explain the scheduling issue that is a barrier and provide recommendations for how it could be overcome.

6. Does concern about the confidentiality of medical information pose a barrier to participation? If this is a barrier, then please provide recommendations or suggestions for how it can be overcome.

7. Does concern that the early identification of dust-related lung disease might adversely affect a miner's career (*e.g.*, prevent career advancement or the ability to get a new coal mining job) pose a barrier to participation? If this is a barrier, then please provide recommendations or suggestions for how it can be overcome.

8. Does concern that early identification of dust-related lung disease might affect subsequent eligibility for compensation through Federal or State programs pose a barrier to participation? If this is a barrier, then please describe the specific compensation programs and how eligibility for them can be affected by early detection of dust-related lung disease. Please also provide recommendations or suggestions for how this barrier could be overcome.

9. Does concern that personal finances will require a miner to continue working despite early identification of dust-related lung disease pose a barrier to participation? If this is a barrier, please provide recommendations or suggestions for how it can be overcome.

10. Are there any other barriers to participation that NIOSH should be aware of?

Interested parties may participate in this activity by submitting written views, opinions, recommendations, and data. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you do not wish to be disclosed. Although your name, contact information, or other information that identifies you in the body of your comments will be on public display, NIOSH will review all submissions and may choose to redact or withhold

submissions containing private or proprietary information such as Social Security numbers, medical information, and/or inappropriate language.

Comments may be submitted on any topic related to this action. All public comments will be posted in the docket for this action at <https://www.regulations.gov>.

John J. Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2018-24700 Filed 11-9-18; 8:45 am]

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2416-N]

Basic Health Program; Final Administrative Order

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of Final Administrative Order.

SUMMARY: This notice serves to announce that a Final Administrative Order related to the Basic Health Program (BHP) was issued to the States of New York and Minnesota on August 24, 2018.

DATES: The Final Administrative Order was effective August 24, 2018.

FOR FURTHER INFORMATION CONTACT: Christopher Truffer, (410) 786-1264; Meg Barry, (410) 786-1536.

SUPPLEMENTARY INFORMATION:

I. Background and Provisions of the Notice

The CMS Administrator issued a Final Administrative Order to set forth the revised payment methodology that applies to the Basic Health Program for 2018 *only* (HHS Revised BHP Payment Methodology). The Administrative Order is an agency action under 5 U.S.C. 551(13), issued pursuant to 5 U.S.C. 555(b) and (e).

The HHS Revised BHP Payment Methodology modifies the existing

methodology for 2018, which is set forth in the payment notice entitled "Basic Health Program; Federal Funding Methodology for Program Years 2017 and 2018" (81 FR 10091, February 29, 2016) (February 2016 Payment Notice). The modification involves the application of a Premium Adjustment Factor (PAF) that considers the premium increases in other states that became effective after the Centers for Medicare & Medicaid Services (CMS), an operating division of the U.S. Department of Health and Human Services (HHS), discontinued payments to issuers for cost-sharing reductions (CSRs) provided to enrollees in qualified health plans (QHPs) offered on health insurance Exchanges.

On July 6, 2018, pursuant to an amended stipulated order issued in *State of New York v. U.S. Department of Health and Human Services*, 18-cv-00683 (S.D.N.Y. filed Jan. 26, 2018), CMS issued a Draft Administrative Order on which New York and Minnesota (the States) had an opportunity to comment. The States each submitted comments on August 6, 2018. CMS considered those comments in issuing the Final Administrative Order, which adopts the HHS Revised BHP Payment Methodology for 2018 as set forth in the Draft Administrative Order.

II. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*) is not required.

III. Addendum

We are publishing the Final Administrative Order as an addendum to this Notice.

Dated: November 2, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

BILLING CODE 4120-01-P

ADDENDUM**FINAL ADMINISTRATIVE ORDER****August 24, 2018**

The Administrator for the Centers for Medicare & Medicaid Services issues this Administrative Order to set forth the revised payment methodology that applies to the Basic Health Program for 2018 *only* (HHS Revised BHP Payment Methodology). This Administrative Order is an agency action under 5 U.S.C. § 551(13), issued pursuant to 5 U.S.C. §§ 555(b) and (e).

The HHS Revised BHP Payment Methodology modifies the existing methodology for 2018, which is set forth in the payment notice entitled *Basic Health Program; Federal Funding Methodology for Program Years 2017 and 2018*, 81 FR 10091 (Feb. 29, 2016) (February 2016 Payment Notice). The modification involves the application of a Premium Adjustment Factor (PAF) that considers the premium increases in other states that became effective after the Centers for Medicare & Medicaid Services (CMS), an operating division of the U.S. Department of Health and Human Services (HHS), discontinued payments to issuers for cost-sharing reductions (CSRs) provided to enrollees in qualified health plans (QHPs) offered on health insurance Exchanges.

On July 6, 2018, pursuant to an amended stipulated order issued in *State of New York, et al, v. U.S. Department of Health and Human Services*, 18-cv-00683 (S.D.N.Y. filed Jan. 26, 2018), CMS issued a Draft Administrative Order on which New York and Minnesota (the States) had an opportunity to comment. The States each submitted comments on August 6, 2018. CMS has considered those comments in issuing this Final Administrative Order. For the reasons set forth below—including in our responses to the States' comments—this Final Administrative Order adopts the HHS Revised BHP Payment Methodology for 2018 as set forth in the Draft Administrative Order.

The result of applying the HHS Revised BHP Payment Methodology to enrollment data provided by the State of New York is \$422,206,235 in additional payment to New York for the first, second, and third quarters of 2018.

The result of applying the HHS Revised BHP Payment Methodology to enrollment data provided by the State of Minnesota is \$46,276,090 in additional payment to Minnesota for the first, second, and third quarters of 2018.

The structure of the HHS Revised BHP Payment Methodology and its application to New York and Minnesota are set forth in greater detail below.

I. Statutory and Regulatory Framework

Section 1331 of the Patient Protection and Affordable Care Act (Pub. L. No. 111-148, enacted March 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. No. 111-152, enacted March 30, 2010) (collectively referred to as the Affordable Care Act (ACA)) provides states with an option to establish a Basic Health Program (BHP). New York and Minnesota elected to operate BHPs for 2018.

The amount of federal funding for a state's BHP is the amount the Secretary determines is equal to 95 percent of the premium tax credits (PTC) under section 36B of the Internal Revenue Code of 1986 (IRC), and the CSRs under ACA § 1402 that would have been provided for the year to eligible individuals enrolled in standard health plans in the state if such eligible individuals were allowed to enroll in a QHP through the state's health insurance Exchange. ACA § 1331(d)(3)(A)(i).

In calculating the BHP payment amount, “[t]he Secretary shall make the determination ... on a per enrollee basis and shall take into account all relevant factors necessary to determine the value of the [PTCs] and [CSRs] that would have been provided” to the eligible individuals. ACA

§ 1331(d)(3)(A)(ii). Relevant factors may include “the age and income of the enrollee, whether the enrollment is for self-only or family coverage, geographic differences in average spending for health care across rating areas, the health status of the enrollee . . . , and whether any reconciliation of the [PTC] or [CSRs] would have occurred if the enrollee had been so enrolled.” *Id.* “This determination *shall take into consideration the experience of other States with respect to participation in an Exchange and such [PTCs] and [CSRs] provided to residents of the other States*, with a special focus on enrollees with income below 200 percent of poverty.” *Id.* (emphasis added).

On March 12, 2014, CMS published a final rule implementing ACA § 1331. *Basic Health Program: State Administration of Basic Health Programs; Eligibility and Enrollment in Standard Health Plans; Essential Health Benefits in Standard Health Plans; Performance Standards for Basic Health Programs; Premium and Cost Sharing for Basic Health Programs; Federal Funding Process; Trust Fund and Financial Integrity*, 79 FR 14112 (March 12, 2014) (BHP Final Rule). The BHP Final Rule establishes standards for administering BHPs—including provisions about eligibility and enrollment, benefits, cost-sharing requirements, and oversight activities—but does not contain the specific information necessary to determine BHP payments. Instead, the BHP Final Rule informs states that the development and publication of the payment methodology, including any data sources, will be addressed in separate annual BHP Payment Notices.

On February 29, 2016, CMS published a final Payment Notice setting forth the BHP payment methodology for 2017 and 2018. *Basic Health Program; Federal Funding Methodology for Program Years 2017 and 2018*, 81 FR 10091 (Feb. 29, 2016) (February 2016 Payment Notice). Thereafter, as indicated in the February 2016 Payment Notice, CMS published a bulletin setting forth the updated factors it would consider when making the BHP payments to states for 2018.

CMCS Informational Bulletin, *Basic Health Program; Federal Funding Methodology for Program Year 2018* (May 17, 2017).

In October 2017, in response to an inquiry from HHS and the Treasury Department, the Attorney General concluded “that the best interpretation of the law is that the permanent appropriation for ‘refunding internal revenue collections,’ 31 U.S.C. § 1324, cannot be used to fund the CSR payments to insurers authorized by 42 U.S.C. § 18071.” Letter from Attorney Gen. Jefferson B. Sessions III to Sec’y of Treasury Steven Mnuchin & Acting Sec’y of HHS Don Wright at 1 (Oct. 11, 2017). The next day, HHS sent a memorandum to CMS explaining that “CSR payments are prohibited unless and until a valid appropriation exists.” Memorandum from Acting Sec’y of HHS Eric Hargan to Adm’r of CMS Seema Verma, Payments to Issuers for Cost-Sharing Reductions (CSRs), at 1 (Oct. 12, 2017).¹ Because to date no CSR appropriation has been enacted, CMS is prohibited from making further payments of the CSR component of any BHP payment.

II. Procedural Background

Starting with the payment for the first quarter (Q1) of 2018 (which began on January 1, 2018), CMS stopped paying the CSR component of the quarterly BHP payments to New York and Minnesota. The States then sued the Secretary for declaratory and injunctive relief in the United States District Court for the Southern District of New York. *See State of New York, et al, v. U.S. Department of Health and Human Services*, 18-cv-00683 (S.D.N.Y. filed Jan. 26, 2018). HHS understands the States’ complaint to seek to compel HHS to either pay the CSR component of their 2018 BHP payments as calculated under the methodology set forth in the February 2016 Payment

¹ The Attorney General’s letter and the subsequent memorandum from the Acting HHS Secretary are available at <https://www.hhs.gov/sites/default/files/csr-payment-memo.pdf>.

Notice, or take other actions that would ostensibly yield BHP payments for 2018 that are greater than what CMS has paid.

On May 2, 2018, the parties filed a stipulation requesting a 60-day stay of the litigation so that HHS may issue an administrative order revising the 2018 BHP payment methodology. As a result of the stipulation, the court dismissed the BHP litigation, although it retained jurisdiction to enforce the stipulation and re-open the docket. On June 8, 2018, the parties revised their stipulation to amend the dates by which HHS would issue an administrative order.

III. The HHS Revised BHP Payment Methodology for 2018

The HHS Revised BHP Payment Methodology, which applies only for 2018, modifies the existing methodology for 2018 set forth in the February 2016 Payment Notice. The modification involves the application of a premium adjustment factor (PAF) to calculate the PTC portion of the BHP payment rates.

Consistent with the February 2016 Payment Notice and prior years, the HHS Revised BHP Payment Methodology for 2018 determines the States' BHP payments based on multiple rate cells² applied to estimated BHP enrollment. CMS calculates the BHP payment rate for each rate cell in two parts. The first part equals 95 percent of the estimated PTC that would have been paid if a BHP enrollee in that rate cell had instead enrolled in a QHP through the State's Exchange. The second part equals 95 percent of the estimated CSR payment that would have been made if a BHP enrollee in that rate cell had instead enrolled in a QHP through the State's Exchange.

² Each rate cell represents a unique combination of age range, geographic area, coverage category (for example, self-only or two-adult coverage through BHP), household size, and income range as a percentage of FPL. There is a distinct rate cell for individuals in each coverage category within a particular age range who reside in a specific geographic area and are in households of the same size and income range. In addition, the HHS Revised BHP Payment Methodology aligns with a state's rules on age rating. Thus, in the case of a state that does not use age as a rating factor on the Exchange, the BHP payment rates will not vary by age.

CMS uses the following equation from the February 2016 Payment Notice for the PTC part of the BHP payment rate calculation for each rate cell:

$$PTC_{a,g,c,h,i} = \left[ARP_{a,g,c} - \frac{\sum_j I_{h,i,j} \times PTCF_{h,i,j}}{n} \right] \times IRF \times 95\%$$

The definitions for the variables in this equation are:

- $PTC_{a,g,c,h,i}$ = PTC portion of BHP payment rate
- a = Age range
- g = Geographic area
- c = Coverage status (self-only or applicable category of family coverage) obtained through BHP
- h = Household size
- i = Income range (as percentage of the federal poverty level (FPL))
- $ARP_{a,g,c}$ = Adjusted reference premium (modified by PAF)
- $I_{h,i,j}$ = Income (in dollars per month) at each 1 percentage-point increment of FPL
- j = j^{th} percentage-point increment FPL
- n = Number of income increments used to calculate the mean PTC
- $PTCF_{h,i,j}$ = PTC formula percentage
- IRF = Income reconciliation factor

The HHS Revised BHP Methodology for 2018 modifies the equation for the PTC part of the BHP payment rate calculation by incorporating the PAF into the adjusted reference premium ($ARP_{a,g,c}$). Under that modification, the $ARP_{a,g,c}$ equals the reference premium ($RP_{a,g,c}$) multiplied by the BHP population health factor (PHF) multiplied by the PAF. In other words:

$$ARP_{a,g,c} = RP_{a,g,c} \times PHF \times PAF$$

We understand that CSR loading in 2018 premiums may have influenced enrollee behavior in terms of metal tier selection. For future years, CMS may consider modifications to

the payment formula based on consideration of the experience of other states regarding enrollee participation in metal tiers.

The total BHP payment rate for each rate cell equals the sum of the PTC and CSR parts. CMS multiplies the rate for each rate cell by the number of BHP enrollees in that cell—that is, the number of enrollees that meet the criteria for each rate cell ($E_{a,g,c,h,i}$)—to calculate the total monthly BHP payment to the state (PMT). The equation for this calculation is:

$$PMT = \sum [(PTC_{a,g,c,h,i} + CSR_{a,g,c,h,i}) \times E_{a,g,c,h,i}]$$

In this equation, CMS assigns a value of zero to the CSR part of the BHP payment rate calculation ($CSR_{a,g,c,h,i}$) because there is presently no available appropriation from which CMS can make the CSR portion of any BHP payment.³

Determination of the PAF

The PAF considers the premium increases in other states that took effect after CMS discontinued payments to issuers for CSRs provided to enrollees in QHPs offered on state insurance Exchanges. The PAF is authorized by ACA § 1331(d)(3)(A)(ii), which says that the determination of the BHP payment amount “shall take into consideration the experience of other States with respect to participation in an Exchange and such [PTCs] and [CSRs] provided to residents of the other States.”

CMS has calculated the PAF for each BHP state for 2018 as follows:

- CMS sought to collect QHP issuer information from QHP issuers in each state and the District of Columbia, and then determine the premium adjustment that the responding QHP

³ In the event that an appropriation for CSRs for 2018 is made, CMS would reconsider whether to zero-out the CSR part of the BHP payment rate calculation ($CSR_{a,g,c,h,i}$) and to include the PAF in the HHS Revised BHP Methodology.

issuers made to each silver level plan in 2018 to account for the discontinuation of CSR payments to QHP issuers.

- Based on the data collected, CMS estimated the median adjustment for silver level QHPs nationwide (excluding those in the two BHP states). To the extent that QHP issuers made no adjustment (or the adjustment was 0), this counted as 0 in determining the median adjustment made to all silver level QHPs nationwide. If the amount of the adjustment was unknown—or CMS determined that it should be excluded for methodological reasons (*e.g.*, the adjustment is negative, an outlier, or unreasonable)—then CMS did not count the adjustment towards determining the median adjustment.
- For each of the two BHP states, CMS determined the median adjustment for all silver level QHPs in that state.
- The PAF for each BHP state equals 1 plus the nationwide median adjustment divided by 1 plus the state median adjustment for the BHP state. In other words,
$$PAF = (1 + \text{Nationwide Median Adjustment}) \div (1 + \text{State Median Adjustment}).$$
- For New York, the PAF is: **1.188**.
- For Minnesota, the PAF is: **1.188**.

Reconciliation of BHP Payments for 2018

In addition to using the HHS Revised BHP Methodology to calculate the remaining 2018 quarterly payments, CMS will remit any additional payments (true-up payments) to the States that are necessary to ensure New York and Minnesota receive the total BHP payments calculated under the HHS Revised BHP Methodology for the first, second, and third quarters of 2018. CMS will make any necessary true-up payments for these quarters on or before September 7, 2018.

In general, CMS has determined these specific true-up payments by calculating the total BHP payments for the first, second, and third quarters of 2018 under the HHS Revised BHP Methodology set forth in this Final Order and subtracting the amounts of the payments already made for those quarters (including the Q2 supplemental payments made to the states on or about May 14, 2018). If a state already received a total quarterly BHP payment exceeding the quarterly payment that CMS calculated under the HHS Revised BHP Methodology set forth in this Final Order, then CMS will offset the overpayment against the next quarterly payment to the state.

CMS will make any future reconciliation payments (*i.e.*, those payments calculated retrospectively and based on final BHP enrollment for 2018, as compared to the quarterly payments based on estimated enrollment) using the HHS Revised BHP Methodology set forth in this Final Order, and otherwise consistent with the February 2016 Payment Notice.

IV. Facts and Data

To determine the PAF described above, CMS requested information from QHP issuers in each state serviced by a Federally-facilitated Exchange (FFE) to determine the premium adjustment those issuers made to each silver level plan offered through the Exchange in 2018 to account for the end of CSR payments. Specifically, CMS requested information showing the percentage change that QHP issuers made to the premium for each of their silver level plans to cover benefit expenditures associated with the CSRs, given the lack of CSR payments in 2018. This percentage change was a portion of the overall premium increase from 2017 to 2018.

According to CMS records, there are 1,233 silver-level QHPs operating on Exchanges in 2018. Of these 1,233 QHPs, 318 QHPs (25.8 percent) responded to CMS's request for the percentage adjustment applied to silver-level QHP premiums in 2018 to account for the discontinuance of the CSRs. These 318 QHPs operated in 26 different states with 10 of those

states running state-based exchanges (SBEs) or SPEs, which were exchanges in states that worked in partnership with CMS to implement the FFE in their state in 2018. Thirteen of these 318 QHPs were in New York (and none were in Minnesota). Excluding these 13 QHPs from the analysis, the nationwide median adjustment was 20.0 percent. Of the 13 QHPs in New York that responded, the state median adjustment was 1.0 percent. CMS believes that this is an appropriate adjustment for QHPs in Minnesota as well. CMS thus calculated the PAF as $(1 + 20\%) \div (1 + 1\%)$ (or $1.20/1.01$), which results in a value of 1.188.

The PAF, therefore, will be set to 1.188 in the formulas described above for New York and Minnesota. This adjustment reflects CMS' estimates that the QHP premiums in Minnesota and New York would have been 18.8 percent higher in 2018 due to the discontinuance of the CSR payments if the States were not operating BHPs.

V. The States' Comments on the Draft Order and CMS' Responses

Comments from New York with Responses from CMS

In its comments submitted to CMS on August 6, 2018, New York maintains that its proposed approach results in a more accurate calculation of the PTC subsidy amount that would have been provided to BHP-eligible individuals in response to the silver-loading that occurred following HHS's decision to stop paying CSR subsidies.⁴

CMS does not have any basis to evaluate the accuracy of the state's proposed approach, and therefore has not adopted it. While we believe the state offered this approach in good faith, New York provided no support, analysis, or detail that would allow CMS to determine if the rates the state proposed accurately reflected premium rate increases issuers would have imposed in 2018 in the absence of the BHP program. In addition, it is unknown whether New York's approach "take[s] into consideration the experience of other States with respect to participation in an

⁴ New York first submitted proposed 2018 premium rates for CMS to use to calculate 2018 BHP payments on November 22, 2017, and reiterated this approach in a submission dated May 22, 2018, which the state incorporated into its August 6, 2018 comments to CMS.

Exchange and such [PTCs] and [CSRs] provided to residents of the other States,” as required by ACA § 1331(d)(3)(A)(ii).

New York’s enumerated comments submitted on August 6, 2018 and CMS’ responses follow:

1. The methodology fails to detail how HHS accounts for the experiences of other states in estimating the median adjustment for silver-level QHPs nationwide. Specifically, the methodology does not set forth how CMS accounted for relative distributions of income, differences in rating rules, actual claims experiences, and differential approaches to adjust for the loss of CSRs.

Response: The methodology described in the Draft Order adequately accounts for the experience of other states with regard to the discontinuance of the CSR payments to QHPs. By surveying QHPs, we have taken into account the experience of states in the aggregate. Accounting for the impact of the discontinuance in each state at the level of detail New York suggests would be impractical, if not impossible, given (i) the multitude of state-specific factors noted above and (ii) the lack of clarity and transparency in how individual QHP issuers took these factors into account in making any adjustments to the QHP premiums.

2. On page 7 of the Draft Administrative Order, CMS outlines how it will determine the PAF and claims that it will “collect QHP issuer information from QHP issuers in each state and the District of Columbia” to account for the discontinuation of CSR payments to QHP issuers. However, page 9 of the Draft Administrative Order indicates that CMS only requested information from QHP issuers in states serviced by Federally-facilitated Exchanges (“FFE’s”). As CMS itself seems to recognize, it cannot exclude states with State-based Exchanges (“SBE’s”) – particularly since the BHPs are only in states with SBEs. CMS must provide clarity on whether it only reached out to QHP issuers in FFEs – and if so, provide an explanation as to why it did so and how that impacts its ability to accurately establish a nationwide median.

Response: We disagree that surveying QHP issuers participating in SBEs is required to accurately establish a nationwide median, as we do not believe that QHP issuers in SBEs responded to the discontinuation of CSR payments differently than QHP issuers in FFEs. That is, we do not believe that the mere type of entity managing the Exchange, standing alone, affected QHP issuer behavior.

Based on our survey of QHP issuers, we found that the mean premium adjustments by state ranged from 3.9 percent to 29.6 percent in states operating SBEs or SPEs in 2018 (9 states, excluding New York) and the median of these was 15.0 percent. The mean premium adjustments by state for states with FFEs in 2018 (15 states) were 9.25 percent to 32.5 percent, and the median of these was 19.9 percent. We believe that these mean premium rate increase ranges and medians are reasonably similar between the SBE/SPE states and FFE states, and that there is no apparent bias between the results. We also note to the

extent there is any difference between the premium rate increases and medians found in SBE/SPE states and FFE states, the rate increases were *lower* in SBE/SPE states.

CMS was able to compile this rate increase data because CMS requested information from all QHP issuers participating in FFEs and SPEs. Because many of these issuers also offered QHPs in SBEs, they also reported adjustments for those QHPs to CMS. Thus, while CMS did not directly solicit information from issuers that only offered QHPs on SBEs, CMS did receive adjustment information for QHPs offered on SBEs. Therefore, we do not believe that this approach impacted our ability to accurately establish a nationwide median.

3. The Draft Order states that the PAF is derived only from a very small pool of silver-level QHPs (25.8%) and does not provide information regarding how many different states that represents. Relying on a small fraction of issuers' rate adjustments from an unspecified number of states does not appear to be sufficient to calculate a "nationwide median adjustment" as provided for in the Proposed Methodology. CMS should provide additional information on the issuers whose information was considered and why that survey is adequate to establish a nationwide median.

Response: We disagree that the PAF is derived from a "very small pool" of silver-level QHPs. On the contrary, QHP issuers representing 26 different states responded to our request for information, including 10 states that operated SBEs/SPEs in 2018. We do not believe, and have no reason to believe, there is any difference in the premium adjustments made by QHP issuers that did report and those that did not report.

The QHPs (and the states) represented in the sample are reasonably representative of the nationwide results. Fundamentally, QHPs faced similar costs in each state's Exchange, because the underlying actuarial values of the silver-level plans and the CSRs were the same. While there may be some underlying variations state-to-state (for example, the relative number of people receiving CSRs compared to those not receiving CSRs) and some states may have provided different instructions to QHPs, we received a range of results that adequately captured the experience across the states and various QHPs.

Also, the results of the survey based on the responses that we received were generally consistent with public domain information regarding QHP issuers' adjustments to premiums to account for the discontinuance of CSR payments. For example, the Kaiser Family Foundation surveyed QHP issuers in October 2017 and found that silver-level QHP premiums were adjusted between 0 and 38 percent for 2018 due to the discontinuance of the CSR payments, with a median adjustment of about 15 percent. (See Kaiser Family Foundation, "How the Loss of Cost-Sharing Subsidy Payments is Affecting 2018 Premiums," October 2017; <http://files.kff.org/attachment/Issue-Brief-How-the-Loss-of-Cost-Sharing-Subsidy-Payments-is-Affecting-2018-Premiums>).

In short, the response rate was sufficient to develop the nationwide median adjustment for use in the payment methodology.

4. In describing the PAF, CMS states that “outlier” QHPs were not included in the factor. However, the Draft Order does not define “outlier” or provide any guidance as to when an adjustment would be excluded on such grounds. “Outlier” should be defined.

Response: CMS considered outliers to be adjustments that were (1) negative or (2) excessively high (for example, above 100 percent). Of the responses CMS received, we considered only 1 an outlier (reporting a 2,000 percent increase), and we suspect this was a typographical error in reporting.

5. CMS states that QHP issuers that made no CSR adjustment will count as “0” in determining the median adjustment made to all silver-level QHPs nationwide. New York disagrees with this determination because including these QHP issuers in the adjustment is contrary to the purpose of the BHP payment methodology. Only issuers that adjusted premiums in response to the CSR defunding should be included in the calculation of the PAF factor, as this is the relevant comparison group when adjusting for the experience of other states. By including issuers with no CSR adjustments, HHS is not calculating the PTC subsidy amount that “would have been provided” to BHP-eligible individuals in New York if they had enrolled in QHPs, as required by statute. *See* 42 U.S.C. § 18051(d)(3)(A)(i); 42 C.F.R. § 600.605(a)(1)-(2).

Response: CMS, in accordance with ACA § 1331, sought to account for all states’ experience in developing the PAF adjustment. No QHP issuers reported an adjustment of 0 for silver-level QHPs on Exchanges, and therefore no 0 adjustments were included in the calculation. That said, some states allowed or required QHP issuers to make no adjustment to 2018 premium amounts to account for the discontinuation of CSR payments. So we believe that “0%” adjustments would be acceptable because they reflect the experience of issuers in other states. Again, though, CMS made no such adjustments.

6. The Proposed Methodology does not address issuance of quarterly payment letters to states. Payment letters providing the states with details on how the payment methodology is applied to the state’s estimated enrollment submission for the following quarter should resume in August 2018 for quarter 4.

Response: CMS intends to provide quarterly payment letters to the States, as it has done in the past, for future quarters starting with Q4 of 2018.

Comments from Minnesota with Responses from CMS

1. In section IV of the draft order, under the heading “Facts and Data,” CMS explains that it requested information from issuers in each state serviced by a federally-facilitated marketplace. From the 25.8% of those issuers that responded, CMS calculated a median nationwide adjustment of 20 percent. It appears that CMS did not attempt to obtain data from issuers in state-based marketplaces and in state-partnership marketplaces. The draft order does not explain whether and how CMS plans to obtain data from issuers in these states to include in the calculation of the nationwide median adjustment. We recommend

that CMS survey all issuers, especially those in state-based marketplaces, before finalizing the value of the premium adjustment factor. As is, the lack of representation from the plans in state-based and partnership marketplaces that are more representative of Minnesota's individual insurance market is likely masking the nationwide experience.

Response: We disagree that surveying QHP issuers participating in SBEs or SPEs is required to accurately establish a nationwide median, as we do not believe that QHP issuers in SBEs or SPEs responded to the discontinuation of CSR payments differently than QHP issuers in FFEs. That is, we do not believe that the mere type of entity managing the Exchange, standing alone, affected QHP issuer behavior.

Based on our survey of QHP issuers, we found that the mean premium adjustments by state ranged from 3.9 percent to 29.6 percent in states operating SBEs or SPEs in 2018 (9 states, excluding New York) and the median of these was 15.0 percent. The mean premium adjustments by state for states with FFEs in 2018 (15 states) were 9.25 percent to 32.5 percent, and the median of these was 19.9 percent. We believe that these mean premium rate increase ranges and medians are reasonably similar between the SBE/SPE states and FFE states, and that there is no apparent bias between the results. We also note to the extent there is any difference between the premium rate increases and medians found in SBE/SPE states and FFE states, the rate increases were *lower* in SBE/SPE states.

CMS was able to compile this rate increase data because CMS requested information from all QHP issuers participating in FFEs and SPEs. Because many of these issuers also offered QHPs in SBEs, they also reported adjustments for those QHPs to CMS. Thus, while CMS did not directly solicit information from issuers that only offered QHPs on SBEs, CMS did receive adjustment information for QHPs offered on SBEs. We do not believe that this approach impacted our ability to accurately establish a nationwide median.

QHP issuers representing 26 different states responded to our request for information, including 10 states that operated SBEs or SPEs in 2018. We do not believe, and have no reason to believe, there is any difference in the premium adjustments made by QHP issuers that did report and those that did not report.

Also, the results of the survey based on the responses that we received were generally consistent with public domain information regarding QHP issuers' adjustments to premiums to account for the discontinuance of CSR payments. For example, the Kaiser Family Foundation surveyed QHP issuers in October 2017 and found that silver-level QHP premiums were adjusted between 0 and 38 percent for 2018 due to the discontinuance of the CSR payments, with a median adjustment of about 15 percent. (See Kaiser Family Foundation, "How the Loss of Cost-Sharing Subsidy Payments is Affecting 2018 Premiums," October 2017; <http://files.kff.org/attachment/Issue-Brief-How-the-Loss-of-Cost-Sharing-Subsidy-Payments-is-Affecting-2018-Premiums>). In short, the response rate was sufficient to develop the nationwide median adjustment for use in the payment methodology.

2. Further, it is especially important that the factor determined for 2018 is based on data from a population including all the silver-level issuers nationwide, and that the 1.188 forms the base for the future adjustments because QHP issuers will not be able to continue calculating the difference in premiums before and after the CSR loss after the 2018 coverage year. If it is not CMS' intent to obtain data from all issuers or from a more representative sample of issuers, then we suggest that the final methodology should itemize the exclusions and justify the resulting adjustment factor as a reasonable approximation of the experience in other states, including those not sampled.

Response: The QHPs (and the states) represented in the sample are reasonably representative of the nationwide results. Fundamentally, QHPs faced similar costs in each state exchange, because the underlying actuarial values of the silver-level plans and the CSRs were the same. While there may be some underlying variations state-to-state (for example, the relative number of people receiving CSRs compared to those not receiving CSRs) and some states may have provided different instructions to QHPs, we received a range of results that adequately captured the experience across the states and various QHPs.

CMS has not committed to a methodology for 2019 or beyond at this point in time.

3. On page 7 of the draft order, CMS notes that issuers that reported a zero increase were counted in the calculation of the median, but that CMS reserves the right to exclude reported amounts that are negative, outliers, or unreasonable. Including zero increases is inconsistent with the purpose of this adjustment factor, given that a zero increase is likely the result of decisions some states made to the detriment of policyholders. Also, for those amounts that were determined to be "outliers" or "unreasonable," CMS should itemize and explain those amounts that were excluded.

Response: CMS, in accordance with ACA § 1331, sought to account for all states' experience in developing the PAF adjustment. No QHP issuers reported an adjustment of 0 for silver-level QHPs on Exchanges, and therefore no 0 adjustments were included in the calculation. That said, some states allowed or required QHP issuers to make no adjustment to 2018 premium amounts to account for the discontinuation of CSR payments. So we believe that "0%" adjustments would be acceptable because they reflect the experience of issuers in other states. Again, though, no such adjustments were made.

CMS considered outliers to be adjustments that were (1) negative or (2) excessively high (for example, above 100 percent). Of the responses CMS received, we considered only 1 an outlier (reporting a 2,000 percent increase), and we suspect this was a typographical error in reporting.

4. Finally, we urge CMS to finalize the payment methodology for 2019 as soon as possible.

Response: CMS concurs, and CMS is at work on the 2019 and 2020 BHP payment methodologies.

VI. BHP Payments for Q1-Q3 2018 Under The HHS Revised Payment Methodology

Using the HHS Revised BHP Payment Methodology with PAF values of 1.188 for both New York and Minnesota as finalized in this Administrative Order and with enrollment data previously provided by the States, CMS calculates the States' BHP payments for the first three quarters of 2018 as listed in the tables below. These tables include the quarterly BHP payments CMS has made for Q1-Q3 2018 to New York and Minnesota, payment amounts for the same periods calculated under the HHS Revised Payment Methodology, Q2 supplemental payments paid to the States in May 2018, and the resulting true-up payments CMS will make to the States by September 7, 2018.

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Table 1. Payment Adjustments to New York BHP for 2018

Quarter	Original Payment	Revised Payment	Difference
2018 Q1	\$833,521,555	\$1,015,683,868	\$182,162,313
2018 Q2	\$884,765,140	\$1,078,636,836	\$193,871,696
2018 Q3	\$903,794,710	\$1,101,841,936	\$198,047,226
Total	\$2,622,081,405	\$3,196,162,640	\$574,081,235
Q2 2018 Supplemental Payment			\$151,875,000
True-Up Payment			\$422,206,235

Table 2. Payment Adjustments to Minnesota BHP for 2018

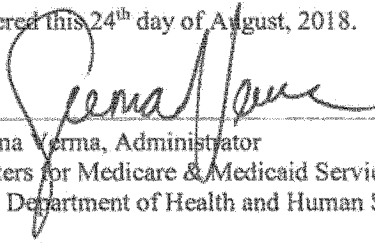
Quarter	Original Payment	Revised Payment	Difference
2018 Q1	\$97,670,055	\$120,707,821	\$23,037,766
2018 Q2	\$84,307,519	\$104,193,418	\$19,885,899
2018 Q3	\$87,345,273	\$107,947,698	\$20,602,425
Total	\$269,322,847	\$332,848,937	\$63,526,090
Q2 2018 Supplemental Payment			\$17,250,000
True-Up Payment			\$46,276,090

These amounts are calculated using the previously submitted enrollment data used to develop the original 2018 BHP payment rates and amounts. CMS will also provide the updated BHP monthly

payment rates to the States.

We are finalizing these revised payment amounts for the first three quarters of 2018 in this Final Administrative Order. In addition, CMS will use the finalized monthly BHP payment rates determined under the HHS Revised BHP Payment Methodology finalized in this Administrative Order to develop the States' reconciled BHP payments (using actual enrollment data the States submit after the close of the benefit year).

Ordered this 24th day of August, 2018.


Seema Verma, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

[FR Doc. 2018-24673 Filed 11-9-18; 8:45 am]

BILLING CODE 4120-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket Nos. FDA-2017-N-0558; FDA-2017-N-1315; FDA-2011-N-0776; FDA-2018-N-3038; FDA-2018-N-0405; FDA-2014-N-1048; FDA-2011-N-0908; FDA-2011-N-0920; and FDA-2018-N-1857]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRStaff@fda.hhs.gov.**SUPPLEMENTARY INFORMATION:** The following is a list of FDA information collections recently approved by OMB under section 3507 of the PaperworkReduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at <http://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Disclosures in Professional and Consumer Prescription Drug Promotion	0910-0860	9/30/2020
Experimental Study of Risk Information Amount and Location in Direct-to-Consumer Print Ads	0910-0861	9/30/2020
Reclassification Petitions for Medical Devices	0910-0138	9/30/2021
Request for Samples and Protocols	0910-0206	9/30/2021
Medical Device Recall Authority	0910-0432	9/30/2021
Food Safety, Health, and Diet Survey	0910-0345	10/31/2020
Medical Device Labeling Regulations	0910-0485	10/30/2021
GFI: Clinical Trial Sponsors on the Establishment and Operation of Clinical Trial Data Monitoring Committees	0910-0581	10/31/2021
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food	0910-0751	10/31/2021
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals	0910-0789	10/31/2021

Dated: November 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-24609 Filed 11-9-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2018-N-4100]

Drug Development Tool Process Under the 21st Century Cures Act and Prescription Drug User Fee Act VI; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing a public meeting entitled “Drug Development Tool Process under the 21st Century Cures Act and PDUFA VI.” This public meeting is intended to fulfill commitments made by FDA under the sixth authorization of the

Prescription Drug User Fee Act (PDUFA VI) and the 21st Century Cures Act (Cures Act) by soliciting comments on Drug Development Tool Qualification at FDA related to the qualification process under section 507 of the Federal Food, Drug, and Cosmetic Act (FD&C Act); discussing taxonomy for biomarkers and related concepts used in drug development; and planning activities to define a framework with appropriate standards and scientific approaches to support qualification for a specified context of use.

DATES: The public meeting will be held on December 11, 2018, from 9 a.m. to 5 p.m. Submit either electronic or written comments on this public meeting by January 31, 2019. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.**ADDRESSES:** The public meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503A (the Great Room), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and securityinformation, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.You may submit comments as follows. Please note that late, untimely filed comments may not be considered. For timely consideration we request that electronic comments be submitted on or before January 31, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time on January 31, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.**Electronic Submissions**

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier:* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-N-4100 for "Drug Development Tools Qualification under the 21st Century Cures Act and PDUFA VI." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on

<https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Valerie Jimenez, Center for Drug Evaluation and Research, Food and Drug Administration, Hillandale Bldg., Rm. 2156, Silver Spring, MD 20993; 301-796-1345, QualificationPublicMeeting@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Development Tool (DDT) provisions in section 507 of the FD&C Act (21 U.S.C. 357) were added in December 2016 by section 3011 of the Cures Act (Pub. L. 114-255). FDA's DDT programs include the Animal Model Qualification Program, the Biomarker Qualification Program, and the Clinical Outcome Assessment Qualification Program. These programs are designed to facilitate drug and biological product development by allowing FDA to qualify DDTs based on certain foundational scientific information, thereby minimizing duplication of research and development efforts. FDA committed to meet certain performance goals under PDUFA VI. This reauthorization, part of the FDA Reauthorization Act of 2017 signed by the President on August 18, 2017, includes a number of performance goals and procedures that are documented in the PDUFA VI Commitment Letter, which is available at <https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf>. These goal

commitments were developed in consultation with patient and consumer advocates, healthcare professionals, and other public stakeholders, as part of negotiations with regulated industry. Section I.J.6.b. of the commitment letter, "Enhancing Drug Development Tools Qualification Pathway for Biomarkers," states that FDA will convene a public meeting to discuss taxonomy for biomarkers used in drug development and a framework with appropriate standards and scientific approaches to support biomarkers under the taxonomy, including scientific criteria to determine acceptance of a biomarker qualification submission and essential elements of a formal biomarker qualification plan. Since there are overlapping deliverables between the Cures Act and PDUFA VI, this public meeting will address and fulfill those deliverables.

II. Topics for Discussion at the Public Meeting

FDA is convening a public meeting to discuss and seek public input regarding the DDT qualification pathway for animal models, biomarkers, and clinical outcome assessments. This public meeting will describe the qualification process under section 507 of the FD&C Act and will discuss taxonomy used in drug development, which will include the scientific criteria to determine the acceptance of a qualification submission and essential elements of a full qualification plan. In addition, we will discuss ongoing activities to develop general evidentiary standards to support qualification by the three qualification programs.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: <https://www.eventbrite.com/e/drug-development-tool-process-under-the-21st-century-cures-legislation-tickets-50528044742>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by 11:59 p.m. Eastern Time on Friday, November 30, 2018. Registrants will receive confirmation when they have been accepted. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization.

If you need special accommodations due to a disability, please contact

QualificationPublicMeeting@fda.hhs.gov no later than Friday, November 30, 2018, by 11:59 p.m. Eastern Time.

Requests for Oral Presentations: There will be time allotted during the public meeting for open public comment. Signup for this session will be on a first-come, first-served basis; there will be a time limit on the day of the workshop. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Webcast Information: FDA plans to provide a free, live webcast of this public meeting. The link to the public meeting is <https://collaboration.fda.gov/r7zu2p7t3ab>, which will not be accessible until 45 minutes prior to the meeting.

FDA plans to post archived webcasts after the meeting; archived webcasts will be available.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**).

Dated: November 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-24656 Filed 11-9-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2970]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Surveys and Interviews With Investigational New Drug Sponsors To Assess Current Communication Practices With Food and Drug Administration Review Staff Under the Sixth Authorization of the Prescription Drug User Fee Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 13, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title "Surveys and Interviews with Investigational New Drug Sponsors to Assess Current Communication Practices with Food and Drug Administration Review Staff Under the Sixth Authorization of the Prescription Drug User Fee Act." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Surveys and Interviews With Investigational New Drug (IND) Sponsors To Assess Current Communication Practices With Food and Drug Administration Review Staff Under the Sixth Authorization of the Prescription Drug User Fee Act (PDUFA VI)

OMB Control Number 0910-NEW

In Fiscal Year 2017, FDA published guidance on communications between FDA review staff and drug sponsors during the IND phase of drug development. As part of PDUFA VI, FDA committed to a third-party assessment of current IND-phase communication practices, which should reflect this guidance. The contractor for the assessment of IND communication practices is Eastern Research Group, Inc. (ERG).

Therefore, in accordance with the PDUFA VI Commitment Letter, FDA proposes to have ERG conduct surveys and interviews with sponsors of up to 150 active commercial INDs as follows:

- For each formal meeting between FDA review staff and active commercial IND sponsors during the assessment period, send a survey to the sponsor to solicit specific feedback about communication practices employed for that meeting. *For the purpose of this assessment, formal meetings are Type A, B, B (End of Phase), and C meetings during the IND phase of drug development.*

- For each active commercial IND in the assessment, conduct an interview with the sponsor to obtain broader feedback about all communications with FDA review staff during the study period, including telephone and email interactions in addition to meetings.

The purpose of this information collection is to understand active commercial IND sponsor perspectives on communication during drug development with a focus on what is working well, ongoing challenges and pain points, lessons learned, and opportunities for improvement. The contractor will develop anonymized aggregated summaries of survey and interview responses, analyze this information to identify common themes, consider these results along with IND data and feedback from FDA review staff to develop a set of findings and recommendations, and prepare a report to be published on FDA's website. The contractor will keep information collected private; ERG will not disclose personally identifying information to FDA or any other party.

In the **Federal Register** of August 16, 2018 (83 FR 40771), FDA published a 60-day notice requesting public

comment on the proposed collection of information. No comments were received.

The number of commercial INDs with activity is approximately 4,000 per year. ERG will interview 1 to 3 sponsor representatives at a time for up to 150

INDs during the annual assessment period.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Type of respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
IND sponsors: Surveys	150	1	150	0.17 (10 minutes) ..	25.50
IND sponsors: Interviews	450	1	450	1.5	675
Total					700.50

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that it will take each IND sponsor a maximum of 10 minutes to complete a survey. Up to 150 respondents will take part in the survey, yielding a maximum burden of 25.5 hours. FDA estimates that it will take each IND sponsor up to 90 minutes to respond to requests for interviews and participate in interviews. Up to 450 respondents will take part in interviews, yielding a maximum burden of 675 hours. FDA’s burden estimates are based on experience with information collections for similar types of PDUFA-related assessments.

Dated: November 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24608 Filed 11–9–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4042]

Agency Information Collection Activities; Proposed Collection; Comment Request; Establishing and Maintaining Lists of U.S. Manufacturers/Processors With Interest in Exporting Center for Food Safety and Applied Nutrition-Regulated Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information,

including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information that FDA uses to establish and maintain lists of U.S. manufacturers and processors with an interest in exporting products regulated by the Center for Food Safety and Applied Nutrition (CFSAN) to countries that require such lists to be maintained. The notice also solicits comments on changes to the electronic registry that will allow manufacturers and processors of CFSAN-regulated products to electronically request inclusion on the export lists.

DATES: Submit either electronic or written comments on the collection of information by January 14, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 14, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 14, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a

third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2018–N–4042 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Establishing and Maintaining Lists of Manufacturers/Processors With Interest in Exporting CFSAN-regulated Products.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential

information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each

proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Establishing and Maintaining Lists of U.S. Manufacturers/Processors With Interest in Exporting CFSAN-Regulated Products

OMB Control Number 0910-0509—Revision

The United States exports a large volume and variety of foods in international trade. For certain food products, foreign governments may require assurances from the responsible authority of the country of origin of an imported food that the processor of the food is in compliance with applicable country of origin regulatory requirements. Some foreign governments establish additional requirements with which exporters are required to comply and ask for additional assurances from the responsible authority. When requested, FDA may provide this information in the form of lists which are provided to the foreign governments.

For products subject to importing country listing requirements, FDA has historically maintained certain export lists of manufacturers/processors that: (1) Have expressed interest in exporting their products to these countries; (2) are subject to FDA's jurisdiction; and (3) are not the subject of a pending enforcement action (e.g., an injunction or seizure) or pending administrative action (e.g., a warning letter).

FDA has generally published guidance documents for these lists under the authority of section 701(h) of the Federal, Food, Drug, and Cosmetic

Act (21 U.S.C. 371(h)), which authorizes the Secretary of Health and Human Services (the Secretary) to develop guidance documents with public participation presenting the views of the Secretary on matters under the jurisdiction of FDA.

The guidance documents generally explain what information manufacturers/processors should submit to FDA to be considered for inclusion on the lists and what criteria FDA intends to use to determine eligibility for placement on the lists. The guidance documents also explain how FDA intends to update the lists and communicate any new information to the governments that requested the lists. Finally, the guidance documents note that the information is provided voluntarily by manufacturers/processors with the understanding that it may be posted on FDA's external website and that it will be communicated to, and possibly further disseminated by, the government that requested the list; thus, FDA considers the information on the lists to be information that is not protected from disclosure under 5 U.S.C. 552(b)(4).

Application for inclusion on each list is voluntary. However, some foreign governments may require inclusion on the list for acceptance of imported products. FDA recommends that U.S. manufacturers/processors that want to be placed on the export lists send FDA the following information: (1) Country to which the food manufacturer/processor wants to export product; (2) type of food product facility; (3) the Food Facility Registration number (the information collected by this module is approved under OMB control number 0910-0502), FDA Establishment Identifier number, or Dun & Bradstreet number for the facility; (4) name and address of the firm and the manufacturing plant; (5) name, telephone number, and email address of the contact person; (6) information on the products intended for export; (7) identities of agencies that inspected the plant; (8) date of last inspection, plant number, and copy of last inspection notice; and (9) if other than an FDA inspection, copy of last inspection report. We request that this information be updated every 2 years.

In addition to the information above, some countries may require additional information such as documentation that the firm has been certified by a third-party certification body that it meets the requirements of the importing country. Other information may need to be submitted to be included on the lists depending on the requirements of the importing country. FDA plans to

provide exporters with information about any such additional information required by a foreign country as a condition for entry and collect the other information to accommodate the importing countries' requirements.

We use the information submitted by firms to determine their eligibility for placement on the export lists, which may be published on our website. The purpose of the lists is to help CFSAN-regulated industries meet the import requirements of foreign governments.

FDA currently maintains export lists for the European Community and China covered under OMB control numbers 0910-0320 and 0910-0839, respectively. These export lists also serve to assist firms to meet the import requirements of foreign governments. OMB control numbers 0910-0509, 0910-0320, and 0910-0839 are very similar in that they allow FDA to collect information from firms for the purpose of establishing export lists for foreign governments that

require these lists before allowing the subject goods to be imported. Thus, with this notice, FDA proposes to consolidate these collections of information for government efficiency and to allow the public to look to one OMB control number for all collections of information for CFSAN export lists. This collection of information is intended to cover all of CFSAN's existing export lists, as well as any additional export lists required by foreign countries.

In 2016, FDA launched the Dairy Listing Module, an electronic registry system (Form FDA 3972) to facilitate applications for inclusion on the dairy export lists. FDA has expanded this system to accommodate applications for inclusion on export lists for CFSAN-regulated products, affording all firms the efficiencies of submitting information electronically. The expanded system is called the Export Listing Module (ELM). The ELM has

data fields that allow firms to input the information identified above that FDA recommends providing. In addition, the ELM contains data fields such as "Additional Information" and "Additional Documents" that allow firms to submit any additional data or information (such as third-party certifications) that foreign governments may require. Screenshots of the ELM are available at <https://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/ucm496929.htm>. If a firm is unable to submit an application via the ELM, it may contact CFSAN and request assistance.

Description of Respondents: Respondents to this collection of information include U.S. manufacturers/processors subject to FDA/CFSAN jurisdiction that wish to export to certain foreign countries that require inclusion on export lists.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
New requests to be placed on the lists	1,460	1	1,460	0.5 (30 minutes)	730
Third-party certification	370	1	370	21	7,770
Biennial update	2,505	1	2,505	0.5 (30 minutes)	1,253
Third-party certification biennial update	555	1	555	21	11,655
Occasional updates	300	1	300	0.5 (30 minutes)	150
Total					21,558

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The information collection reflects an increase in burden by 18,458 hours due to the consolidation of the information collections covered by OMB control numbers 0910-0839 and 0910-0320. Also, our current estimate of the number of foreign countries that may require us to establish lists in the next 3 years and the type of information they may require us to collect in order to maintain such lists has also resulted in an increase. At the same time, we have developed an electronic reporting portal that is expected to reduce the overall reporting time per submission. The portal will enhance the ability of firms to more efficiently request inclusion on export lists.

We base our estimate on the number of manufacturers/processors that have submitted new written requests, biennial updates, and occasional updates over the past 10 years. The estimate of the number of burden hours it will take a manufacturer/processor to gather the information needed to be placed on the list or update its

information is based on our experience with manufacturers/processors submitting similar requests. We believe that the information to be submitted will be readily available to manufacturers/processors. This collection is incorporating additional information collected to maintain lists of eligible exporters of CFSAN-regulated products who wish to export to foreign markets, including the European Union, Chile and China under OMB control numbers 0910-0320, "Request for Information from U.S. Processors that Export to the European Community" and 0910-0839, "Establishing and Maintaining Lists of U.S. Manufacturers/Processors with Interest in Exporting CFSAN-Regulated Products to China."

We estimate that 1,460 firms will average 30 minutes (0.5 hour) to submit new requests for inclusion on the list, 2,505 firms will average 30 minutes (0.5 hour) to update their information every 2 years, and 300 firms will average 30

minutes (0.5 hour) to occasionally update their information in this system.

Some firms will need to provide documentation that they obtained third-party certification to certify that they have met the requirements of the importing country. Currently, only China has this requirement. Based on our experience with this program, 370 firms will spend about 21 hours to complete the third-party certification for a total of 7,770 burden hours. During the biennial update, we estimate that about half of the 1,110 manufacturers/processors for which the importing country requires third-party certification will be recertified, meaning that 555 manufacturers/processors (1110 manufacturers/processors × 0.5) will get recertified each year. We estimate that it will take each such manufacturer/processor about 21 hours to complete the certification process for a total of 11,655 burden hours (555 manufacturers/processors × 21 hours).

We calculate, therefore, that the total burden for this collection is 21,558 hours.

Dated: November 2, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24618 Filed 11–9–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection

Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Maternal and Child Health Bureau Performance Measures for Discretionary Grant Information System (DGIS), OMB No. 0915–0298—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR must be received no later than January 14, 2019.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Maternal and Child Health Bureau

Performance Measures for Discretionary Grant Information System (DGIS), OMB No. 0915–0298—Revision

Abstract: This Information Collection Request is for continued approval of performance measures for HRSA's Maternal and Child Health Bureau (MCHB) discretionary grants, specifically, the continued use of reporting requirements for grant programs administered by MCHB in accordance with the "Government Performance and Results Act of 1993" (Pub. L. 103–62). This Act requires the preparation of an annual performance plan covering each program activity set forth in the agency's budget, which includes establishment of measurable goals that may be reported in an annual financial statement to support the linkage of funding decisions with performance. Performance measures for MCHB discretionary grants were initially approved in 2003, and the latest approval was obtained in 2016 for significant revisions. Continued approval from OMB is currently being sought to continue the use of performance measures with minor revisions. Most of these measures are specific to certain types of programs and are not required of all grantees. The measures are categorized by domains (Adolescent Health, Capacity Building, Child Health, Children with Special Health Care Needs, Lifecourse/Crosscutting, Maternal/Women Health, and Perinatal/Infant Health). In addition, there are some program-specific measures. Grant programs are assigned domains based on their activities. HRSA is proposing to make changes to the DGIS to more closely align data collection forms with current program activities. These revisions will facilitate more accurate reporting of descriptive information related to Long-term Trainees in Maternal and Child Health, as well as activities related to Technical Assistance for programs. Proposed changes include the following:

- Trainee Information (Long-term Trainees Only) form:
 - Changes will incorporate options and titles that were omitted from the final submission of the previous OMB package, providing clarification for the reporting of specific descriptive information about Long-term Trainees on the form.
 - Changes will list the following options for "Type": "Non-Degree

Seeking," "Undergraduate," "Masters," "Doctoral," Post-doctoral," "Other."

- Changes will list the title "Student Status" next to the options for "Part-time student" and "Full-time student."
- Technical Assistance/Collaboration form:

- Add a field asking for the "Total number of TA recipients." This change will allow for better alignment with this data that was previously collected by program, but omitted due to a DGIS paper form error.

- Add an "Other" category to List B under "Topic of Technical Assistance/Collaboration." This change would facilitate more accurate data reporting by providing programs an additional category to choose from if their current Technical Assistance activities do not closely align with the existing categories in List B.

Need and Proposed Use of the Information: The performance data collected through the DGIS serves several purposes, including grantee monitoring, program planning, performance reporting, and the ability to demonstrate alignment between MCHB discretionary programs and the Title V MCH Services Block Grant program. This revision will facilitate more accurate reporting of descriptive information related to Long-term Trainees in Maternal and Child Health, as well as activities related to Technical Assistance for programs.

Likely Respondents: The grantees for Maternal and Child Health Bureau Discretionary Grant Programs.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form	Number of respondents	Responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Grant Report	700	1	700	36	25,200
Total	700	700	25,200

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018-24659 Filed 11-9-18; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Practitioner Data Bank Guidebook

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: HRSA's Division of Practitioner Data Bank (DPDB) announces the release of the revised user National Practitioner Data Bank (NPDB) Guidebook. NPDB is a confidential information clearinghouse created by Congress and intended to facilitate a comprehensive review of the professional credentials of health care practitioners, entities, providers, and suppliers. The NPDB Guidebook is the primary policy document explaining the statutes and regulations behind and operation of the NPDB. It serves as an essential reference for NPDB users, offering reporting and querying examples, explanations, definitions, and frequently asked questions.

FOR FURTHER INFORMATION CONTACT: David Loewenstein, Director, DPDB, Bureau of Health Workforce, Health Resources and Services Administration, 301-443-2300, NPDBPolicy@hrsa.gov.

SUPPLEMENTARY INFORMATION: When the NPDB Guidebook was last revised in April 2015, substantial updates altered the regulatory scope, content, and display of the Guidebook. The new Guidebook incorporates information and infographics that augment or further clarify existing Guidebook topics and does not include any significant policy changes. The new NPDB Guidebook is now available at www.npdb.hrsa.gov.

Dated: November 6, 2018.

George Sigounas,
Administrator.

[FR Doc. 2018-24694 Filed 11-9-18; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Lasker Clinical Research Scholars Program (Si2/R00 Clinical Trial Optional).

Date: November 26, 2018.

Time: 9:30 a.m. to 11:30 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Louis A. Rosenthal, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities,

Rm. 3G42B, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9834, Bethesda, MD 20892-9834, (240) 669-5070, rosenthalla@niaid.nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Impact of Initial Influenza Exposure on Immunity in Infants (U01 Clinical Trial Not Allowed).

Date: December 3-4, 2018.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Maryam Feili-Hariri, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 5601 Fishers Lane, Rockville, MD 20852, 240-669-5026, haririmf@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 2, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-24622 Filed 11-9-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which

would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; NIMH HIV/AIDS Review (P30, T32).

Date: November 30, 2018.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: David W. Miller, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd, Room 6140, MSC 9608, Bethesda, MD 20892-9608, 301-443-9734, millerda@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; NIMH HIV/AIDS Research Education Applications (R25).

Date: November 30, 2018.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Rebecca Steiner Garcia, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6149, MSC 9608, Bethesda, MD 20892-9608, 301-443-4525, steinerr@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: November 6, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-24623 Filed 11-9-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant

applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Structural Biology and Molecular Biophysics.

Date: December 4-5, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sergei Ruvinov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892, 301-435-1180, ruvinser@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Toxicology and Digestive, Kidney and Urological Systems AREA Review.

Date: December 5, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Aiping Zhao, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2188, MSC 7818, Bethesda, MD 20892-7818, (301) 435-0682, zhaoa2@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cardiovascular Sciences.

Date: December 5, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kimm Hamann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118A, MSC 7814, Bethesda, MD 20892, 301-435-5575, hamannkj@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Hepatology.

Date: December 5, 2018.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Julia Spencer Barthold, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-402-3073, julia.barthold@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR15-359: Biomarker Studies for Diagnosing Alzheimer's Disease and Predicting Progression.

Date: December 5, 2018.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Mary G. Schueler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7846, Bethesda, MD 20892, 301-915-6301, marygs@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fogarty HIV Research Training Programs in Low and Middle Income Country Institutions.

Date: December 6, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Shalanda A. Bynum, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, Bethesda, MD 20892, 301-755-4355, bynumsa@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Neuroscience Assay, Diagnostics and Animal Model Development.

Date: December 6-7, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn, Washington, DC, 1199 Vermont Ave. NW, Washington, DC 20005.

Contact Person: Susan Gillmor, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 240-762-3076, susan.gillmor@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Psycho/Neuropathology, Lifespan Development, and STEM Education.

Date: December 6, 2018.

Time: 10:30 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Elia E. Femia, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3108, Bethesda, MD 20892, 301-827-7189, femiaee@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cellular and Molecular Neuroscience.

Date: December 6, 2018.

Time: 1:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Laurent Taupenot, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 4188, MSC 7850, Bethesda, MD 20892, 301-435-1203, laurent.taupenot@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 6, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-24625 Filed 11-9-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2018-0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: New or modified Base (1-percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities. The flood hazard determinations modified by each LOMR

will be used to calculate flood insurance premium rates for new buildings and their contents.

DATES: Each LOMR was finalized as in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at <https://msc.fema.gov>.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646-7659, or (email) patrick.sacbibit@fema.dhs.gov; or visit the FEMA Map Information eXchange (FMIX) online at https://www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

This new or modified flood hazard information, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

This new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP and are used to calculate the appropriate flood insurance premium rates for new buildings, and for the contents in those buildings. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at <https://msc.fema.gov>.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

David I. Maurstad,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Alabama:					
Colbert (FEMA Docket No.: B-1845).	City of Muscle Shoals (17-04-1041P).	The Honorable David H. Bradford, Mayor, City of Muscle Shoals, P.O. Box 2624, Muscle Shoals, AL 35662.	Engineering Department, 2010 East Avalon Avenue, Muscle Shoals, AL 35662.	Sept. 24, 2018	010047
Colbert (FEMA Docket No.: B-1845).	Unincorporated areas of Colbert County (17-04-1041P).	The Honorable Daroll Bendall, Chairman, Colbert County Board of Commissioners, 201 North Main Street, Tuscumbia, AL 35674.	Colbert County Courthouse, 201 North Main Street, Tuscumbia, AL 35674.	Sept. 24, 2018	010318
Mobile (FEMA Docket No.: B-1840).	City of Semmes (18-04-1945P).	The Honorable David Baker, Mayor, City of Semmes, P.O. Box 1757, Semmes, AL 36575.	City Hall, 7875 Moffett Road Unit #F, Semmes, AL 36575.	Sept. 10, 2018	015016
Mobile (FEMA Docket No.: B-1840).	Unincorporated Areas of Mobile County (18-04-1945P).	The Honorable Connie Hudson, Chair, Mobile County Board of Commissioners, 205 Government Street Mobile, AL 36644.	Mobile County Engineering Department, 205 Government Street, Mobile, AL 36644.	Sept. 10, 2018	015008
Colorado:					
Boulder (FEMA Docket No.: B-1840).	City of Boulder (18-08-0166P).	The Honorable Suzanne Jones, Mayor, City of Boulder, P.O. Box 791, Boulder, CO 80306.	Planning and Development Services Department, 1739 Broadway, Boulder, CO 80302.	Oct. 3, 2018	080024
Eagle (FEMA Docket No.: B-1840).	Town of Basalt (17-08-1316P).	Mr. Ryan Mahoney, Manager, Town of Basalt, 101 Midland Avenue, Basalt, CO 81621.	Town Hall, 101 Midland Avenue, Basalt, CO 81621.	Sept. 28, 2018	080052

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Eagle (FEMA Docket No.: B-1840).	Unincorporated areas of Eagle County (17-08-1316P).	The Honorable Kathy Chandler-Henry, Chair, Eagle County Board of Commissioners, P.O. Box 850, Eagle, CO 81631.	Eagle County Building and Engineering Department, 500 Broadway Street, Eagle, CO 81631.	Sep. 28, 2018	080051
El Paso (FEMA Docket No.: B-1840).	Unincorporated areas of El Paso County (18-08-0013P).	The Honorable Darryl Glenn, President, El Paso County, Board of Commissioners, 200 South Cascade Avenue, Suite 100, Colorado Springs, CO 80903.	Pikes Peak Regional Building Department, 2880 International Circle, Colorado Springs, CO 80910.	Oct. 3, 2018	080059
Jefferson (FEMA Docket No.: B-1840).	City of Westminster (18-08-0279P).	The Honorable Herb Atchison, Mayor, City of Westminster, 4800 West 92nd Avenue, Westminster, CO 80031.	Engineering Department, 4800 West 92nd Avenue, Westminster, CO 80031.	Sep. 21, 2018	080008
Jefferson (FEMA Docket No.: B-1845).	Unincorporated areas of Jefferson County (18-08-0676X).	The Honorable Libby Szabo, Chair, Jefferson County Board of Commissioners, 100 Jefferson County Parkway, Golden, CO 80419.	Jefferson County Department of Planning and Zoning, 100 Jefferson County Parkway, Golden, CO 80419.	Oct. 5, 2018	080087
Larimer (FEMA Docket No.: B-1840).	Town of Wellington (17-08-1283P).	The Honorable Troy Hamman, Mayor, Town of Wellington, P.O. Box 127, Wellington, CO 80549.	Town Hall, 3735 Cleveland Avenue, Wellington, CO 80549.	Oct. 9, 2018	080104
Larimer (FEMA Docket No.: B-1840).	Unincorporated areas of Larimer County (17-08-1283P).	The Honorable Steve Johnson, Chairman, Larimer County Board of Commissioners, P.O. Box 1190, Fort Collins, CO 80522.	Larimer County Engineering Department, 200 West Oak Street, Suite 3000, Fort Collins, CO 80522.	Oct. 9, 2018	080101
Pitkin (FEMA Docket No.: B-1840).	Unincorporated areas of Pitkin County (17-08-1316P).	The Honorable Patti Clapper, Chair, Pitkin County Board of Commissioners, 530 East Main Street, Suite 302, Aspen, CO 81611.	Pitkin County Building Department, 530 East Main Street, Suite 205, Aspen, CO 81611.	Sep. 28, 2018	080287
Florida:					
Broward (FEMA Docket No.: B-1840).	City of Fort Lauderdale (18-04-3005P).	The Honorable Dean J. Trantalis, Mayor, City of Fort Lauderdale, 100 North Andrews Avenue, Fort Lauderdale, FL 33311.	Building Services Department, 700 Northwest 19th Avenue, Fort Lauderdale, FL 33311.	Oct. 3, 2018	125105
Broward (FEMA Docket No.: B-1840).	Unincorporated areas of Broward County (18-04-3005P).	The Honorable Bertha Henry, Administrator, Broward County, 115 South Andrews Avenue, Fort Lauderdale, FL 33301.	Broward County Environmental Engineering and Permitting Division, 1 North University Drive, Plantation, FL 33324.	Oct. 3, 2018	125093
Collier (FEMA Docket No.: B-1840).	City of Naples (18-04-2880P).	The Honorable Bill Barnett, Mayor, City of Naples, 735 8th Street South, Naples, FL 34102.	Building Department, 295 Riverside Circle, Naples, FL 34102.	Sep. 19, 2018	125130
Orange (FEMA Docket No.: B-1840).	Unincorporated areas of Orange County (17-04-3962P).	The Honorable Teresa Jacobs, Mayor, Orange County, 201 South Rosalind Avenue, 5th Floor, Orlando, FL 32801.	Orange County Stormwater Management Department, 4200 South John Young Parkway, Orlando, FL 32839.	Oct. 4, 2018	120179
Osceola (FEMA Docket No.: B-1840).	Unincorporated areas of Osceola County (18-04-3037X).	The Honorable Fred Hawkins, Jr., Chairman, Osceola County Board of Commissioners, 1 Courthouse Square, Suite 4700, Kissimmee, FL 34741.	Osceola County Stormwater Department, 1 Courthouse Square, Suite 1400, Kissimmee, FL 34741.	Sep. 28, 2018	120189
Sarasota (FEMA Docket No.: B-1840).	Unincorporated areas of Sarasota County (18-04-3583P).	The Honorable Nancy C. Deter, Chair, Sarasota County Board of Commissioners, 1660 Ringling Boulevard, Sarasota, FL 34236.	Sarasota County Planning and Development Services Department, 1001 Sarasota Center Boulevard, Sarasota, FL 34240.	Oct. 1, 2018	125144
Kentucky: Hardin (FEMA Docket No.: B-1840).	City of Elizabethtown (18-04-2385P).	The Honorable Edna Berger, Mayor, City of Elizabethtown, P.O. Box 550, Elizabethtown, KY 42702.	Department of Stormwater Management, 200 West Dixie Avenue, Elizabethtown, KY 42702.	Sep. 28, 2018	210095
Maryland: Baltimore (FEMA Docket No.: B-1840).	Unincorporated areas of Baltimore County (17-03-2477P).	The Honorable Kevin Kamenetz, Baltimore County Executive, 400 Washington Avenue, Towson, MD 21204.	Baltimore County Planning Department, 105 West Chesapeake Avenue, Suite 101, Towson, MD 21204.	Sep. 19, 2018	240010
New Hampshire: Cheshire (FEMA Docket No.: B-1840).	Town of Jaffrey (17-01-2389P).	Mr. Jon Frederick, Manager, Town of Jaffrey, 10 Goodnow Street, Jaffrey, NH 03452.	Town Hall, 10 Goodnow Street, Jaffrey, NH 03452.	Sep. 28, 2018	330215
New Mexico: Bernalillo (FEMA Docket No.: B-1845).	Unincorporated areas of Bernalillo County (18-06-0450P).	Ms. Julie Morgas Baca, Bernalillo County Manager, 1 Civic Plaza Northwest, Albuquerque, NM 87102.	Bernalillo County Public Works Division, 2400 Broadway Boulevard Southeast, Albuquerque, NM 87102.	Oct. 5, 2018	350001
North Carolina:					
Greene (FEMA Docket, No.: B-1848).	Unincorporated areas of Greene County (18-04-2055P).	The Honorable Bennie Heath, Chairman, Board of Commissioners, 229 Kingold Boulevard, Suite D, Snow Hill, NC 28580.	Greene County Department of Building Inspections, 104 Hines Street, Snow Hill, NC 28580.	Oct. 5, 2018	370378
Pitt (FEMA Docket, No.: B-1848).	Unincorporated areas of Pitt County (18-04-2055P).	The Honorable Mark W. Owens, Jr., Chairman, Board of Commissioners, 1717 West 5th Street, Greenville, NC 27834.	Pitt County Planning Department, 1717 West 5th Street, Greenville, NC 27834.	Oct. 5, 2018	370372
Watauga (FEMA Docket No.: B-1845).	Town of Boone (18-04-0473P).	The Honorable Rennie Brantz, Mayor, Town of Boone, 567 West King Street, Boone, NC 28607.	Planning and Inspections Department, 680 West King Street, Boone, NC 28607.	Oct. 4, 2018	370253
Watauga (FEMA Docket No.: B-1845).	Unincorporated Areas of Watauga County (18-04-0473P).	The Honorable John Welch, Chairman, Watauga County Board of Commissioners, 814 West King Street, Suite 205, Boone, NC 28607.	Watauga County Planning and Inspections Department, 331 Queen Street, Suite A, Boone, NC 28607.	Oct. 4, 2018	370251

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
North Dakota: Cass (FEMA Docket No.: B-1840).	City of Fargo (17-08-1355P).	The Honorable Tim Mahoney, Mayor, City of Fargo, 200 3rd Street North, Fargo, ND 58102.	City Hall, 200 3rd Street North, Fargo, ND 58102.	Sep. 18, 2018	385364
South Dakota:					
Codington (FEMA Docket No.: B-1840).	City of Watertown (18-08-0263P).	The Honorable Sarah Caron, Mayor, City of Watertown, P.O. Box 910, Watertown, SD 57201.	Engineering Department, 23 2nd Street Northeast, Watertown, SD 57201.	Sep. 28, 2018	460016
Codington (FEMA Docket No.: B-1840).	Unincorporated areas of Codington County (18-08-0263P).	The Honorable Myron Johnson, Chairman, Codington County Board of Commissioners, P.O. Box 910, Watertown, SD 57201.	Codington County Extension Complex, Zoning Office, 1910 West Kemp Avenue, Watertown, SD 57201.	Sep. 28, 2018	460260
Minnehaha (FEMA Docket No.: B-1840).	City of Dell Rapids (17-08-1525P).	The Honorable Tom Earley, Mayor, City of Dell Rapids, P.O. Box 10, Dell Rapids, SD 57022.	City Hall, 302 East 4th Street, Dell Rapids, SD 57022.	Oct. 1, 2018	460059
Minnehaha (FEMA Docket No.: B-1840).	Unincorporated areas of Minnehaha County (17-08-1525P).	The Honorable Cindy Heiberger, Chair, Minnehaha County, Board of Commissioners, 415 North Dakota Avenue, Sioux Falls, SD 57104.	Minnehaha County Planning and Zoning Department, 415 North Dakota Avenue, Sioux Falls, SD 57104.	Oct. 1, 2018	460057
Texas:					
Bexar (FEMA Docket No.: B-1840).	City of San Antonio (18-06-0004P).	The Honorable Ron Nirenberg, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283.	Transportation and Capital Improvements Department, Storm Water Division, 1901 South Alamo Street, 2nd Floor, San Antonio, TX 78204.	Sep. 24, 2018	480045
Bexar (FEMA Docket No.: B-1840).	Unincorporated areas of Bexar County (18-06-0004P).	The Honorable Nelson W. Wolff, Bexar County Judge, 101 West Nueva Street, 10th Floor, San Antonio, TX 78205.	Bexar County Public Works Department, 233 North Pecos-La Trinidad Street, Suite 420, San Antonio, TX 78207.	Sep. 24, 2018	480035
Collin (FEMA Docket No.: B-1840).	City of Allen (18-06-0216P).	The Honorable Stephen Terrell, Mayor, City of Allen, 305 Century Parkway, Allen, TX 75013.	Engineering Department, 305 Century Parkway, Allen, TX 75013.	Sep. 21, 2018	480131
El Paso (FEMA Docket No.: B-1840).	City of El Paso (17-06-3843P).	Mr. Tommy Gonzalez, Manager, City of El Paso, 300 North Campbell Street, El Paso, TX 79901.	City Hall, 801 Texas Avenue, El Paso, TX 79901.	Sep. 24, 2018	480214
Harris (FEMA Docket No.: B-1840).	City of Houston (17-06-3450P).	The Honorable Sylvester Turner, Mayor, City of Houston, P.O. Box 1562, Houston, TX 77251.	Floodplain Management Department, 1002 Washington Avenue, 3rd Floor, Houston, TX 77002.	Sep. 24, 2018	480296
Harris (FEMA Docket No.: B-1840).	City of Hunter's Creek Village (17-06-3450P).	The Honorable Jim Pappas, Mayor, City of Hunter's Creek Village, 1 Hunters Creek Place, Houston, TX 77024.	City Hall, 1 Hunters Creek Place, Houston, TX 77024.	Sep. 24, 2018	480298
Hidalgo (FEMA Docket No.: B-1840).	Unincorporated areas of Hidalgo County (18-06-0700P).	The Honorable Ramon Garcia, Hidalgo County Judge, 100 East Cano Street, 2nd Floor, Edinburg, TX 78539.	Hidalgo County Drainage District No. 1, 902 North Doolittle Road, Edinburg, TX 78542.	Oct. 5, 2018	480334
Tarrant (FEMA Docket No.: B-1845).	City of Fort Worth (18-06-0617P).	The Honorable Betsy Price, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102.	Transportation and Public Works Department, 200 Texas Street, Fort Worth, TX 76102.	Oct. 9, 2018	480596
Tarrant (FEMA Docket No.: B-1845).	City of Saginaw (18-06-0328P).	The Honorable Todd Flipppo, Mayor, City of Saginaw, 333 West McLeroy Boulevard, Saginaw, TX 76179.	Public Works Department, 205 Brenda Lane, Saginaw, TX 76179.	Oct. 4, 2018	480610
Virginia:					
Fauquier (FEMA Docket No.: B-1840).	Unincorporated areas of Fauquier County (17-03-1930P).	Mr. Paul S. McCulla, Fauquier County Administrator, 10 Hotel Street, Suite 204, Warrenton, VA 20186.	Fauquier County Zoning and Development Services Department, 29 Ashby Street, 3rd Floor, Warrenton, VA 20186.	Sep. 20, 2018	510055
Loudoun (FEMA Docket No.: B-1840).	Unincorporated areas of Loudoun County (18-03-0512P).	Mr. Tim Hemstreet, Loudoun County Administrator, P.O. Box 7000, Leesburg, VA 20177.	Loudoun County Department of Development, 1 Harrison Street Southeast, Leesburg, VA 20175.	Sep. 28, 2018	510090
West Virginia: Preston (FEMA Docket No.: B-1845).	Unincorporated areas of Preston County (18-03-0988P).	The Honorable T. Craig Jennings, President, Preston County Commission, 106 West Main Street, Suite 202, Kingwood, WV 26537.	Preston County Office of Emergency Management, 300 Rich Wolfe Drive, Kingwood, WV 26537.	Oct. 9, 2018	540160

[FR Doc. 2018-24628 Filed 11-9-18; 8:45 am]

BILLING CODE 9110-12-P

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA-3408-EM]; [Docket ID FEMA-2018-0001]

Commonwealth of the Northern Mariana Islands; 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 Commonwealth of the Northern Mariana Islands (FEMA-3408-EM), dated October 23, 2018, and related determinations.

DATES: The declaration was issued October 23, 2018.

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 October 23, 2018, 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 the Commonwealth of the Northern Mariana Islands resulting from Typhoon Yutu beginning on October 24, 2018, 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 Commonwealth of the Northern Mariana Islands.

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, Benigno Bern Ruiz, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following areas of the Commonwealth of the Northern Mariana Islands have been designated as adversely affected by this declared emergency:

The municipalities of Rota, Saipan, Tinian, and the Northern Islands 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.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018-24675 Filed 11-9-18; 8:45 am]

BILLING CODE 9111-11-P

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA-4393-DR; Docket ID FEMA-2018-0001]

North Carolina; Amendment No. 9 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of North Carolina (FEMA-4393-DR), dated September 14, 2018, and related determinations.

DATES: This amendment was issued October 25, 2018.

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 North Carolina 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 September 14, 2018.

Chatham County for Individual Assistance (already designated for Public Assistance, including direct federal assistance).

Durham and Guilford Counties 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.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018-24630 Filed 11-9-18; 8:45 am]

BILLING CODE 9111-11-P

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA-4404-DR; Docket ID FEMA-2018-0001]

Commonwealth of the Northern Mariana Islands; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the Commonwealth of the Northern Mariana Islands (FEMA-4404-DR), dated October 26, 2018, and related determinations.

DATES: The declaration was issued October 26, 2018.

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 October 26, 2018, 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 the Commonwealth of the Northern Mariana Islands resulting from Super Typhoon Yutu beginning on October 24, 2018, 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 Commonwealth of the Northern Mariana Islands.

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 and assistance for emergency protective measures (Category B) under the Public Assistance program in the designated areas, Hazard Mitigation throughout the Commonwealth, and any other forms of assistance under the Stafford Act that you deem appropriate subject to completion of Preliminary Damage Assessments (PDAs). Direct Federal assistance is authorized.

Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance, Hazard Mitigation, and Other Needs Assistance will be limited to 75 percent of the total eligible costs. For a period of 30 days, you are authorized to

fund assistance for emergency protective measures, including direct Federal assistance, at 100 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, Benigno Bern Ruiz, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the Commonwealth of the Northern Mariana Islands have been designated as adversely affected by this major disaster:

The municipalities of Rota, Saipan, Tinian, and the Northern Islands for Individual Assistance.

The municipalities of Rota, Saipan, Tinian, and the Northern Islands for emergency protective measures (Category B), including direct federal assistance, under the Public Assistance program.

All areas within the Commonwealth of the Northern Mariana Islands 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.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018-24676 Filed 11-9-18; 8:45 am]

BILLING CODE 9111-11-P

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA-4390-DR; Docket ID FEMA-2018-0001]

Minnesota; 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 Minnesota (FEMA-4390-DR), dated September 5, 2018, and related determinations.

DATES: This amendment was issued November 2, 2018.

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 Minnesota 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 September 5, 2018.

Kanabec County for 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.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018-24691 Filed 11-9-18; 8:45 am]

BILLING CODE 9111-11-P

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA-4401-DR; Docket ID FEMA-2018-0001]

Virginia; 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 Commonwealth of Virginia (FEMA-4401-DR), dated October 15, 2018, and related determinations.

DATES: This amendment was issued October 18, 2018.

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 Commonwealth of Virginia 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 October 15, 2018.

The counties of Charles City, Halifax, King William, and Northumberland and the independent city of Franklin 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.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018-24678 Filed 11-9-18; 8:45 am]

BILLING CODE 9111-11-P

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA-4402-DR; Docket ID FEMA-2018-0001]

Wisconsin; 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 Wisconsin (FEMA-4402-DR), dated October 18, 2018, and related determinations.

DATES: This amendment was issued November 1, 2018.

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 Wisconsin 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 October 18, 2018.

Marquette County for Individual Assistance (already designated 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.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018-24674 Filed 11-9-18; 8:45 am]

BILLING CODE 9111-11-P

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA-4401-DR; Docket ID FEMA-2018-0001]

Virginia; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the Commonwealth of Virginia (FEMA-4401-DR), dated October 15, 2018, and related determinations.

DATES: The declaration was issued October 15, 2018.

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 October 15, 2018, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the “Stafford Act”), as follows:

I have determined that the damage in certain areas of the Commonwealth of Virginia resulting from Hurricane Florence during the period of September 8-21, 2018, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the “Stafford Act”). Therefore, I declare that such a major disaster exists in the Commonwealth of Virginia.

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 Commonwealth. 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, Donald L. Keldsen, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the Commonwealth of Virginia have been designated as adversely affected by this major disaster:

Henry, King and Queen, Lancaster, Nelson, Patrick, Pittsylvania, and Russell Counties and the Independent Cities of Newport News, Richmond, and Williamsburg for Public Assistance.

All areas within the Commonwealth of Virginia 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.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018–24677 Filed 11–9–18; 8:45 am]

BILLING CODE 9111–11–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4399–DR; Docket ID FEMA–2018–0001]

Florida; 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 Florida (FEMA–4399–DR), dated October 11, 2018, and related determinations.

DATES: This amendment was issued October 23, 2018.

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 Florida 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 October 11, 2018.

Bay, Calhoun, Gadsden, Gulf, Jackson, and Liberty 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).

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.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018–24629 Filed 11–9–18; 8:45 am]

BILLING CODE 9111–11–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2018–0002; Internal Agency Docket No. FEMA–B–1860]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or

regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before February 11, 2019.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location <https://www.fema.gov/preliminaryfloodhazarddata> and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at <https://msc.fema.gov> for comparison.

You may submit comments, identified by Docket No. FEMA–B–1860, to Rick Sacbbit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) patrick.sacbbit@fema.dhs.gov.

FOR FURTHER INFORMATION CONTACT: Rick Sacbbit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) patrick.sacbbit@fema.dhs.gov; or visit the FEMA Map Information eXchange (FMIX) online at https://www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the

floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements

outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at https://www.floodsrp.org/pdfs/srp_overview.pdf.

The watersheds and/or communities affected are listed in the tables below.

The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location https://www.fema.gov/preliminary_floodhazarddata and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at <https://msc.fema.gov> for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

David I. Maurstad,
Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Jefferson County, Alabama and Incorporated Areas Project: 12-04-1070S Preliminary Date: April 26, 2018	
City of Argo	Argo City Hall, 100 Blackjack Road, Trussville, AL 35173.
City of Bessemer	City Hall, 1700 3rd Avenue North, Bessemer, AL 35020.
City of Birmingham	Department of Planning, Engineering, and Permits, 710 North 20th Street, 5th Floor, Birmingham, AL 35203.
City of Brighton	City Hall, 3700 Main Street, Brighton, AL 35020.
City of Clay	Clay City Hall, 2441 Old Springville Road, Birmingham, AL 35215.
City of Helena	Municipal Building, 816 Highway 52 East, Helena, AL 35080.
City of Homewood	City Hall, 2850 19th Street South, Homewood, AL 35209.
City of Hoover	City Hall, 100 Municipal Lane, Hoover, AL 35216.
City of Irondale	City Hall, 101 20th Street South, Irondale, AL 35210.
City of Leeds	Department of Inspection Services, 1404 9th Street Northeast, Leeds, AL 35094.
City of Lipscomb	Lipscomb City Hall, 5512 Avenue H, Lipscomb, Bessemer, AL 35020.
City of Mountain Brook	City Hall, 56 Church Street, Mountain Brook, AL 35213.
City of Trussville	City Hall, 131 Main Street, Trussville, AL 35173.
City of Vestavia Hills	City Hall, 1032 Montgomery Highway, Vestavia Hills, AL 35216.
Unincorporated Areas of Jefferson County	Jefferson County Land Development Office, 716 Richard Arrington Jr. Boulevard North, Room 260, Birmingham, AL 35203.
Shelby County, Alabama and Incorporated Areas Project: 12-04-1070S Preliminary Date: April 26, 2018	
City of Birmingham	Department of Planning, Engineering, and Permits, 710 North 20th Street, 5th Floor, Birmingham, AL 35203.
City of Helena	Municipal Building, 816 Highway 52 East, Helena, AL 35080.
City of Hoover	City Hall, 100 Municipal Lane, Hoover, AL 35216.
City of Pelham	City Hall, 3162 Pelham Parkway, Pelham, AL 35124.
City of Vestavia Hills	City Hall, 1032 Montgomery Highway, Vestavia Hills, AL 35216.
Town of Indian Springs Village	Town Hall, 2635 Cahaba Valley Road, Indian Springs Village, AL 35124.
Unincorporated Areas of Shelby County	Shelby County Engineer's Office, 506 Highway 70, Columbiana, AL 35051.
St. Clair County, Alabama and Incorporated Areas Project: 12-04-1070S Preliminary Date: April 26, 2018	
City of Leeds	Department of Development Services, 1404 9th Street Northeast, Leeds, AL 35094.
City of Moody	City Hall, 670 Park Avenue, Moody, AL 35004.
City of Trussville	City Hall, 131 Main Street, Trussville, AL 35173.
Unincorporated Areas of St. Clair County	St. Clair County Road Department, 31588 U.S. Highway 231, Ashville, AL 35953.

Community	Community map repository address
Metropolitan Government of Louisville and Jefferson County, Kentucky and Incorporated Areas Project: 10-04-7840S Preliminary Date: February 28, 2018	

Metropolitan Government of Louisville and Jefferson County	Louisville/Jefferson County Metropolitan Sewer District, 700 West Liberty Street, Louisville, KY 40203.
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Brazoria County, Texas and Incorporated Areas
Project: 16-06-1963S Preliminary Date: June 30, 2017 and June 29, 2018

City of Alvin	Public Services Facility Building Engineering Department, 1100 West Highway 6, Alvin, TX 77511.
City of Angleton	City Secretary's Office, 121 South Velasco Street, Angleton, TX 77515.
City of Brazoria	City Hall, 201 South Main Street, Brazoria, TX 77422.
City of Brookside Village	City Hall, 6243 Brookside Road, Brookside Village, TX 77581.
City of Clute	City Hall, 108 East Main Street, Clute, TX 77531.
City of Danbury	City Hall, 6102 5th Street, Danbury, TX 77534.
City of Freeport	City Hall, 200 West 2nd Street, Freeport, TX 77541.
City of Hillcrest Village	Hillcrest Village City Hall, 106 West Blackstone Lane, Alvin, TX 77511.
City of Iowa Colony	City Hall, 12003 County Road 65, Rosharon, TX 77583.
City of Lake Jackson	City Hall, 25 Oak Drive, Lake Jackson, TX 77566.
City of Liverpool	City Hall, 8901 Calhoun Street, Liverpool, TX 77577.
City of Manvel	City Hall, 20025 Highway 6, Manvel, TX 77578.
City of Oyster Creek	City Hall, 3210 FM 523, Oyster Creek, TX 77541.
City of Pearland	Engineering and Capital Projects Department Engineering Division, 3519 Liberty Drive, Pearland, TX 77581.
City of Richwood	City Hall, 1800 Brazosport Boulevard North, Richwood, TX 77531.
City of Sandy Point	Brazoria County West Annex Building, 451 North Velasco Street, Suite 210, Angleton, TX 77515.
City of Surfside Beach	City Hall, 1304 Monument Drive, Surfside Beach, TX 77541.
City of Sweeny	City Hall, 102 West Ashley Wilson Road, Sweeny, TX 77480.
City of West Columbia	City Hall, 512 East Brazos Avenue, West Columbia, TX 77486.
Town of Holiday Lakes	City Hall, 195 North Texas Avenue, Holiday Lakes, TX 77515.
Town of Quintana	Town Hall, 814 North Lamar Street, Quintana, TX 77541.
Unincorporated Areas of Brazoria County	Brazoria County West Annex Building, 451 North Velasco Street, Suite 210, Angleton, TX 77515.
Village of Bailey's Prairie	Bailey's Prairie Floodplain Administrator's Office, 201 South Velasco Street, Angleton, TX 77515.
Village of Bonney	Brazoria County West Annex Building, 451 North Velasco Street, Suite 210, Angleton, TX 77515.
Village of Jones Creek	City Hall, 7207 Stephen F. Austin Road, Jones Creek, TX 77541.

Grand County, Utah and Incorporated Areas
Project: 17-08-0649S Preliminary Date: May 29, 2018

Unincorporated Areas of Grand County	Grand County Courthouse, 125 East Center Street, Moab, UT 84532.
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[FR Doc. 2018-24627 Filed 11-9-18; 8:45 am]
BILLING CODE 9110-12-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4390-DR; Docket ID FEMA-2018-0001]

Minnesota; 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 for the State of Minnesota (FEMA-4390-DR), dated September 5, 2018, and related determinations.

DATES: This amendment was issued November 2, 2018.

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 now June 15 to July 12, 2018.

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.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018-24693 Filed 11-9-18; 8:45 am]

BILLING CODE 9111-11-P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2018-0042]

Next Generation First Responder (NGFR)

AGENCY: Science and Technology Directorate, Department of Homeland Security.

ACTION: 60-Day notice of information collection; new request for comment.

SUMMARY: The Department of Homeland Security (DHS), Science and Technology Directorate (S&T) Next Generation First Responder (NGFR) program seeks to develop and integrate next-generation technologies by testing and evaluating first responder technologies during integration demonstration events. During these events, first responder participants use prototype technologies in a fictional scenario—such as a missing person case, an active shooter event, or a chemical spill—and are asked to share their feedback on how the technology worked in the context of their emergency response to the scenario, including whether the technologies made them more effective, efficient or safe.

The information collected during these events will help provide insight about how to improve technologies for first responders and will help DHS define whether or not the event was successful. Additionally, the feedback and evaluation DHS receives will be used in knowledge products that will then be distributed to other state and local first responder organizations.

DATES: Comments are encouraged and accepted until January 14, 2019.

ADDRESSES: You may submit comments, identified by docket number DHS–2018–0042, at:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Please follow the instructions for submitting comments.
- *Mail and hand delivery or commercial delivery:* Science and Technology Directorate, ATTN: Chief Information Office—Mary Cantey, 245 Murray Drive, Mail Stop 0202, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number DHS–2018–0042. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: DHS/S&T/NGFR Program Manager: Sridhar Kowdley, Sridhar.kowdley@hq.dhs.gov or 202–254–8804 (Not a toll free number).

SUPPLEMENTARY INFORMATION: DHS, in accordance with the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et*

seq., provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. DHS is soliciting comments on the proposed information collection request (ICR) that is described below. DHS is especially interested in public comments addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology? Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Next Generation First Responder Technology Evaluation Survey.

Type of Review: New.

Respondents/Affected Public: Law Enforcement, Firefighters.

Frequency of Collection: Quarterly.

Average Burden per Response: 15 minutes.

Total Estimated Number of Annual Responses: 900.

Total Estimated Number of Annual Burden Hours: 225.

Gregg Piermarini,

Chief Technology Officer/Deputy CIO, Science and Technology Directorate.

[FR Doc. 2018–24707 Filed 11–9–18; 8:45 am]

BILLING CODE 9110–9F–P

INTER-AMERICAN FOUNDATION

Sunshine Act Meetings

TIME AND DATE: November 19, 2018, 1:30 p.m.—5:10 p.m.

PLACE: Offices of Baker/McKenzie LLP, 815 Connecticut Avenue NW, Washington, DC 20006.

STATUS: Meeting of the Board of Directors and Advisory Council, open to the public, portion closed to the public.

MATTERS TO BE CONSIDERED:

- Approval of Past Meeting Minutes
- President's Report
- Management Report
- Advisory Council
- Executive Session
- Adjournment

PORTIONS CLOSED TO THE PUBLIC:

- Executive session closed to the public as provided for by 22 CFR 1004.4(b) & (f)

CONTACT PERSON FOR MORE INFORMATION: Paul Zimmerman, General Counsel, (202) 683–7118.

Paul Zimmerman,
General Counsel.

[FR Doc. 2018–24837 Filed 11–8–18; 4:15 pm]

BILLING CODE 7025–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–MB–2017–0092; 91200–FF09M20300–189–FXMB123109EAGLE]

Updated Collision Risk Model Priors for Estimating Eagle Fatalities at Wind Energy Facilities

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Reopening of the comment period.

SUMMARY: The U.S. Fish and Wildlife Service (Service) uses a collision risk model (CRM) to predict the number of golden and bald eagles that may be killed at new wind facilities. The model incorporates existing information on eagle exposure and collision probability in the form of prior distributions (priors). The Service has updated the priors for both species of eagle and, on June 21 of this year, announced the availability of a report of the analysis conducted to generate the new priors (83 FR 28858). The notice solicited public comments on how the Service should use the new bald eagle priors. Today's notice reopens the comment period for 30 days, and provides additional information requested by commenters.

DATES: To ensure consideration of written comments, they must be submitted on or before December 13, 2018.

ADDRESSES: You may submit written comments by one of the following methods:

Electronically: Go to the Federal e-Rulemaking Portal: <http://www.regulations.gov>. Search for FWS–HQ–MB–2017–0092, which is the docket number for this notice, and follow the directions for submitting comments.

By hard copy: Submit by U.S. mail or hand-delivery to Public Comments Processing, Attn: FWS–HQ–MB–2017–0092; Division of Policy, Performance, and Management Programs; U.S. Fish and Wildlife Service; MS: BPHC; 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We will post all comments on <https://www.regulations.gov>. This generally

means that we will post any personal information you provide us (see Request for Information below for more information).

We request that you send comments by only one of the methods described above. We will post all information received on <http://www.regulations.gov>. This generally means that we will post any personal information you provide us (see the Public Availability of Comments section below for more information).

FOR FURTHER INFORMATION CONTACT: Ken Richkus, at 703-358-1780 (telephone), or ken_richkus@fws.gov (email). Individuals who are hearing impaired or speech impaired may call the Federal Relay Service at 800-877-8337 for TTY assistance.

SUPPLEMENTARY INFORMATION:

Background

The U.S. Fish and Wildlife Service (Service) uses a collision risk model (CRM) to predict the number of golden and bald eagles that may be killed at new wind facilities (USFWS 2013; New *et al.* 2015). The CRM incorporates existing knowledge of eagle use around a proposed wind facility (exposure) and the probability of an eagle colliding with an operating turbine (collision probability).

The CRM is constructed using a Bayesian framework, and as such incorporates existing information on eagle exposure and collision probability in the form of prior distributions (priors). The priors are formally combined with site-specific data on exposure and the amount of hazardous area and operational time for a site to estimate the expected number of annual eagle collision fatalities.

The Service recently updated the priors for both species of eagle using all available data that meet specific criteria, substantially more data than were available when the original priors were established. We released a report of the analysis undertaken to generate the updated priors and announced the availability of the report in a June 21, 2018, **Federal Register** notice published on (83 FR 28858). In that notice we asked for public input on options for how we should apply the new bald eagle priors. Several of the comments we received during the initial comment period requested that the Service provide the values for the shape and rate parameters of the gamma and beta distributions described in the referenced report. In response to these comments, we have posted an updated version of the report that provides those parameter values on the Service's website at:

<https://www.fws.gov/birds/management/managedspecies/eaglemanagement.php>. You can also find the report on the Federal e-Rulemaking Portal: <http://www.regulations.gov>. Search for FWS-HQ-MB-2017-0092.

Because the bald eagle collision prior is based on data from only 14 sites that do not span the range of bald eagle density conditions that exist across the country, the prior may not be as representative as it would be if data from a wider range of location had been available. Given this uncertainty, the Service is considering three alternatives for how to incorporate species-specific priors for bald eagles into the CRM and fatality modeling process:

(1) Use the updated species-specific priors, and use the 80th quantile of the CRM fatality estimates as the initial permitted take number for permits, as is the current practice.

(2) Use the updated species-specific priors, but because the status of bald eagles is secure, adopt a risk-tolerant policy for bald eagles and select a more liberal quantile on the CRM fatality distribution as the initial permitted take number for this species.

(3) Given the limitations in data available to inform the bald eagle priors, initiate an expert elicitation process to further refine the bald eagle priors.

Under any of these scenarios, the Service would use data submitted under permits to make updates to the priors in the future.

Alternative 1 would mean that for a similar level of eagle use observed at a project site, the Service would use higher fatality estimates for bald eagles than for golden eagles. Alternative 2 would be a decision by the Service to be more 'risk-tolerant' for bald eagles. This would mean that initial fatality predictions would be lower, however it would also likely mean that more permits would have to be amended to increase the permitted take over time (*i.e.*, the Service would be underestimating take more often). Alternative 3 would be a decision by the Service that more information is needed to understand the potential variability of exposure and collision probability for bald eagles. Such a process could result in either higher or lower (or more variable) priors. We are soliciting input from the public on these three alternatives. We are not seeking input on the CRM itself, which has been peer-reviewed and been the subject of multiple rounds of public comment in the past.

Public Availability of Comments

Written comments we receive become part of the public record associated with this action. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that the 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. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Dated: October 29, 2018.

Andrea Travnicek,

Principal Deputy Assistant Secretary, Water and Science, Exercising the authority of the Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2018-24718 Filed 11-9-18; 8:45 am]

BILLING CODE 4333-55-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R4-ES-2018-N107;
FXES11140400000-189-FF04E00000]

Endangered Species; Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received applications for permits to conduct activities intended to enhance the propagation or survival of endangered species under the Endangered Species Act of 1973, as amended. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive written data or comments on the applications by December 13, 2018.

ADDRESSES:

Reviewing Documents: Documents and other information submitted with the applications are available for review, subject to the requirements of the

Privacy Act and Freedom of Information Act. Submit a request for a copy of such documents to Karen Marlowe (see **FOR FURTHER INFORMATION CONTACT**).

Submitting Comments: If you wish to comment, you may submit comments by one of the following methods:

- *U.S. mail or hand-delivery:* U.S. Fish and Wildlife Service Regional Office, Ecological Services, 1875 Century Boulevard, Atlanta, GA 30345 (Attn: Karen Marlowe, Permit Coordinator).

- *Email:* permitsR4ES@fws.gov. Please include your name and return address in your email message. If you do not receive a confirmation from the U.S. Fish and Wildlife Service that we have received your email message, contact us directly at the telephone number listed in **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Karen Marlowe, Permit Coordinator, 404-679-7097 (telephone), karen_marlowe@fws.gov (email), or 404-679-7081 (fax). Individuals who are hearing or speech impaired may call the Federal Relay Service at 1-800-877-8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We invite review and comment from local, State, and Federal agencies and the public on

applications we have received for permits to conduct certain activities with endangered and threatened species under section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and our regulations in the Code of Federal Regulations (CFR) at 50 CFR part 17. With some exceptions, the ESA prohibits activities that constitute take of listed species unless a Federal permit is issued that allows such activities. The ESA's definition of "take" includes hunting, shooting, harming, wounding, or killing, and also such activities as pursuing, harassing, trapping, capturing, or collecting.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered or threatened species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. These activities often include such prohibited actions as capture and collection. Our regulations implementing section 10(a)(1)(A) for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species,

and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

Proposed activities in the following permit requests are for the recovery and enhancement of propagation or survival of the species in the wild. The ESA requires that we invite public comment before issuing these permits. Accordingly, we invite local, State, Tribal, and Federal agencies and the public to submit written data, views, or arguments with respect to these applications. The comments and recommendations that will be most useful and likely to influence agency decisions are those supported by quantitative information or studies.

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.

Permit application No.	Applicant	Species/numbers	Location	Activity	Type of take	Permit action
TE 676379-6	National Oceanic and Atmospheric Administration, National Marine Fisheries Service, Southeast Fisheries Science Center, Miami, FL.	Hawksbill (<i>Eretmochelys imbricata</i>), Kemp's ridley (<i>Lepidochelys kempii</i>), and Leatherback (<i>Derموchelys coriacea</i>) sea turtles.	Florida, Mississippi, and Texas.	Turtle Excluder Device (TED) certification trials and nest surveys and excavation.	Conduct nest surveys, locate egg chambers, screen and mark nests, monitor nests for hatching, and excavate nests. Remove Kemp's ridley sea turtle hatchlings from wild to rear in captivity for a period of 1-2 years for use in TED certification trials.	Renewal and Amendment.
TE 97308A-1	John L. Harris, Scott, AR.	19 species of freshwater mussels.	Alabama, Arkansas, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Ohio, Oklahoma, Pennsylvania, South Dakota, Tennessee, Virginia, West Virginia, and Wisconsin.	Presence/absence surveys, population estimate surveys, and DNA sampling.	Remove from substrate, handle, identify, collect tissue swabs, return to substrate, and salvage relic shells.	Renewal.
TE 48576B-1	Carson Wood, Castle Hayne, NC.	Red-cockaded woodpecker (<i>Picoides borealis</i>).	Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, North Carolina, and South Carolina.	Population management and monitoring.	Capture, band, monitor nest cavities, construct and monitor artificial nest cavities and restrictors, and salvage.	Renewal.
TE 86956C-0	Robert Davis, Tallahassee, FL.	16 species of freshwater mussels.	Alabama, Florida, and Georgia.	Presence/absence surveys.	Remove from the substrate, handle, identify, and return to substrate.	New.

Permit application No.	Applicant	Species/numbers	Location	Activity	Type of take	Permit action
TE 041314-6	U.S. Army, Fort Polk, LA.	Red-cockaded woodpecker (<i>Picoides borealis</i>) and Louisiana pine snake (<i>Pituophis ruthveni</i>).	Fort Polk Military Base, Fort Polk, Louisiana. Red-cockaded woodpecker translocation activities also in Arkansas, Louisiana, Oklahoma, and Texas.	Population management and monitoring and screening for disease.	Red-cockaded woodpecker: Capture, band, translocate, monitor nest cavities, construct and monitor artificial nest cavities and restrictors. Louisiana pine snake: capture, handle, measure, weigh, PIT-tag, swab, remove radio transmitters, and collect blood, fecal, and shed skin samples.	Renewal and Amendment.
TE 88796C-0	Geological Survey of Alabama, Tuscaloosa, AL.	Watercress darter (<i>Etheostoma nuchale</i>).	Watercress Darter National Wildlife Refuge, Bessemer, Alabama.	Presence/absence and population surveys.	Capture with seine nets, identify, and release.	New.
TE 89030C-0	Mark Strong, Smithsonian Institution, Washington, DC.	25 species of plants ...	Lake Wales Ridge National Wildlife Refuge, Florida.	Collect genomic tissue samples and herbarium vouchers.	Collect leaf tissue samples and a single branch or small above-ground portion of the plant.	New.
TE 171594-1	Craig Martin, Wetland Sciences, Inc., Pensacola, FL.	Alabama beach mouse (<i>Peromyscus polionotus ammobates</i>), Choctawhatchee beach mouse (<i>Peromyscus polionotus allophrys</i>), and Perdido Key beach mouse (<i>Peromyscus polionotus trissyllepsis</i>).	Alabama and Florida	Presence/absence surveys.	Capture, identify, and release.	Renewal and Amendment.
TE 97394A-3	Zachary Couch, Pleasureville, KY.	Gray bats (<i>Myotis grisescens</i>), Indiana bats (<i>Myotis sodalis</i>), Northern long-eared bats (<i>Myotis septentrionalis</i>), and Virginia big-eared bats (<i>Corynorhinus townsendii virginianus</i>).	Alabama, Arkansas, Connecticut, Delaware, District of Columbia, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming.	Presence/absence surveys, population monitoring, and studies to document habitat use.	Enter hibernacula or maternity roost caves, capture with mist nets or harp traps, handle, identify, band, radio-tag, light-tag, collect hair samples, wing-punch, and salvage.	Renewal.
TE 02200B-1	Atlanta Botanical Garden, Atlanta, GA.	<i>Helonias bullata</i> (Swamp pink), <i>Platanthera integrilabia</i> (White fringeless orchid), <i>Sarracenia oreophila</i> (Green pitcher plant), <i>Spiraea virginiana</i> (Virginia spiraea), <i>Trillium persistens</i> (Persistent trillium), <i>Trillium reliquum</i> (Relict trillium), and <i>Xyris tennesseensis</i> (Tennessee yellow-eyed grass).	Federal lands in Alabama, Georgia, North Carolina, and Tennessee.	Long-term storage, artificial propagation, and <i>ex situ</i> safeguarding.	Remove and reduce to possession (collect) seeds.	Renewal and Amendment.

Permit application No.	Applicant	Species/numbers	Location	Activity	Type of take	Permit action
TE 35594A-3	Alabama Power Company, Birmingham, AL.	Gray bats (<i>Myotis grisescens</i>), Indiana bats (<i>Myotis sodalis</i>), Northern long-eared bats (<i>Myotis septentrionalis</i>), Gopher tortoise (<i>Gopherus polyphemus</i>), Black Warrior waterdog (<i>Necturus alabamensis</i>).	Alabama	Presence/absence surveys, population monitoring, upper respiratory tract disease testing, and DNA analysis.	Bats: Capture with mist-nets, handle, identify, band, and radio-tag. Gopher tortoise: Add authorization to trap, attach radio transmitters, and collect blood. Black Warrior waterdog: Trap, handle, identify, and collect tail sample.	Amendment.

Authority We publish this notice under section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Leopoldo Miranda,

Assistant Regional Director, Ecological Services, Southeast Region.

[FR Doc. 2018-24607 Filed 11-9-18; 8:45 am]

BILLING CODE 4333-15-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[18X.LLES964000.L14400000.FR0000; FLES-58597]

Notice of Proposed Withdrawal Extension and Opportunity for Public Meeting for the Pelican Island National Wildlife Refuge; Florida

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Secretary of the Interior proposes to extend the duration of Public Land Order (PLO) No. 5683 for an additional 40-year term. PLO No. 5683 withdrew 37.50 acres of public land from settlement, sale, location, or entry under the general land laws, including the mining laws, but not from leasing under the mineral leasing laws and reserved under the jurisdiction of the Department of the Interior as part of the Pelican Island National Wildlife Refuge (PINWR), administered by the United States Fish and Wildlife Service (USFWS). This Notice gives an opportunity for the public to comment on the petition/application for the proposed withdrawal extension and to request a public meeting.

DATES: For a period until February 11, 2019, all persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal extension may do so in writing.

ADDRESSES: Written comments should be sent to the BLM Southeastern States District Office, Attn: Victoria Craft, 273

Market Street, Flowood, MS 39232 or by email to: vcraft@blm.gov.

FOR FURTHER INFORMATION CONTACT:

Sally Spencer, phone: 202-912-7700; email: sspencer@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.

SUPPLEMENTARY INFORMATION: The withdrawal created by PLO No. 5683 (44 FR 53084, 1979), will expire on September 11, 2019, unless extended. The USFWS has filed a petition/application requesting extension of the withdrawal created by the PLO for an additional 40-year term. The PLO withdrew the following described public land from settlement, sale, location, or entry under the general land laws, including the mining laws, but not from leasing under the mineral leasing laws, and reserved them as part of the PINWR:

Tallahassee Meridian, Florida

T. 31 S, R. 39 E,
Sec. 9, lot 9

The land withdrawn by PLO No. 5683 are located in Indian River County (formerly a portion of Brevard County), Florida.

The purpose of the withdrawal extension is to continue to provide an upland buffer zone between the existing refuge and the adjacent privately held land. The withdrawn land is home to PINWR's Centennial Trail, Boardwalk, and Observation Pavilion, which were developed in recognition of the 2003 Centennial Celebration of the National Wildlife Refuge System, at the home of the first National Wildlife Refuge. The PINWR contains 5,400 acres and is visited by over 100,000 people annually who come to experience nature and learn about the Refuge.

The use of a right-of-way, interagency agreement, or cooperative agreement would not provide adequate protection

for the wildlife habitat and unique resource values within the PINWR.

No additional water rights would be needed to fulfill the purpose of the requested withdrawal extension.

There are no suitable alternative sites since the lands described herein contain the natural and biological resources of interest for protection.

All persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal extension may present their views in writing to the BLM Eastern States, at the address indicated above. Comments, including names and street addresses of respondents, will be available for public review at the address stated above, during regular business hours, 7:30 a.m. to 4:30 p.m., Monday through Friday, except holidays.

Before including your address, phone number, email address, or other personally identifiable information in your comment, you should be aware that your entire comment—including your personally identifiable information—may be made publicly available at any time. While you can ask the BLM in your comment to withhold your personally identifiable information from public review, we cannot guarantee that we will be able to do so.

Notice is hereby given that an opportunity for a public meeting is afforded in connection with the proposed withdrawal extension. All interested persons who desire a public meeting for the purpose of being heard on the proposed withdrawal extension must submit a written request to the District Manager, BLM Southeastern States District Office at the address provided in the **ADDRESSES** section, within 90 days from the date of publication of this Notice. If the authorized officer determines that a public meeting will be held, a Notice of the date, time, and place will be published in the **Federal Register** and local newspapers and posted on the BLM website at: www.blm.gov at least

30 days before the scheduled date of the meeting.

All statements received will be considered before any recommendation concerning the proposed extension is submitted to the Assistant Secretary—Land and Minerals Management for final action. This withdrawal extension proposal will be processed in accordance with the regulations set forth in 43 CFR 2310.4.

Authority: 43 CFR 2310.3–1.

Dated: November 6, 2018.

Ryan K. Zinke,

Secretary of the Interior.

[FR Doc. 2018–24717 Filed 11–9–18; 8:45 am]

BILLING CODE 4310–GJ–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0026717; PPWOCRADNO–PCU00RP14.R50000]

Notice of Inventory Completion: Kansas State Historical Society, Topeka, KS

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Kansas State Historical Society has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Kansas State Historical Society. If no additional requesters come forward, transfer of control of the human remains to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Kansas State Historical Society at the address in this notice by December 13, 2018.

ADDRESSES: Dr. Robert J. Hoard, Kansas State Historical Society, 6425 SW 6th Avenue, Topeka, KS 66615–1099, telephone 785–272–8681, Ext. 269, email Robert.hoard@ks.gov.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Kansas State Historical Society, Topeka, KS. The human remains were removed from Barber, Cowley, Marion, Rice, and Sumner Counties, KS.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Kansas State Historical Society professional staff in consultation with representatives of the Wichita and Affiliated Tribes (Wichita, Keechi, Waco, and Tawakonie), Oklahoma.

History and Description of the Remains

On or before 1985, human remains representing, at minimum, one individual were removed from portions of site 14BA401, the JJ Lemon Ranch site (UBS 2001–22) in Barber County, KS, by an artifact collector in Pratt, KS. In 2001, the collector showed his collection to Kansas State Historical Society staff, who identified and took possession of the human remains—cranial fragments, a mandible fragment with teeth, three vertebrae, and two fragments of a femur—all of which belong to a single, 45–55-year-old male. No known individuals were identified. No associated funerary objects are present.

The site is affiliated with the Middle Ceramic (ca. A.D. 1100–1400) Pratt complex based on diagnostic artifacts observed at the site. The Pratt complex material culture recovered from the site—charred corn cobs, small triangular Washita points, beveled knives, bison scapula hoes, other bone tools, and attributes of ceramic vessel sherds—is representative of the people who are ancestral to the Great Bend aspect and, ultimately, to the Wichita and Affiliated Tribes, as asserted by Brosowske and Bevitt in the volume *Kansas Archaeology* (Hoard and Banks 2006:180–205), as well as by others. Previously recovered human remains from this site were repatriated to the Wichita and Affiliated Tribes in 1999 (**Federal Register** March 12, 1999, vol. 64, no. 48, pp. 12349–12351).

In 1969, human remains representing, at minimum, one individual was removed from 14SR303, the Buresh site (UBS 2000–12) in Sumner County, KS. Kansas State Historical Society staff excavated the site to save information from the site before it was destroyed by collectors. A human occipital belonging to an adult was recovered from a large basin-shaped feature containing charcoal, tools, and other cultural debris. These human remains were not noted during the excavation, but were found only later, during analysis of the Kansas State Historical Society collections. No known individuals were identified. No associated funerary objects are present.

The site dates to ca. A.D. 1100. The material culture recovered from the site—charred corn cobs, small triangular Washita points, beveled knives, bison scapula hoes, other bone tools, and sherds from globular jars with decorated lips and rims—is consistent with the Washita focus, whose people are considered to be ancestral to the Great Bend aspect and, ultimately, to the Wichita and Affiliated Tribes, as asserted by Brosowske and Bevitt in the volume *Kansas Archaeology* (Hoard and Banks 2006:180–205), as well as by others.

In 1986, human remains representing, at minimum, one individual were removed from 14MN328, the Mem site (UBS 2001–26) in advance of highway construction. The collections from the site, including ceramic vessel sherds and side-notched arrow pints, are consistent with the Great Bend aspect. Subsequent analysis of collections from the investigations recovered a human deciduous incisor belonging to a single individual. No associated funerary objects are present.

The Great Bend aspect, ca. A.D. 1350–1700, is widely understood to be ancestral to the modern-day Wichita and Affiliated Tribes. This understanding is based on radiocarbon dates, geographic region, material culture, oral tradition, and historical documents such as the entradas of Coronado and Oñate in A.D. 1541 and 1601, respectively, as well as historical continuity into the nineteenth and twentieth centuries. This evidence is strongly asserted in Waldo Wedel's 1959 publication *An Introduction to Kansas Archeology* and in many subsequent archeological publications.

In 1977, human remains representing, at minimum, one individual were removed from 14RC2, the Major site (UBS 2001–32) in Rice County, KS. A private individual excavated a trash pit at the site, and subsequently donated the collection to the Kansas State

Historical Society. The collections from the site, including ceramic vessel sherds and side-notched arrow pints, are consistent with the Great Bend aspect. The collection included a mandible fragment with four teeth, belonging to a single adult individual. No known individuals were identified. No associated funerary objects are present.

In 1977 and 1978, human remains representing, at minimum, one individual were removed from 14RC8, the Tobias site (UBS 2011–01) in Rice County, KS. Research excavations by the Kansas State Historical Society led to the collection of extensive amounts of cultural material with a clear affiliation to the ancestral Wichita Great Bend aspect. An adult human tooth was recovered from this collection in 2011. No known individuals were identified. No associated funerary objects are present.

In 2005, human remains representing, at minimum, two individuals were removed from 14RC410, the Little River site (UBS 2005–08) in Rice County, KS. Excavations in advance of the construction of a water treatment plant encountered a human burial. Because artifacts consistent with the Great Bend aspect were present at the site, the Wichita and Affiliated Tribes were contacted, and the burial was left in place. During subsequent analysis of the site collection, small, fragmentary remains belonging to two individuals were discovered. No known individuals were identified. No associated funerary objects are present.

Between 1994 and 1996, human remains representing, at minimum, one individual were removed from 14CO1, the Larcum-Haggard site (UBS 2015–08), in Cowley County, KS. Kansas State Historical Society staff excavated this Great Bend aspect site in advance of highway construction. Representatives of the Wichita and Affiliated Tribes were actively consulted during investigations. Subsequent analysis of the materials collected led to the discovery of a single human deciduous incisor. No known individuals were identified. No associated funerary objects are present.

Between 1994 and 1996, human remains representing, at minimum, one individual were removed from 14CO3, the County Club site (UBS 2006–05), in Cowley County, KS. Kansas State Historical Society staff excavated this Great Bend aspect site in advance of highway construction. Representatives of the Wichita and Affiliated Tribes were actively consulted during investigations. Subsequent analysis of the materials collected led to the discovery of a single human deciduous

incisor. No known individuals were identified. No associated funerary objects are present.

Between 1994 and 1996, human remains representing, at minimum, one individual were removed from 14CO332, the Havelock site (UBS 2001–20), in Cowley County, KS. Kansas State Historical Society staff excavated this Great Bend aspect site in advance of highway construction. Representatives of the Wichita and Affiliated Tribes were actively consulted during investigations. Subsequent analysis of the materials collected led to the discovery of a single human deciduous incisor. No known individuals were identified. No associated funerary objects are present.

Determinations Made by the Kansas State Historical Society

Officials of the Kansas State Historical Society have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 10 individuals of Native American ancestry.

- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Dr. Robert J. Hoard, Kansas State Historical Society, 6425 SW 6th Avenue, Topeka, KS 66615–1099, telephone 785–272–8681, Ext. 269, email Robert.hoard@ks.gov, by December 13, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remains to the Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma may proceed.

The Kansas State Historical Society is responsible for notifying the Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma that this notice has been published.

Dated: October 9, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018–24663 Filed 11–9–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0026787; PPWOCRADNO–PCU00RP14.R50000]

Notice of Inventory Completion: University of Arkansas Museum Collections, Fayetteville, AR

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The University of Arkansas Museum Collections has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the University of Arkansas Museum Collections. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the University of Arkansas Museum Collections at the address in this notice by December 13, 2018.

ADDRESSES: Mary Suter, University of Arkansas Museum Collections, Biomass Building 125, 2435 North Hatch Avenue, Fayetteville, AR 72704, telephone (479) 575–3456, email msuter@uark.edu.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the University of Arkansas Museum Collections, Fayetteville, AR. The human remains and associated funerary objects were removed from multiple locations in Arkansas.

This notice is published as part of the National Park Service's administrative

responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the University of Arkansas Museum Collections professional staff in consultation with representatives of The Quapaw Tribe of Indians.

History and Description of the Remains

In 1966, human remains representing, at minimum, one individual were removed from Roland Mound (3AR30) in Arkansas County, AR. The human remains are those of an adult of unknown sex. The human remains were excavated by James A. Scholtz for the University of Arkansas Museum. No known individuals were identified. No associated funerary objects are present.

In 1967, human remains representing, at minimum, two individuals were removed from the Dumond Site (3AR40) in Arkansas County, AR. These remains were excavated by James A. Scholtz for the University of Arkansas Museum. No known individuals were identified. The one associated funerary object, a pottery vessel, is currently missing from the museum's collections.

At an unknown date, human remains representing, at minimum, three individuals were removed from the McDuffie Site (3CG21) in Craighead County, AR. These human remains were donated to the museum by a collector in 1967. No known individuals were identified. No associated funerary objects are present.

In 1929, human remains representing, at minimum, one individual were removed from an unknown site in Conway County, AR. The individual was an adult of unknown sex. Accession records for these remains and associated artifact are incomplete. No known individuals were identified. The one associated funerary object is an engraved long-necked tripod bottle.

In 1933, human remains representing, at minimum, 40 individuals were removed from Togo/Neely's Ferry Site (3CS24) in Cross County, AR. The human remains and associated funerary objects were excavated by the University of Arkansas Museum. No known individuals were identified. The 196 associated funerary objects are: One deer antler tine, one arrow point, one bone awl, two modified gar jaws, one

bone bead, 31 shell beads, 13 mammal bone fragments, 32 fish bones, 19 ceramic bottles, 15 ceramic bowls, one lot of charred corn cobs, one stone disc, one ceramic disc, two marine shell ear spools, one effigy bottle, one effigy bowl, one bird effigy bowl, one snake effigy bowl, 19 fish hook fragments, one fired clay object, nine ceramic jars, one deer mandible, one pebble, one shell tempered clay pipe, three deer scapula fragments, one shell ornament, 34 mussel shell fragments, and one pot sherd. An additional three associated funerary objects are currently missing from the museum's collections. They are one shell ear plug, one bone ring, and one gar scale.

In 1933, human remains representing, at minimum, 104 individuals were removed from the Vernon Paul Site (3CS25) in Cross County, AR. These human remains and associated funerary objects were excavated by the University of Arkansas Museum. No known individuals were identified. The 692 associated funerary objects are six deer antler fragments, two arrow points, one sample of ashes, 11 bone awls, five beads, 171 shell beads, 15 animal bone fragments, 44 ceramic bottles, 51 ceramic bowls, 56 fragments of turtle shell, three stone celts, one piece of charcoal, two unmodified cobbles, one cache of charred corn, three ceramic discoidals, one stone discoidal, seven shell ear plugs, 13 effigy bowls, one antler tool, one sample of gravel, one hammer stone, one piece of hematite, 20 ceramic jars, two fish bone needles, one lot pebbles, one bone pin, two pipes, two ceramic cylinders, 151 fragments of a turtle shell rattle, two turtle scapulae, 14 mussel shell fragments, 79 shell-tempered body sherds, and 21 shell tempered rim sherds. One additional associated funerary object is currently missing from the museum's collections. It is one lot of pot sherds.

In 1950, 1967, and another unknown date, human remains representing, at minimum, seven individuals were removed from the Rose Mound Site (3CS27) in Cross County, AR. The human remains removed in 1950 were excavated by the University of Arkansas as part of a Field School. The human remains from 1967 were donated to the University of Arkansas Museum. Human remains from one of the listed individuals were donated to the University of Arkansas at an unknown date and transferred to the control of the University of Arkansas Museum in 2006. No known individuals were identified. The five associated funerary objects are five fragments of copper.

At an unknown date, human remains representing, at minimum, one

individual were removed from the Delta Site (3CS69) in Cross County, AR and donated to the University of Arkansas Museum in 1966. No known individuals were identified. No associated funerary objects are present.

In 1967, human remains representing, at minimum, 17 individuals were removed from the Wapanocca Mound Site (3CT9) in Crittenden County, AR. These human remains and associated funerary objects were excavated by the University of Arkansas Museum. No known individuals were identified. The 49 associated funerary objects are: Nine ceramic bottles, 10 ceramic bowls, two effigy bowls, seven ceramic jars, one mano, three mussel shells, seventeen sherds. No known individuals were identified. No associated funerary objects are present.

In 1932 and at an unknown date, human remains representing, at minimum, 37 individuals were removed from the Banks Site (3CT13) in Crittenden County, AR. The human remains removed from the site in 1932 were excavated by the University of Arkansas Museum. In 1960 the University of Arkansas received a donation of additional human remains from this site. No known individuals were identified. The one associated funerary object is a ceramic bottle.

In 1932, human remains representing, at minimum, eight individuals were removed from the Barton Ranch Site (3CT18) in Crittenden County, AR. These human remains and associated funerary objects were excavated by the University of Arkansas Museum. No known individuals were identified. The nine associated funerary objects are three bottles, one bowl, two effigy bowls, and two jars.

In 1932, human remains representing, at minimum, 42 individuals were removed from the Golightly Place Site (3CT19) in Crittenden County, AR. These human remains and associated funerary objects were excavated by the University of Arkansas Museum. No known individuals were identified. The 129 associated funerary objects are: Three deer antler, three arrow points, one sample of ash, three bone awls, 12 ceramic bottles, 17 ceramic bowls, two discoidals, 10 effigy vessels, one hammer stone, eight jars, one lump of tempered clay, 44 pebbles, four mussel shells, 18 fragments of turtle bone and shell, and two pot sherds. An additional two associated funerary objects are currently missing from the museum's collections. They are one ceramic bottle and one ceramic bowl.

At an unknown date, human remains representing, at minimum, one individual were removed from the Belle

Mead Site (3CT30) in Crittenden County, AR. These human remains were donated to the University of Arkansas, Department of Anthropology and entered the University of Arkansas Museum collections in 2006. No known individuals were identified. No associated funerary objects are present.

In 1967, human remains representing, at minimum, one individual were removed from the Glover Site (3CT37) in Crittenden County, AR. These remains and associated objects were excavated by the University of Arkansas Museum. No known individuals were identified. No associated funerary objects are present.

In 1932, human remains representing, at minimum, three individuals were removed from the Warner Smith Place Site (3CT44) in Crittenden County, AR. These human remains and associated funerary objects were excavated by the University of Arkansas Museum. No known individuals were identified. The two associated funerary objects are one clay pipe and one ceramic bottle.

At an unknown date, human remains representing, at minimum, one individual were removed from the McClure Site (3CW34) in Crawford County, AR, and donated to the University of Arkansas Museum in 1962. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, three individuals were removed from the Toltec Mounds Site (3LN42) in Lonoke County, AR. These human remains were donated to the University of Arkansas Museum in 1966. No known individuals were identified. No associated funerary objects are present.

In 1932, human remains representing, at minimum, 16 individuals were removed from the Middle Nodena Site (3MS3) in Mississippi County, AR. These human remains and associated funerary objects were excavated by the University of Arkansas Museum. No known individuals were identified. The 22 associated funerary objects are: Seven ceramic bottles, one effigy bottle, seven ceramic bowls, one effigy bowl, two ceramic jars, and four pot sherds.

In 1932, human remains representing, at minimum, 92 individuals were removed from the Upper Nodena Site (3MS4) in Mississippi County, AR. These human remains and associated funerary objects were excavated by the University of Arkansas Museum. No known individuals were identified. The 143 associated funerary objects are: Two arrow points, seven bone awls, 33 shell beads, 25 ceramic bottles, 18 ceramic bowls, eight celts, two ceramic

discoidals, three marine shell ear plugs, two effigy bottles, eight effigy bowls, three effigy jars, 11 ceramic jars, one stone pendant, one mussel shell, 18 pot sherds, and one sphere of burned clay.

In 1953, human remains representing, at minimum, 15 individuals were removed from the Gant Site (3MS11) in Mississippi County, AR. These human remains and associated funerary objects were excavated by the University of Arkansas Museum. No known individuals were identified. The six associated funerary objects are: Two ceramic bottles, two ceramic bowls, one ceramic jar, and one pot sherd.

At an unknown date, human remains representing, at minimum, 106 individuals were removed from the Golden Lake Site (3MS60) in Mississippi County, AR. No known individuals were identified. These human remains were donated to the University of Arkansas, Department of Anthropology and entered the University of Arkansas Museum collections in 2006. No known individuals were identified. No associated funerary objects are present.

In 1933, human remains representing, at minimum, four individuals were removed from the Tschudy Lumber Company Site (3PO1) in Poinsett County, AR. These human remains and associated funerary objects were excavated by the University of Arkansas Museum. No known individuals were identified. The 17 associated funerary objects are: Seven pot sherds, nine fire cracked rock pieces, and one ceramic bowl.

In 1933, human remains representing, at minimum, three individuals were removed from the Norris Place Site (3PO3) in Poinsett County, AR. These human remains and associated funerary objects were excavated by the University of Arkansas Museum. No known individuals were identified. The four associated funerary objects are: Two ceramic bowls, one ceramic bottle, and one ceramic jar.

In 1933, human remains representing, at minimum, one individual was removed from the Cart's Camp Site (3PO4) in Poinsett County, AR. These human remains were excavated by the University of Arkansas Museum. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed from the St. Francis Site in St. Francis County, AR. These human remains were purchased by the University of Arkansas Museum in 1959. No known individuals were identified. No associated funerary objects are present.

In 1961 and at an unknown date, human remains representing, at minimum, three individuals were removed from the Castile Landing Site (3SF12) in St. Francis County, AR. The human remains removed in 1961 were excavated by the University of Arkansas Museum. The human remains of the remaining individuals were donated to the University of Arkansas, Department of Anthropology and entered the University of Arkansas Museum collections in 2006. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, seven individuals were removed from the Manley Site (3SF25) in St. Francis County, AR. These human remains were donated to the University of Arkansas, Department of Anthropology and entered the University of Arkansas Museum collections in 2006. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, two individuals were removed from the Hollingsworth Place Site (3WH2) in White County, AR. These human remains were donated to the University of Arkansas Museum in 1964. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, four individuals were removed from the Charles Figley/Lost Hill Site (3WH34) in White County, AR. These human remains were donated to the University of Arkansas Museum in 1966. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed from the Churchman Place Site on the Black River in an unknown county in Arkansas. Accession records for this collection are incomplete. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed from the JB Redmann Site (3PO42) in Poinsett County, AR. Accession records for this collection are incomplete. No known individuals were identified. No associated funerary objects are present.

In 1932, human remains representing, at minimum, two individuals were removed from the Randolph Landing Site in Tipton County, TN. These human remains were excavated by the University of Arkansas Museum. No known individuals were identified. The

two associated funerary objects are one ceramic bowl and one ceramic jar.

In 1933, human remains representing, at minimum, 206 individuals were removed from the Hazel Site (3PO6) in Poinsett County, AR. These human remains and associated funerary objects were excavated by the University of Arkansas Museum. No known individuals were identified. The 1148 associated funerary objects are: One abrader, three antler fragments, one arrow point, two bone awls, one ground stone axe, one raccoon baculum, 30 bone beads, two ceramic beads, four crinoid beads, 435 shell beads, four bird bone fragments, three deer bone fragments, 118 fish bones, four unidentified animal bone fragments, 80 bottles, 84 bowls, one piece of burned clay, one mass of burned clay, wood and animal bone, two pieces of charcoal, one lot of charred plant remains including basketry, one sample of red clay, one sample of white clay, one burned clay hearth, one copper ornament, two pieces of sheet copper, one corn cob, nine daub fragments, three ceramic discoids, one ear plug, six shell ear plugs, one stone ear plug, two effigy bottles, 12 effigy bowls, one effigy jar, one effigy pipe, five fragments of a shell gorget, 43 jars, one chipped stone knife, one bone needle, one shell pendant, 21 bone pin fragments, two clay pipes, 26 mussel shell pieces, 215 pot sherds, two soil samples, one textile fragment, one piece of copper and textile, three beaver teeth, three turtle shell fragments, and two twigs. An additional 76 associated funerary objects are currently missing from the museum's collections. They are: One antler tine, one lot of charcoal and shell, one bird bill awl, two bone awls, six shell ear plugs, one lot of beads, seven shell beads, two pieces of modified animal bone, eight ceramic bottles, 11 ceramic bowls, one lot of charred wood and grass, one effigy bottle, three effigy bowls, two bone needles, one ceramic sphere, one clay pipe, one piece of sheet copper, 19 mussel shell pieces, one pot sherd, five ceramic vessels, and one sample of soil.

During the Mississippi period (A.D. 950–1541) in the Mississippi valley, distinctive local groups emerge in the archeological record that correspond in geographical extent and cultural cohesiveness to present-day groups that include the Quapaw. Quapaw communities occupied villages located around the confluence of the Arkansas and Mississippi Rivers at the time of late 17th century French exploration. Based on the archeological context for these sites and what is presently known about the peoples who pre-date the historic Quapaw people, the University

of Arkansas Museum Collections has determined the human remains and associated funerary objects listed here are culturally affiliated with The Quapaw Tribe of Indians.

Determinations Made by the University of Arkansas Museum

Officials of the University of Arkansas Museum have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 736 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 2,426 objects described and included in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and The Quapaw Tribe of Indians.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Mary Suter, University of Arkansas Museum, Biomass Building 125, 2435 N Hatch Ave., Fayetteville, AR 72704, telephone (479) 575–3456, email msuter@uark.edu, by December 13, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to The Quapaw Tribe of Indians may proceed.

The University of Arkansas Museum Collections is responsible for notifying The Quapaw Tribe of Indians that this notice has been published.

Dated: October 12, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018–24660 Filed 11–9–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0026666; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: University of California, Davis, Davis, CA

AGENCY: National Park Service, Interior.
ACTION: Notice.

SUMMARY: The University of California, Davis, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of unassociated funerary objects. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to the University of California, Davis. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to the University of California, Davis at the address in this notice by December 13, 2018.

ADDRESSES: Megon Noble, NAGPRA Project Manager, University of California, Davis, 433 Mrak Hall, One Shields Avenue, Davis, CA 95616, telephone (530) 752–8501, email mnnoble@ucdavis.edu.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the University of California, Davis, Davis, CA, that meet the definition of unassociated funerary objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

Sometime before 1904, 13 cultural items were removed from a cremation knoll on Mameluke Hill in El Dorado County, CA. A schoolteacher and her son removed the cultural items from the cremation knoll and gave them to Mr. C. Hart Merriam in 1904. In 1962, C. Hart Merriam's daughter sold the collections accumulated by her father to the University of California, Davis. The 13 unassociated funerary objects are 11 sets of trade beads, one set of barita beads, and one stone amulet.

C. Hart Merriam noted that the cultural items show evidence of burning, and were collected from a cremation knoll. Cremation is the historically documented burial practice of Nisenan peoples. Merriam affiliated the cultural items with the Nisenan. Mameluke Hill is located in the historically documented aboriginal territory of the Nisenan, who are today represented by the Ione Band of Miwok Indians of California; Jackson Band of Miwok Indians (previously listed as the Jackson Rancheria of Me-Wuk Indians of California); Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California; United Auburn Indian Community of the Auburn Rancheria of California; and the Wilton Rancheria, California, hereafter referred to as "The Tribes." The glass trade beads date to the historic period.

Determinations Made by the University of California, Davis

Officials of the University of California, Davis have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), the 13 cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and The Tribes.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Megon Noble, NAGPRA Project Manager, University of California,

Davis, 433 Mrak Hall, One Shields Avenue, Davis, CA 95616, telephone (530) 752-8501, email mnoble@ucdavis.edu, by December 13, 2018.

After that date, if no additional claimants have come forward, transfer of control of the unassociated funerary objects to The Tribes may proceed.

The University of California, Davis is responsible for notifying The Tribes that this notice has been published.

Dated: October 4, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018-24661 Filed 11-9-18; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0026715; PPWOCRADNO-PCU00RP14.R50000]

Notice of Inventory Completion: Historic Westville, Inc., Columbus, GA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: Historic Westville, Inc. has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and associated funerary objects and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to Historic Westville, Inc. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Historic Westville, Inc. at the address in this notice by December 13, 2018.

ADDRESSES: Terra Martinez, Historic Westville, Inc., 1130 Martin Luther King Jr. Blvd., Columbus, GA 31906, telephone (706) 940-0057, email office@westville.org.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of Historic Westville, Inc., Columbus, GA. The human remains and associated funerary objects were removed from unknown parts of northern Georgia and southern Tennessee.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Historic Westville, Inc. professional staff in consultation with representatives of the Absentee-Shawnee Tribe of Indians of Oklahoma; Alabama-Coushatta Tribe of Texas (previously listed as the Alabama-Coushatta Tribes of Texas); Cherokee Nation; Eastern Band of Cherokee Indians; Poarch Band of Creek Indians (previously listed as the Poarch Band of Creek Indians of Alabama); Seminole Tribe of Florida (previously listed as the Seminole Tribe of Florida (Dania, Big Cypress, Brighton, Hollywood & Tampa Reservations)); The Choctaw Nation of Oklahoma; The Muscogee (Creek) Nation; The Seminole Nation of Oklahoma; and the United Keetoowah Band of Cherokee Indians in Oklahoma, hereafter referred to as "The Consulted Tribes."

History and Description of the Remains

In 1985, human remains representing, at minimum, four individuals were donated to Historic Westville, Inc. along with approximately 13,000 other Native American artifacts and reproductions. The collection was donated by Dr. Austin Flint. All attempts by the staff of Historic Westville to reach Dr. Flint or his descendants have been unsuccessful. Documentation of the donation consists of a handwritten inventory done by an appraiser preceding the donation and a signed deed of gift. The collection was re-discovered by current staff in 2016. The four individuals include one subadult of indeterminate sex based on the mandible fragment with unerupted teeth and three individuals of indeterminate

age and sex. The 150 associated funerary objects are: 37 beads, 27 gorgets and possible gorgets, 34 celts and possible celts, 18 turtle and mollusk shells, 21 clay pots that may be reproductions, five flutes that are possible reproductions, five large decorated sherds, one pipe, one mask that is a possible reproduction, and one unknown ceramic.

Consulting archeologists identified a percentage of the collection to aid in determining point of origin for the collection. A 5% random sampling of over 1,000 project points revealed that over 80% originated from Georgia and Tennessee. A 20% sampling of pottery sherds also verified that over 80% of the sherds were from Georgia and Tennessee.

Determinations Made by Historic Westville, Inc.

Officials of Historic Westville, Inc. have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on their inclusion in a collection of over 13,000 Native American artifacts.

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of four individuals of Native American ancestry.

- Pursuant to 25 U.S.C. 3001(3)(A), the 150 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.

- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and associated funerary objects and any present-day Indian Tribe.

- According to the final judgement of the Indian Claims Commission or the Court of Federal Claims, the land from which the Native American human remains and associated funerary objects were removed is aboriginal land of the Alabama-Coushatta Tribe of Texas (previously listed as the Alabama-Coushatta Tribes of Texas); Alabama-Quassarte Tribal Town; Catawba Indian Nation (aka Catawba Tribe of South Carolina); Cherokee Nation; Coushatta Tribe of Louisiana; Eastern Band of Cherokee Indians; Eastern Shawnee Tribe of Oklahoma; Mississippi Band of Choctaw Indians; Poarch Band of Creeks (previously listed as the Poarch Band of Creek Indians of Alabama); Sac & Fox Tribe of the Mississippi in Iowa; Seminole Tribe of Florida (previously listed as the Seminole Tribe of Florida (Dania, Big Cypress, Brighton,

Hollywood & Tampa Reservation)); Shawnee Tribe; The Chickasaw Nation; The Choctaw Nation of Oklahoma; The Muscogee (Creek) Nation; The Seminole Nation of Oklahoma; Thlopthlocco Tribal Town; and the United Keetoowah Band of Cherokee Indians in Oklahoma, hereafter referred to as "The Tribes."

- Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains and associated funerary objects may be to The Tribes.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Terra Martinez, Historic Westville, Inc., 1130 Martin Luther King Jr. Blvd., Columbus, GA 31906, telephone (706) 940-0057, email office@westville.org, by December 13, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to The Tribes may proceed.

Historic Westville, Inc. is responsible for notifying The Tribes and The Consulted Tribes that this notice has been published.

Dated: October 9, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018-24664 Filed 11-9-18; 8:45 am]

BILLING CODE 4312-52-P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Electronic Nicotine Delivery Systems and Components Thereof*, DN 3346; the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC

20436, telephone (202) 205-2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at <https://edis.usitc.gov>, and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205-2000.

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at <https://www.usitc.gov>. The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at <https://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission has received an amended complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Juul Labs, Inc., on October 26, 2018. The original complaint was filed on October 3, 2018 and a notice of receipt of complaint; solicitation of comments relating to the public interest was published in the **Federal Register** on October 11, 2018. The amended complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain electronic nicotine delivery systems and components thereof. The complaint names as respondents: J Well France S.A.S. of France; Bo Vaping of Garden City, NY; MMS Distribution LLC of Rock Hill, NY; The Electric Tobacconist, LLC of Boulder, CO; Vapor 4 Life Holdings, Inc. of Northbrook, IL; Eonsmoke, LLC of Clifton, NJ; ZLab S.A. of Uruguay; Ziip Lab Co., Limited of China; Shenzhen Yibo Technology Co., Ltd. of China; XFire, Inc. of Stafford, TX; ALD Group Limited of China; Flair Vapor LLC of South Plainfield, NJ; Shenzhen Joecig Technology Co., Ltd. of China; Myle Vape Inc. of Jamaica, NY; Vapor Hub International, Inc. of Simi Valley, CA; Limitless Mod Co. of Simi Valley, CA; Asher Dynamics, Inc. of Chino, CA; Ply Rock of Chino, CA; Infinite-N Technology Limited of China; King Distribution LLC of Elmwood Park, NJ; and Keep Vapor Electronic Tech. Co., Ltd. of China. The amended

complaint alleges infringement of U.S. Patent Nos. 10,070,669; 10,076,139; 10,045,568; 10,058,130 and 10,104,915. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders and impose a bond during the 60-day review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues should be filed no later than by close of business nine calendar days after the date of publication of this notice in the **Federal Register**. Complainant may file a reply to any written submission no later than the date on which complainant's reply would be due under § 210.8(c)(2) of the Commission's

Rules of Practice and Procedure (19 CFR 210.8(c)(2)).

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to § 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number ("Docket No. 3346") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, Electronic Filing Procedures.¹) Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,² solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.³

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337),

¹ Handbook for Electronic Filing Procedures: https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.

² All contract personnel will sign appropriate nondisclosure agreements.

³ Electronic Document Information System (EDIS): <https://edis.usitc.gov>.

and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: October 30, 2018.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2018-24679 Filed 11-9-18; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731-TA-1387-1391 (Final)]

Polyethylene Terephthalate Resin From Brazil, Indonesia, Korea, Pakistan, and Taiwan; Determinations

On the basis of the record¹ developed in the subject investigations, the United States International Trade Commission ("Commission") determines, pursuant to the Tariff Act of 1930 ("the Act"), that an industry in the United States is not materially injured or threatened with material injury by reason of imports of polyethylene terephthalate ("PET") resin from Brazil, Indonesia, Korea, Pakistan, and Taiwan that have been found by the U.S. Department of Commerce ("Commerce") to be sold in the United States at less than fair value ("LTFV").^{2,3}

Background

The Commission, pursuant to section 735(b) of the Act (19 U.S.C. 1673d(b)), instituted these investigations effective September 26, 2017, following receipt of petitions filed with the Commission and Commerce by DAK Americas LLC, Charlotte, North Carolina; Indorama Ventures USA, Inc., Decatur, Alabama; M&G Polymers USA, LLC, Houston, Texas; and Nan Ya Plastics Corporation, America, Lake City, South Carolina. The Commission scheduled the final phase of the investigations following notification of preliminary determinations by Commerce that imports of PET resin from Brazil, Indonesia, Korea, Pakistan, and Taiwan were being sold at LTFV within the meaning of section 733(b) of the Act (19 U.S.C. 1673b(b)). Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies

¹ The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

² 83 FR 48278-48289 (September 24, 2018).

³ Whether the establishment of an industry in the United States is materially retarded is not an issue in these investigations.

of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of June 6, 2018 (53 FR 26306). The hearing was held in Washington, DC, on September 13, 2018, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made these determinations pursuant to section 735(b) of the Act (19 U.S.C. 1673d(b)). It completed and filed its determinations in these investigations on November 6, 2018. The views of the Commission are contained in USITC Publication 4835 (November 2018), entitled *Polyethylene Terephthalate Resin from Brazil, Indonesia, Korea, Pakistan, and Taiwan: Investigation Nos. 731-TA-1387-1391 (Final)*.

By order of the Commission.

Issued: November 6, 2018.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2018-24621 Filed 11-9-18; 8:45 am]

BILLING CODE 7020-02-P

NATIONAL CREDIT UNION ADMINISTRATION

Sunshine Act: Notice of Agency Meeting

TIME AND DATE: 10:00 a.m., Thursday, November 15, 2018.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street (All visitors must use Diagonal Road Entrance), Alexandria, VA 22314-3428.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Share Insurance Fund Quarterly Report.
2. 2019-2020 NCUA Budget.
3. NCUA Rules and Regulations, Fidelity Bonds.

CONTACT PERSON FOR MORE INFORMATION: Gerard Poliquin, Secretary of the Board, Telephone: 703-518-6304.

Gerard Poliquin,

Secretary of the Board.

[FR Doc. 2018-24836 Filed 11-8-18; 4:15 pm]

BILLING CODE 7535-01-P

NATIONAL SCIENCE FOUNDATION

Request for Information on Update to the 2016 Federal Cybersecurity Research and Development Strategic Plan

AGENCY: National Coordination Office (NCO) for Networking and Information

Technology Research and Development (NITRD); submitted by the National Science Foundation.

ACTION: Notice of request for information.

SUMMARY: Pursuant to the Cybersecurity Enhancement Act of 2014, Federal agencies must update the Federal cybersecurity research and development (R&D) strategic plan every four years. The NITRD NCO seeks public input for the 2019 update of the Federal cybersecurity R&D strategic plan. The updated plan will be used to guide and coordinate federally funded research in cybersecurity, including cybersecurity education and workforce development, and the development of consensus-based standards and best practices in cybersecurity.

DATES: To be considered, submissions must be received on or before 11:59 p.m. (ET) on January 15, 2019.

ADDRESSES: Submissions to this notice may be sent by any of the following methods:

(a) *Email:* cybersecurity@nitrd.gov. Submissions should include "RFI Response: Federal Cybersecurity R&D Strategic Plan" in the subject line of the message.

(b) *Fax:* 202-459-9673, Attn: Tomas Vagoun.

(c) *Mail:* NCO/NITRD, Attn: Tomas Vagoun, 2415 Eisenhower Avenue, Alexandria, VA 22314, USA.

Instructions: Response to this RFI is voluntary. Submissions must not exceed 25 pages in 12-point or larger font, with a page number provided on each page. Responses should include the name of the person(s) or organization(s) providing the submission.

Responses to this RFI may be posted online at <http://www.nitrd.gov>. Therefore, we request that no business-proprietary information, copyrighted information, or personally identifiable information be submitted in response to this RFI.

In accordance with FAR 15.202(3), responses to this notice are not offers and cannot be accepted by the Federal Government to form a binding contract. Responders are solely responsible for all expenses associated with responding to this RFI.

FOR FURTHER INFORMATION CONTACT:

Tomas Vagoun at cybersecurity@nitrd.gov or 202-459-9674, or by mailing to NCO/NITRD, 2415 Eisenhower Avenue, Alexandria, VA 22314, USA. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339

between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The Cybersecurity Enhancement Act of 2014 (<https://www.gpo.gov/fdsys/pkg/PLAW-113publ274/pdf/PLAW-113publ274.pdf>) requires that every four years the applicable Federal agencies, working through the National Science and Technology Council and the Networking and Information Technology R&D (NITRD) program, develop and update a Federal cybersecurity research and development strategic plan.

The most recent version of the strategic plan was released in February 2016 (<https://www.nitrd.gov/pubs/2016-Federal-Cybersecurity-Research-and-Development-Strategic-Plan.pdf>). This strategic plan identifies four categories of defensive capabilities (deter, protect, detect, adapt) and six critical dependent areas (scientific foundations, risk management, human aspects, transition to practice, workforce development, and infrastructure for research) as the structure for focusing and coordinating Federal cybersecurity R&D activities. The quadrennial strategic plan update (to be released by end of 2019) will leverage this structure.

On behalf of Federal agencies and the NITRD Cyber Security and Information Assurance Interagency Working Group, the NCO for NITRD seeks public input on Federal priorities in cybersecurity R&D. Responders should consider a 10-year time frame when characterizing the challenges, prospective research activities, and desired outcomes. Responders are asked to answer one or more of the following questions:

1. What innovative, transformational technologies have the potential to greatly enhance the security, reliability, resiliency, and trustworthiness of the digital infrastructure, and to protect consumer privacy?

2. What progress has been made against the goals of the 2016 Federal Cybersecurity R&D Strategic Plan? Are there mature private-sector solutions that address the deficiencies raised in the 2016 Strategic Plan? What areas of research or topics of the 2016 Strategic Plan no longer need to be prioritized for federally funded basic research?

3. What areas of research or topics of the 2016 Strategic Plan should continue to be a priority for federally funded research and require continued Federal R&D investments?

4. What challenges or objectives not included in the 2016 Strategic Plan should be strategic priorities for federally funded R&D in cybersecurity? Discuss what new capabilities would be desired, what objectives should guide

such research, and why those capabilities and objectives should be strategic priorities.

5. What changes to cybersecurity education and workforce development, at all levels of education, should be considered to prepare students, faculty, and the workforce in the next decade for emerging cybersecurity challenges, such as the implications of artificial intelligence, quantum computing, and the Internet of Things on cybersecurity?

6. What other research and development strategies, plans, or activities, domestic or in other countries, should inform the U.S. Federal cybersecurity R&D strategic plan?

Following the receipt of comments, the NITRD Cyber Security and Information Assurance Interagency Working Group under the National Science and Technology Council will consider the input provided when updating the Federal cybersecurity R&D strategic plan.

Submitted by the National Science Foundation on behalf of the Networking and Information Technology Research and Development (NITRD) National Coordination Office (NCO) on November 7, 2018.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2018-24668 Filed 11-9-18; 8:45 am]

BILLING CODE 7555-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-0609; NRC-2018-0225]

Exemption; Issuance: Northwest Medical Isotopes, LLC; Medical Radioisotope Production Facility

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an exemption to Northwest Medical Isotopes, LLC (NWMI) from the requirement that an application for an NRC license to possess and use special nuclear material for processing and fuel fabrication, scrap recovery or conversion of uranium hexafluoride, or for the conduct of any other activity which the NRC has determined will significantly affect the quality of the environment (and the associated environmental report), be submitted at least 9 months prior to commencement of construction of the plant or facility in which the activity will be conducted.

DATES: This exemption is being issued on November 13, 2018.

ADDRESSES: Please refer to Docket ID NRC-2018-0225 when contacting the NRC about the availability of information regarding this document. You may access publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2018-0225. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301-287-9127; email: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "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.

FOR FURTHER INFORMATION CONTACT: David Tiktinsky, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-8740, email: David.Tiktinsky@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

NWMI is the holder of Construction Permit No. CPMIF-002 (issued on May 9, 2018 (ADAMS Accession No. ML18037A308) under Part 50 of title 10 of the *Code of Federal Regulations* (10 CFR)), which authorizes NWMI to construct a medical radioisotope production facility (RPF) in Columbia, Missouri. The facility would fabricate low-enriched uranium (LEU) targets and ship them to a network of U.S. research reactors for irradiation, receive irradiated LEU targets, disassemble and dissolve irradiated LEU targets, and recover and purify Molybdenum-99 (Mo-99). These processes would take place in a single RPF building divided

into two separate areas where processes subject to different regulatory regimes would take place. The processes involved in the production area, which include receipt of irradiated LEU targets, LEU target disassembly and dissolution, and Mo-99 recovery and purification, are subject to the NRC licensing requirements of 10 CFR part 50. The processes involved in target fabrication that NWMI plans to perform in a separate area of the RPF would be subject to the separate NRC licensing requirements of 10 CFR part 70.

NWMI submitted an environmental report with its construction permit application, providing environmental information about all of the processes that would occur in both portions of the RPF. In accordance with Section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and the NRC's regulations in 10 CFR part 51, the NRC staff prepared an environmental impact statement (EIS), NUREG-2209, "Environmental Impact Statement for the Construction Permit for the Northwest Medical Isotopes Radioisotope Production Facility," dated May 2017 (ADAMS Accession No. ML17130A862) assessing the potential impacts of the construction, operation, and decommissioning of the proposed RPF on the quality of the human environment and reasonable alternatives. The construction and operation impacts from the portion of the RPF in which 10 CFR part 70 target fabrication activities would occur were evaluated as a connected action to the 10 CFR part 50 construction permit. A 10 CFR part 50 construction permit was issued to NWMI on May 9, 2018.

II. Request/Action

The exemption request from NWMI was submitted by letter dated December 18, 2017 (ADAMS Accession No. ML17362A040), as supplemented by a letter dated March 12, 2018 (ADAMS Accession No. ML18088A175). NWMI is requesting an exemption from the requirement that the application (and associated environmental report required by 10 CFR part 51) for 10 CFR part 70 activities be submitted at least 9 months prior to commencement of construction of the 10 CFR part 70 components of the RPF. The activities that will be subject to the 10 CFR part 70 license application are described in the construction permit application that NWMI previously submitted to the NRC under 10 CFR part 50 for an RPF to be constructed in Columbia, Missouri. NWMI Preliminary Safety Analyses Report, Chapter 19, "Environmental Report" Corvallis, OR, Revision 0A

dated June 2015 (ADAMS Accession Nos. ML15210A123, ML15210A128, ML15210A129, and ML15210A131).

The NRC evaluated the environmental impacts from the 10 CFR part 70 target fabrication activities in the RPF as part of its EIS supporting NWMI's 10 CFR part 50 construction permit application. The exemption would allow NWMI to initiate construction of the 10 CFR part 70 components of the RPF upon the issuance of the 10 CFR part 50 construction permit for the RPF even if the 10 CFR 70.21(f) timing requirement is not met.

III. Discussion

Pursuant to 10 CFR 70.17(a), the Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of 10 CFR part 70 as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Authorized by Law

The applicant has stated that the requested exemption from the requirement to submit an application and associated environmental report at least 9 months prior to the commencement of construction of the RPF, including 10 CFR part 70 components (*i.e.*, the target fabrication facility), will enable it to initiate construction of the entire RPF based upon the environmental review for the 10 CFR part 50 construction permit. The applicant has also stated there have been no significant changes to the environmental information that was previously submitted to the NRC as part of the 10 CFR part 50 construction permit application. NWMI also stated that it will submit the application and environmental report required by 10 CFR 70.21(f) as part of a consolidated operating license application for both the 10 CFR part 50 Production Facility and to possess and use special nuclear material for the 10 CFR part 70 target fabrication facility activities.

The staff evaluated the environmental impacts of the RPF, including the 10 CFR part 70 target fabrication activities as a connected action, in the EIS dated May 31, 2017 (NUREG-2209, "Environmental Impact Statement for the Construction Permit for the Northwest Medical Isotopes Radioisotope Production Facility", ADAMS Accession No. ML17130A862). The staff concludes, as documented in the EIS, that after weighing the environmental, economic, technical, and other benefits against environmental and other costs, and

considering reasonable alternatives, the NRC staff's recommendation, unless safety issues mandate otherwise, is the issuance of a construction permit to NWMI.

The NRC regulation, 10 CFR 70.17, allows the NRC to grant exemptions from the requirements of 10 CFR part 70 provided certain findings are made. Granting the applicant's proposed exemption is not otherwise inconsistent with NRC regulations or other applicable laws. As explained below, the proposed exemption will not endanger life or property, or the common defense and security, and is otherwise in the public interest.

NWMI indicates that it will submit an environmental report with its application for an operating license for the entire RPF which the NRC will be able to review for any significant new information. The NRC will not make a decision on an application to operate the production portion of the facility under 10 CFR part 50 or a license to possess and use special nuclear material for target fabrication under 10 CFR part 70 until after the NRC has completed a NEPA review based on NWMI's proposed application and environmental report, and made the appropriate regulatory findings. Therefore, the exemption is authorized by law.

Will Not Endanger Life or Property or the Common Defense and Security

Construction of the facility has not yet begun. Since the exemption request relates to the timing of when construction may begin, the proposed exemption would not: (a) impact the probabilities of evaluated accidents; (b) affect margins of safety; (c) affect effectiveness of programs contained in licensing documents; (d) increase effluents; (e) increase occupational radiological exposures; or (f) impact operations or decommissioning activities. The proposed exemption also will not have an impact on common defense and security since the exemption only relates to the timing of construction. NWMI's construction permit does not authorize possession of any nuclear material at the RPF.

Based on its evaluation, the NRC staff has determined that this exemption will not endanger life or property or the common defense and security.

Otherwise in the Public Interest

The NRC staff has determined that granting the proposed exemption would allow for efficient construction of the NWMI RPF at an earlier date. The purpose of the NWMI RPF is to produce medical isotopes and help meet the U.S.

goal of establishing a domestic supply of Mo-99 as stated in the American Medical Isotopes Production Act, 42 U.S.C. 2065 *et seq.* Accordingly, the NRC staff has determined that granting the requested exemption is otherwise in the public interest.

IV. Environmental Consideration

As required by 10 CFR 51.21, the NRC performed an environmental assessment (EA) that analyzes the environmental impacts of the proposed exemption in accordance with NEPA. Based on that EA, the NRC staff has determined not to prepare an EIS for the proposed exemption, and has issued a finding of no significant impact (FONSI). The EA and FONSI were published in the **Federal Register** on August 29, 2018 (83 FR 44068-44070).

V. Conclusion

Accordingly, the NRC has determined that, pursuant to 10 CFR 70.17, the exemption is authorized by law, will not endanger life or property or the common defense and security, and is otherwise in the public interest. Therefore, the NRC hereby grants NWMI an exemption from the 10 CFR 70.21(f) requirement to submit a 10 CFR part 70 application, and the associated environmental report, 9 months prior to the commencement of construction, to allow NWMI to begin construction of the 10 CFR part 70 portions of the facility along with the rest of the RPF.

Dated at Rockville, Maryland, this 1st day of November 2018.

For the Nuclear Regulatory Commission.

LaDonna Suggs,

Acting Deputy Director, Division of Fuel Cycle Safety, Safeguards, and Environmental Review, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2018-24312 Filed 11-9-18; 8:45 am]

BILLING CODE 7590-01-P

OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION

Privacy Act of 1974; System of Records

AGENCY: Occupational Safety and Health Review Commission.

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Occupational Safety and Health Review Commission (OSHRC) is revising the notice for Privacy Act system-of-records OSHRC-4.

DATES: Comments must be received by OSHRC on or before December 13, 2018.

The revised system of records will become effective on that date, without any further notice in the **Federal Register**, unless comments or government approval procedures necessitate otherwise.

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

- *Email:* rbailey@oshrc.gov. Include "PRIVACY ACT SYSTEM OF RECORDS" in the subject line of the message.

- *Fax:* (202) 606-5417.

- *Mail:* One Lafayette Centre, 1120 20th Street NW, Ninth Floor, Washington, DC 20036-3457.

- *Hand Delivery/Courier:* Same as mailing address.

Instructions: All submissions must include your name, return address, and email address, if applicable. Please clearly label submissions as "PRIVACY ACT SYSTEM OF RECORDS."

FOR FURTHER INFORMATION CONTACT: Ron Bailey, Attorney-Advisor, Office of the General Counsel, via telephone at (202) 606-5410, or via email at rbailey@oshrc.gov.

SUPPLEMENTARY INFORMATION: The Privacy Act of 1974, 5 U.S.C. 552a(e)(4), requires federal agencies such as OSHRC to publish in the **Federal Register** notice of any new or modified system of records. As detailed below, OSHRC is revising Payroll and Related Records, OSHRC-4, to (1) eliminate the agency's regional offices in Denver, CO and Atlanta, GA as system locations; (2) account for changes in the names of the pertinent office and positions within the agency; (3) account for changes in how time and attendance records are processed (paper records are no longer maintained); (4) revise the category of records to more accurately reflect the types of information maintained; (5) revise the method by which records are retrieved (folders are organized only by name, and not social security number), stored, and safeguarded; and (6) update the reference to the applicable General Records Schedule for disposal of records. In addition, OSHRC has previously relied on blanket routine uses to describe the circumstances under which records may be disclosed. Going forward, as revised notices are published for new and modified systems of records, a full description of the routine uses—rather than a reference to blanket routine uses—will be included in each notice. This is simply a change in format that has not resulted in any substantive changes to the routine uses for this system of records.

The notice for OSHRC-4, provided below in its entirety, is as follows.

SYSTEM NAME AND NUMBER:

Payroll and Related Records, OSHRC-4.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

(1) Paper and electronic files are maintained by the Office of the Executive Director, OSHRC, 1120 20th Street NW, Ninth Floor, Washington, DC 20036-3457; (2) pursuant to an interagency agreement, payroll records are stored electronically by the U.S. Department of Agriculture, National Finance Center (NFC), P.O. Box 60000, New Orleans, LA 70160-0001.

SYSTEM MANAGER(S):

Human Resources Specialist, OSHRC, 1120 20th Street NW, Ninth Floor, Washington, DC 20036-3457; (202) 606-5100.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, 5516, 5517, 5520; 26 U.S.C. 6011, 6109; 29 U.S.C. 661; 44 U.S.C. 3101.

PURPOSE(S) OF THE SYSTEM:

Records are used by OSHRC and NFC employees to maintain adequate payroll information for OSHRC employees and Commission members.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system of records covers current and former employees of OSHRC and Commission members.

CATEGORIES OF RECORDS IN THE SYSTEM:

The records maintained in this system, and the categories of records referenced therein, are as follows. (1) direct deposit records that include the employee's name and signature, address, and telephone number; the type of depositor account selected for direct deposit, and the account and routing numbers; and a voided check; (2) tax records that include the employee's name and signature, social security number, marital status, and home address; the number of allowances for which the employee qualifies; and further information which may be required on state, county, or city withholding certificates; (3) employee retirement estimates that include the employee's name and social security number; (4) records maintained pursuant to the Family Medical Leave Act that include the employee's name, signature, and job description; identity of certain family members and, if a child, date of birth; and medical information pertinent to leave requests; and (5) records necessary for payroll

processing by NFC, including those pertaining to time and attendance and leave records, that may include some or all of the information specified above, as well as additional information concerning deductions, salary and benefits.

RECORD SOURCE CATEGORIES:

Information in this system either comes from the individual to whom it applies or is derived from information compiled by OSHRC employees performing administrative duties.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to disclosures generally permitted under 5 U.S.C. 552a(b), all or a portion of the records or information contained in this system of records may be disclosed as a routine use pursuant to 5 U.S.C. 552a(b)(3) under the circumstances or for the purposes described below, to the extent such disclosures are compatible with the purposes for which the information was collected:

(1) To the Department of Justice (DOJ), or to a court or adjudicative body before which OSHRC is authorized to appear, when any of the following entities or individuals—(a) OSHRC, or any of its components; (b) any employee of OSHRC in his or her official capacity; (c) any employee of OSHRC in his or her individual capacity where DOJ (or OSHRC where it is authorized to do so) has agreed to represent the employee; or (d) the United States, where OSHRC determines that litigation is likely to affect OSHRC or any of its components—is a party to litigation or has an interest in such litigation, and OSHRC determines that the use of such records by DOJ, or by a court or other tribunal, or another party before such tribunal, is relevant and necessary to the litigation.

(2) To an appropriate agency, whether federal, state, local, or foreign, charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, when a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes civil, criminal or regulatory violations, and such disclosure is proper and consistent with the official duties of the person making the disclosure.

(3) To a federal, state, or local agency maintaining civil, criminal or other relevant enforcement information, such as current licenses, if necessary to obtain information relevant to an OSHRC decision concerning the hiring,

appointment, or retention of an employee; the issuance, renewal, suspension, or revocation of a security clearance; the execution of a security or suitability investigation; the letting of a contract; or the issuance of a license, grant or other benefit.

(4) To a federal, state, or local agency, in response to that agency's request for a record, and only to the extent that the information is relevant and necessary to the requesting agency's decision in the matter, if the record is sought in connection with the hiring, appointment, or retention of an employee; the issuance, renewal, suspension, or revocation of a security clearance; the execution of a security or suitability investigation; the letting of a contract; or the issuance of a license, grant or other benefit by the requesting agency.

(5) To an authorized appeal grievance examiner, formal complaints manager, equal employment opportunity investigator, arbitrator, or other duly authorized official engaged in investigation or settlement of a grievance, complaint, or appeal filed by an employee, only to the extent that the information is relevant and necessary to the case or matter.

(6) To OPM in accordance with the agency's responsibilities for evaluation and oversight of federal personnel management.

(7) To officers and employees of a federal agency for the purpose of conducting an audit, but only to the extent that the record is relevant and necessary to this purpose.

(8) To OMB in connection with the review of private relief legislation at any stage of the legislative coordination and clearance process, as set forth in Circular No. A-19.

(9) To a Member of Congress or to a person on his or her staff acting on the Member's behalf when a written request is made on behalf and at the behest of the individual who is the subject of the record.

(10) To the National Archives and Records Administration (NARA) for records management inspections and such other purposes conducted under the authority of 44 U.S.C. 2904 and 2906.

(11) To appropriate agencies, entities, and persons when: (a) OSHRC suspects or has confirmed that there has been a breach of the system of records; (b) OSHRC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, OSHRC, the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist

in connection with OSHRC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

(12) To NARA, Office of Government Information Services (OGIS), to the extent necessary to fulfill its responsibilities in 5 U.S.C. 552(h), to review administrative agency policies, procedures and compliance with FOIA, and to facilitate OGIS' offering of mediation services to resolve disputes between persons making FOIA requests and administrative agencies.

(13) To another federal agency or federal entity, when OSHRC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (a) responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

(14) To the Internal Revenue Service (IRS) for investigation, and to private attorneys, pursuant to a power of attorney.

(15) To the IRS, a copy of an employee's Department of the Treasury Form W-2, Wage and Tax Statement.

(16) To state, city, or other local jurisdictions which are authorized to tax the employee's compensation, a copy of an employee's Form W-2. The record will be provided in accordance with a withholding agreement between the state, city, or other local jurisdiction and the Department of the Treasury pursuant to 5 U.S.C. 5516, 5517, and 5520, or in response to a written request from an appropriate official of the taxing jurisdiction. The request must include a copy of the applicable statute or ordinance authorizing the taxation of compensation and should indicate whether the authority of the jurisdiction to tax the employee is based on place of residence, place of employment, or both.

(17) To a city, copies of executed city tax withholding certifications, pursuant to a withholding agreement between the city and the Department of the Treasury (5 U.S.C. 5520), and in response to written requests from an appropriate city official to OSHRC's Office of the Executive Director.

(18) To NFC to effect issuance of paychecks via electronic fund transfers (EFT) to employees, and distribution of allotments and deductions to financial and other institutions, and for other authorized purposes.

(19) To the Federal Retirement Thrift Investment Board to update Section 401K type records and benefits; to the Social Security Administration to establish social security records and benefits; to the Department of Labor, Office of Worker's Compensation to process compensation claims; to the Department of Defense to adjust military retirement; to health insurance carriers to process insurance claims; and to the Department of Veterans Affairs for the purpose of evaluating veteran's benefits to which the individual may be entitled.

(20) To other federal agencies to effect salary or administrative offsets, or for other purposes connected with the collection of debts owed to the United States, pursuant to sections 5 and 10 of the Debt Collection Act of 1982, as amended by the Debt Collection Improvement Act of 1996.

(21) To other federal, state, local or foreign agencies conducting computer matching programs to help eliminate fraud and abuse and to detect unauthorized overpayments made to individuals. When disclosures are made as part of computer matching programs, OSHRC will comply with the Computer Matching and Privacy Protection Act of 1988, and the Computer Matching and Privacy Protections Amendments of 1990.

(22) To the Office of Child Support Enforcement, Administration for Children and Families, Department of Health and Human Services, the names, social security numbers, home addresses, dates of birth, dates of hire, quarterly earnings, employer identifying information, and state of hire of employees for the purpose of locating individuals to establish paternity, identifying sources of income, and for other child support enforcement actions as required by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, 42 U.S.C. 653(n).

(23) To "consumer reporting agencies" as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)) in accordance with 31 U.S.C. 3711(f).

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are stored on paper in file cabinets at OSHRC's National Office in Washington, DC, and electronically on an access-restricted shared OSHRC drive. Records are also stored electronically on the NFC's personnel/payroll system.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved manually and electronically by name.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are retained and disposed of in accordance with NARA's General Records Schedule 2.4.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Paper records are maintained in locked file cabinets, and access is limited to personnel who require access to perform their official functions. Access to electronic records maintained on an OSHRC shared drive is restricted to personnel who require access to perform their official functions.

OSHRC records electronically transmitted to its contractor, NFC, are stored on servers in a secured federal complex with access codes, security codes, and/or security guards. Access to networks and data requires a valid username and password and is further restricted to personnel who have the need to know the information for the performance of their official duties.

RECORD ACCESS PROCEDURES:

Individuals who wish to gain access to their records should notify: Privacy Officer, OSHRC, 1120 20th Street NW, Ninth Floor, Washington, DC 20036-3457. For an explanation on how such requests should be drafted, refer to 29 CFR 2400.6 (procedures for requesting records).

CONTESTING RECORD PROCEDURES:

Individuals who wish to contest their records should notify: Privacy Officer, OSHRC, 1120 20th Street NW, Ninth Floor, Washington, DC 20036-3457. For an explanation on the specific procedures for contesting the contents of a record, refer to 29 CFR 2400.8 (Procedures for requesting amendment), and 29 CFR 2400.9 (Procedures for appealing).

NOTIFICATION PROCEDURES:

Individuals interested in inquiring about their records should notify: Privacy Officer, OSHRC, 1120 20th Street NW, Ninth Floor, Washington, DC 20036-3457. For an explanation on how such requests should be drafted, refer to 29 CFR 2400.5 (notification), and 29 CFR 2400.6 (procedures for requesting records).

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

April 14, 2006, 71 FR 19556; August 4, 2008, 73 FR 45256; October 5, 2015,

80 FR 60182; and September 28, 2017, 82 FR 45324.

Dated: November 5, 2018.

Nadine N. Mancini,

General Counsel, Senior Agency Official for Privacy.

[FR Doc. 2018-24690 Filed 11-9-18; 8:45 am]

BILLING CODE 7600-01-P

POSTAL SERVICE**Temporary Emergency Committee of the Board of Governors; Sunshine Act Meeting**

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 83 FR 55761.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Tuesday, November 13, 2018, at 10:30 a.m.; and Wednesday, November 14, 2018, at 8:30 a.m.

PLACE: Washington, DC, at U.S. Postal Service Headquarters, 475 L'Enfant Plaza SW, in the Benjamin Franklin Room.

STATUS: Tuesday, November 13, 2018, at 10:30 a.m.; Wednesday, November 14, 2018, at 8:30 a.m.—Open.

CHANGES IN THE MEETING: Two agenda items combined and additional information added related to public comment period.

REVISED MATTERS TO BE CONSIDERED:

Tuesday, November 13, 2018, at 10:30 a.m. (Closed)

1. Strategic Issues.
2. Financial Matters.
3. Compensation and Personnel Matters.

4. Executive Session—Discussion of prior agenda items and Board governance.

Wednesday, November 14, 2018, at 8:30 a.m. (Open)

1. Remarks of the Chairman of the Temporary Emergency Committee of the Board.
2. Remarks of the Postmaster General and CEO.
3. Approval of Minutes of Previous Meetings.
4. Committee Reports.
5. FY2018 10K and Financial Statements and Approval of Annual Report and Comprehensive Statement.
6. FY2019 IFP and Financing Resolution.
7. FY2020 Appropriations Request.
8. Quarterly Service Performance Report.
9. Approval of Annual Report and Comprehensive Statement.
10. Draft Agenda for February meetings.

A public comment period will begin immediately following the adjournment of the open session on November 14, 2018. During the public comment period, which shall not exceed 30 minutes, members of the public may comment on any item or subject listed on the agenda for the open session above. Registration of speakers at the public comment period is required. No more than three minutes shall be allotted to each speaker. The time allotted to each speaker will be determined after registration closes. Participation in the public comment period is governed by 39 CFR 232.1(n).

CONTACT PERSON FOR MORE INFORMATION:

Acting Secretary of the Board, U.S. Postal Service, 475 L'Enfant Plaza SW, Washington, DC 20260-1000. Telephone: (202) 268-4800.

Michael J. Elston,

Acting Secretary.

[FR Doc. 2018-24835 Filed 11-8-18; 4:15 pm]

BILLING CODE 7710-12-P

PRESIDIO TRUST**Notice of Receipt of and Availability for Public Comment on an Application for Wireless Telecommunications Facilities Site; The Presidio of San Francisco, California**

AGENCY: The Presidio Trust.

ACTION: Public notice.

SUMMARY: This notice announces the Presidio Trust's receipt of and availability for public comment on an application from GTE Mobilnet of California d/b/a Verizon Wireless for installation of a wireless telecommunications facilities site ("Project") in The Presidio of San Francisco. The proposed location of the Project is in the vicinity of 386 Moraga Avenue.

The Project involves (i) installing a new 70-foot monopole to accommodate nine panel antenna panels, and (ii) placing the associated radio equipment on a concrete pad within a 20-foot by 20-foot fenced area. Power and telecommunications service will be brought to the site by underground trench.

Comments: Comments on the proposed project must be sent to Steve Carp, Presidio Trust, 103 Montgomery Street, P.O. Box 29052, San Francisco, CA 94129-0052, and be received by December 11, 2018. A copy of Verizon's application is available upon request to the Presidio Trust.

FOR FURTHER INFORMATION CONTACT: Steve Carp, 103 Montgomery Street,

P.O. Box 29052, San Francisco, CA 94129-0052. Email: *scarp@presidiotrust.gov*. Telephone: 415.561.5300.

Dated: November 5, 2018.

Steve Carp,
Legal Analyst.

[FR Doc. 2018-24698 Filed 11-9-18; 8:45 am]

BILLING CODE 4310-4R-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-84544; File No. SR-NYSE-2018-51]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Section 303A.00 of the Manual To Change the Threshold for Qualifying as a Smaller Reporting Company To Qualify for Certain Exemptions From the Compensation Committee Requirements

November 6, 2018.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (“Act”)² and Rule 19b-4 thereunder,³ notice is hereby given that on October 26, 2018, New York Stock Exchange LLC (“NYSE” or the “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Section 303A.00 of the NYSE Listed Company Manual (the “Manual”) to change the threshold for listed companies to benefit from the exemptions from the NYSE compensation committee requirements applicable to smaller reporting companies so that all companies that qualify for smaller reporting company status under the revised SEC definition will qualify for those exemptions.

The proposed rule change is available on the Exchange’s website at *www.nyse.com*, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The SEC recently adopted⁴ amendments to the definition of “smaller reporting company” set forth in Item 10(f)(1) of Regulation S-K,⁵ Rule 12b-2 under the Act⁶ and Rule 405 under the Securities Act of 1933.⁷ The amendments raise the smaller reporting company cap from less than \$75 million in public float to less than \$250 million and also include as smaller reporting companies issuers with less than \$100 million in annual revenues if they also have either no public float or a public float that is less than \$700 million. The amendments became effective on September 10, 2018. The Exchange estimates that a consequence of the SEC rule changes is that a significantly larger number of its listed companies will qualify for smaller reporting company status than was previously the case.

Smaller reporting companies are entitled to avail themselves of certain exemptions from the NYSE’s compensation committee requirements.⁸ Section 303A.00 includes a provision describing the period within which a company must comply with all

⁴ Release Nos. 33-10513 and 34-83550 (June 28, 2018); 83 FR 31992 (July 10, 2018).

⁵ 17 CFR 229.10(F)(1).

⁶ 17 CFR 240.12b-2.

⁷ 17 CFR 230.405.

⁸ Specifically, listed companies that satisfy the definition of smaller reporting company are not required to comply with (i) the enhanced requirements with respect to the independence of compensation committee members set forth in Section 303A.02(a)(ii) and the second paragraph of the Commentary to Section 303A.02(a) of the Manual; or (ii) the requirements set forth under Section 303A.05(c)(iv) of the Manual with respect to the analysis of the independence of any compensation consultant, legal counsel or other adviser to the compensation committee. Listed smaller reporting companies must comply with all other applicable Exchange corporate governance requirements, including all other applicable compensation committee requirements.

applicable compensation committee requirements after it ceases to be a smaller reporting company.⁹ This provision currently states explicitly that a smaller reporting company must have less than \$75 million in public float. In light of the recent changes to the SEC’s rules with respect to smaller reporting companies, the Exchange proposes to delete this reference to the \$75 million public float cap and revise the provision to state simply that a smaller reporting company that fails to meet the requirements for smaller reporting company status as of the last business day of its second fiscal quarter will cease to be a smaller reporting company as of the beginning of the following fiscal year. The effect of this amendment will be to change the threshold for listed companies to be eligible to benefit from the exemptions from the NYSE compensation committee requirements applicable to smaller reporting companies so that all companies that qualify for smaller reporting company status under the revised SEC definition will qualify for those exemptions.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,¹⁰ in general, and furthers the objectives of Section 6(b)(5) of the Act¹¹ in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and is not designed to permit unfair

⁹ Under the SEC rules set forth above with respect to smaller reporting companies, a company tests its status as a smaller reporting company on an annual basis at the end of its most recently completed second fiscal quarter (the “Smaller Reporting Company Determination Date”). A smaller reporting company ceases to be a smaller reporting company as of the beginning of the fiscal year following the Smaller Reporting Company Determination Date. The compensation committee of a company that has ceased to be a smaller reporting company as of its Smaller Reporting Company Determination Date [sic] must comply with Section 303A.05(c)(iv) as of six months from the date it ceases to be a smaller reporting company and must have: One member of its compensation committee that meets the independence standard of Section 303A.02(a)(ii) and the second paragraph of the commentary to Section 303A.02(a) within six months of that date; a majority of directors on its compensation committee meeting those requirements within nine months of that date; and a compensation committee comprised solely of members that meet those requirements within twelve months of that date.

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(5).

discrimination between customers, issuers, brokers, or dealers. As noted above, the effect of the proposed rule change is to change the threshold for listed companies to benefit from the exemptions from the NYSE compensation committee requirements applicable to smaller reporting companies so that all companies that qualify for smaller reporting company status under the revised SEC definition will qualify for those exemptions. Listed smaller reporting companies must comply with all other applicable Exchange corporate governance requirements, including all other applicable compensation committee requirements. The Commission has already determined through its own rulemaking that the revised thresholds for smaller reporting company status proposed in this rule proposal are consistent with the goal of the Act to further the protection of investors and the public interest¹² and the Exchange believes that its own proposal is consistent with Section 6(b)(5) of the Act for the same reasons.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change will not impose any burden competition as its sole purpose is to change the threshold for listed companies to benefit from the exemptions from the NYSE compensation committee requirements applicable to smaller reporting companies so that all companies that qualify for smaller reporting company status under the revised SEC definition will qualify for those exemptions.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act¹³ and Rule 19b-4(f)(6) thereunder.¹⁴ Because the proposed rule change does not: (i) Significantly affect the protection of

investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b-4(f)(6)(iii) thereunder.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)¹⁵ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NYSE-2018-51 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to File Number SR-NYSE-2018-51. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the

Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSE-2018-51, and should be submitted on or before December 4, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁶

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018-24637 Filed 11-9-18; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-84542; File No. SR-Phlx-2018-67]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to New Derivative Securities Products

November 6, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on October 24, 2018, Nasdaq PHLX LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the 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 Phlx Rule 803 related to derivative

¹² See footnote 4, supra.

¹³ 15 U.S.C. 78s(b)(3)(A)(iii).

¹⁴ 17 CFR 240.19b-4(f)(6).

¹⁵ 15 U.S.C. 78s(b)(2)(B).

¹⁶ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

securities traded under unlisted trading privileges (“UTP”) to remove the requirement in Rule 803(o)(3) for the Exchange to file with the Commission a Form 19b-4(e) for each “new derivative securities product” as defined in Rule 19b-4(e) under the Act³ (“Derivative Security”) traded under UTP and renumber the remaining provisions of Rule 803(o) to maintain an organized rule structure. The Exchange has designated this rule change as “non-controversial” under Section 19(b)(3)(A) of the Act⁴ and provided the Commission with the notice required by Rule 19b-4(f)(6) thereunder.⁵

The text of the proposed rule change is available on the Exchange’s website at <http://nasdaqphlx.cchwallstreet.com/>, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend Rule 803 related to derivative securities traded under UTP by removing the requirement in Rule 803(o)(3) for the Exchange to file with the Commission a Form 19b-4(e) for each Derivative Security, and renumbering the remaining rules of Rule 803(o) to maintain an organized rule structure, as described below.

Rule 803(o)(3) sets forth the requirement for Phlx to file with the Commission a Form 19b-4(e) with respect to each Derivative Security that is traded under UTP. However, Phlx believes that it should not be necessary to file a Form 19b-4(e) with the Commission if it begins trading a Derivative Security on a UTP basis, because Rule 19b-4(e)(1) under the Act

refers to the “listing and trading” of a “new derivative securities product.”

The Exchange believes that the requirements of that rule refers [sic] to when an exchange lists and trades a Derivative Security, and not when an exchange seeks only to trade such product on a UTP basis pursuant to Rule 12f-2 under the Act.⁶ Therefore, Phlx proposes to delete the requirement in current Rule 803(o)(3) for Phlx to file a Form 19b-4(e) with the Commission with respect to each Derivative Security it begins trading on a UTP basis. In addition, as a result of the deletion of current Rule 803(a)(1) Phlx proposes to renumber current Rule 803(o)(4), as Rule 803(o)(3).

2. Statutory Basis

Phlx believes that the proposed rule change is consistent with the provisions of Section 6(b)⁷ of the Act in general, and furthers the objectives of Section 6(b)(5) of the Act⁸ in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Specifically, eliminating the requirement to file a Form 19b-4(e) for each Derivative Security the Exchange begins trading on a UTP basis removes an unnecessary regulatory requirement thereby providing for a more efficient process for adding Derivative Securities to trading on the Exchange on a UTP basis.

In addition, the Exchange notes that a substantially identical proposed rule change by NYSE National, Inc. (“NYSE National”) was recently approved by the Commission.⁹ In particular, the Commission noted in the approval order that it “believes that the filing of a Form 19b-4(e) is not required when an Exchange is trading a new derivative securities product on a UTP basis only”¹⁰ and also found that the NYSE National’s proposed rule change is “consistent with the requirements of Section 6(b)(5) of the Act.”¹¹

With respect to the renumbering of current Rule 803(o)(4) as Rule 803(o)(3), the Exchange believes that this change is consistent with the Act because they [sic] will allow the Exchange to

maintain a clear and organized rule structure, thus preventing investor confusion.

For these reasons, Phlx believes the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

B. Self-Regulatory Organization’s Statement on Burden on Competition

Phlx does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, removing the requirement to file a Form 19b-4(e) will serve to enhance competition by providing for the efficient addition of Derivative Securities for trading under UTP on Phlx. To the extent that a competitor marketplace believes that the proposed rule change places it at a competitive disadvantage, it may file with the Commission a proposed rule change to adopt the same or similar rule.

In addition, the proposal to renumber the current Rules [sic] 803(o)(4) as Rule 803(o)(3) does not impact competition in any respect since it merely maintains a clear and organized rule structure.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; or (iii) become operative prior to 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 Act¹² and Rule 19b-4(f)(6) thereunder.¹³

The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. Waiving the 30-day delay would permit the Exchange to more efficiently add Derivative Securities to the

¹² 15 U.S.C. 78s(b)(3)(A).

¹³ 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.

⁶ 17 CFR 240.12f-2.

⁷ 15 U.S.C. 78f(b).

⁸ 15 U.S.C. 78f(b)(5).

⁹ See Securities Exchange Act Release No. 83289 (May 17, 2018), 83 FR 23968 (May 23, 2018) (Order Approving File No. SR-NYSE-NAT-2018-02).

¹⁰ See *supra* note 9 at page 23975 at footnote 149.

¹¹ See *supra* note 9 at page 23975-6.

³ 17 CFR 240.19b-4(e)

⁴ 15 U.S.C. 78s(b)(3)(A).

⁵ 17 CFR 240.19b-4(f)(6).

Exchange under UTP without the unnecessary requirement to file a 19b-4(e) with the Commission. The Commission also notes that because Phlx is adopting a rule that is substantially identical to a similar NYSE National rule, the proposed change does not present any new or novel issues. Thus, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest and hereby waives the 30-day operative delay and designates the proposed rule change to be operative upon filing.¹⁴

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-Phlx-2018-67 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-Phlx-2018-67. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the

Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-Phlx-2018-67 and should be submitted on or before December 4, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁵

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018-24636 Filed 11-9-18; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-84545; File No. SR-Phlx-2018-68]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Rule 3400 Series

November 6, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on October 25, 2018, Nasdaq PHLX LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Rule 3400 Series concerning the Order

Audit Trail System to make conforming and technical changes.

The text of the proposed rule change is available on the Exchange's website at <http://nasdaqphlx.cchwallstreet.com/>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to amend the Rule 3400 Series concerning the Order Audit Trail System to: (1) Renummer the Rule 3400 Series to conform it to the numbering convention used by the Nasdaq Stock Market LLC ("Nasdaq") and FINRA; (2) amend Rule 7410A to expand two existing exemptions and to make technical changes to text under the rule; (3) incorporate by reference FINRA Rules 7430, 7440 and 7450 in Rules 7430A, 7440A and 7450A, respectively, and make conforming changes thereto; and (4) delete Rule 3407.³

The Exchange's Rule 3400 Series imposes an obligation on Exchange members to record in electronic form and report to FINRA on a daily basis certain information with respect to orders originated, received, transmitted, modified, canceled, or executed by members in Nasdaq- and Exchange-listed stocks. FINRA's Order Audit Trail System ("OATS") captures this order information and integrates it with quote and transaction information to create a time-sequenced record of orders, quotes, and transactions. This information is used by FINRA staff to conduct surveillance and investigations of

¹⁴ For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

¹⁵ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ The Exchange is filing a request for an exemption under Section 36 of the Act from the rule filing requirements of Section 19(b) of the Act for certain rules included in this proposal, and will implement the changes proposed herein upon approval of the exemption request.

members for potential violation of Exchange rules and federal securities laws.

The Exchange adopted the Rule 3400 Series to copy Nasdaq and FINRA OATS rules, where appropriate. As a general principle, the Exchange endeavors to keep its rules that are corresponding to FINRA rules as closely worded and structured as possible to the FINRA rules on which they are based, including FINRA's OATS rules under the FINRA Rule 7000 Series. In certain instances, the Exchange has not copied a FINRA OATS rule because it is not relevant. For example, the Exchange has not copied FINRA Rule 7410(o)(2), which concerns an exception to the definition of a Reporting Member relating to members operating on equities floors, because the Exchange does not operate an equities floor. Generally, the Exchange also seeks to keep the Rule 3400 Series consistent with Nasdaq's Rule 7400A Series, the substance of which is identical to the related rules of the Exchange. The proposed changes will harmonize Exchange rules with analogous Nasdaq and FINRA rules, which have changed since the Exchange first adopted its rules.

First Change

The Exchange is proposing to renumber the Rule 3400 Series to a new Rule 7000A Series, which is identical to how Nasdaq presents its OATS rules. The Exchange does not currently have a Rule 7000A Series and the Exchange is proposing to follow the numbering convention used by FINRA and NASDAQ. As part of this change, the Exchange is also updating cross references in the Rule 7000A Series.

Second Change

The Exchange is amending renumbered Rule 7410A to make several changes to conform it to the rules of Nasdaq. The Exchange is proposing to add new text noting that the terms under the rule have the same meaning as those defined in the Exchange's By-Laws and rules, unless otherwise noted, which is identical to Nasdaq's Rule 7410A(a). The Exchange is also amending Rule 7410A to make technical changes that harmonize the definitions of "Index Arbitrage Trade," "Program Trade," and "Proprietary Trading Firm" with the definitions of those terms in the Nasdaq rules.⁴

⁴ The Exchange is not adopting the definition of "NMS Stock" found under Nasdaq Rule 7410A(j). The term is not used in the Exchange's OATS rules. In addition, the term is not used in the Nasdaq OATS rules. The term is used in FINRA Rule 7410(k) defining "Order Audit Trail System,

The Exchange is also proposing to adopt the same limited exemption from OATS order data recordation requirements for Exchange members that are registered market makers in standardized options on any market. Renumbered Rule 7410A(j) defines the term "Order" as any oral, written, or electronic instruction to effect a transaction in an equity security listed on the Exchange or Nasdaq that is received by a member from another person for handling or execution, or that is originated by a department of a member for execution by the same or another member, other than any such instruction to effect a proprietary transaction originated by a trading desk in the ordinary course of a member's market making activities in an Exchange-listed equity security. The Exchange is proposing to adopt the limited exemption currently available under Nasdaq's analogous definition of "Order,"⁵ which excludes from the definition a *bona fide* hedge transaction involving a Nasdaq-listed equity security originated by a trading desk in the ordinary course of the member's options market making activities.⁶ As noted by Nasdaq in adopting the exemption, OATS was designed to provide an accurate, time-sequenced record of orders and transactions, beginning with the receipt of an equity order at the first point of contact between the broker-dealer and the customer or counterparty and further documenting the life of the equity order through the process of execution.⁷ The proposed rule change does not impact the customer protection orientation of OATS since, by definition, *bona fide* hedging transactions in equity securities that are undertaken by options market makers do not involve customer orders in those equity securities. Rather, *bona fide* hedging transactions in equity securities are undertaken by an options market maker to hedge against the firm risk that it creates through its conduct as a registered options market maker. Accordingly, *bona fide* hedge transactions do not implicate customer protection issues, and requiring reporting of such transactions would not

whereas the Exchange and Nasdaq instead reference Exchange and Nasdaq listed securities under Exchange renumbered Rule 7410A(k) and Nasdaq listed securities under Nasdaq Rule 7410A(l).

⁵ See Nasdaq Rule 7410A(k).

⁶ The Exchange notes that Nasdaq capitalizes the term "Bona Fide Hedge Transaction" in Nasdaq Rule 7410A(k), although the term is not defined in Nasdaq's rules. The Exchange believes that capitalizing the term was an error and is therefore not capitalizing the term in Rule 7410A(j).

⁷ See Securities Exchange Act Release No. 59369 (February 6, 2009), 74 FR 7278 (February 13, 2009) (SR-NASDAQ-2008-097).

provide a regulatory benefit. It is also very expensive for firms that are not currently FINRA members or that do not currently trade Exchange or Nasdaq equities to develop and maintain the compliance systems and compliance staff required to continuously monitor the daily transmission of OATS data. For these reasons, the Exchange is proposing to adopt such an exemption, available to its options market makers.

The Exchange is proposing to amend Rule 7410A(n)(1) to harmonize the rule with FINRA Rule 7410(o)(1)(A) and Nasdaq Rule 7410A(o)(1)(A). Rule 7410A(n) provides the definition of "Reporting Member Organization," which means a member organization that receives or originates an order and has an obligation to record and report information under renumbered Rules 7440A and 7450A. The Rule also provides an exception to the general definition if the member organization meets four conditions. The first condition in subparagraph (n)(1), which is the only condition at issue in this proposal, is that currently the member organization engages in a non-discretionary order routing process, pursuant to which it immediately routes, by electronic or other means, all of its orders to a single receiving Reporting Member Organization. On May 12, 2014, FINRA amended FINRA Rule 7410(o)(1)(A) to allow a member to satisfy this condition by permitting a member to alternatively route its orders to two receiving Reporting Members, if two related requirements were met.⁸ First, the orders must be routed by the member to each receiving Reporting Member on a pre-determined schedule approved by FINRA. Second, the orders must be routed by the member to two receiving Reporting Members pursuant to the schedule for a time period not to exceed one year. FINRA noted in adopting the change that the rule was intended to accommodate introducing firms that transition to a different clearing firm over time and, during the transition, route their orders to two different clearing firms, both of which report the introducing firm's information to OATS during the transition time. Nasdaq recently amended its rule to incorporate this change.⁹ The Exchange believes that this additional limited exception is appropriate for its member organizations, which likewise may encounter a transition to a clearing firm

⁸ See Securities Exchange Act Release No. 72191 (May 20, 2014), 79 FR 30219 (May 27, 2014) (SR-FINRA-2014-024).

⁹ See Securities Exchange Act Release No. 83115 (April 26, 2018), 83 FR 19384 (May 2, 2018) (SR-NASDAQ-2018-030).

whereby they would no longer be eligible for the exception to the definition of Reporting Member Organization. Accordingly, the Exchange is proposing to adopt the FINRA rule text under renumbered Rule 7410A(n)(1)(B).

Third Change

The Exchange is proposing to incorporate by reference FINRA Rules 7430, 7440 and 7450 in Rules 7430A, 7440A and 7450A, respectively, and make conforming changes thereto.¹⁰ Current Rule 3403 concerns synchronization of Member Organization business clocks and is substantially identical to FINRA Rule 4590(a). Nasdaq Rule 7430A requires Nasdaq members to comply with FINRA Rule 4590 as if such rule were part of Nasdaq's rules and provides that references to "the FINRA By-Laws or other FINRA rules" shall be construed as references to "the Nasdaq Rules," for purposes of Nasdaq Rule 7430A. The Exchange is proposing to conform its rule text to that of Nasdaq.¹¹

With respect to Rule 7440A, the Exchange is proposing to copy Nasdaq Rule 7440A and incorporate by reference FINRA Rule 7440. Current Rule 3404 is meant to copy FINRA Rule 7440; however, FINRA amended FINRA Rule 7440 subsequent to the Exchange adopting Rule 3404 and the Exchange did not update its rule to reflect these changes. Specifically, FINRA amended Rules 7440(a)(2),¹² (a)(4),¹³ (b)(9),¹⁴

(b)(19),¹⁵ (b)(21),¹⁶ (c)(1)(H),¹⁷ (c)(2)(A)(viii) and

(ix),¹⁸ (c)(3)(A)(ix) and (x),¹⁹ (c)(4)(A)(x) and (xi),²⁰ (c)(5)(A)(x) and (xi),²¹ (c)(6)(k) and (l),²² and (d)(4).²³ The Exchange believes that these changes are appropriate for the reasons described by FINRA when it adopted the changes, and because adopting these changes will harmonize the Exchange's rules with those of Nasdaq and FINRA. Last and consistent with Nasdaq Rule 7440A(b), the Exchange is proposing to add new Rule 7440A(c), which provides that references to certain FINRA Rules are to be construed as references to certain Rules of the Exchange. Specifically, Rule 7440A(c)(1) provides that references to Rules FINRA Rules 7420 through 7460 shall be construed as references to Rules 7420A through 7460A.²⁴ Rule 7440A(c)(2) provides that references to FINRA Rules 5320, 7440, and 7450 shall be construed as references to Rules 765, 7440A, and 7450A, respectively.

Current Rule 3405 concerns order data transmission requirements and is meant to copy FINRA Rule 7450. Unlike Nasdaq, which incorporated by reference FINRA Rule 7450 into Nasdaq Rule 7450A, the Exchange instead adopted actual rule text that copied the requirements of FINRA Rule 7450 under Rule 3405. The Exchange is proposing to adopt the approach followed by Nasdaq by incorporating by reference the FINRA rule. Specifically, the Exchange is incorporating by reference FINRA Rule 7450 into Rule 7450A, amending existing paragraphs (a)–(d) to conform them to Nasdaq's Rule 7450A(a)–(d), and deleting paragraphs (e) and (f), which are no longer needed since the Exchange is incorporating by reference FINRA Rule 7450. The Exchange notes that FINRA amended

FINRA Rule 7450 subsequent to the Exchange adopting Rule 3405; however, the Exchange did not update its rule to reflect these changes. Specifically, FINRA amended Rule 7450(b),²⁵ which concerns the method and timing of transmitting data and which is covered under Rule 3405(e). The changes made by FINRA provided greater specificity to the timing of certain reports required by the rule. The Exchange believes that the changes to FINRA Rule 7450(b) are appropriate for the reasons described by FINRA when it adopted the changes, and because adopting these changes will harmonize the Exchange's rules with those of Nasdaq and FINRA. Last, the Exchange notes that renumbered Rule 7450A(b) requires both Proprietary Trading Firms as well as their associated persons to comply with FINRA Rule 7450 in limited circumstances, whereas Nasdaq's Rule 7450A only requires compliance by Proprietary Trading Firms. The Exchange believes that this is an omission in the Nasdaq rule and is accordingly not adjusting the Exchange rule.

Fourth Change

The Exchange is proposing to delete current Rule 3407, which will be renumbered Rule 7470A and held in reserve. Current Rule 3407 provided an exemption from the order recording and data transmission requirements of current Rules 3404 and 3405, which are OATS rules applicable to manual orders. To qualify for the exemption, a member must have met the following criteria: (1) The member and current control affiliates and associated persons of the member have not been subject within the last five years to any final disciplinary action, and within the last ten years to any disciplinary action involving fraud; (2) the member has annual revenues of less than \$2 million; (3) the member does not conduct any market making activities in equity securities listed on the Exchange; (4) the member does not execute principal transactions with its customers (with a limited exception for principal transactions executed pursuant to error corrections); and (5) the member does not conduct clearing or carrying activities for other firms. The exemption was limited to a maximum time of two years although a member was able to request an additional exemption prior to the expiration of a grant of existing exemptive relief. The exemptive authority provided by the rule permitted the Exchange to grant relief to members that meet certain criteria in situations

¹⁰ The Exchange is proposing to add text to Rules 7440A and 7450A, which notes that Exchange and FINRA are parties to the FINRA Regulatory Contract pursuant to which FINRA has agreed to perform certain functions on behalf of the Exchange, and also notes that members are complying with Rules 7440A and 7450A by complying with FINRA Rules 7440 and 7450, respectively. Nasdaq places the same text under Nasdaq Rules 7440A(a) and 7450A(a), respectively.

¹¹ The Exchange is not including text from Nasdaq Rule 7440A(a) and 7450A(a), which notes that members are complying with these rules by complying with the related FINRA rules, in Rules 7440A(a) and 7450A(a). The Exchange believes these sentences are duplicative of the first sentence of Rules 7440A(a) and 7450A(a).

¹² See Securities Exchange Act Release No. 71623 (February 27, 2014), 79 FR 12558 (March 5, 2014) (SR-FINRA-2013-050).

¹³ See Securities Exchange Act Release No. 63784 (January 27, 2011), 76 FR 5850 (February 2, 2011) (SR-FINRA-2010-052).

¹⁴ See Securities Exchange Act Release No. 63032 (October 4, 2010), 75 FR 62439 (October 8, 2010) (SR-FINRA-2010-043).

¹⁵ See Securities Exchange Act Release No. 77523 (April 5, 2016), 81 FR 21427 (April 11, 2016) (SR-FINRA-2016-006).

¹⁶ See Securities Exchange Act Release No. 77164 (February 17, 2016), 81 FR 9043 (February 23, 2016) (SR-FINRA-2015-048).

¹⁷ See Securities Exchange Act Release No. 66021 (December 21, 2011), 76 FR 81551 (December 28, 2011) (SR-FINRA-2011-063).

¹⁸ See Securities Exchange Act Release No. 63032 (October 4, 2010), 75 FR 62439 (October 8, 2010) (SR-FINRA-2010-043).

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

²³ See Securities Exchange Act Release No. 77164 (February 17, 2016), 81 FR 9043 (February 23, 2016) (SR-FINRA-2015-048).

²⁴ The Exchange notes that Nasdaq Rules 7440A(b)(1) and (2) do not state that certain rules referenced under Nasdaq Rule 7440A are FINRA rules. The Exchange is making it clear under Rules 7440A(c)(1) and (2) that the rules referenced under Rule 7440A are FINRA rules.

²⁵ See note 16, *supra*.

where, for example, the reporting of order information would be unduly burdensome for the member or where temporary relief from the OATS Rules, in the form of additional time to achieve compliance, would permit the members to avoid unnecessary expense or hardship. The exemption has not been requested by any Exchange member to date and the Exchange does not believe that Exchange members are likely to need the exemption, since the vast majority of such members to which the rule applies are electronic proprietary trading firms that would not qualify for the exemption. Moreover, Nasdaq does not have an analogous rule, having eliminated similar text recently for the same reasons.²⁶ Thus, the Exchange is proposing to eliminate the rule text under Rule 3407 from its rule book, renumber the rule to Rule 7470A, and hold the rule in reserve.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,²⁷ in general, and furthers the objectives of Section 6(b)(5) of the Act,²⁸ in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by harmonizing the Exchange's OATS rules with those of FINRA, on which they are based, and with those of Nasdaq, which they should largely match. Consequently, the proposed change will conform Exchange Rules to changes made to corresponding FINRA and Nasdaq rules, thus promoting consistent regulatory standards with respect to rules that FINRA enforces pursuant to its Regulatory Services Agreements with the Exchange and Nasdaq. With respect to the proposed amendment to Rule 7410A(n)(1), the exemption will provide Exchange members with the same flexibility to transition to a new clearing firm that both Nasdaq and FINRA members currently enjoy. The rule is intended to accommodate introducing firms that transition to a different clearing firm over time and, during the transition, route their orders to two different clearing firms, both of which report the introducing firm's information to OATS during the transition time. Adopting the new and amended rule text under Rule 7410A will also align the Exchange rulebook with Nasdaq's and FINRA's, thereby

reducing complexity from FINRA's work under a regulatory services agreement with the Exchange.

The Exchange believes that adopting the new limited exception to the definition of "Order" is consistent with the Act because it provides a very narrow exemption from reporting transactions that are done to manage risk and facilitate options market making. *Bona fide* hedging transactions in equity securities that are undertaken by options market makers do not involve customer orders in those equity securities and thus do not implicate customer protection issues. Moreover, information regarding *bona fide* hedging transactions retained by a registered Phlx Options Market market maker is otherwise available to FINRA and Phlx Regulation through the Exchange's electronic delivery systems, upon request. This information includes trade reporting data, including order time and sales data captured by the Exchange system.

With respect to the proposed technical corrections to the rules, the Exchange believes that these changes are consistent with the Act because they will prevent investor confusion that may be caused by including in the Rules incorrect rule citations, defunct rule text and expired exemptions

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 aligns the Exchange's rules with those of Nasdaq and FINRA, which will assist FINRA in its oversight work done pursuant to a regulatory services agreement. The proposed changes also provide uniform standards with which market participants must comply. Consequently, the Exchange does not believe that the proposed changes implicate competition at all.

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 Act²⁹ and subparagraph (f)(6) of Rule 19b-4 thereunder.³⁰

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-Phlx-2018-68 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.
- All submissions should refer to File Number SR-Phlx-2018-68. 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

²⁹ 15 U.S.C. 78s(b)(3)(A)(iii).

³⁰ 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.

²⁶ *Id.*

²⁷ 15 U.S.C. 78f(b).

²⁸ 15 U.S.C. 78f(b)(5).

Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-Phlx-2018-68, and should be submitted on or before December 4, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³¹

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018-24638 Filed 11-9-18; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 33289; File No. 812-14855]

Stellus Capital Investment Corporation, et al.

November 6, 2018.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice.

Notice of application for an order ("Order") under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the "Act") and rule 17d-1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d-1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain business development companies and certain closed-end management investment companies to co-invest in portfolio companies with each other and with affiliated investment funds and accounts. The Order would supersede the prior order.¹

APPLICANTS: Stellus Capital Investment Corporation (the "Company"); Stellus Credit Master Fund I, LLC, Stellus Credit VCOF Fund I, LLC, Stellus Credit Master Fund II, LLC, and Stellus Credit VCOF Fund II, LLC (collectively, "Existing Affiliated Funds"); Stellus Capital SBIC LP, Stellus Capital SBIC GP, LLC, SCIC-Consolidated Blocker, Inc., SCIC-CC Blocker 1, Inc., SCIC-ERC Blocker 1, Inc., SCIC-SKP Blocker 1, Inc., SCIC-APE Blocker 1, Inc., SCIC-HUF Blocker 1, Inc., and SCIC-Hollander Blocker 1, Inc. (collectively, "Existing Wholly-Owned Subsidiaries"); and Stellus Capital Management, LLC ("SCM" and collectively with the Company, the Existing Affiliated Funds and the Existing Wholly-Owned Subsidiaries, the "Applicants").

FILING DATES: The application was filed on December 19, 2017 and amended on September 17, 2018.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on December 3, 2018, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0-5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F St. NE, Washington, DC 20549-1090. Applicants: 4400 Post Oak Parkway, Suite 2200, Houston, TX 77027.

FOR FURTHER INFORMATION CONTACT: Barbara T. Heussler, Senior Counsel, at (202) 551-6990, or Andrea Ottomaneli Magovern, Branch Chief, at (202) 551-6821 (Chief Counsel's Office, Division of Investment Management).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at <http://www.sec.gov/search/search.htm> or by calling (202) 551-8090.

Introduction

1. The Applicants request an Order of the Commission under sections 17(d) and 57(i) of the Act and rule 17d-1 under the Act to permit, subject to the terms and conditions set forth in the application (the "Conditions"), a Regulated Fund² and one or more other Regulated Funds and/or one or more Affiliated Funds³ to enter into Co-Investment Transactions with each other. "Co-Investment Transaction" means any transaction in which one or more Regulated Funds (or its Wholly-Owned Investment Sub, defined below) participated together with one or more Affiliated Funds and/or one or more other Regulated Funds in reliance on the Order. "Potential Co-Investment Transaction" means any investment opportunity in which a Regulated Fund (or its Wholly-Owned Investment Sub) could not participate together with one or more Affiliated Funds and/or one or more other Regulated Funds without obtaining and relying on the Order.⁴

Applicants

2. The Company is a closed-end management investment company incorporated in Maryland that has elected to be regulated as a BDC under the Act.⁵ The Company's Board⁶ currently consists of seven members, of

² "Regulated Fund" means the Company and any Future Regulated Fund. "Future Regulated Fund" means a closed-end management investment company (a) that is registered under the Act or has elected to be regulated as a business development company ("BDC") and (b) whose investment adviser is an Adviser. "Adviser" means SCM together with any future investment adviser that (i) controls, is controlled by or is under common control with SCM, (ii) is registered as an investment adviser under the Investment Advisers Act of 1940 (the "Advisers Act"), and (iii) is not a Regulated Fund or a subsidiary of a Regulated Fund.

³ "Affiliated Fund" means any Existing Affiliated Fund, any Future Affiliated Fund or any Stellus Proprietary Account. "Future Affiliated Fund" means any entity (a) whose investment adviser is an Adviser, (b) that would be an investment company but for section 3(c)(1), 3(c)(5)(C) or 3(c)(7) of the Act, and (c) that intends to participate in the program of co-investments described in the application. "Stellus Proprietary Account" means any direct or indirect, wholly- or majority-owned subsidiary of SCM that is formed in the future that, from time to time, may hold various financial assets in a principal capacity.

⁴ All existing entities that currently intend to rely on the Order have been named as Applicants and any existing or future entities that may rely on the Order in the future will comply with the terms and Conditions set forth in the application.

⁵ Section 2(a)(48) defines a BDC to be any closed-end investment company that operates for the purpose of making investments in securities described in section 55(a)(1) through 55(a)(3) and makes available significant managerial assistance with respect to the issuers of such securities.

⁶ "Board" means the board of directors (or the equivalent) of the applicable Regulated Fund.

³¹ 17 CFR 200.30-3(a)(12).

¹ Stellus Capital Investment Corporation, et al., Investment Company Act Rel. Nos. 30739 (Sep. 30, 2013) (notice) and 30754 (Oct. 23, 2013) (order).

which four members are Independent Directors.⁷

3. SCM, a Delaware limited liability company that is registered under the Advisers Act, serves as the investment adviser to the Company pursuant to an investment advisory agreement. SCM also serves as investment adviser to each Existing Affiliated Fund.

4. Applicants represent that each Existing Affiliated Fund is a separate and distinct legal entity and each would be an investment company but for section 3(c)(1), 3(c)(5)(C) or 3(c)(7) of the Act.

5. Applicants state that a Regulated Fund may, from time to time, form one or more Wholly-Owned Investment Subs.⁸ Such a subsidiary may be prohibited from investing in a Co-Investment Transaction with a Regulated Fund (other than its parent) or any Affiliated Fund because it would be a company controlled by its parent Regulated Fund for purposes of section 57(a)(4) and rule 17d-1. Applicants request that each Wholly-Owned Investment Sub be permitted to participate in Co-Investment Transactions in lieu of the applicable parent Regulated Fund that owns it and that the Wholly-Owned Investment Sub's participation in any such transaction be treated, for purposes of the Order, as though the parent Regulated Fund were participating directly. Applicants represent that this treatment is justified because a Wholly-Owned Investment Sub would have no purpose other than serving as a holding vehicle for the Regulated Fund's investments and, therefore, no conflicts of interest could arise between the

⁷ "Independent Director" means a member of the Board of any relevant entity who is not an "interested person" as defined in section 2(a)(19) of the Act. No Independent Director of a Regulated Fund will have a financial interest in any Co-Investment Transaction, other than indirectly through share ownership in one of the Regulated Funds.

⁸ "Wholly-Owned Investment Sub" means an entity (i) that is wholly-owned by a Regulated Fund (with such Regulated Fund at all times holding, beneficially and of record, 100% of the voting and economic interests); (ii) whose sole business purpose is to hold one or more investments on behalf of such Regulated Fund (and, in the case of a SBIC Subsidiary (defined below), maintains a license under the SBA Act (defined below) and issues debentures guaranteed by the SBA (defined below)); (iii) with respect to which such Regulated Fund's Board has the sole authority to make all determinations with respect to the entity's participation under the Conditions; and (iv) that would be an investment company but for section 3(c)(1) or 3(c)(7) of the Act. "SBIC Subsidiary" means a Wholly-Owned Investment Sub that is licensed by the Small Business Administration (the "SBA") to operate under the Small Business Investment Act of 1958, as amended, (the "SBA Act") as a small business investment company. The Existing Wholly-Owned Subsidiaries are Wholly-Owned Investment Subs.

parent Regulated Fund and the Wholly-Owned Investment Sub. The Board of the parent Regulated Fund would make all relevant determinations under the Conditions with regard to a Wholly-Owned Investment Sub's participation in a Co-Investment Transaction, and the Board would be informed of, and take into consideration, any proposed use of a Wholly-Owned Investment Sub in the Regulated Fund's place. If the parent Regulated Fund proposes to participate in the same Co-Investment Transaction with any of its Wholly-Owned Investment Subs, the Board of the parent Regulated Fund will also be informed of, and take into consideration, the relative participation of the Regulated Fund and the Wholly-Owned Investment Sub.

Applicants' Representations

A. Allocation Process

6. Applicants state that SCM is presented with hundreds of investment opportunities each year on behalf of its clients and SCM determines how to allocate those opportunities in a manner that, over time, is fair and equitable to all of its clients. Such investment opportunities may be Potential Co-Investment Transactions.

7. Applicants represent that SCM has established processes for allocating initial investment opportunities, opportunities for subsequent investments in an issuer and dispositions of securities holdings reasonably designed to treat all clients fairly and equitably. Further, Applicants represent that these processes will be extended and modified in a manner reasonably designed to ensure that the additional transactions permitted under the Order will both (i) be fair and equitable to the Regulated Funds and the Affiliated Funds and (ii) comply with the Conditions.

8. If the requested Order is granted, the Adviser will establish, maintain and implement policies and procedures reasonably designed to ensure that when such opportunities arise, the Adviser to the relevant Regulated Funds is promptly notified and receives the same information about the opportunity as any other Adviser considering the opportunity for its clients. In particular, consistent with Condition 1, if a Potential Co-Investment Transaction falls within the then-current Objectives and Strategies⁹ and any Board-

⁹ "Objectives and Strategies" means a Regulated Fund's investment objectives and strategies, as described in its most current registration statement on Form N-2, other current filings with the Commission under the Securities Act of 1933 (the "Securities Act") or under the Securities Exchange

Act of 1934, as amended, and its most current report to stockholders.

Established Criteria¹⁰ of a Regulated Fund, the policies and procedures will require that the Adviser to such Regulated Fund receive sufficient information to allow such Adviser's investment committee to make its independent determination and recommendations under the Conditions.

9. The Adviser to each applicable Regulated Fund will then make an independent determination of the appropriateness of the investment for the Regulated Fund in light of the Regulated Fund's then-current circumstances. If the Adviser to a Regulated Fund deems the Regulated Fund's participation in any Potential Co-Investment Transaction to be appropriate, it will formulate a recommendation regarding the proposed order amount for the Regulated Fund.

10. Applicants state that, for each Regulated Fund and Affiliated Fund whose Adviser recommends participating in a Potential Co-Investment Transaction, such Adviser's investment committee will approve an investment amount to be allocated to each Regulated Fund and/or Affiliated Fund participating in the Potential Co-Investment Transaction. Applicants state further that, each proposed order amount may be reviewed and adjusted, in accordance with the Adviser's written allocation policies and procedures, by the Adviser's investment committee.¹¹ The order of a Regulated Fund or Affiliated Fund resulting from this process is referred to as its "Internal

Act of 1934, as amended, and its most current report to stockholders.

¹⁰ "Board-Established Criteria" means criteria that the Board of a Regulated Fund may establish from time to time to describe the characteristics of Potential Co-Investment Transactions regarding which the Adviser to such Regulated Fund should be notified under Condition 1. The Board-Established Criteria will be consistent with the Regulated Fund's Objectives and Strategies. If no Board-Established Criteria are in effect, then the Regulated Fund's Adviser will be notified of all Potential Co-Investment Transactions that fall within the Regulated Fund's then-current Objectives and Strategies. Board-Established Criteria will be objective and testable, meaning that they will be based on observable information, such as industry/sector of the issuer, minimum EBITDA of the issuer, asset class of the investment opportunity or required commitment size, and not on characteristics that involve a discretionary assessment. The Adviser to the Regulated Fund may from time to time recommend criteria for the Board's consideration, but Board-Established Criteria will only become effective if approved by a majority of the Independent Directors. The Independent Directors of a Regulated Fund may at any time rescind, suspend or qualify its approval of any Board-Established Criteria, though Applicants anticipate that, under normal circumstances, the Board would not modify these criteria more often than quarterly.

¹¹ The reason for any such adjustment to a proposed order amount will be documented in writing and preserved in the records of each Adviser.

Order.” The Internal Order will be submitted for approval by the Required Majority of any participating Regulated Funds in accordance with the Conditions.¹²

11. Applicants acknowledge that some of the Affiliated Funds may not be funds advised by an Adviser because they are Stellus Proprietary Accounts. Applicants do not believe these Stellus Proprietary Accounts should raise issues under the Conditions because the allocation policies and procedures of the Advisers provide that investment opportunities are offered to client accounts before they are offered to Stellus Proprietary Accounts.

12. If the aggregate Internal Orders for a Potential Co-Investment Transaction do not exceed the size of the investment opportunity immediately prior to the submission of the orders to the underwriter, broker, dealer or issuer, as applicable (the “External Submission”), then each Internal Order will be fulfilled as placed and to the extent there is excess amount available to invest, a Stellus Proprietary Account shall be permitted to invest. If, on the other hand, the aggregate Internal Orders for a Potential Co-Investment Transaction exceed the size of the investment opportunity immediately prior to the External Submission, then the allocation of the opportunity will be made pro rata on the basis of the size of the Internal Orders and the Stellus Proprietary Accounts shall not be permitted to invest.¹³ If, subsequent to such External Submission, the size of the opportunity is increased or decreased, or if the terms of such opportunity, or the facts and circumstances applicable to the Regulated Funds’ or the Affiliated Funds’ consideration of the opportunity, change, the participants will be permitted to submit revised Internal Orders in accordance with written allocation policies and procedures that

¹² “Required Majority” means a required majority, as defined in section 57(o) of the Act. In the case of a Regulated Fund that is a registered closed-end fund, the Board members that make up the Required Majority will be determined as if the Regulated Fund were a BDC subject to section 57(o).

¹³ Each Adviser will maintain records of all proposed order amounts, Internal Orders and External Submissions in conjunction with Potential Co-Investment Transactions. Each applicable Adviser will provide the Eligible Directors with information concerning the Affiliated Funds’ and Regulated Funds’ order sizes to assist the Eligible Directors with their review of the applicable Regulated Fund’s investments for compliance with the Conditions. “Eligible Directors” means, with respect to a Regulated Fund and a Potential Co-Investment Transaction, the members of the Regulated Fund’s Board eligible to vote on that Potential Co-Investment Transaction under section 57(o) of the Act.

the Advisers will establish, implement and maintain.¹⁴

B. Follow-On Investments

13. Applicants state that from time to time the Regulated Funds and Affiliated Funds may have opportunities to make Follow-On Investments¹⁵ in an issuer in which a Regulated Fund and one or more other Regulated Funds and/or Affiliated Funds previously have invested.

14. Applicants propose that Follow-On Investments would be divided into two categories depending on whether the prior investment was a Co-Investment Transaction or a Pre-Boarding Investment.¹⁶ If the Regulated Funds and Affiliated Funds have previously participated in a Co-Investment Transaction with respect to the issuer, then the terms and approval of the Follow-On Investment would be subject to the Standard Review Follow-Ons described in Condition 8. If the Regulated Funds and Affiliated Funds have not previously participated in a Co-Investment Transaction with respect to the issuer but hold a Pre-Boarding Investment, then the terms and approval of the Follow-On Investment would be subject to the Enhanced-Review Follow-Ons described in Condition 9. All Enhanced Review Follow-Ons require the approval of the Required Majority. For a given issuer, the participating Regulated Funds and Affiliated Funds need to comply with the requirements of Enhanced-Review Follow-Ons only for the first Co-Investment Transaction. Subsequent Co-Investment Transactions with respect to the issuer would be

¹⁴ However, if the size of the opportunity is decreased such that the aggregate of the original Internal Orders would exceed the amount of the remaining investment opportunity, then upon submitting any revised order amount to the Board of a Regulated Fund for approval, the Adviser to the Regulated Fund will also notify the Board promptly of the amount that the Regulated Fund would receive if the remaining investment opportunity were allocated pro rata on the basis of the size of the original Internal Orders. The Board of the Regulated Fund will then either approve or disapprove of the investment opportunity in accordance with condition 2, 6, 7, 8 or 9, as applicable.

¹⁵ “Follow-On Investment” means an additional investment in the same issuer, including, but not limited to, through the exercise of warrants, conversion privileges or other rights to purchase securities of the issuer.

¹⁶ “Pre-Boarding Investments” are investments in an issuer held by a Regulated Fund as well as one or more Affiliated Funds and/or one or more other Regulated Funds that were acquired prior to participating in any Co-Investment Transaction: (i) In transactions in which the only term negotiated by or on behalf of such funds was price in reliance on one of the JT No-Action Letters (defined below); or (ii) in transactions occurring at least 90 days apart and without coordination between the Regulated Fund and any Affiliated Fund or other Regulated Fund.

governed by the requirements of Standard Review Follow-Ons.

15. A Regulated Fund would be permitted to invest in Standard Review Follow-Ons either with the approval of the Required Majority under Condition 8(c) or without Board approval under Condition 8(b) if it is (i) a Pro Rata Follow-On Investment¹⁷ or (ii) a Non-Negotiated Follow-On Investment.¹⁸ Applicants believe that these Pro Rata and Non-Negotiated Follow-On Investments do not present a significant opportunity for overreaching on the part of any Adviser and thus do not warrant the time or the attention of the Board. Pro Rata Follow-On Investments and Non-Negotiated Follow-On Investments remain subject to the Board’s periodic review in accordance with Condition 10.

C. Dispositions

16. Applicants propose that Dispositions¹⁹ would be divided into two categories. If the Regulated Funds and Affiliated Funds holding investments in the issuer have previously participated in a Co-Investment Transaction with respect to the issuer, then the terms and approval of the Disposition would be subject to the Standard Review Dispositions described in Condition 6. If the Regulated Funds and Affiliated Funds have not previously participated in a Co-Investment Transaction with respect to the issuer but hold a Pre-Boarding Investment, then the terms and approval of the Disposition would be subject to the Enhanced Review Dispositions described in Condition 7. Subsequent

¹⁷ A “Pro Rata Follow-On Investment” is a Follow-On Investment (i) in which the participation of each Affiliated Fund and each Regulated Fund is proportionate to its outstanding investments in the issuer or security, as appropriate, immediately preceding the Follow-On Investment, and (ii) in the case of a Regulated Fund, a majority of the Board has approved the Regulated Fund’s participation in the pro rata Follow-On Investments as being in the best interests of the Regulated Fund. The Regulated Fund’s Board may refuse to approve, or at any time rescind, suspend or qualify, its approval of Pro Rata Follow-On Investments, in which case all subsequent Follow-On Investments will be submitted to the Regulated Fund’s Eligible Directors in accordance with Condition 8(c).

¹⁸ A “Non-Negotiated Follow-On Investment” is a Follow-On Investment in which a Regulated Fund participates together with one or more Affiliated Funds and/or one or more other Regulated Funds (i) in which the only term negotiated by or on behalf of the funds is price and (ii) with respect to which, if the transaction were considered on its own, the funds would be entitled to rely on one of the JT No-Action Letters. “JT No-Action Letters” means SMC Capital, Inc., SEC No-Action Letter (pub. avail. Sept. 5, 1995) and Massachusetts Mutual Life Insurance Company, SEC No-Action Letter (pub. avail. June 7, 2000).

¹⁹ “Disposition” means the sale, exchange or other disposition of an interest in a security of an issuer.

Dispositions with respect to the same issuer would be governed by Condition 6 under the Standard Review Dispositions.²⁰

17. A Regulated Fund may participate in a Standard Review Disposition either with the approval of the Required Majority under Condition 6(d) or without Board approval under Condition 6(c) if (i) the Disposition is a Pro Rata Disposition²¹ or (ii) the securities are Tradable Securities²² and the Disposition meets the other requirements of Condition 6(c)(ii). Pro Rata Dispositions and Dispositions of a Tradable Security remain subject to the Board's periodic review in accordance with Condition 10.

D. Delayed Settlement

18. Applicants represent that under the terms and Conditions of the application, all Regulated Funds and Affiliated Funds participating in a Co-Investment Transaction will invest at the same time, for the same price and with the same terms, conditions, class,

²⁰ However, with respect to an issuer, if a Regulated Fund's first Co-Investment Transaction is an Enhanced Review Disposition, and the Regulated Fund does not dispose of its entire position in the Enhanced Review Disposition, then before such Regulated Fund may complete its first Standard Review Follow-On in such issuer, the Eligible Directors must review the proposed Follow-On Investment not only on a stand-alone basis but also in relation to the total economic exposure in such issuer (*i.e.*, in combination with the portion of the Pre-Boarding Investment not disposed of in the Enhanced Review Disposition), and the other terms of the investments. This additional review is required because such findings were not required in connection with the prior Enhanced Review Disposition, but they would have been required had the first Co-Investment Transaction been an Enhanced Review Follow-On.

²¹ A "Pro Rata Disposition" is a Disposition (i) in which the participation of each Affiliated Fund and each Regulated Fund is proportionate to its outstanding investment in the security subject to Disposition immediately preceding the Disposition; and (ii) in the case of a Regulated Fund, a majority of the Board has approved the Regulated Fund's participation in pro rata Dispositions as being in the best interests of the Regulated Fund. The Regulated Fund's Board may refuse to approve, or at any time rescind, suspend or qualify, its approval of Pro Rata Dispositions, in which case all subsequent Dispositions will be submitted to the Regulated Fund's Eligible Directors.

²² "Tradable Security" means a security that meets the following criteria at the time of Disposition: (i) It trades on a national securities exchange or designated offshore securities market as defined in rule 902(b) under the Securities Act; (ii) it is not subject to restrictive agreements with the issuer or other security holders; and (iii) it trades with sufficient volume and liquidity (findings as to which are documented by the Advisers to any Regulated Funds holding investments in the issuer and retained for the life of the Regulated Fund) to allow each Regulated Fund to dispose of its entire position remaining after the proposed Disposition within a short period of time not exceeding 30 days at approximately the value (as defined by section 2(a)(41) of the Act) at which the Regulated Fund has valued the investment.

registration rights and any other rights, so that none of them receives terms more favorable than any other. However, the settlement date for an Affiliated Fund in a Co-Investment Transaction may occur up to ten business days after the settlement date for the Regulated Fund, and vice versa.²³ Nevertheless, in all cases, (i) the date on which the commitment of the Affiliated Funds and Regulated Funds is made will be the same even where the settlement date is not and (ii) the earliest settlement date and the latest settlement date of any Affiliated Fund or Regulated Fund participating in the transaction will occur within ten business days of each other.

E. Holders

19. Under Condition 15, if an Adviser, its principals, or any person controlling, controlled by, or under common control with the Adviser or its principals, and the Affiliated Funds (collectively, the "Holders") own in the aggregate more than 25 percent of the outstanding voting shares of a Regulated Fund (the "Shares"), then the Holders will vote such Shares as directed by an independent third party when voting on matters specified in the Condition. Applicants believe that this Condition will ensure that the Independent Directors will act independently in evaluating Co-Investment Transactions, because the ability of an Adviser or its principals to influence the Independent Directors by a suggestion, explicit or implied, that the Independent Directors can be removed will be limited significantly. The Independent Directors shall evaluate and approve any independent party, taking into account its qualifications, reputation for independence, cost to the shareholders, and other factors that they deem relevant.

Applicants' Legal Analysis

1. Section 17(d) of the Act and rule 17d-1 under the Act prohibit participation by a registered investment company and an affiliated person in any "joint enterprise or other joint arrangement or profit-sharing plan," as defined in the rule, without prior

²³ Applicants state this may occur for two reasons. First, when the Affiliated Fund or Regulated Fund is not yet fully funded because, when the Affiliated Fund or Regulated Fund desires to make an investment, it must call capital from its investors to obtain the financing to make the investment, and in these instances, the notice requirement to call capital could be as much as ten business days. Second, where, for tax or regulatory reasons, an Affiliated Fund or Regulated Fund does not purchase new issuances immediately upon issuance but only after a short seasoning period of up to ten business days.

approval by the Commission by order upon application. Section 17(d) of the Act and rule 17d-1 under the Act are applicable to Regulated Funds that are registered closed-end investment companies.

2. Similarly, with regard to BDCs, section 57(a)(4) of the Act generally prohibits certain persons specified in section 57(b) from participating in joint transactions with the BDC or a company controlled by the BDC in contravention of rules as prescribed by the Commission. Section 57(i) of the Act provides that, until the Commission prescribes rules under section 57(a)(4), the Commission's rules under section 17(d) of the Act applicable to registered closed-end investment companies will be deemed to apply to transactions subject to section 57(a)(4). Because the Commission has not adopted any rules under section 57(a)(4), rule 17d-1 also applies to joint transactions with Regulated Funds that are BDCs.

3. Co-Investment Transactions are prohibited by either or both of rule 17d-1 and section 57(a)(4) without a prior exemptive order of the Commission to the extent that the Affiliated Funds and the Regulated Funds participating in such transactions fall within the category of persons described by rule 17d-1 and/or section 57(b), as applicable, vis-à-vis each participating Regulated Fund. Each of the participating Regulated Funds and Affiliated Funds may be deemed to be affiliated persons vis-à-vis a Regulated Fund within the meaning of section 2(a)(3) by reason of common control because (i) the Adviser manages each of the Affiliated Funds and may be deemed to control any Future Regulated Fund and any Future Affiliated Fund, and (ii) the Adviser manages the Company pursuant to its investment advisory agreement. Thus, each of the Affiliated Funds could be deemed to be a person related to the Company in a manner described by section 57(b) and related to Future Regulated Funds in a manner described by rule 17d-1; and therefore the prohibitions of rule 17d-1 and section 57(a)(4) would apply respectively to prohibit the Affiliated Funds from participating in Co-Investment Transactions with the Regulated Funds. In addition, because the Stellus Proprietary Accounts are controlled by SCM and, therefore, may be under common control with the Company, any future Advisers, and any Future Regulated Funds, the Stellus Proprietary Accounts could be deemed to be persons related to the Regulated Funds (or a company controlled by the Regulated Funds) in a manner described by section 57(b) and also prohibited

from participating in the Co-Investment Program.

4. In passing upon applications under rule 17d-1, the Commission considers whether the company's participation in the joint transaction is consistent with the provisions, policies, and purposes of the Act and the extent to which such participation is on a basis different from or less advantageous than that of other participants.

5. Applicants state that in the absence of the requested relief, in many circumstances the Regulated Funds would be limited in their ability to participate in attractive and appropriate investment opportunities. Applicants state that, as required by rule 17d-1(b), the Conditions ensure that the terms on which Co-Investment Transactions may be made will be consistent with the participation of the Regulated Funds being on a basis that it is neither different from nor less advantageous than other participants, thus protecting the equity holders of any participant from being disadvantaged. Applicants further state that the Conditions ensure that all Co-Investment Transactions are reasonable and fair to the Regulated Funds and their shareholders and do not involve overreaching by any person concerned, including the Advisers. Applicants state that the Regulated Funds' participation in the Co-Investment Transactions in accordance with the Conditions will be consistent with the provisions, policies, and purposes of the Act and would be done in a manner that is not different from, or less advantageous than, that of other participants.

Applicants' Conditions

Applicants agree that the Order will be subject to the following Conditions:

1. Identification and Referral of Potential Co-Investment Transactions.

(a) The Advisers will establish, maintain and implement policies and procedures reasonably designed to ensure that each Adviser is promptly notified of all Potential Co-Investment Transactions that fall within the then-current Objectives and Strategies and Board-Established Criteria of any Regulated Fund the Adviser manages.

(b) When an Adviser to a Regulated Fund is notified of a Potential Co-Investment Transaction under Condition 1(a), the Adviser will make an independent determination of the appropriateness of the investment for the Regulated Fund in light of the Regulated Fund's then-current circumstances.

2. Board Approvals of Co-Investment Transactions.

(a) If the Adviser deems a Regulated Fund's participation in any Potential Co-Investment Transaction to be appropriate for the Regulated Fund, it will then determine an appropriate level of investment for the Regulated Fund.

(b) If the aggregate amount recommended by the Advisers to be invested in the Potential Co-Investment Transaction by the participating Regulated Funds and any participating Affiliated Funds, collectively, exceeds the amount of the investment opportunity, the investment opportunity will be allocated among them pro rata based on the size of the Internal Orders, as described in section III.A.1.b. of the application. Each Adviser to a participating Regulated Fund will promptly notify and provide the Eligible Directors with information concerning the Affiliated Funds' and Regulated Funds' order sizes to assist the Eligible Directors with their review of the applicable Regulated Fund's investments for compliance with these Conditions.

(c) After making the determinations required in Condition 1(b) above, each Adviser to a participating Regulated Fund will distribute written information concerning the Potential Co-Investment Transaction (including the amount proposed to be invested by each participating Regulated Fund and each participating Affiliated Fund) to the Eligible Directors of its participating Regulated Fund(s) for their consideration. A Regulated Fund will enter into a Co-Investment Transaction with one or more other Regulated Funds or Affiliated Funds only if, prior to the Regulated Fund's participation in the Potential Co-Investment Transaction, a Required Majority concludes that:

(i) The terms of the transaction, including the consideration to be paid, are reasonable and fair to the Regulated Fund and its equity holders and do not involve overreaching in respect of the Regulated Fund or its equity holders on the part of any person concerned;

(ii) the transaction is consistent with:

(A) The interests of the Regulated Fund's equity holders; and

(B) the Regulated Fund's then-current Objectives and Strategies;

(iii) the investment by any other Regulated Fund(s) or Affiliated Fund(s) would not disadvantage the Regulated Fund, and participation by the Regulated Fund would not be on a basis different from, or less advantageous than, that of any other Regulated Fund(s) or Affiliated Fund(s) participating in the transaction; provided that the Required Majority shall not be prohibited from reaching

the conclusions required by this Condition 2(c)(iii) if:

(A) The settlement date for another Regulated Fund or an Affiliated Fund in a Co-Investment Transaction is later than the settlement date for the Regulated Fund by no more than ten business days or earlier than the settlement date for the Regulated Fund by no more than ten business days, in either case, so long as: (x) The date on which the commitment of the Affiliated Funds and Regulated Funds is made is the same; and (y) the earliest settlement date and the latest settlement date of any Affiliated Fund or Regulated Fund participating in the transaction will occur within ten business days of each other; or

(B) any other Regulated Fund or Affiliated Fund, but not the Regulated Fund itself, gains the right to nominate a director for election to a portfolio company's board of directors, the right to have a board observer or any similar right to participate in the governance or management of the portfolio company so long as: (x) The Eligible Directors will have the right to ratify the selection of such director or board observer, if any; (y) the Adviser agrees to, and does, provide periodic reports to the Regulated Fund's Board with respect to the actions of such director or the information received by such board observer or obtained through the exercise of any similar right to participate in the governance or management of the portfolio company; and (z) any fees or other compensation that any other Regulated Fund or Affiliated Fund or any affiliated person of any other Regulated Fund or Affiliated Fund receives in connection with the right of one or more Regulated Funds or Affiliated Funds to nominate a director or appoint a board observer or otherwise to participate in the governance or management of the portfolio company will be shared proportionately among any participating Affiliated Funds (who may, in turn, share their portion with their affiliated persons) and any participating Regulated Fund(s) in accordance with the amount of each such party's investment; and

(iv) the proposed investment by the Regulated Fund will not involve compensation, remuneration or a direct or indirect²⁴ financial benefit to the Advisers, any other Regulated Fund, the Affiliated Funds or any affiliated person of any of them (other than the parties to

²⁴ For example, procuring the Regulated Fund's investment in a Potential Co-Investment Transaction to permit an affiliate to complete or obtain better terms in a separate transaction would constitute an indirect financial benefit.

the Co-Investment Transaction), except (A) to the extent permitted by Condition 14, (B) to the extent permitted by section 17(e) or 57(k), as applicable, (C) indirectly, as a result of an interest in the securities issued by one of the parties to the Co-Investment Transaction, or (D) in the case of fees or other compensation described in Condition 2(c)(iii)(B)(z).

3. *Right to Decline.* Each Regulated Fund has the right to decline to participate in any Potential Co-Investment Transaction or to invest less than the amount proposed.

4. *General Limitation.* Except for Follow-On Investments made in accordance with Conditions 8 and 9 below,²⁵ a Regulated Fund will not invest in reliance on the Order in any issuer in which a Related Party has an investment.²⁶

5. *Same Terms and Conditions.* A Regulated Fund will not participate in any Potential Co-Investment Transaction unless (i) the terms, conditions, price, class of securities to be purchased, date on which the commitment is entered into and registration rights (if any) will be the same for each participating Regulated Fund and Affiliated Fund and (ii) the earliest settlement date and the latest settlement date of any participating Regulated Fund or Affiliated Fund will occur as close in time as practicable and in no event more than ten business days apart. The grant to one or more Regulated Funds or Affiliated Funds, but not the respective Regulated Fund, of the right to nominate a director for election to a portfolio company's board of directors, the right to have an observer on the board of directors or similar rights to participate in the governance or management of the portfolio company will not be interpreted so as to violate this Condition 5, if Condition 2(c)(iii)(B) is met.

²⁵ This exception applies only to Follow-On Investments by a Regulated Fund in issuers in which that Regulated Fund already holds investments.

²⁶ "Related Party" means (i) any Close Affiliate and (ii) in respect of matters as to which any Adviser has knowledge, any Remote Affiliate. "Close Affiliate" means the Advisers, the Regulated Funds, the Affiliated Funds and any other person described in section 57(b) (after giving effect to Rule 57b-1) in respect of any Regulated Fund (treating any registered investment company or series thereof as a BDC for this purpose) except for limited partners included solely by reason of the reference in section 57(b) to section 2(a)(3)(D). "Remote Affiliate" means any person described in section 57(e) in respect of any Regulated Fund (treating any registered investment company or series thereof as a BDC for this purpose) and any limited partner holding 5% or more of the relevant limited partner interests that would be a Close Affiliate but for the exclusion in that definition.

6. *Standard Review Dispositions.*

(a) *General.* If any Regulated Fund or Affiliated Fund elects to sell, exchange or otherwise dispose of an interest in a security and one or more Regulated Funds and Affiliated Funds have previously participated in a Co-Investment Transaction with respect to the issuer, then:

(i) The Adviser to such Regulated Fund or Affiliated Fund²⁷ will notify each Regulated Fund that holds an investment in the issuer of the proposed Disposition at the earliest practical time; and

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to participation by such Regulated Fund in the Disposition.

(b) *Same Terms and Conditions.* Each Regulated Fund will have the right to participate in such Disposition on a proportionate basis, at the same price and on the same terms and conditions as those applicable to the Affiliated Funds and any other Regulated Fund.

(c) *No Board Approval Required.* A Regulated Fund may participate in such a Disposition without obtaining prior approval of the Required Majority if:

(i)(A) The participation of each Regulated Fund and Affiliated Fund in such Disposition is proportionate to its then-current holding of the security (or securities) of the issuer that is (or are) the subject of the Disposition;²⁸ (B) the Board of the Regulated Fund has approved as being in the best interests of the Regulated Fund the ability to participate in such Dispositions on a pro rata basis (as described in greater detail in the application); and (C) the Board of the Regulated Fund is provided on a quarterly basis with a list of all Dispositions made in accordance with this Condition; or

(ii) each security is a Tradable Security and (A) the Disposition is not to the issuer or any affiliated person of the issuer; and (B) the security is sold for cash in a transaction in which the only term negotiated by or on behalf of the participating Regulated Funds and Affiliated Funds is price.

(d) *Standard Board Approval.* In all other cases, the Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors and the Regulated

²⁷ Any Stellus Proprietary Account that is not advised by an Adviser is itself deemed to be an Adviser for purposes of conditions 6(a)(i), 7(a)(i), 8(a)(i) and 9(a)(i).

²⁸ In the case of any Disposition, proportionality will be measured by each participating Regulated Fund's and Affiliated Fund's outstanding investment in the security in question immediately preceding the Disposition.

Fund will participate in such Disposition solely to the extent that a Required Majority determines that it is in the Regulated Fund's best interests.

7. *Enhanced Review Dispositions.*

(a) *General.* If any Regulated Fund or Affiliated Fund elects to sell, exchange or otherwise dispose of a Pre-Boarding Investment in a Potential Co-Investment Transaction and the Regulated Funds and Affiliated Funds have not previously participated in a Co-Investment Transaction with respect to the issuer:

(i) The Adviser to such Regulated Fund or Affiliated Fund will notify each Regulated Fund that holds an investment in the issuer of the proposed Disposition at the earliest practical time;

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to participation by such Regulated Fund in the Disposition; and

(iii) the Advisers will provide to the Board of each Regulated Fund that holds an investment in the issuer all information relating to the existing investments in the issuer of the Regulated Funds and Affiliated Funds, including the terms of such investments and how they were made, that is necessary for the Required Majority to make the findings required by this Condition.

(b) *Enhanced Board Approval.* The Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors, and the Regulated Fund will participate in such Disposition solely to the extent that a Required Majority determines that:

(i) The Disposition complies with Condition 2(c)(i), (ii), (iii)(A), and (iv); and

(ii) the making and holding of the Pre-Boarding Investments were not prohibited by section 57 or rule 17d-1, as applicable, and records the basis for the finding in the Board minutes.

(c) *Additional Requirements.* The Disposition may only be completed in reliance on the Order if:

(i) *Same Terms and Conditions.* Each Regulated Fund has the right to participate in such Disposition on a proportionate basis, at the same price and on the same terms and conditions as those applicable to the Affiliated Funds and any other Regulated Fund;

(ii) *Original Investments.* All of the Affiliated Funds' and Regulated Funds' investments in the issuer are Pre-Boarding Investments;

(iii) *Advice of counsel.* Independent counsel to the Board advises that the making and holding of the investments in the Pre-Boarding Investments were

not prohibited by section 57 (as modified by rule 57b-1) or rule 17d-1, as applicable;

(iv) *Multiple Classes of Securities.* All Regulated Funds and Affiliated Funds that hold Pre-Boarding Investments in the issuer immediately before the time of completion of the Co-Investment Transaction hold the same security or securities of the issuer. For the purpose of determining whether the Regulated Funds and Affiliated Funds hold the same security or securities, they may disregard any security held by some but not all of them if, prior to relying on the Order, the Required Majority is presented with all information necessary to make a finding, and finds, that: (x) Any Regulated Fund's or Affiliated Fund's holding of a different class of securities (including for this purpose a security with a different maturity date) is immaterial²⁹ in amount, including immaterial relative to the size of the issuer; and (y) the Board records the basis for any such finding in its minutes. In addition, securities that differ only in respect of issuance date, currency, or denominations may be treated as the same security; and

(v) *No control.* The Affiliated Funds, the other Regulated Funds and their affiliated persons (within the meaning of section 2(a)(3)(C) of the Act), individually or in the aggregate, do not control the issuer of the securities (within the meaning of section 2(a)(9) of the Act).

8. *Standard Review Follow-Ons.*

(a) *General.* If any Regulated Fund or Affiliated Fund desires to make a Follow-On Investment in an issuer and the Regulated Funds and Affiliated Funds holding investments in the issuer previously participated in a Co-Investment Transaction with respect to the issuer:

(i) The Adviser to each such Regulated Fund or Affiliated Fund will notify each Regulated Fund that holds securities of the portfolio company of the proposed transaction at the earliest practical time; and

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to the proposed participation, including the amount of the proposed investment, by such Regulated Fund.

(b) *No Board Approval Required.* A Regulated Fund may participate in the

Follow-On Investment without obtaining prior approval of the Required Majority if:

(i)(A) The proposed participation of each Regulated Fund and each Affiliated Fund in such investment is proportionate to its outstanding investments in the issuer or the security at issue, as appropriate,³⁰ immediately preceding the Follow-On Investment; and (B) the Board of the Regulated Fund has approved as being in the best interests of the Regulated Fund the ability to participate in Follow-On Investments on a pro rata basis (as described in greater detail in the application); or

(ii) it is a Non-Negotiated Follow-On Investment.

(c) *Standard Board Approval.* In all other cases, the Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors and the Regulated Fund will participate in such Follow-On Investment solely to the extent that a Required Majority makes the determinations set forth in Condition 2(c). If the only previous Co-Investment Transaction with respect to the issuer was an Enhanced Review Disposition the Eligible Directors must complete this review of the proposed Follow-On Investment both on a stand-alone basis and together with the Pre-Boarding Investments in relation to the total economic exposure and other terms of the investment.

(d) *Allocation.* If, with respect to any such Follow-On Investment:

(i) The amount of the opportunity proposed to be made available to any Regulated Fund is not based on the Regulated Funds' and the Affiliated Funds' outstanding investments in the issuer or the security at issue, as appropriate, immediately preceding the Follow-On Investment; and

(ii) the aggregate amount recommended by the Advisers to be invested in the Follow-On Investment by the participating Regulated Funds and any participating Affiliated Funds,

collectively, exceeds the amount of the investment opportunity, then the Follow-On Investment opportunity will be allocated among them *pro rata* based on the size of the Internal Orders, as described in section III.A.1.b. of the application.

(e) *Other Conditions.* The acquisition of Follow-On Investments as permitted by this Condition will be considered a Co-Investment Transaction for all purposes and subject to the other Conditions set forth in the application.

9. *Enhanced Review Follow-Ons.*

(a) *General.* If any Regulated Fund or Affiliated Fund desires to make a Follow-On Investment in an issuer that is a Potential Co-Investment Transaction and the Regulated Funds and Affiliated Funds holding investments in the issuer have not previously participated in a Co-Investment Transaction with respect to the issuer:

(i) The Adviser to each such Regulated Fund or Affiliated Fund will notify each Regulated Fund that holds securities of the portfolio company of the proposed transaction at the earliest practical time;

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to the proposed participation, including the amount of the proposed investment, by such Regulated Fund; and

(iii) the Advisers will provide to the Board of each Regulated Fund that holds an investment in the issuer all information relating to the existing investments in the issuer of the Regulated Funds and Affiliated Funds, including the terms of such investments and how they were made, that is necessary for the Required Majority to make the findings required by this Condition.

(b) *Enhanced Board Approval.* The Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors, and the Regulated Fund will participate in such Follow-On Investment solely to the extent that a Required Majority reviews the proposed Follow-On Investment both on a stand-alone basis and together with the Pre-Boarding Investments in relation to the total economic exposure and other terms and makes the determinations set forth in Condition 2(c). In addition, the Follow-On Investment may only be completed in reliance on the Order if the Required Majority of each participating Regulated Fund determines that the making and holding of the Pre-Boarding Investments were not prohibited by section 57 (as modified by rule 57b-1) or rule 17d-1,

²⁹ In determining whether a holding is "immaterial" for purposes of the Order, the Required Majority will consider whether the nature and extent of the interest in the transaction or arrangement is sufficiently small that a reasonable person would not believe that the interest affected the determination of whether to enter into the transaction or arrangement or the terms of the transaction or arrangement.

³⁰ To the extent that a Follow-On Investment opportunity is in a security or arises in respect of a security held by the participating Regulated Funds and Affiliated Funds, proportionality will be measured by each participating Regulated Fund's and Affiliated Fund's outstanding investment in the security in question immediately preceding the Follow-On Investment using the most recent available valuation thereof. To the extent that a Follow-On Investment opportunity relates to an opportunity to invest in a security that is not in respect of any security held by any of the participating Regulated Funds or Affiliated Funds, proportionality will be measured by each participating Regulated Fund's and Affiliated Fund's outstanding investment in the issuer immediately preceding the Follow-On Investment using the most recent available valuation thereof.

as applicable. The basis for the Board's findings will be recorded in its minutes.

(c) *Additional Requirements.* The Follow-On Investment may only be completed in reliance on the Order if:

(i) *Original Investments.* All of the Affiliated Funds' and Regulated Funds' investments in the issuer are Pre-Boarding Investments;

(ii) *Advice of counsel.* Independent counsel to the Board advises that the making and holding of the investments in the Pre-Boarding Investments were not prohibited by section 57 (as modified by rule 57b-1) or rule 17d-1, as applicable;

(iii) *Multiple Classes of Securities.* All Regulated Funds and Affiliated Funds that hold Pre-Boarding Investments in the issuer immediately before the time of completion of the Co-Investment Transaction hold the same security or securities of the issuer. For the purpose of determining whether the Regulated Funds and Affiliated Funds hold the same security or securities, they may disregard any security held by some but not all of them if, prior to relying on the Order, the Required Majority is presented with all information necessary to make a finding, and finds, that: (x) Any Regulated Fund's or Affiliated Fund's holding of a different class of securities (including for this purpose a security with a different maturity date) is immaterial in amount, including immaterial relative to the size of the issuer; and (y) the Board records the basis for any such finding in its minutes. In addition, securities that differ only in respect of issuance date, currency, or denominations may be treated as the same security; and

(iv) *No control.* The Affiliated Funds, the other Regulated Funds and their affiliated persons (within the meaning of section 2(a)(3)(C) of the Act), individually or in the aggregate, do not control the issuer of the securities (within the meaning of section 2(a)(9) of the Act).

(d) *Allocation.* If, with respect to any such Follow-On Investment:

(i) The amount of the opportunity proposed to be made available to any Regulated Fund is not based on the Regulated Funds' and the Affiliated Funds' outstanding investments in the issuer or the security at issue, as appropriate, immediately preceding the Follow-On Investment; and

(ii) the aggregate amount recommended by the Advisers to be invested in the Follow-On Investment by the participating Regulated Funds and any participating Affiliated Funds, collectively, exceeds the amount of the investment opportunity,

then the Follow-On Investment opportunity will be allocated among them pro rata based on the size of the Internal Orders, as described in section III.A.1.b. of the application.

(e) *Other Conditions.* The acquisition of Follow-On Investments as permitted by this Condition will be considered a Co-Investment Transaction for all purposes and subject to the other Conditions set forth in the application.

10. *Board Reporting, Compliance and Annual Re-Approval.*

(a) Each Adviser to a Regulated Fund will present to the Board of each Regulated Fund, on a quarterly basis, and at such other times as the Board may request, (i) a record of all investments in Potential Co-Investment Transactions made by any of the other Regulated Funds or any of the Affiliated Funds during the preceding quarter that fell within the Regulated Fund's then-current Objectives and Strategies and Board-Established Criteria that were not made available to the Regulated Fund, and an explanation of why such investment opportunities were not made available to the Regulated Fund; (ii) a record of all Follow-On Investments in and Dispositions of investments in any issuer in which the Regulated Fund holds any investments by any Affiliated Fund or other Regulated Fund during the prior quarter; and (iii) all information concerning Potential Co-Investment Transactions and Co-Investment Transactions, including investments made by other Regulated Funds or Affiliated Funds that the Regulated Fund considered but declined to participate in, so that the Independent Directors, may determine whether all Potential Co-Investment Transactions and Co-Investment Transactions during the preceding quarter, including those investments that the Regulated Fund considered but declined to participate in, comply with the Conditions.

(b) All information presented to the Regulated Fund's Board pursuant to this Condition will be kept for the life of the Regulated Fund and at least two years thereafter, and will be subject to examination by the Commission and its staff.

(c) Each Regulated Fund's chief compliance officer, as defined in rule 38a-1(a)(4), will prepare an annual report for its Board each year that evaluates (and documents the basis of that evaluation) the Regulated Fund's compliance with the terms and Conditions of the application and the procedures established to achieve such compliance.

(d) The Independent Directors will consider at least annually whether

continued participation in new and existing Co-Investment Transactions is in the Regulated Fund's best interests.

11. *Record Keeping.* Each Regulated Fund will maintain the records required by section 57(f)(3) of the Act as if each of the Regulated Funds were a BDC and each of the investments permitted under these Conditions were approved by the Required Majority under section 57(f).

12. *Director Independence.* No Independent Director of a Regulated Fund will also be a director, general partner, managing member or principal, or otherwise be an "affiliated person" (as defined in the Act) of any Affiliated Fund.

13. *Expenses.* The expenses, if any, associated with acquiring, holding or disposing of any securities acquired in a Co-Investment Transaction (including, without limitation, the expenses of the distribution of any such securities registered for sale under the Securities Act) will, to the extent not payable by the Advisers under their respective advisory agreements with the Regulated Funds and the Affiliated Funds, be shared by the Regulated Funds and the participating Affiliated Funds in proportion to the relative amounts of the securities held or being acquired or disposed of, as the case may be.

14. *Transaction Fees.*³¹ Any transaction fee (including break-up, structuring, monitoring or commitment fees but excluding brokerage or underwriting compensation permitted by section 17(e) or 57(k)) received in connection with any Co-Investment Transaction will be distributed to the participants on a pro rata basis based on the amounts they invested or committed, as the case may be, in such Co-Investment Transaction. If any transaction fee is to be held by an Adviser pending consummation of the transaction, the fee will be deposited into an account maintained by an Adviser at a bank or banks having the qualifications prescribed in section 26(a)(1), and the account will earn a competitive rate of interest that will also be divided pro rata among the participants. None of the Adviser, the Affiliated Funds, the other Regulated Funds or any affiliated person of the Affiliated Funds or the Regulated Funds will receive any additional compensation or remuneration of any kind as a result of or in connection with a Co-Investment Transaction other than (i) in the case of the Regulated Funds and the Affiliated Funds, the pro rata

³¹ Applicants are not requesting and the Commission is not providing any relief for transaction fees received in connection with any Co-Investment Transaction.

transaction fees described above and fees or other compensation described in Condition 2(c)(iii)(B)(z), (ii) brokerage or underwriting compensation permitted by section 17(e) or 57(k) or (iii) in the case of the Adviser, investment advisory compensation paid in accordance with investment advisory agreements Fund(s) or Affiliated Fund(s) and its Adviser.

15. *Independence.* If the Holders own in the aggregate more than 25 percent of the Shares of a Regulated Fund, then the Holders will vote such Shares as directed by an independent third party when voting on (1) the election of directors; (2) the removal of one or more directors; or (3) any other matter under either the Act or applicable State law affecting the Board's composition, size or manner of election.

16. *Proprietary Accounts.* The Stellus Proprietary Accounts will not be permitted to invest in a Potential Co-Investment Transaction except to the extent the aggregate demand from the Regulated Funds and the other Affiliated Funds is less than the total investment opportunity.

For the Commission, by the Division of Investment Management, under delegated authority.

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018-24635 Filed 11-9-18; 8:45 am]

BILLING CODE 8011-01-P

TENNESSEE VALLEY AUTHORITY

Sunshine Act Meeting Notice; Meeting No. 18-04

The TVA Board of Directors will hold a public meeting on November 14, 2018, in the Bancorp South Conference Center, 387 East Main Street, Tupelo, Mississippi. The meeting will be called to order at 9:30 a.m. CT to consider the agenda items listed below. TVA management will answer questions from the news media following the Board meeting.

On November 13, the public may comment on any agenda item or subject at a board-hosted *public listening session* which begins at 2:30 p.m. CT and will last until 4:30 p.m. Preregistration is required to address the Board.

Status: Open.

Agenda

1. Approval of minutes of the August 22, 2018, Board Meeting
2. Report from President and CEO
3. Report of the Finance, Rates, and Portfolio Committee

4. Report of the People and Performance Committee
 - A. Fiscal Year 2018 Performance and Compensation
 - B. CEO Compensation for Fiscal Year 2019
5. Report of the Audit, Risk, and Regulation Committee
 - A. Regulatory Assets
6. Report of the External Relations Committee
7. Report of the Nuclear Oversight Committee

For more information: Please call TVA Media Relations at (865) 632-6000, Knoxville, Tennessee. People who plan to attend the meeting and have special needs should call (865) 632-6000.

Anyone who wishes to comment on any of the agenda in writing may send their comments to: TVA Board of Directors, Board Agenda Comments, 400 West Summit Hill Drive, Knoxville, Tennessee 37902.

Dated: November 7, 2018.

Sherry A. Quirk,
General Counsel.

[FR Doc. 2018-24842 Filed 11-8-18; 4:15 pm]

BILLING CODE 8120-08-P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Comment Request; Leveraged Lending

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to take this opportunity to comment on a continuing information collection as required by the Paperwork Reduction Act of 1995 (PRA).

In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and respondents are not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The OCC is soliciting comment concerning the renewal of its information collection titled "Leveraged Lending."

DATES: Comments must be received by January 14, 2019.

ADDRESSES: Commenters are encouraged to submit comments by email, if

possible. You may submit comments by any of the following methods:

- *Email:* prainfo@occ.treas.gov.
- *Mail:* Legislative and Regulatory

Activities Division, Office of the Comptroller of the Currency, Attention: 1557-0315, 400 7th Street SW, Suite 3E-218, Washington, DC 20219.

- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E-218, Washington, DC 20219.

Instructions: You must include "OCC" as the agency name and "1557-0315" in your comment. In general, the OCC will publish comments on www.reginfo.gov without change, including any business or personal information that you provide, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice for this collection¹ by any of the following methods:

- *Viewing Comments Electronically:*

Go to www.reginfo.gov. Click on the "Information Collection Review" tab. Underneath the "Currently under Review" section heading, from the drop-down menu, select "Department of Treasury" and then click "submit." This information collection can be located by searching by OMB control number "1557-0315" or "Leveraged Lending." Upon finding the appropriate information collection, click on the related "ICR Reference Number." On the next screen, select "View Supporting Statement and Other Documents" and then click on the link to any comment listed at the bottom of the screen.

- For assistance in navigating www.reginfo.gov, please contact the Regulatory Information Service Center at (202) 482-7340.

- *Viewing Comments Personally:* You may personally inspect comments at the OCC, 400 7th Street SW, Washington, DC. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649-6700 or, for persons who are deaf or hearing impaired, TTY, (202) 649-5597. Upon arrival, visitors will be required to

¹ Following the close of the 60-Day comment period for this notice, the OCC will publish a notice for 30 days of comment for this collection.

present valid government-issued photo identification and submit to security screening in order to inspect comments.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, Clearance Officer, (202) 649-5490 or, for persons who are deaf or hearing impaired, TTY, (202) 649-5597, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include Agency recommendations, requests, or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of title 44 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the OCC is publishing notice of the proposed collection of information set forth in this document.

Title: Leveraged Lending.

OMB Control No.: 1557-0315.

Description: On March 22, 2013, the agencies² issued guidance to the financial institutions they supervise³ on how to evaluate and monitor credit risks in leveraged loans, understand the effect of changes in borrowers' enterprise values on credit portfolio quality, and assess the sensitivity of future credit losses to these changes in enterprise values.⁴ In regard to the underwriting of such credits, the guidance provides information for financial institutions to consider in assessing whether borrowers have the ability to repay credits when due and whether borrowers have sustainable capital structures, including bank borrowings and other debt, to support their continued operations through economic cycles. The guidance also provides information to financial institutions on the risks and potential impact of stressful events and circumstances on a borrower's financial condition.

The final guidance recommends that financial institutions consider

developing: (i) Underwriting policies for leveraged lending, including stress-testing procedures for leveraged credits; (ii) risk management policies, including stress-testing procedures for pipeline exposures; and, (iii) policies and procedures for incorporating the results of leveraged credit and pipeline stress tests into the firm's overall stress-testing framework. While not requirements, these recommended policies qualify as "collections of information" as defined in the PRA.

Respondents are financial institutions with leveraged lending activities as defined in the guidance that may develop policies recommended in the guidance.

Title: Guidance on Leveraged Lending.

OMB Control No.: 1557-0315.

Frequency of Response: Annual.

Affected Public: Financial institutions with leveraged lending.

Burden Estimates:

Estimated number of respondents: 29.

Estimated total annual burden: 39,162 hours to build; 49,462 hours for ongoing use.

Total estimated annual burden: 88,624 hours.

Comments submitted in response to this notice will be summarized, included in the request for OMB approval, and become a matter of public record. Comments are invited on:

(a) Whether the information collections are necessary for the proper performance of the OCC's functions, including whether the information has practical utility;

(b) The accuracy of the OCC's estimates of the burden of the information collections, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of information collections on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: November 6, 2018.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2018-24616 Filed 11-9-18; 8:45 am]

BILLING CODE 4810-33-P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities; Information Collection Renewal; Comment Request; Fiduciary Activities

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to take this opportunity to comment on a continuing information collection as required by the Paperwork Reduction Act of 1995 (PRA).

An agency may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid OMB control number.

The OCC is soliciting comment concerning the renewal of its information collection titled, "Fiduciary Activities."

DATES: You should submit written comments by January 14, 2019.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

• *Email:* prainfo@occ.treas.gov.

• *Mail:* Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557-0140, 400 7th Street SW, Suite 3E-218, Washington, DC 20219.

• *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E-218, Washington, DC 20219.

• *Fax:* (571) 465-4326.

Instructions: You must include "OCC" as the agency name and "1557-0140" in your comment. In general, the OCC will publish your comment on www.reginfo.gov without change, including any business or personal information that you provide, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice

² OCC, Board of Governors of the Federal Reserve System, and Federal Deposit Insurance Corporation.

³ For the OCC, the term "financial institution" or "institution" includes national banks, federal savings associations, and federal branches and agencies supervised by the OCC.

⁴ 78 FR 17766 (March 22, 2013).

for this collection¹ by any of the following methods:

- *Viewing Comments Electronically:* Go to www.reginfo.gov. Click on the “Information Collection Review” tab. Underneath the “Currently under Review” section heading, from the drop-down menu, select “Department of Treasury” and then click “submit.” This information collection can be located by searching by OMB control number “1557–0140” or “Fiduciary Activities.” Upon finding the appropriate information collection, click on the related “ICR Reference Number.” On the next screen, select “View Supporting Statement and Other Documents” and then click on the link to any comment listed at the bottom of the screen.

- For assistance in navigating www.reginfo.gov, please contact the Regulatory Information Service Center at (202) 482–7340.

- *Viewing Comments Personally:* You may personally inspect comments at the OCC, 400 7th Street SW, Washington, DC. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect comments.

FOR FURTHER INFORMATION CONTACT:

Shaquita Merritt, Clearance Officer, (202) 649–5490 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597, Chief Counsel’s Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests and requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of part 44 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the OCC is publishing notice of the proposed

extension of this collection of information.

Title: Fiduciary Activities.

OMB Control No.: 1557–0140.

Description: The OCC regulates the fiduciary activities of national banks and federal savings associations (FSAs), including the administration of collective investment funds (CIFs), pursuant to 12 U.S.C. 92a and 12 U.S.C. 1464(n), respectively. Twelve CFR part 9 contains the regulations that national banks must follow when conducting fiduciary activities, and 12 CFR part 150 contains the regulations that FSAs must follow when conducting fiduciary activities. Regulations adopted by the former Office of Thrift Supervision, now recodified as OCC rules pursuant to Title III of the Dodd-Frank Wall Street Reform and Consumer Protection Act,² have long required FSAs to comply with the requirements of the OCC’s CIF regulation.³ Thus, 12 CFR 9.18 governs CIFs managed by both national banks and FSAs.

Twelve CFR 9.8 and 150.410–150.430 require that national banks and FSAs document the establishment and termination of each fiduciary account and maintain adequate records. Records must be retained for a period of three years from the later of the termination of the account or the termination of any litigation. The records must be separate and distinct from other records of the institution.

Twelve CFR 9.9 and 12 CFR 150.480 require national banks and FSAs to note the results of any audit conducted (including significant actions taken as a result of the audit) in the minutes of the board of directors. National banks and FSAs that adopt a continuous audit system must note the results of all discrete audits performed since the last audit report (including significant actions taken as a result of the audits) in the minutes of the board of directors at least once during each calendar year.

Twelve CFR 9.17(a) and 150.530 require that a national bank or FSA seeking to surrender its fiduciary powers file with the OCC a certified copy of the resolution of its board of directors evidencing that intent.

Twelve CFR 9.18(b)(1) (and 12 CFR 150.260 by cross-reference) require national banks and FSAs to establish and maintain each CIF in accordance with a written plan approved by the board of directors or a committee authorized by the board. The plan must include provisions relating to:

- Investment powers and policies with respect to the fund;

- Allocation of income, profits, and losses;
- Fees and expenses that will be charged to the fund and to participating accounts;
- Terms and conditions regarding admission and withdrawal of participating accounts;
- Audits of participating accounts;
- Basis and method of valuing assets in the fund;
- Expected frequency for income distribution to participating accounts;
- Minimum frequency for valuation of fund assets;
- Amount of time following a valuation date during which the valuation must be made;
- Bases upon which the institution may terminate the fund; and
- Any other matters necessary to define clearly the rights of participating accounts.

Twelve CFR 9.18(b)(1) (and 150.260 by cross-reference) require that a national bank or FSA make a copy of any CIF plan available for public inspection at its main office and provide a copy of the plan to any person who requests it.

Twelve CFR 9.18(b)(4)(iii)(E) (and 150.260 by cross-reference) require that national banks and FSAs adopt portfolio and issuer qualitative standards and concentration restrictions for short-term investment funds (STIFs), a type of CIF.

Twelve CFR 9.18(b)(4)(iii)(F) (and 150.260 by cross-reference) require that national banks and FSAs adopt liquidity standards and include provisions that address contingency funding needs for STIFs.

Twelve CFR 9.18(b)(4)(iii)(G) (and 150.260 by cross-reference) require that national banks and FSAs adopt shadow pricing procedures for STIFs that calculate the extent of difference, if any, of the mark-to-market net asset value per participating interest from the STIF’s amortized cost per participating interest, and to take certain actions if that difference exceeds \$0.005 per participating interest.

Twelve CFR 9.18(b)(4)(iii)(H) (and 150.260 by cross-reference) require that national banks and FSAs adopt, for STIFs, procedures for stress testing the STIF’s ability to maintain a stable net asset value per participating interest and provide for reporting the results.

Twelve CFR 9.18(b)(4)(iii)(I) (and 150.260 by cross-reference) require that national banks and FSAs adopt, for STIFs, procedures that require a national bank or FSA to disclose to the OCC and to STIF participants within five business days after each calendar month-end the following information about the fund: Total assets under

¹ Following the close of the 60-Day comment period for this notice, the OCC will publish a notice for 30 days of comment for this collection.

² 76 FR 48950 (August 9, 2011).

³ See 12 CFR 150.260(b)(3).

management; mark-to-market and amortized cost net asset values; dollar-weighted average portfolio maturity; dollar-weighted average portfolio life maturity as of the last business day of the prior calendar month; and certain other security-level information for each security held.

Twelve CFR 9.18(b)(4)(iii)(J) (and 150.260 by cross-reference) require that national banks and FSAs adopt, for STIFs, procedures that require a national bank or FSA that manages a STIF to notify the OCC prior to or within one business day thereafter of certain events.

Twelve CFR 9.18(b)(4)(iii)(K) (and 150.260 by cross-reference) require that national banks and FSAs adopt, for STIFs, certain procedures in the event that the STIF has repriced its net asset value below \$0.995 per participating interest.

Twelve CFR 9.18(b)(4)(iii)(L) (and 150.260 by cross-reference) require that national banks and FSAs adopt, for STIFs, procedures for initiating liquidation of a STIF upon the suspension or limitation of withdrawals as a result of redemptions.

Twelve CFR 9.18(b)(6)(ii) (and 150.260 by cross-reference) require, for CIFs, that national banks and FSAs, at least once during each 12-month period, prepare a financial report of the fund based on the audit required by 12 CFR 9.18(b)(6)(i). The report must disclose the fund's fees and expenses in a manner consistent with applicable state law in the state in which the national bank or FSA maintains the fund and must contain:

- A list of investments in the fund showing the cost and current market value of each investment;
- A statement covering the period after the previous report showing the following (organized by type of investment):
 - A summary of purchases (with costs);
 - A summary of sales (with profit or loss and any investment change);
 - Income and disbursements; and
 - An appropriate notation of any investments in default.

Twelve CFR 9.18(b)(6)(iv) (and 150.260 by cross-reference) require that a national bank or FSA managing a CIF provide a copy of the financial report, or provide notice that a copy of the report is available upon request without charge, to each person who ordinarily would receive a regular periodic accounting with respect to each participating account. The national bank or FSA may provide a copy to prospective customers. In addition, the national bank or FSA must provide a

copy of the report upon request to any person for a reasonable charge.

Twelve CFR 9.18(c)(5) (and 150.260 by cross-reference) require that, for special exemption CIFs, national banks and FSAs must submit to the OCC a written plan that sets forth:

- The reason the proposed fund requires a special exemption;
- The provisions of the fund that are inconsistent with 12 CFR 9.18(a) and (b);
- The provisions of 12 CFR 9.18(b) for which the national bank or FSA seeks an exemption; and
- The manner in which the proposed fund addresses the rights and interests of participating accounts.

Type of Review: Regular.

Affected Public: Businesses or other for-profit.

Estimated Number of Respondents: 320.

Frequency of Response: On occasion.

Estimated Total Annual Burden: 115,125 hours.

Comments submitted in response to this notice will be summarized, included in the request for OMB approval, and become a matter of public record. Comments are invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: November 6, 2018.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2018-24612 Filed 11-9-18; 8:45 am]

BILLING CODE 4810-33-P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Request for Comment; Identity Theft Red Flags and Address Discrepancies Under the Fair and Accurate Credit Transactions Act of 2003

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to take this opportunity to comment on a continuing information collection as required by the Paperwork Reduction Act of 1995 (PRA).

An agency may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid OMB control number.

The OCC is soliciting comment concerning the renewal of its information collection titled, "Identity Theft Red Flags and Address Discrepancies under the Fair and Accurate Credit Transactions Act of 2003."

DATES: Comments must be received by January 14, 2019.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email:* prainfo@occ.treas.gov.
- *Mail:* Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557-0237, 400 7th Street SW, Suite 3E-218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E-218, Washington, DC 20219.
- *Fax:* (571) 465-4326.

Instructions: You must include "OCC" as the agency name and "1557-0237" in your comment. In general, the OCC will publish your comment on www.reginfo.gov without change, including any business or personal information that you provide, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that

you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice for this collection¹ by any of the following methods:

- *Viewing Comments Electronically:* Go to www.reginfo.gov. Click on the "Information Collection Review" tab. Underneath the "Currently under Review" section heading, from the drop-down menu, select "Department of Treasury" and then click "submit." This information collection can be located by searching by OMB control number "1557-0237" or "Identity Theft Red Flags and Address Discrepancies under the Fair and Accurate Credit Transactions Act of 2003." Upon finding the appropriate information collection, click on the related "ICR Reference Number." On the next screen, select "View Supporting Statement and Other Documents" and then click on the link to any comment listed at the bottom of the screen.

- For assistance in navigating www.reginfo.gov, please contact the Regulatory Information Service Center at (202) 482-7340.

- *Viewing Comments Personally:* You may personally inspect comments at the OCC, 400 7th Street SW, Washington, DC. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649-6700 or, for persons who are deaf or hearing impaired, TTY, (202) 649-5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect comments.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, Clearance Officer, (202) 649-5490 or, for persons who are deaf or hearing impaired, TTY, (202) 649-5597, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests and requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of part 44 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to provide a

60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the OCC is publishing notice of the proposed extension of this collection of information.

Title: Identity Theft Red Flags and Address Discrepancies under the Fair and Accurate Credit Transactions Act of 2003.

OMB Control No.: 1557-0237.

Description: Section 114 of the Fair and Accurate Credit Transactions Act of 2003 (FACT Act)² amended section 615 of the Fair Credit Reporting Act (FCRA)³ to require the Agencies⁴ to issue jointly:

- Guidelines for financial institutions and creditors regarding identity theft with respect to their account holders and customers; (in developing the guidelines, the Agencies are required to identify patterns, practices, and specific forms of activity that indicate the possible existence of identity theft; the guidelines must be updated as often as necessary and must be consistent with the policies and procedures required under section 326 of the USA PATRIOT Act, (31 U.S.C. 5318(l));

- Regulations that require each financial institution and each creditor to establish reasonable policies and procedures for implementing the guidelines in order to identify possible risks to account holders or customers or to the safety and soundness of the institution or creditor; and

- Regulations generally requiring credit and debit card issuers to assess the validity of change of address requests under certain circumstances.

Section 315 of the FACT Act also amended section 605 of FCRA to require the Agencies to issue regulations providing guidance regarding what reasonable policies and procedures a user of consumer reports must have in place and employ when a user receives a notice of address discrepancy from a consumer reporting agency (CRA).

² 15 U.S.C. 1681m(e).

³ 15 U.S.C. 1681m.

⁴ Section 114 required the guidelines and regulations to be issued jointly by the federal banking agencies (OCC, Board of Governors of the Federal Reserve System, and Federal Deposit Insurance Corporation), the National Credit Union Administration, and the Federal Trade Commission. Therefore, for purposes of this filing, "Agencies" refers to these entities. Note that Section 1088(a)(8) of the Dodd-Frank Act further amended section 615 of FCRA to also require the Securities and Exchange Commission and the Commodity Futures Trading Commission to issue Red Flags guidelines and regulations.

These regulations are required to describe reasonable policies and procedures for users of consumer reports to:

- Enable a user to form a reasonable belief that it knows the identity of the person for whom it has obtained a consumer report; and
- Reconcile the address of the consumer with the CRA, if the user establishes a continuing relationship with the consumer and regularly and, in the ordinary course of business, furnishes information to the CRA.

As required by section 114 of the FACT Act, appendix J to 12 CFR part 41 contains guidelines for financial institutions and creditors to use in identifying patterns, practices, and specific forms of activity that may indicate the existence of identity theft. In addition, 12 CFR 41.90 requires each financial institution or creditor that is a national bank, federal savings association, federal branch or agency of a foreign bank, and any of their operating subsidiaries that are not functionally regulated, to establish an Identity Theft Prevention Program (Program) designed to detect, prevent, and mitigate identity theft in connection with accounts. Pursuant to § 41.91, credit card and debit card issuers must implement reasonable policies and procedures to assess the validity of a request for a change of address under certain circumstances.

Section 41.90 requires each OCC-regulated financial institution or creditor that offers or maintains one or more covered accounts to develop and implement a Program. In developing a Program, financial institutions and creditors are required to consider the guidelines in appendix J and include the suggested provisions, as appropriate. The initial Program must be approved by the institution's board of directors or by an appropriate committee thereof. The board, an appropriate committee thereof, or a designated employee at the level of senior management must be involved in the oversight of the Program. In addition, staff members must be trained to carry out the Program. Pursuant to § 41.91, each credit and debit card issuer is required to establish and implement policies and procedures to assess the validity of a change of address request if it is followed by a request for an additional or replacement card. Before issuing the additional or replacement card, the card issuer must notify the cardholder of the request and provide the cardholder a reasonable means to report incorrect address changes or use another means to assess the validity of the change of address.

¹ Following the close of the 60-day comment period for this notice, the OCC will publish a notice for 30 days of comment for this collection.

As required by section 315 of the FACT Act, § 1022.82⁵ requires users of consumer reports to have in place reasonable policies and procedures that must be followed when a user receives a notice of address discrepancy from a CRA.

Section 1022.82 requires each user of consumer reports to develop and implement reasonable policies and procedures designed to enable the user to form a reasonable belief that a consumer report relates to the consumer about whom it requested the report when it receives a notice of address discrepancy from a CRA. A user of consumer reports also must develop and implement reasonable policies and procedures for furnishing a customer address that the user has reasonably confirmed to be accurate to the CRA from which it receives a notice of address discrepancy when the user can: (1) Form a reasonable belief that the consumer report relates to the consumer about whom the user has requested the report; (2) establish a continuing relationship with the consumer; and (3) establish that it regularly and in the ordinary course of business furnishes information to the CRA from which it received the notice of address discrepancy.

Type of Review: Regular.

Affected Public: Individuals; Businesses or other for-profit.

Estimated Number of Respondents: 1,186.

Estimated Total Annual Burden: 132,007 hours.

Comments submitted in response to this notice will be summarized, included in the request for OMB approval, and become a matter of public record. Comments are invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including

through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: November 6, 2018.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2018-24615 Filed 11-9-18; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 4255

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Recapture of Investment Credit.

DATES: Written comments should be received on or before January 14, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Martha R. Brinson, at (202) 317-5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at Martha.R.Brinson@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Recapture of Investment Credit.

OMB Number: 1545-0166.

Form Number: 4255.

Abstract: Internal Revenue Code section 50(a) requires that a taxpayer's income tax be increased by the investment credit recapture tax if the taxpayer disposes of investment credit

property before the close of the recapture period used in figuring the original investment credit. Form 4255 provides for the computation of the recapture tax.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals, and farms.

Estimated Number of Respondents: 13,200.

Estimated Time per Respondent: 9 hrs. 49 min.

Estimated Total Annual Burden Hours: 129,492.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments will be of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: October 25, 2018.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2018-24666 Filed 11-9-18; 8:45 am]

BILLING CODE 4830-01-P

⁵ Title X of the Dodd-Frank Wall Street Reform and Consumer Protection Act transferred this regulation to the BCFP. The OCC retains enforcement authority for this regulation for institutions with \$10 billion in total assets or less.



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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 424, 484, et al.

Medicare and Medicaid Programs; CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; Home Infusion Therapy Requirements; and Training Requirements for Surveyors of National Accrediting Organizations; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Parts 409, 424, 484, 486, and 488****[CMS-1689-FC]****RIN 0938-AT29****Medicare and Medicaid Programs; CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; Home Infusion Therapy Requirements; and Training Requirements for Surveyors of National Accrediting Organizations****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule with comment period.

SUMMARY: This final rule with comment period updates the home health prospective payment system (HH PPS) payment rates, including the national, standardized 60-day episode payment rates, the national per-visit rates, and the non-routine medical supply (NRS) conversion factor, effective for home health episodes of care ending on or after January 1, 2019. This rule also: Updates the HH PPS case-mix weights for calendar year (CY) 2019 using the most current, complete data available at the time of rulemaking; discusses our efforts to monitor the potential impacts of the rebasing adjustments that were implemented in CYs 2014 through 2017; finalizes a rebasing of the HH market basket (which includes a decrease in the labor-related share); finalizes the methodology used to determine rural add-on payments for CYs 2019 through 2022, as required by section 50208 of the Bipartisan Budget Act of 2018 (Pub. L. 115-123) hereinafter referred to as the “BBA of 2018”; finalizes regulations text changes regarding certifying and recertifying patient eligibility for Medicare home health services; and finalizes the definition of “remote patient monitoring” and the recognition of the costs associated with it as allowable administrative costs.

This rule also summarizes the case-mix methodology refinements for home health services beginning on or after January 1, 2020, which includes the elimination of therapy thresholds for payment and a change in the unit of payment from a 60-day episode to a 30-day period, as mandated by section

51001 of the Bipartisan Budget Act of 2018. This rule also finalizes changes to the Home Health Value-Based Purchasing (HHVBP) Model. In addition, with respect to the Home Health Quality Reporting Program, this rule discusses the Meaningful Measures Initiative; finalizes the removal of seven measures to further the priorities of this initiative; discusses social risk factors and provides an update on implementation efforts for certain provisions of the IMPACT Act; and finalizes a regulatory text change regarding OASIS data.

For the home infusion therapy benefit, this rule finalizes health and safety standards that home infusion therapy suppliers must meet; finalizes an approval and oversight process for accrediting organizations (AOs) that accredit home infusion therapy suppliers; finalizes the implementation of temporary transitional payments for home infusion therapy services for CYs 2019 and 2020; and responds to the comments received regarding payment for home infusion therapy services for CY 2021 and subsequent years.

Lastly, in this rule, we are finalizing only one of the two new requirements we proposed to implement in the regulations for the oversight of AOs that accredit Medicare-certified providers and suppliers. More specifically, for reasons set out more fully in the section X. of this final rule with comment period, we have decided not to finalize our proposal to require that all surveyors for AOs that accredit Medicare-certified providers and suppliers take the same relevant and program-specific CMS online surveyor training that the State Agency surveyors are required to take.

However, we are finalizing our proposal to require that each AO must provide a written statement with their application to CMS, stating that if one of its fully accredited providers or suppliers, in good-standing, provides written notification that they wish to voluntarily withdraw from the AO’s CMS-approved accreditation program, the AO must continue the provider or supplier’s current accreditation until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

DATES:

Effective Date: This final rule with comment period is effective on January 1, 2019.

Implementation Date: The Patient-Driven Groupings Model (PDGM) case-mix methodology refinements and the change in the unit of payment from 60-

day episodes of care to 30-day periods of care will be for home health services (30-day periods of care) beginning on or after January 1, 2020.

Comment Date: To be assured consideration, comments on the definition of “infusion drug administration calendar day” at § 486.505 and discussed in section VI.D. of this final rule with comment period must be received at one of the addresses provided below, no later than 5 p.m. on December 31, 2018.

ADDRESSES: In commenting, please refer to file code CMS-1689-FC. 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-1689-FC, P.O. Box 8013, Baltimore, MD 21244-8013.

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-1689-FC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850. [Note: This zipcode for express mail or courier delivery only. This zipcode specifies the agency’s physical location.]

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

For general information about the Home Health Prospective Payment System (HH PPS), send your inquiry via email to: HomehealthPolicy@cms.hhs.gov.

For general information about home infusion payment, send your inquiry via email to: HomeInfusionPolicy@cms.hhs.gov.

For information about the Home Health Value-Based Purchasing (HHVBP) Model, send your inquiry via email to: HHVBPquestions@cms.hhs.gov.

For information about the Home Health Quality Reporting Program (HH QRP) contact: Joan Proctor, (410) 786-0949.

For information about home infusion therapy health and safety standards, contact: CAPT Jacqueline Leach, (410) 786-4282 or Sonia Swancy, (410) 786-8445.

For information about health infusion therapy accreditation and oversight, contact: Caroline Gallaher (410) 786-8705.

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://regulations.gov>. Follow the search instructions on that website to view public comments.

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I. Executive Summary

A. Purpose

1. Home Health Prospective Payment System (HH PPS)

This final rule with comment period updates the payment rates for home health agencies (HHAs) for calendar year (CY) 2019, as required under section 1895(b) of the Social Security Act (the Act). This rule also updates the case-mix weights under sections 1895(b)(4)(A)(i) and (b)(4)(B) of the Act for CY 2019. For home health services beginning on or after January 1, 2020, this rule finalizes case-mix methodology refinements, which eliminate the use of therapy thresholds for case-mix adjustment purposes; and changes the unit of payment from a 60-day episode

of care to a 30-day period of care, as mandated by section 51001 of the Bipartisan Budget Act of 2018 (hereinafter referred to as the “BBA of 2018”). This final rule with comment period also: Finalizes the methodology used to determine rural add-on payments for CYs 2019 through 2022, as required by section 50208 of the BBA of 2018; finalizes regulations text changes regarding certifying and recertifying patient eligibility for Medicare home health services under sections 1814(a) and 1835(a) of the Act; and finalizes our proposal on how to define “remote patient monitoring” under the Medicare home health benefit and include the costs of such monitoring as an allowable administrative costs. Lastly, this rule finalizes changes to the Home Health Value Based Purchasing (HHVBP) Model under the authority of section 1115A of the Act, and the Home Health Quality Reporting Program (HH QRP) requirements under the authority of section 1895(b)(3)(B)(v) of the Act.

2. Home Infusion Therapy Services

a. Payment for Home Infusion Therapy Services

This final rule with comment period establishes a transitional payment for home infusion therapy services for CYs 2019 and 2020, as required by section 50401 of the BBA of 2018. In addition, this rule finalizes health and safety standards for home infusion therapy and an accreditation and oversight process for qualified home infusion therapy suppliers.

b. Safety Standards for Home Infusion Therapy Services

This final rule with comment period implements health and safety standards for qualified home infusion therapy suppliers as required by section 5012 of the 21st Century Cures Act. These standards provide a foundation for ensuring patient safety and quality care by establishing requirements for the plan of care to be initiated and updated by a physician; 7-day-a-week, 24-hour-a-day access to services and remote monitoring; and patient education and training regarding their home infusion therapy care.

c. Accreditation of Home Infusion Therapy Suppliers

This final rule with comment period also implements regulations for the approval and oversight of AOs that accredit home infusion therapy suppliers.

B. Summary of the Major Provisions

1. Home Health Prospective Payment System (HH PPS)

In the CY 2015 HH PPS final rule (79 FR 66072), we finalized our proposal to recalibrate the case-mix weights every year with the most current and complete data available at the time of rulemaking. In section III.B. of this rule, we are recalibrating the HH PPS case-mix weights, using the most current cost and utilization data available, in a budget-neutral manner. In section III.C. of this rule, we are finalizing the rebasing of the home health market basket and updates to the payment rates under the HH PPS by the home health payment update percentage of 2.2 percent (using the 2016-based Home Health Agency (HHA) market basket update of 3.0 percent, minus 0.8 percentage point for multifactor productivity) as required by section 1895(b)(3)(B)(vi)(I) of the Act. Also in section III.C. of this final rule with comment period, we are finalizing a reduction in the labor-related share from 78.5 to 76.1 percent of total costs on account of the rebasing of the home health market basket. Lastly, in section III.C. of this rule, we update the CY 2019 home health wage index using FY 2015 hospital cost report data. In section III.D. of this final rule with comment period, we are finalizing a methodology for applying rural add-on payments for CYs 2019 through 2022, as required by section 50208 of the BBA of 2018. In section III.E. of this rule, we are finalizing a reduction to the fixed-dollar loss ratio from 0.55 to 0.51 for CY 2019 in order to increase outlier payments as a percentage of total payments so that this percentage is closer to, but no more than, 2.5 percent.

In section III.F. of this rule, we are finalizing case-mix methodology refinements and a change in the unit of payment from a 60-day episode of care to a 30-day period of care effective January 1, 2020 and in a budget neutral manner, as required by section 51001 of the BBA of 2018. The “Patient-Driven Groupings Model”, or PDGM, relies more heavily on clinical characteristics and other patient information to place patients into meaningful payment categories and eliminates the use of therapy service thresholds, as required by section 51001(a)(3) of the BBA of 2018, that are currently used to case-mix adjust payments under the HH PPS.

In section III.G. of this rule, we are finalizing regulation text changes at 42 CFR 424.22(b)(2) to eliminate the requirement that the certifying physician must estimate how much longer skilled services will be needed as part of the recertification statement. In

addition, in section III.G. of this rule, consistent with section 51002 of the BBA of 2018, we are finalizing a proposal to align the regulations text at § 424.22(c) with current subregulatory guidance to allow medical record documentation from the HHA to be used to support the basis for certification and/or recertification of home health eligibility, if certain requirements are met.

In section III.H. of this rule, we are finalizing our proposal to define “remote patient monitoring” under the Medicare home health benefit and changes to the regulations at § 409.46 to include costs of remote patient monitoring as allowable administrative costs.

2. Home Health Value Based Purchasing

In section IV. of this final rule with comment period, we are finalizing changes to the Home Health Value Based Purchasing (HHVBP) Model implemented January 1, 2016. Specifically, we are finalizing, beginning with performance year (PY) 4, the following policy changes: removal of two Outcome and Assessment Information Set (OASIS) based measures, Influenza Immunization Received for Current Flu Season and Pneumococcal Polysaccharide Vaccine Ever Received, from the set of applicable measures; replacement of three OASIS-based measures (Improvement in Ambulation- Locomotion, Improvement in Bed Transferring, and Improvement in Bathing) with two new composite measures on total normalized composite change in self-care and mobility; changes to how we calculate the Total Performance Scores by changing the weighting methodology for the OASIS-based, claims-based, and HHCAHPS measures; and a change to the scoring methodology by reducing the maximum amount of improvement points an HHA can earn, from 10 points to 9 points. We are also providing an update on the progress towards developing public reporting of performance under the HHVBP Model and providing a summary of public comments received in response to our solicitation of feedback on what information we should consider making publicly available in the future.

3. Home Health Quality Reporting Program

In section V. of this final rule with comment period, we are finalizing updates to our the Home Health (HH) Quality Reporting Program (QRP) by adopting eight measure removal factors, removing seven measures, and updating

our regulations to clarify that not all OASIS data are required for the HH QRP. We are also providing an update on the implementation of certain provisions of the IMPACT Act, and are finalizing our proposal to increase the number of years of data used to calculate the Medicare Spending per Beneficiary measure for purposes of display from 1 year to 2 years.

4. Home Infusion Therapy

In section VI.A. of this final rule with comment period, we discuss general background of home infusion therapy services and how this relates to the implementation of the new home infusion benefit. In section VI.B. of this final rule with comment period, we have finalized the addition of a new subpart I under the regulations at 42 CFR part 486 to incorporate health and safety requirements for home infusion therapy suppliers. These regulations provide a framework for CMS to approve home infusion therapy accreditation organizations. Subpart I includes General Provisions (Scope and Purpose, and Definitions) and Standards for Home Infusion Therapy (Plan of Care and Required Services). Section VI.D. of this final rule with comment period provides information on temporary transitional payments for home infusion therapy services for CYs 2019 and 2020 as mandated by section 50401 of the BBA of 2018, and responds to the comments received regarding issues such as the regulatory definition of “Infusion Drug Administration Calendar Day.”

In section VI.C. of this final rule with comment period, we discuss the requirements set forth in section 1861(iii)(3)(D)(III) of the Act, which mandates that suppliers of home infusion therapy receive accreditation from a CMS-approved accrediting organization (AO) in order to receive Medicare payment. The Secretary must designate AOs to accredit suppliers furnishing home infusion therapy not later than January 1, 2021. Qualified home infusion therapy suppliers are required to receive accreditation before receiving Medicare payment for services provided to Medicare beneficiaries.

Until now, no regulations have addressed the following elements of CMS’ approval and oversight of the AOs that accredit suppliers of home infusion therapy: (1) The required components to be included in a home infusion therapy AO’s initial or renewal accreditation program application; (2) regulations related to CMS’ review and approval of the home infusion therapy AOs application for approval of its accreditation program; and (3) the

ongoing monitoring and oversight of CMS approved home infusion therapy AOs. However, this final rule with comment period finalizes a set of regulations that will govern the CMS approval and oversight process for all home infusion therapy AOs.

In this final rule with comment period, we are not finalizing our proposal to modify 42 CFR 488.5 by adding a requirement that all surveyors, that work for AOs that accredit

Medicare certified providers and suppliers, must complete the relevant program specific CMS online trainings.

However, in this final rule with comment period, we are finalizing the proposed requirement to be added at § 488.5 which requires the AOs for Medicare certified providers and suppliers to provide a written statement with their application stating that if a fully accredited facility deemed to be in good-standing provides written

notification that they wish to voluntarily withdraw from the AO's CMS-approved accreditation program, the AO must continue the facility's current accreditation until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

C. Summary of Costs, Transfers, and Benefits

BILLING CODE 4120-01-P

TABLE 1: SUMMARY OF COSTS, TRANSFERS, AND BENEFITS

Provision Description	Costs and Cost Savings	Transfers	Benefits
CY 2019 HH PPS Payment Rate Update		The overall economic impact of the HH PPS payment rate update is an estimated \$420 million (2.2 percent) in increased payments to HHAs in CY 2019.	To ensure home health payments are consistent with statutory payment authority for CY 2019.
CY 2019 Temporary Transitional Payments for Home Infusion Therapy Services		The overall economic impact of the temporary transitional payment for home infusion therapy services is an estimated \$60 million in increased payments to home infusion therapy suppliers in CY 2019 (\$48 million in Medicare payments and \$12 million in beneficiary cost-sharing).	To ensure temporary transitional payments for home infusion therapy are consistent with statutory authority for CY 2019.
CY 2019 HHVBP Model		The overall economic impact of the HHVBP Model for CY 2018 through 2022 is an estimated \$378 million in total savings to Medicare from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the HH industry (none of which is attributable to the changes in this final rule with comment period). As for payments to HHAs, there are no aggregate increases or decreases expected to be applied to the HHAs competing in the model.	
CY 2020 OASIS Changes	The overall economic impact of the HH QRP and the case-mix adjustment methodology changes is annual savings to HHAs of an estimated \$60 million.		A reduction in burden to HHAs of approximately 73 hours annually for a savings of approximately \$5,150 annually per HHA.
CY 2020 Case-Mix Adjustment Methodology Changes, Including a Change in the Unit of Service from 60 to 30 days.		The overall economic impact of the case-mix adjustment methodology changes, including a change in the unit of service from 60 to 30 days, for CY 2020 results in no estimated dollar impact to HHAs, as section 51001(a) of the BBA of 2018 requires such change to be implemented in a budget-neutral manner.	To ensure home health payments are consistent with statutory payment authority for CY 2020.

Provision Description	Costs and Cost Savings	Transfers	Benefits
<p>Accreditation for Home Infusion Therapy suppliers</p>	<p>The cost related to an AO obtaining CMS approval of a home infusion therapy accreditation program is estimated to be \$8,014.50 per each AO, for AOs that have previously submitted an accreditation application to CMS. The cost across the potential 8 home infusion therapy AOs will be \$64,116.</p> <p>The cost related to each home infusion therapy AO for obtaining CMS approval of a home infusion therapy accreditation program is estimated to be \$12,453 per each AO, for AOs that <i>have not</i> previously submitted an accreditation application to CMS. The cost across the potential 8 home infusion therapy AOs will be \$99,624.</p> <p>We further estimate that each home infusion therapy AO will incur an estimated cost burden in the amount of \$23,258 for compliance with the home infusion therapy AO approval and oversight regulations at §§488.1010 through 488.1050 (including the filing of an application). The cost across the 8 potential home infusion therapy AOs will be \$186,064.</p>		<p>Accreditation of HIT suppliers will be required in order for HIT suppliers to receive payment from Medicare, effective 01/01/2021.</p> <p>The CMS AO approval and oversight regulations are necessary so that CMS has a process in place for the approval and oversight of the AOs that will be CMS-approved home infusion therapy accrediting organizations available to accredit the home infusion therapy suppliers, so that they can continue to receive payment from Medicare when the permanent benefits go into effect on 01/01/2021.</p>

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D. Improving Patient Outcomes and Reducing Burden Through Meaningful Measures

In the CY 2019 HH PPS proposed rule, we stated that regulatory reform and reducing regulatory burden are high priorities for us. To reduce the regulatory burden on the healthcare industry, lower health care costs, and

enhance patient care, in October 2017, we launched the Meaningful Measures Initiative.¹ This initiative is one component of our agency-wide Patients Over Paperwork Initiative² which is

¹ Meaningful Measures web page: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html>.

² See Remarks by Administrator Seema Verma at the Health Care Payment Learning and Action

aimed at evaluating and streamlining regulations with a goal to reduce unnecessary cost and burden, increase efficiencies, and improve beneficiary experience. The Meaningful Measures Initiative is aimed at identifying the highest priority areas for quality

Network (LAN) Fall Summit, as prepared for delivery on October 30, 2017 <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html>.

measurement and quality improvement in order to assess the core quality of care issues that are most vital to advancing our work to improve patient outcomes. The Meaningful Measures Initiative represents a new approach to quality measures that fosters operational efficiencies, and will reduce costs including, the collection and reporting burden while producing quality measurement that is more focused on meaningful outcomes.

The Meaningful Measures Framework has the following objectives:

- Address high-impact measure areas that safeguard public health;
- Patient-centered and meaningful to patients;
- Outcome-based where possible;
- Fulfill each program’s statutory requirements;
- Minimize the level of burden for health care providers (for example, through a preference for EHR-based measures where possible, such as electronic clinical quality measures);

- Provide significant opportunity for improvement;
- Address measure needs for population based payment through alternative payment models; and
- Align across programs and/or with other payers.

In order to achieve these objectives, stated in the proposed rule that we had identified 19 Meaningful Measures areas and mapped them to six overarching quality priorities as shown in Table 2:

TABLE 2—MEANINGFUL MEASURES FRAMEWORK DOMAINS AND MEASURE AREAS

Quality Priority	Meaningful Measure Area
Making Care Safer by Reducing Harm Caused in the Delivery of Care	Healthcare-Associated Infections.
	Preventable Healthcare Harm.
Strengthen Person and Family Engagement as Partners in Their Care	Care is Personalized and Aligned with Patient’s Goals.
	End of Life Care according to Preferences.
	Patient’s Experience of Care.
	Patient Reported Functional Outcomes.
Promote Effective Communication and Coordination of Care	Medication Management.
	Admissions and Readmissions to Hospitals.
	Transfer of Health Information and Interoperability.
Promote Effective Prevention and Treatment of Chronic Disease	Preventive Care.
	Management of Chronic Conditions.
	Prevention, Treatment, and Management of Mental Health.
	Prevention and Treatment of Opioid and Substance Use Disorders.
	Risk Adjusted Mortality.
Work with Communities to Promote Best Practices of Healthy Living	Equity of Care.
	Community Engagement.
Make Care Affordable	Appropriate Use of Healthcare.
	Patient-focused Episode of Care.
	Risk Adjusted Total Cost of Care.

By including Meaningful Measures in our programs, we stated our belief that we can also address the following cross-cutting measure criteria:

- Eliminating disparities;
- Tracking measurable outcomes and impact;
- Safeguarding public health;
- Achieving cost savings;
- Improving access for rural communities; and
- Reducing burden.

We also stated the we believe that the Meaningful Measures Initiative will improve outcomes for patients, their families, and health care providers while reducing burden and costs for clinicians and providers and promoting operational efficiencies.

II. Background

A. Statutory Background

1. Home Health Prospective Payment System

a. Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, enacted August 5, 1997), significantly changed the way Medicare pays for Medicare home health services. Section 4603 of the BBA mandated the development of the HH PPS. Until the implementation of the HH PPS on October 1, 2000, HHAs received payment under a retrospective reimbursement system.

Section 4603(a) of the BBA mandated the development of a HH PPS for all Medicare-covered home health services provided under a plan of care (POC) that were paid on a reasonable cost basis by adding section 1895 of the Act, entitled “Prospective Payment For Home Health

Services.” Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of home health services paid under Medicare. Section 1895(b)(2) of the Act requires that, in defining a prospective payment amount, the Secretary will consider an appropriate unit of service and the number, type, and duration of visits provided within that unit, potential changes in the mix of services provided within that unit and their cost, and a general system design that provides for continued access to quality services.

Section 1895(b)(3)(A) of the Act requires the following: (1) The computation of a standard prospective payment amount that includes all costs for HH services covered and paid for on a reasonable cost basis, and that such amounts be initially based on the most recent audited cost report data available to the Secretary (as of the effective date

of the 2000 final rule), and (2) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs.

Section 1895(b)(3)(B) of the Act requires the standard prospective payment amounts be annually updated by the home health applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of an appropriate case-mix change adjustment factor for significant variation in costs among different units of services.

Similarly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to home health services furnished in a geographic area compared to the applicable national average level. Under section 1895(b)(4)(C) of the Act, the wage-adjustment factors used by the Secretary may be the factors used under section 1886(d)(3)(E) of the Act.

Section 1895(b)(5) of the Act gives the Secretary the option to make additions or adjustments to the payment amount otherwise paid in the case of outliers due to unusual variations in the type or amount of medically necessary care. Section 3131(b)(2) of the Affordable Care Act revised section 1895(b)(5) of the Act so that total outlier payments in a given year would not exceed 2.5 percent of total payments projected or estimated. The provision also made permanent a 10 percent agency-level outlier payment cap.

In accordance with the statute, as amended by the BBA, we published a final rule in the July 3, 2000 **Federal Register** (65 FR 41128) to implement the HH PPS legislation. The July 2000 final rule established requirements for the new HH PPS for home health services as required by section 4603 of the BBA, as subsequently amended by section 5101 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999 (OCESAA), (Pub. L. 105–277, enacted October 21, 1998); and by sections 302, 305, and 306 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, (BBRA) (Pub. L. 106–113, enacted November 29, 1999). The requirements include the implementation of a HH PPS for home health services, consolidated billing requirements, and a number of other

related changes. The HH PPS described in that rule replaced the retrospective reasonable cost-based system that was used by Medicare for the payment of home health services under Part A and Part B. For a complete and full description of the HH PPS as required by the BBA, see the July 2000 HH PPS final rule (65 FR 41128 through 41214).

Section 5201(c) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted February 8, 2006) added new section 1895(b)(3)(B)(v) to the Act, requiring HHAs to submit data for purposes of measuring health care quality, and linking the quality data submission to the annual applicable payment percentage increase. This data submission requirement is applicable for CY 2007 and each subsequent year. If an HHA does not submit quality data, the home health market basket percentage increase is reduced by 2 percentage points. In the November 9, 2006 **Federal Register** (71 FR 65884, 65935), we published a final rule to implement the pay-for-reporting requirement of the DRA, which was codified at § 484.225(h) and (i) in accordance with the statute. The pay-for-reporting requirement was implemented on January 1, 2007.

The Affordable Care Act made additional changes to the HH PPS. One of the changes in section 3131 of the Affordable Care Act is the amendment to section 421(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) as amended by section 5201(b) of the DRA. Section 421(a) of the MMA, as amended by section 3131 of the Affordable Care Act, requires that the Secretary increase, by 3 percent, the payment amount otherwise made under section 1895 of the Act, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act) with respect to episodes and visits ending on or after April 1, 2010, and before January 1, 2016.

Section 210 of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) (MACRA) amended section 421(a) of the MMA to extend the 3 percent rural add-on payment for home health services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act) through January 1, 2018. In addition, section 411(d) of MACRA amended section 1895(b)(3)(B) of the Act such that CY 2018 home health payments be updated by a 1 percent market basket increase. Section 50208(a)(1) of the BBA of 2018 again extended the 3 percent rural add-on through the end of 2018. In addition, this section of the BBA of 2018 made

some important changes to the rural add-on for CYs 2019 through 2022, to be discussed later in this final rule with comment period.

B. Current System for Payment of Home Health Services

Generally, Medicare currently makes payment under the HH PPS on the basis of a national, standardized 60-day episode payment rate that is adjusted for the applicable case-mix and wage index. The national, standardized 60-day episode rate includes the six home health disciplines (skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, and medical social services). Payment for non-routine supplies (NRS) is not part of the national, standardized 60-day episode rate, but is computed by multiplying the relative weight for a particular NRS severity level by the NRS conversion factor. Payment for durable medical equipment covered under the HH benefit is made outside the HH PPS payment system. To adjust for case-mix, the HH PPS uses a 153-category case-mix classification system to assign patients to a home health resource group (HHRG). The clinical severity level, functional severity level, and service utilization are computed from responses to selected data elements in the OASIS assessment instrument and are used to place the patient in a particular HHRG. Each HHRG has an associated case-mix weight which is used in calculating the payment for an episode. Therapy service use is measured by the number of therapy visits provided during the episode and can be categorized into nine visit level categories (or thresholds): 0 to 5; 6; 7 to 9; 10; 11 to 13; 14 to 15; 16 to 17; 18 to 19; and 20 or more visits.

For episodes with four or fewer visits, Medicare pays national per-visit rates based on the discipline(s) providing the services. An episode consisting of four or fewer visits within a 60-day period receives what is referred to as a low-utilization payment adjustment (LUPA). Medicare also adjusts the national standardized 60-day episode payment rate for certain intervening events that are subject to a partial episode payment adjustment (PEP adjustment). For certain cases that exceed a specific cost threshold, an outlier adjustment may also be available.

C. Updates to the Home Health Prospective Payment System

As required by section 1895(b)(3)(B) of the Act, we have historically updated the HH PPS rates annually in the **Federal Register**. The August 29, 2007

final rule with comment period set forth an update to the 60-day national episode rates and the national per-visit rates under the HH PPS for CY 2008. The CY 2008 HH PPS final rule included an analysis performed on CY 2005 home health claims data, which indicated a 12.78 percent increase in the observed case-mix since 2000. Case-mix represents the variations in conditions of the patient population served by the HHAs. Subsequently, a more detailed analysis was performed on the 2005 case-mix data to evaluate if any portion of the 12.78 percent increase was associated with a change in the actual clinical condition of home health patients. We identified 8.03 percent of the total case-mix change as real, and therefore, decreased the 12.78 percent of total case-mix change by 8.03 percent to get a final nominal case-mix increase measure of 11.75 percent ($0.1278 * (1 - 0.0803) = 0.1175$).

To account for the changes in case-mix that were not related to an underlying change in patient health status, we implemented a reduction, over 4 years, to the national, standardized 60-day episode payment rates. That reduction was to be 2.75 percent per year for 3 years beginning in CY 2008 and 2.71 percent for the fourth year in CY 2011. In the CY 2011 HH PPS final rule (76 FR 68532), we updated our analyses of case-mix change and finalized a reduction of 3.79 percent, instead of 2.71 percent, for CY 2011 and deferred finalizing a payment reduction for CY 2012 until further study of the case-mix change data and methodology was completed.

In the CY 2012 HH PPS final rule (76 FR 68526), we updated the 60-day national episode rates and the national per-visit rates. In addition, as discussed in the CY 2012 HH PPS final rule (76 FR 68528), our analysis indicated that there was a 22.59 percent increase in overall case-mix from 2000 to 2009 and that only 15.76 percent of that overall observed case-mix percentage increase was due to real case-mix change. As a result of our analysis, we identified a 19.03 percent nominal increase in case-mix. At that time, to fully account for the 19.03 percent nominal case-mix growth identified from 2000 to 2009, we finalized a 3.79 percent payment reduction in CY 2012 and a 1.32 percent payment reduction for CY 2013.

In the CY 2013 HH PPS final rule (77 FR 67078), we implemented the 1.32 percent reduction to the payment rates for CY 2013 finalized the previous year, to account for nominal case-mix growth from 2000 through 2010. When taking into account the total measure of case-mix change (23.90 percent) and the

15.97 percent of total case-mix change estimated as real from 2000 to 2010, we obtained a final nominal case-mix change measure of 20.08 percent from 2000 to 2010 ($0.2390 * (1 - 0.1597) = 0.2008$). To fully account for the remainder of the 20.08 percent increase in nominal case-mix beyond that which was accounted for in previous payment reductions, we estimated that the percentage reduction to the national, standardized 60-day episode rates for nominal case-mix change would be 2.18 percent. Although we considered proposing a 2.18 percent reduction to account for the remaining increase in measured nominal case-mix, we finalized the 1.32 percent payment reduction to the national, standardized 60-day episode rates in the CY 2012 HH PPS final rule (76 FR 68532). Section 3131(a) of the Affordable Care Act added new section 1895(b)(3)(A)(iii) to the Act, which required that, beginning in CY 2014, we apply an adjustment to the national, standardized 60-day episode rate and other amounts that reflect factors such as changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other relevant factors. Additionally, we were required to phase in any adjustment over a 4-year period in equal increments, not to exceed 3.5 percent of the payment amount (or amounts) as of the date of enactment of the Affordable Care Act in 2010, and fully implement the rebasing adjustments by CY 2017. Therefore, in the CY 2014 HH PPS final rule (78 FR 72256) for each year, CY 2014 through CY 2017, we finalized a fixed-dollar reduction to the national, standardized 60-day episode payment rate of \$80.95 per year, increases to the national per-visit payment rates per year, and a decrease to the NRS conversion factor of 2.82 percent per year. We also finalized three separate LUPA add-on factors for skilled nursing, physical therapy, and speech-language pathology and removed 170 diagnosis codes from assignment to diagnosis groups in the HH PPS Grouper. In the CY 2015 HH PPS final rule (79 FR 66032), we implemented the second year of the 4-year phase-in of the rebasing adjustments to the HH PPS payment rates and made changes to the HH PPS case-mix weights. In addition, we simplified the face-to-face encounter regulatory requirements and the therapy reassessment timeframes.

In the CY 2016 HH PPS final rule (80 FR 68624), we implemented the third year of the 4-year phase-in of the rebasing adjustments to the national,

standardized 60-day episode payment amount, the national per-visit rates and the NRS conversion factor (as discussed previously). In the CY 2016 HH PPS final rule, we also recalibrated the HH PPS case-mix weights, using the most current cost and utilization data available, in a budget-neutral manner and finalized reductions to the national, standardized 60-day episode payment rate in CY 2016, CY 2017, and CY 2018 of 0.97 percent in each year to account for estimated case-mix growth unrelated to increases in patient acuity (that is, nominal case-mix growth) between CY 2012 and CY 2014. Finally, section 421(a) of the MMA, as amended by section 210 of the MACRA, extended the payment increase of 3 percent for HH services provided in rural areas (as defined in section 1886(d)(2)(D) of the Act) to episodes or visits ending before January 1, 2018.

In the CY 2017 HH PPS final rule (81 FR 76702), we implemented the last year of the 4-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit rates and the NRS conversion factor (as outlined previously). We also finalized changes to the methodology used to calculate outlier payments under the authority of section 1895(b)(5) of the Act. Lastly, in accordance with section 1834(s) of the Act, as added by section 504(a) of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113, enacted December 18, 2015), we implemented changes in payment for furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device for patients under a home health plan of care for which payment would otherwise be made under section 1895(b) of the Act.

2. Home Infusion Therapy

Section 5012 of the 21st Century Cures Act (“the Cures Act”) (Pub. L. 114–255), which amended sections 1861(s)(2) and 1861(iii) of the Act, established a new Medicare home infusion therapy benefit. The Medicare home infusion therapy benefit covers the professional services, including nursing services furnished in accordance with the plan of care, patient training and education (not otherwise covered under the durable medical equipment benefit), remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier. This benefit will ensure consistency in coverage for home infusion benefits for all Medicare beneficiaries. Section 50401 of the BBA of 2018 amended section 1834(u) of the

Act by adding a new paragraph (7) that establishes a home infusion therapy services temporary transitional payment for eligible home infusion suppliers for certain items and services furnished in coordination with the furnishing of transitional home infusion drugs beginning January 1, 2019. This temporary payment covers the cost of the same items and services, as defined in section 1861(iii)(2)(A) and (B) of the Act, related to the administration of home infusion drugs. The temporary transitional payment would begin on January 1, 2019 and end the day before the full implementation of the home infusion therapy benefit on January 1, 2021, as required by section 5012 of the 21st Century Cures Act.

Home infusion therapy is a treatment option for patients with a wide range of acute and chronic conditions, ranging from bacterial infections to more complex conditions such as late-stage heart failure and immune deficiencies. Home infusion therapy affords a patient independence and better quality of life, because it is provided in the comfort of the patient's home at a time that best fits his or her needs. This is significant, because generally patients can return to their daily activities after they receive their infusion treatments and, in many cases, they can continue their activities while receiving their treatments. In addition, home infusion therapy can provide improved safety and better outcomes. The home has been shown to be a safe setting for patients to receive infusion therapy.³ Additionally, patients receiving treatment outside of the hospital setting may be at lower risk of hospital-acquired infections, which can be more difficult to treat because of multidrug resistance than those that are community-acquired. This is particularly important for vulnerable patients such as those who are immunocompromised, as hospital-acquired infections are increasingly caused by antibiotic-resistant pathogens.

Infusion therapy typically means that a drug is administered intravenously, but the term may also refer to situations where drugs are provided through other non-oral routes, such as intramuscular injections and epidural routes (into the membranes surrounding the spinal

cord). Diseases that may require infusion therapy include infections that are unresponsive to oral antibiotics, cancer and cancer-related pain, dehydration, and gastrointestinal diseases or disorders which prevent normal functioning of the gastrointestinal system. Other conditions treated with specialty infusion therapies may include some forms of cancers, congestive heart failure, Crohn's Disease, hemophilia, hepatitis, immune deficiencies, multiple sclerosis and rheumatoid arthritis. Infusion therapy originates with a prescription order from a physician or another qualified prescriber who is overseeing the care of the patient. The prescription order is sent to a home infusion therapy supplier, which is a state-licensed pharmacy, physician, or other provider of services or suppliers licensed by the state.

A 2010 Government Accountability Office (GAO) report (10–426) found that most health insurers rely on credentialing, accreditation, or both to help ensure that plan members receive quality home infusion services from their network suppliers.⁴ Home infusion AOs conduct on-site surveys to evaluate all components of the service, including medical equipment, nursing, and pharmacy. Accreditation standards can include such requirements as the CMS Conditions of Participation for home health services, other Federal government regulations, and industry best practices. All of the accreditation standards evaluate a range of provider competencies, such as having a complete plan of care, response to adverse events, and implementation of a quality improvement plan.

Sections 1861(iii)(3)(D)(III) and 1834(u)(5) of the Act, as amended by section 5012 of the Cures Act requires that, in order to participate in Medicare, home infusion therapy suppliers must select a CMS-approved AO and undergo an accreditation review process to demonstrate that the home infusion therapy program meets the accreditation organization's standards. Section 1861(iii) of the Act, as amended by section 5012 of the Cures Act, sets forth standards in three areas: (1) Ensuring that all patients have a plan of care established and updated by a physician that sets out the care and prescribed infusion therapy necessary to meet the patient-specific needs; (2) having procedures to ensure that remote monitoring services associated with administering infusion drugs in a patient's home are provided; and (3) having procedures to ensure that

patients receive education and training on the effective use of medications and equipment in the home.

III. Provisions of the Proposed Rule: Payment Under the Home Health Prospective Payment System (HH PPS) and Responses to Comments

In the July 12, 2018 **Federal Register** (83 FR 32340 through 32522), we published the proposed rule titled "Medicare and Medicaid Programs; CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; Home Infusion Therapy Requirements; and Training Requirements for Surveyors of National Accrediting Organizations". We received approximately 1,125 timely comments from the public, including comments from home health agencies, home infusion therapy providers, DME suppliers, manufacturers of remote patient monitoring technology, national and state provider associations, patient and other advocacy organizations, physicians, nurses, therapists, pharmacists, and accrediting organizations. In the following sections, we summarize the proposed provisions and the public comments, and provide the responses to comments.

A. Monitoring for Potential Impacts—Affordable Care Act Rebasing Adjustments

In the CY 2019 proposed rule (83 FR 32348), we provided a summary of analysis on fiscal (FY) 2016 HHA cost report data and how such data, if used, would impact our estimate of the percentage difference between Medicare payments and HHA costs. In addition, we presented information on Medicare home health utilization statistics and trends that included HHA claims data through CY 2017. We will continue monitoring the impacts due to the rebasing adjustments and other policy changes and will provide the industry with periodic updates on our analysis in rulemaking and/or announcements on the HHA Center web page at: <https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html>.

B. CY 2019 HH PPS Case-Mix Weights

In the CY 2015 HH PPS final rule (79 FR 66072), we finalized a policy to annually recalibrate the HH PPS case-mix weights—adjusting the weights relative to one another—using the most current, complete data available. To recalibrate the HH PPS case-mix weights for CY 2019, we will use the same methodology finalized in the CY 2008

³ Bhole, M.V., Burton, J., & Chapel, H.M., (2008). Self-infusion programs for immunoglobulin replacement at home: Feasibility, safety and efficacy. *Immunology and Allergy Clinics of North America*, 28(4), 821–832. doi:10.1016/j.jiac.2008.06.005.

⁴ Souayah, N., Hasan, A., Khan, H., et al. (2011). The safety profile of home infusion of intravenous immunoglobulin in patients with neuroimmunologic disorders. *Journal of Clinical Neuromuscular Disease*, 12(supp 4), S1–10. doi: 10.1097/CND.0b013e3182212589.

⁴ <https://www.gao.gov/assets/310/305261.pdf>.

HH PPS final rule (72 FR 49762), the CY 2012 HH PPS final rule (76 FR 68526), and the CY 2015 HH PPS final rule (79 FR 66032). Annual recalibration of the HH PPS case-mix weights ensures that the case-mix weights reflect, as accurately as possible, current home health resource use and changes in utilization patterns.

To generate the final CY 2019 HH PPS case-mix weights, we used CY 2017 home health claims data (as of June 30, 2018) with linked OASIS data. These data are the most current and complete data available at this time. We noted in

the proposed rule that we would use CY 2017 home health claims data (as of June 30, 2018 or later) with linked OASIS data to generate the CY 2019 HH PPS case-mix weights for this final rule with comment period. The process we used to calculate the HH PPS case-mix weights is outlined in this section.

Step 1: Re-estimate the four-equation model to determine the clinical and functional points for an episode using wage-weighted minutes of care as our dependent variable for resource use. The wage-weighted minutes of care are determined using the CY 2016 Bureau of

Labor Statistics national hourly wage plus fringe rates for the six home health disciplines and the minutes per visit from the claim. The points for each of the variables for each leg of the model, updated with CY 2017 home health claims data, are shown in Table 3. The points for the clinical variables are added together to determine an episode's clinical score. The points for the functional variables are added together to determine an episode's functional score.

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TABLE 3: CY 2019 CASE-MIX ADJUSTMENT VARIABLES AND SCORES

	Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
	Therapy visits	0-13	14+	0-13	14+
	<i>EQUATION:</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>
CLINICAL DIMENSION					
1	Primary or Other Diagnosis = Blindness/Low Vision
2	Primary or Other Diagnosis = Blood disorders	.	2	.	.
3	Primary or Other Diagnosis = Cancer, selected benign neoplasms	.	4	.	4
4	Primary Diagnosis = Diabetes	.	3	.	3
5	Other Diagnosis = Diabetes	1	.	.	.
6	Primary or Other Diagnosis = Dysphagia AND Primary or Other Diagnosis = Neuro 3 – Stroke	2	14	.	10
7	Primary or Other Diagnosis = Dysphagia AND M1030 (Therapy at home) = 3 (Enteral)	.	5	.	5
8	Primary or Other Diagnosis = Gastrointestinal disorders	.	1	.	2
9	Primary or Other Diagnosis = Gastrointestinal disorders AND M1630 (ostomy)= 1 or 2	.	5	.	.
10	Primary or Other Diagnosis = Gastrointestinal disorders AND Primary or Other Diagnosis = Neuro 1 - Brain disorders and paralysis, OR Neuro 2 - Peripheral neurological disorders, OR Neuro 3 - Stroke, OR Neuro 4 - Multiple Sclerosis
11	Primary or Other Diagnosis = Heart Disease OR Hypertension	2	3	.	3
12	Primary Diagnosis = Neuro 1 - Brain disorders and paralysis	2	7	4	7
13	Primary or Other Diagnosis = Neuro 1 - Brain disorders and paralysis AND M1840 (Toilet transfer) = 2 or more	.	2	.	.
14	Primary or Other Diagnosis = Neuro 1 - Brain disorders and paralysis OR Neuro 2 - Peripheral neurological disorders AND M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3	3	4	1	3
15	Primary or Other Diagnosis = Neuro 3 - Stroke	3	6	2	.
16	Primary or Other Diagnosis = Neuro 3 - Stroke AND M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3	.	4	.	4
17	Primary or Other Diagnosis = Neuro 3 - Stroke AND M1860 (Ambulation) = 4 or more

18	Primary or Other Diagnosis = Neuro 4 - Multiple Sclerosis AND AT LEAST ONE OF THE FOLLOWING: M1830 (Bathing) = 2 or more OR M1840 (Toilet transfer) = 2 or more OR M1850 (Transferring) = 2 or more OR M1860 (Ambulation) = 4 or more	2	6	3	8
19	Primary or Other Diagnosis = Ortho 1 - Leg Disorders or Gait Disorders AND M1324 (most problematic pressure ulcer stage)= 1, 2, 3 or 4	7	2	7	.
20	Primary or Other Diagnosis = Ortho 1 - Leg OR Ortho 2 - Other orthopedic disorders AND M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	1	2	3	.
21	Primary or Other Diagnosis = Psych 1 – Affective and other psychoses, depression
22	Primary or Other Diagnosis = Psych 2 - Degenerative and other organic psychiatric disorders
23	Primary or Other Diagnosis = Pulmonary disorders	.	.	.	1
24	Primary or Other Diagnosis = Pulmonary disorders AND M1860 (Ambulation) = 1 or more	.	1	.	.
25	Primary Diagnosis = Skin 1 -Traumatic wounds, burns, and post-operative complications	2	15	6	15
26	Other Diagnosis = Skin 1 - Traumatic wounds, burns, post- operative complications	5	11	7	11
27	Primary or Other Diagnosis = Skin 1 -Traumatic wounds, burns, and post-operative complications OR Skin 2 – Ulcers and other skin conditions AND M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)
28	Primary or Other Diagnosis = Skin 2 - Ulcers and other skin conditions	2	15	8	15
29	Primary or Other Diagnosis = Tracheostomy	1	10	.	10
30	Primary or Other Diagnosis = Urostomy/Cystostomy	.	17	.	9
31	M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	.	10	1	10
32	M1030 (Therapy at home) = 3 (Enteral)	.	12	.	6
33	M1200 (Vision) = 1 or more	1	.	.	.
34	M1242 (Pain)= 3 or 4	3	.	2	1
35	M1311 = Two or more pressure ulcers at stage 3 or 4	2	4	2	4
36	M1324 (Most problematic pressure ulcer stage)= 1 or 2	4	17	6	16
37	M1324 (Most problematic pressure ulcer stage)= 3 or 4	6	27	8	23
38	M1334 (Stasis ulcer status)= 2	3	12	5	12
39	M1334 (Stasis ulcer status)= 3	5	15	7	15
40	M1342 (Surgical wound status)= 2	2	6	5	12
41	M1342 (Surgical wound status)= 3	.	5	4	8
42	M1400 (Dyspnea) = 2, 3, or 4	1	1	.	.
43	M1620 (Bowel Incontinence) = 2 to 5	.	3	.	3
44	M1630 (Ostomy)= 1 or 2	2	9	2	7
45	M2030 (Injectable Drug Use) = 0, 1, 2, or 3
FUNCTIONAL DIMENSION					
46	M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3	1	2	.	.

47	M1830 (Bathing) = 2 or more	6	4	5	.
48	M1840 (Toilet transferring) = 2 or more	1	.	.	.
49	M1850 (Transferring) = 2 or more	2	1	2	.
50	M1860 (Ambulation) = 1, 2 or 3	6	.	4	.
51	M1860 (Ambulation) = 4 or more	7	7	6	6

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of June 30, 2018) for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded.

Note(s): Points are additive; however, points may not be given for the same line item in the table more than once. Please see Medicare Home Health Diagnosis Coding guidance at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/coding_billing.html for definitions of primary and secondary diagnoses.

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In updating the four-equation model for CY 2019, using 2017 home health claims data (the last update to the four-equation model for CY 2018 used CY 2016 home health claims data), there were few changes to the point values for the variables in the four-equation model. These relatively minor changes reflect the change in the relationship between the grouper variables and resource use between CY 2016 and CY 2017. The final CY 2019 four-equation model resulted in 119 point-giving variables being used in the model (as compared to the 119 variables for the CY 2018 recalibration, which can be found in Table 2 of the CY 2018 HH PPS final rule (82 FR 51684)). There were 9 variables that were added to the model due to the presence of additional resources associated with those variables and 9 variables that were dropped from the model due to the absence of additional resources associated with those variables. Of the variables that were in both the four-

equation model for CY 2019 and the four-equation model for CY 2018, the points for 7 variables increased in the CY 2019 four-equation model and the points for 68 variables decreased in the CY 2019 4-equation model. There were 35 variables with the same point values.

Step 2: Redefining the clinical and functional thresholds so they are reflective of the new points associated with the CY 2019 four-equation model. After estimating the points for each of the variables and summing the clinical and functional points for each episode, we look at the distribution of the clinical score and functional score, breaking the episodes into different steps. The categorizations for the steps are as follows:

- Step 1: First and second episodes, 0–13 therapy visits.
- Step 2.1: First and second episodes, 14–19 therapy visits.
- Step 2.2: Third episodes and beyond, 14–19 therapy visits.
- Step 3: Third episodes and beyond, 0–13 therapy visits.

- Step 4: Episodes with 20+ therapy visits.

Then, we divide the distribution of the clinical score for episodes within a step such that a third of episodes are classified as low clinical score, a third of episodes are classified as medium clinical score, and a third of episodes are classified as high clinical score. The same approach is then done looking at the functional score. It was not always possible to evenly divide the episodes within each step into thirds due to many episodes being clustered around one particular score.⁵

Also, we looked at the average resource use associated with each clinical and functional score and used that as a guide for setting our thresholds. We grouped scores with similar average resource use within the same level (even if it meant that more or less than a third of episodes were placed within a level). The new thresholds, based off the final CY 2019 four-equation model points are shown in Table 4.

⁵ For Step 1, 33.7 percent of episodes were in the medium functional level (All with score 13). For Step 2.1, 86.7% of episodes were in the low functional level (Most with scores 6 to 7). For Step

2.2, 81.5 percent of episodes were in the low functional level (Most with score 0). For Step 3, 46.6 percent of episodes were in the medium functional level (Most with score 9). For Step 4,

33.2 percent of episodes were in the medium functional level (Most with score 6).

TABLE 4: CY 2019 CLINICAL AND FUNCTIONAL THRESHOLDS

		1 st and 2 nd Episodes		3rd+ Episodes		All Episodes
		0 to 13 therapy visits	14 to 19 therapy visits	0 to 13 therapy visits	14 to 19 therapy visits	20+ therapy visits
Grouping Step		1	2	3	4	5
Equations used to calculate points (see Table 2)		1	2	3	4	(2&4)
Dimension	Severity Level					
Clinical	C1	0 to 1	0 to 1	0 to 1	0 to 1	0 to 3
	C2	2 to 3	2 to 7	2	2 to 9	4 to 16
	C3	4+	8+	3+	10+	17+
Functional	F1	0 to 12	0 to 7	0 to 6	0 to 2	0 to 2
	F2	13	8 to 12	7 to 10	3 to 7	3 to 6
	F3	14+	13+	11+	8+	7+

Step 3: Once the clinical and functional thresholds are determined and each episode is assigned a clinical and functional level, the payment regression is estimated with an episode’s wage-weighted minutes of care as the dependent variable. Independent variables in the model are

indicators for the step of the episode as well as the clinical and functional levels within each step of the episode. Like the four-equation model, the payment regression model is also estimated with robust standard errors that are clustered at the beneficiary level. Table 5 shows the regression coefficients for the

variables in the payment regression model updated with CY 2017 home health claims data. The R-squared value for the final CY 2019 payment regression model is 0.5429 (an increase from 0.5095 for the CY 2018 recalibration).

TABLE 5: CY 2019 PAYMENT REGRESSION MODEL

	Payment Regression from 4-Equation Model for CY 2019
Step 1, Clinical Score Medium	\$20.57
Step 1, Clinical Score High	\$56.45
Step 1, Functional Score Medium	\$68.66
Step 1, Functional Score High	\$96.85
Step 2.1, Clinical Score Medium	\$52.45
Step 2.1, Clinical Score High	\$126.15
Step 2.1, Functional Score Medium	\$20.24
Step 2.1, Functional Score High	\$31.91
Step 2.2, Clinical Score Medium	\$51.44
Step 2.2, Clinical Score High	\$180.61
Step 2.2, Functional Score Medium	\$47.44
Step 2.2, Functional Score High	\$0.00
Step 3, Clinical Score Medium	\$16.38
Step 3, Clinical Score High	\$85.55
Step 3, Functional Score Medium	\$56.26
Step 3, Functional Score High	\$81.57
Step 4, Clinical Score Medium	\$70.36
Step 4, Clinical Score High	\$246.36
Step 4, Functional Score Medium	\$32.71
Step 4, Functional Score High	\$38.77
Step 2.1, 1st and 2nd Episodes, 14 to 19 Therapy Visits	\$505.27
Step 2.2, 3rd+ Episodes, 14 to 19 Therapy Visits	\$497.02
Step 3, 3rd+ Episodes, 0-13 Therapy Visits	-\$53.16
Step 4, All Episodes, 20+ Therapy Visits	\$851.24
Intercept	\$373.81

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of June 30, 2018) for which we had a linked OASIS assessment.

Step 4: We use the coefficients from the payment regression model to predict each episode's wage-weighted minutes of care (resource use). We then divide these predicted values by the mean of the dependent variable (that is, the average wage-weighted minutes of care across all episodes used in the payment regression). This division constructs the weight for each episode, which is simply the ratio of the episode's predicted wage-weighted minutes of care divided by the average wage-weighted minutes of care in the sample. Each episode is then aggregated into one of the 153 home health resource groups (HHRGs) and the "raw" weight for each HHRG was calculated as the average of the episode weights within the HHRG.

Step 5: The raw weights associated with 0 to 5 therapy visits are then increased by 3.75 percent, the weights

associated with 14–15 therapy visits are decreased by 2.5 percent, and the weights associated with 20+ therapy visits are decreased by 5 percent. These adjustments to the case-mix weights were finalized in the CY 2012 HH PPS final rule (76 FR 68557) and were done to address concerns that the HH PPS over-values therapy episodes and undervalues non-therapy episodes and to better align the case-mix weights with episode costs estimated from cost report data.⁶

Step 6: After the adjustments in step 5 are applied to the raw weights, the weights are further adjusted to create an increase in the payment weights for the therapy visit steps between the therapy

thresholds. Weights with the same clinical severity level, functional severity level, and early/late episode status were grouped together. Then within those groups, the weights for each therapy step between thresholds are gradually increased. We do this by interpolating between the main thresholds on the model (from 0–5 to 14–15 therapy visits, and from 14–15 to 20+ therapy visits). We use a linear model to implement the interpolation so the payment weight increase for each step between the thresholds (such as the increase between 0–5 therapy visits and 6 therapy visits and the increase between 6 therapy visits and 7–9 therapy visits) are constant. This interpolation is identical to the process finalized in the CY 2012 HH PPS final rule (76 FR 68555).

⁶ Medicare Payment Advisory Commission (MedPAC), *Report to Congress: Medicare Payment Policy*. March 2011, page 176.

Step 7: The interpolated weights are then adjusted so that the average case-mix for the weights is equal to 1.0000.⁷

This last step creates the CY 2019 case-mix weights shown in Table 6.

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TABLE 6: CY 2019 CASE-MIX PAYMENT WEIGHTS

Pay Group	Description	Clinical and Functional Levels (1 = Low; 2 = Medium; 3= High)	CY 2019 Weight
10111	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F1S1	0.5468
10112	1st and 2nd Episodes, 6 Therapy Visits	C1F1S2	0.6791
10113	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F1S3	0.8115
10114	1st and 2nd Episodes, 10 Therapy Visits	C1F1S4	0.9438
10115	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F1S5	1.0761
21111	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2085
21112	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F1S2	1.3526
21113	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F1S3	1.4968
10121	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F2S1	0.6473
10122	1st and 2nd Episodes, 6 Therapy Visits	C1F2S2	0.7651
10123	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F2S3	0.8829
10124	1st and 2nd Episodes, 10 Therapy Visits	C1F2S4	1.0007
10125	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1185
21121	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2363
21122	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F2S2	1.3858
21123	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F2S3	1.5352
10131	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F3S1	0.6885
10132	1st and 2nd Episodes, 6 Therapy Visits	C1F3S2	0.8013
10133	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F3S3	0.9140
10134	1st and 2nd Episodes, 10 Therapy Visits	C1F3S4	1.0268
10135	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F3S5	1.1396
21131	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F3S1	1.2523
21132	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F3S2	1.3992
21133	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F3S3	1.5460
10211	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F1S1	0.5769
10212	1st and 2nd Episodes, 6 Therapy Visits	C2F1S2	0.7176
10213	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8584
10214	1st and 2nd Episodes, 10 Therapy Visits	C2F1S4	0.9991
10215	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1398
21211	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F1S1	1.2806
21212	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F1S2	1.4321
21213	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F1S3	1.5836
10221	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F2S1	0.6773
10222	1st and 2nd Episodes, 6 Therapy Visits	C2F2S2	0.8035
10223	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F2S3	0.9298
10224	1st and 2nd Episodes, 10 Therapy Visits	C2F2S4	1.0560
10225	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F2S5	1.1822
21221	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3084

⁷ When computing the average, we compute a weighted average, assigning a value of one to each

normal episode and a value equal to the episode length divided by 60 for PEPs.

Pay Group	Description	Clinical and Functional Levels (1 = Low; 2 = Medium; 3= High)	CY 2019 Weight
21222	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F2S2	1.4653
21223	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F2S3	1.6221
10231	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F3S1	0.7186
10232	1st and 2nd Episodes, 6 Therapy Visits	C2F3S2	0.8397
10233	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F3S3	0.9609
10234	1st and 2nd Episodes, 10 Therapy Visits	C2F3S4	1.0821
10235	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F3S5	1.2033
21231	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F3S1	1.3244
21232	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F3S2	1.4787
21233	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F3S3	1.6329
10311	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F1S1	0.6294
10312	1st and 2nd Episodes, 6 Therapy Visits	C3F1S2	0.7799
10313	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F1S3	0.9304
10314	1st and 2nd Episodes, 10 Therapy Visits	C3F1S4	1.0809
10315	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F1S5	1.2314
21311	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F1S1	1.3819
21312	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F1S2	1.5782
21313	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F1S3	1.7746
10321	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F2S1	0.7298
10322	1st and 2nd Episodes, 6 Therapy Visits	C3F2S2	0.8658
10323	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0018
10324	1st and 2nd Episodes, 10 Therapy Visits	C3F2S4	1.1378
10325	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F2S5	1.2737
21321	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F2S1	1.4097
21322	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F2S2	1.6114
21323	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F2S3	1.8130
10331	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F3S1	0.7711
10332	1st and 2nd Episodes, 6 Therapy Visits	C3F3S2	0.9020
10333	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F3S3	1.0329
10334	1st and 2nd Episodes, 10 Therapy Visits	C3F3S4	1.1639
10335	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F3S5	1.2948
21331	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F3S1	1.4258
21332	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F3S2	1.6248
21333	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F3S3	1.8238
30111	3rd+ Episodes, 0 to 5 Therapy Visits	C1F1S1	0.4691
30112	3rd+ Episodes, 6 Therapy Visits	C1F1S2	0.6147
30113	3rd+ Episodes, 7 to 9 Therapy Visits	C1F1S3	0.7603
30114	3rd+ Episodes, 10 Therapy Visits	C1F1S4	0.9059
30115	3rd+ Episodes, 11 to 13 Therapy Visits	C1F1S5	1.0515
22111	3rd+ Episodes, 14 to 15 Therapy Visits	C1F1S1	1.1971
22112	3rd+ Episodes, 16 to 17 Therapy Visits	C1F1S2	1.3451
22113	3rd+ Episodes, 18 to 19 Therapy Visits	C1F1S3	1.4930
40111	All Episodes, 20+ Therapy Visits	C1F1S1	1.6409
30121	3rd+ Episodes, 0 to 5 Therapy Visits	C1F2S1	0.5514
30122	3rd+ Episodes, 6 Therapy Visits	C1F2S2	0.6936
30123	3rd+ Episodes, 7 to 9 Therapy Visits	C1F2S3	0.8358
30124	3rd+ Episodes, 10 Therapy Visits	C1F2S4	0.9780

Pay Group	Description	Clinical and Functional Levels (1 = Low; 2 = Medium; 3= High)	CY 2019 Weight
30125	3rd+ Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1202
22121	3rd+ Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2624
22122	3rd+ Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4031
22123	3rd+ Episodes, 18 to 19 Therapy Visits	C1F2S3	1.5439
40121	All Episodes, 20+ Therapy Visits	C1F2S1	1.6847
30131	3rd+ Episodes, 0 to 5 Therapy Visits	C1F3S1	0.5884
30132	3rd+ Episodes, 6 Therapy Visits	C1F3S2	0.7232
30133	3rd+ Episodes, 7 to 9 Therapy Visits	C1F3S3	0.8580
30134	3rd+ Episodes, 10 Therapy Visits	C1F3S4	0.9928
30135	3rd+ Episodes, 11 to 13 Therapy Visits	C1F3S5	1.1276
22131	3rd+ Episodes, 14 to 15 Therapy Visits	C1F3S1	1.2624
22132	3rd+ Episodes, 16 to 17 Therapy Visits	C1F3S2	1.4058
22133	3rd+ Episodes, 18 to 19 Therapy Visits	C1F3S3	1.5493
40131	All Episodes, 20+ Therapy Visits	C1F3S1	1.6928
30211	3rd+ Episodes, 0 to 5 Therapy Visits	C2F1S1	0.4930
30212	3rd+ Episodes, 6 Therapy Visits	C2F1S2	0.6480
30213	3rd+ Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8030
30214	3rd+ Episodes, 10 Therapy Visits	C2F1S4	0.9579
30215	3rd+ Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1129
22211	3rd+ Episodes, 14 to 15 Therapy Visits	C2F1S1	1.2679
22212	3rd+ Episodes, 16 to 17 Therapy Visits	C2F1S2	1.4236
22213	3rd+ Episodes, 18 to 19 Therapy Visits	C2F1S3	1.5794
40211	All Episodes, 20+ Therapy Visits	C2F1S1	1.7352
30221	3rd+ Episodes, 0 to 5 Therapy Visits	C2F2S1	0.5753
30222	3rd+ Episodes, 6 Therapy Visits	C2F2S2	0.7269
30223	3rd+ Episodes, 7 to 9 Therapy Visits	C2F2S3	0.8784
30224	3rd+ Episodes, 10 Therapy Visits	C2F2S4	1.0300
30225	3rd+ Episodes, 11 to 13 Therapy Visits	C2F2S5	1.1815
22221	3rd+ Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3331
22222	3rd+ Episodes, 16 to 17 Therapy Visits	C2F2S2	1.4817
22223	3rd+ Episodes, 18 to 19 Therapy Visits	C2F2S3	1.6303
40221	All Episodes, 20+ Therapy Visits	C2F2S1	1.7790
30231	3rd+ Episodes, 0 to 5 Therapy Visits	C2F3S1	0.6123
30232	3rd+ Episodes, 6 Therapy Visits	C2F3S2	0.7565
30233	3rd+ Episodes, 7 to 9 Therapy Visits	C2F3S3	0.9006
30234	3rd+ Episodes, 10 Therapy Visits	C2F3S4	1.0448
30235	3rd+ Episodes, 11 to 13 Therapy Visits	C2F3S5	1.1889
22231	3rd+ Episodes, 14 to 15 Therapy Visits	C2F3S1	1.3331
22232	3rd+ Episodes, 16 to 17 Therapy Visits	C2F3S2	1.4844
22233	3rd+ Episodes, 18 to 19 Therapy Visits	C2F3S3	1.6357
40231	All Episodes, 20+ Therapy Visits	C2F3S1	1.7871
30311	3rd+ Episodes, 0 to 5 Therapy Visits	C3F1S1	0.5942
30312	3rd+ Episodes, 6 Therapy Visits	C3F1S2	0.7644
30313	3rd+ Episodes, 7 to 9 Therapy Visits	C3F1S3	0.9347
30314	3rd+ Episodes, 10 Therapy Visits	C3F1S4	1.1049
30315	3rd+ Episodes, 11 to 13 Therapy Visits	C3F1S5	1.2752
22311	3rd+ Episodes, 14 to 15 Therapy Visits	C3F1S1	1.4454

Pay Group	Description	Clinical and Functional Levels (1 = Low; 2 = Medium; 3 = High)	CY 2019 Weight
22312	3rd+ Episodes, 16 to 17 Therapy Visits	C3F1S2	1.6206
22313	3rd+ Episodes, 18 to 19 Therapy Visits	C3F1S3	1.7957
40311	All Episodes, 20+ Therapy Visits	C3F1S1	1.9709
30321	3rd+ Episodes, 0 to 5 Therapy Visits	C3F2S1	0.6765
30322	3rd+ Episodes, 6 Therapy Visits	C3F2S2	0.8433
30323	3rd+ Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0102
30324	3rd+ Episodes, 10 Therapy Visits	C3F2S4	1.1770
30325	3rd+ Episodes, 11 to 13 Therapy Visits	C3F2S5	1.3438
22321	3rd+ Episodes, 14 to 15 Therapy Visits	C3F2S1	1.5106
22322	3rd+ Episodes, 16 to 17 Therapy Visits	C3F2S2	1.6787
22323	3rd+ Episodes, 18 to 19 Therapy Visits	C3F2S3	1.8467
40321	All Episodes, 20+ Therapy Visits	C3F2S1	2.0147
30331	3rd+ Episodes, 0 to 5 Therapy Visits	C3F3S1	0.7135
30332	3rd+ Episodes, 6 Therapy Visits	C3F3S2	0.8729
30333	3rd+ Episodes, 7 to 9 Therapy Visits	C3F3S3	1.0324
30334	3rd+ Episodes, 10 Therapy Visits	C3F3S4	1.1918
30335	3rd+ Episodes, 11 to 13 Therapy Visits	C3F3S5	1.3512
22331	3rd+ Episodes, 14 to 15 Therapy Visits	C3F3S1	1.5106
22332	3rd+ Episodes, 16 to 17 Therapy Visits	C3F3S2	1.6814
22333	3rd+ Episodes, 18 to 19 Therapy Visits	C3F3S3	1.8521
40331	All Episodes, 20+ Therapy Visits	C3F3S1	2.0228

To ensure the changes to the HH PPS case-mix weights are implemented in a budget neutral manner, we then apply a case-mix budget neutrality factor to the CY 2019 national, standardized 60-day episode payment rate (see section III.C.3. of this final rule with comment period). The case-mix budget neutrality factor is calculated as the ratio of total payments when the CY 2019 HH PPS case-mix weights (developed using CY 2017 home health claims data) are applied to CY 2017 utilization (claims) data to total payments when CY 2018 HH PPS case-mix weights (developed using CY 2016 home health claims data) are applied to CY 2017 utilization data. This produces a case-mix budget neutrality factor for CY 2019 of 1.0169.

The following is a summary of the comments received and our responses to comments on the CY 2019 HH PPS case-mix weights.

Comment: Some commenters believe that CMS should not recalibrate the case-mix weights for CY 2019 because annual changes are too frequent. Other commenters indicated that CMS should provide more detail on how the recalibration works and why the model is recalibrated every year.

Response: As stated in the CY 2019 HH PPS proposed rule (83 FR 32340), the methodology used to recalibrate the

weights is identical to the methodology used in the CY 2012 recalibration except for the minor exceptions as noted in the CY 2015 HH PPS proposed and final rules (79 FR 38366 and 79 FR 66032, respectively). In the CY 2015 HH PPS final rule, we finalized annual recalibration and the methodology to be used for each year's recalibration (79 FR 66072). As stated in the CY 2019 HH PPS proposed rule (83 FR 32353), annual recalibration of the HH PPS case-mix weights ensures that the case-mix weights reflect, as accurately as possible, current home health resource use and changes in utilization patterns. For more detail, we also encourage commenters to refer to the CY 2012 HH PPS proposed and final rules (76 FR 40988 and 76 FR 68526, respectively) and the November 1, 2011 "Revision of the Case-Mix Weights for the HH PPS Report" on our home page at: <https://www.cms.gov/center/provider-Type/home-Health-AgencyHHA-Center.html> for additional information about the recalibration methodology. We note that in comparing the final CY 2019 HH PPS case-mix weights (see Table 6) to the final CY 2018 HH PPS case-mix weights (82 FR 51676), the case-mix weights change very little, with most case-mix weights either increasing or decreasing by 1 to 2 percent with no case-mix

weights increasing by more than 3 percent or decreasing by more than 3 percent. Aggregate increases or decreases in the case-mix weights are offset by the case-mix budget neutrality factor, which is applied to the national, standardized 60-day episode payment rate. In other words, although the case-mix weights themselves may increase or decrease from year-to-year, we correspondingly offset any estimated increases or decreases in total payments under the HH PPS, as a result of the case-mix recalibration, by applying a budget neutrality factor to the national, standardized 60-day episode payment rate. For CY 2019, the case-mix budget neutrality factor will be 1.0169 as described previously. The recalibration of the case-mix weights is not intended to increase or decrease overall HH PPS payments, but rather is used to update the relative differences in resource use amongst the 153 groups in the HH PPS case-mix system to reflect current practice patterns.

Comment: Another commenter suggested that CMS should adjust for any nominal case-mix changes observed between 2015 and 2017.

Response: We will continue to monitor real and nominal case-mix growth and may propose additional

reductions for nominal case-mix growth, as needed, in the future.

Final Decision: We are finalizing the recalibrated scores for the case-mix adjustment variables, clinical and functional thresholds, payment regression model, and case-mix weights in Tables 3 through 6. For this final rule with comment period, the CY 2019 scores for the case-mix variables, the clinical and functional thresholds, and the case-mix weights were developed using complete CY 2017 claims data as of June 30, 2018. We note that we finalized the recalibration methodology and the proposal to annually recalibrate the HH PPS case-mix weights in the CY 2015 HH PPS final rule (79 FR 66072). No additional proposals were made with regards to the recalibration methodology in the CY 2019 HH PPS proposed rule.

C. CY 2019 Home Health Payment Rate Update

1. Rebasing and Revising of the Home Health Market Basket

a. Background

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2019 be increased by a factor equal to the applicable home health market basket update for those HHAs that submit quality data as required by the Secretary. Effective for cost reporting periods beginning on or after July 1, 1980, we developed and adopted an HHA input price index (that is, the home health “market basket”). Although “market basket” technically describes the mix of goods and services used to produce home health care, this term is also commonly used to denote the input price index derived from that market basket. Accordingly, the term “home health market basket” used in this document refers to the HHA input price index.

The percentage change in the home health market basket reflects the average change in the price of goods and services purchased by HHAs in providing an efficient level of home health care services. We first used the home health market basket to adjust HHA cost limits by an amount that reflected the average increase in the prices of the goods and services used to furnish reasonable cost home health care. This approach linked the increase in the cost limits to the efficient utilization of resources. For a greater discussion on the home health market basket, see the notice with comment period published in the February 15, 1980 **Federal Register** (45 FR 10450 and 10451), the notice with comment period

published in the February 14, 1995 **Federal Register** (60 FR 8389 through 8392), and the notice with comment period published in the July 1, 1996 **Federal Register** (61 FR 34344 through 34347). Beginning with the FY 2002 HHA PPS payments, we used the home health market basket to update payments under the HHA PPS. We last rebased the home health market basket effective with the CY 2013 update (77 FR 67081).

The home health market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type 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 are not measured.

The index itself is constructed in three steps. First, a base period is selected (in this final rule with comment period, we are using 2016 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called “cost weights” or “expenditure weights.” Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a “price proxy.” In almost 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 index 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 previously, 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 provide HHA services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a HHA hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the

HHA, but would not be factored into the price change measured by a fixed-weight home health market basket. Only when the index is rebased would 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 HHAs purchase (HHA inputs) to furnish inpatient care between base periods.

Comment: A commenter had concerns that the data used for the market rebasing does not reflect current costs.

Response: For the 2016-based home health market basket, we use the 2016 Medicare cost reports for freestanding HHAs (CMS Form 1728–94) as the primary data source; the 2016 data are the most recent and comprehensive set of cost report data available to CMS at the time of rebasing. As we discussed in the CY 2019 HH PPS proposed rule (83 FR 32361), we use data from freestanding HHAs, which account for over 90 percent of HHAs (82 FR 35383), because we have determined that they better reflect HHAs’ actual cost structure. Expense data for hospital-based HHAs can be affected by the allocation of overhead costs over the entire institution. The 2010-based home health market basket was primarily based on the 2010 Medicare cost report data. Therefore, we believe that rebasing the home health market basket alleviates the concerns that the market basket does not reflect the most current costs.

b. Rebasing and Revising the Home Health Market Basket

We believe that it is desirable to rebase the home health market basket periodically so that the cost category weights reflect changes in the mix of goods and services that HHAs purchase in furnishing home health care. We based the cost category weights in the current home health market basket on CY 2010 data. We proposed to rebase and revise the home health market basket to reflect 2016 Medicare cost report (MCR) data, the latest available and most complete data on the actual structure of HHA costs.

The terms “rebasing” and “revising,” while often used interchangeably, denote different activities. The term “rebasing” means moving the base year for the structure of costs of an input price index (that is, in this exercise, we moved the base year cost structure from CY 2010 to CY 2016) without making any other major changes to the methodology. The term “revising” means changing data sources, cost

categories, and/or price proxies used in the input price index.

For this rebasing and revising, we released the detailed wages and salaries and benefits cost weights to reflect 2016 BLS Occupational Employment Statistics (OES) data for HHAs. The 2010-based home health market basket used 2010 BLS OES data for HHAs. We also proposed to break out the All Other (residual) cost category weight into more detailed cost categories, based on the 2007 Benchmark U.S. Department of Commerce, Bureau of Economic Analysis (BEA) Input-Output (I-O) Table for HHAs. The 2010-based home health market basket used the 2002 I-O data. Finally, due to its small weight, we proposed to eliminate the cost category 'Postage' and include these expenses in the 'All Other Services' cost weight.

Comment: Another commenter supported the rebasing of the home health market basket.

Response: We appreciate the commenter's support.

c. Derivation of the 2016-Based Home Health Market Basket Cost Weights

The major cost weights for this revised and rebased home health market basket are derived from the Medicare cost reports (MCR; CMS Form 1728-94) data for freestanding HHAs whose cost reporting period began on or after October 1, 2015 and before October 1, 2016. Of the 2016 Medicare cost reports for freestanding HHAs, approximately 84 percent of the reports had a begin date on January 1, 2016, approximately 6 percent had a begin date on July 1, 2016, and approximately 4 percent had a begin date on October 1, 2015. Using this methodology allowed our sample to include HHAs with varying cost report years including, but not limited to, the Federal fiscal or calendar year. We referred to the market basket as a calendar year market basket because the base period for all price proxies and weights are set to CY 2016.

We maintained our policy of using data from freestanding HHAs (77 FR 67081), which account for over 90 percent of HHAs (82 FR 35383), because we have determined that they better reflect HHAs' actual cost structure. Expense data for hospital-based HHAs can be affected by the allocation of overhead costs over the entire institution.

We derived eight major expense categories (Wages and Salaries, Benefits, Contract Labor, Transportation, Professional Liability Insurance (PLI), Fixed Capital, Movable Capital, and a residual "All Other") from the 2016 Medicare HHA cost reports. Due to its small weight, we eliminated the cost

category 'Postage' and included these expenses in the "All Other (residual)" cost weight. These major expense categories are based on those cost centers that are reimbursable under the HHA PPS, specifically Skilled Nursing Care, Physical Therapy, Occupational Therapy, Speech Pathology, Medical Social Services, Home Health Aide, and Supplies. These are the same cost centers that were used in the 2014 base payment rebasing (78 FR 72276), which are described in the Abt Associates Inc. June 2013, Technical Paper, "Analyses In Support of Rebasing and Updating Medicare Home Health Payment Rates" (<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/Analyses-in-Support-of-Rebasing-and-Updating-the-Medicare-Home-Health-Payment-Rates-Technical-Report.pdf>). Total costs for the HHA PPS reimbursable services reflect overhead allocation. We provide detail on the calculations for each major expense category.

1. *Wages and Salaries:* Wages and Salaries costs reflect direct patient care wages and salaries costs as well as wages and salaries costs associated with Plant Operations and Maintenance, Transportation, and Administrative and General. Specifically, we calculated Wages and Salaries by summing costs from Worksheet A, column 1, lines 3 through 12 and subtracting line 5.03 (A&G nonreimbursable costs).

2. *Benefits:* Benefits costs reflect direct patient care benefit costs as well as benefit costs associated with Plant Operations and Maintenance, Transportation, and Administrative and General. Specifically, we calculated Benefits by summing costs from Worksheet A, column 2, lines 3 through 12 and subtracting line 5.03 (A&G nonreimbursable costs).

3. *Direct Patient Care Contract Labor:* Contract Labor costs reflect direct patient care contract labor. Specifically, we calculated Contract Labor by summing costs from Worksheet A, column 4, lines 6 through 11.

4. *Transportation:* Transportation costs reflect direct patient care costs as well as transportation costs associated with Capital Expenses, Plant Operations and Maintenance, and Administrative and General. Specifically, we calculated Transportation by summing costs from Worksheet A, column 3, lines 1 through 12 and subtracting line 5.03 (A&G Nonreimbursable costs).

5. *Professional Liability Insurance:* Professional Liability Insurance reflects premiums, paid losses, and self-insurance costs. Specifically we calculated Professional Liability Insurance by summing costs from

Worksheet S2, lines 27.01, 27.02 and 27.03.

6. *Fixed Capital:* Fixed Capital-related costs reflect the portion of Medicare-allowable costs reported in "Capital Related Buildings and Fixtures" (Worksheet A, column 5, line 1). We calculated this Medicare allowable portion by first calculating a ratio for each provider that reflects fixed capital costs as a percentage of HHA reimbursable services. Specifically this ratio was calculated as the sum of costs from Worksheet B, column 1, lines 6 through 12 divided by the sum of costs from Worksheet B, column 1, line 1 minus lines 3 through 5. This percentage is then applied to the sum of the costs from Worksheet A, column 5, line 1.

7. *Movable Capital:* Movable Capital-related costs reflect the portion of Medicare-allowable costs reported in "Capital Related Moveable Equipment" (Worksheet A, column 5, line 2). We calculated this Medicare allowable portion by first calculating a ratio for each provider that reflects movable capital costs as a percentage of HHA reimbursable services. Specifically this ratio was calculated as the sum of costs from Worksheet B, column 2, lines 6 through 12 divided by the sum of costs from Worksheet B, column 2, line 2 minus lines 3 through 5. This percentage is then applied to the sum of the costs from Worksheet A, column 5, line 2.

8. *All Other (residual):* The "All Other" cost weight is a residual and was calculated by subtracting the major cost weight percentages (Wages and Salaries, Benefits, Direct Patient Care Contract Labor, Transportation, Professional Liability Insurance, Fixed Capital, and Movable Capital) from 1.

As prescription drugs and DME are not payable under the HH PPS, we maintained our policy to exclude those items from the home health market basket. Totals within each of the major cost categories were edited to remove reports where the data were deemed unreasonable (for example, when total costs were not greater than zero). We then determined the proportion of total Medicare allowable costs that each category represents. For all of the major cost categories except the "residual" All Other cost weight, we then removed those providers whose derived cost weights fall in the top and bottom 5 percent of provider-specific cost weights to ensure the removal of outliers. After the outliers were removed, we summed the costs for each category across all remaining providers. Then, we divided this by the sum of total Medicare allowable costs across all remaining

providers to obtain a cost weight for the 2016-based home health market basket for the given category.

Table 7 shows the major cost categories and their respective cost weights as derived from the Medicare

cost reports for this final rule with comment period.

TABLE 7: MAJOR COST CATEGORIES AS DERIVED FROM THE MEDICARE COST REPORTS

Major Cost Categories	2010 Based	2016 Based
Wages and Salaries (including allocated direct patient care contract labor)	66.3	65.1
Benefits (including allocated direct patient care contract labor)	12.2	10.9
Transportation	2.5	2.6
Professional Liability Insurance (Malpractice)	0.4	0.3
Fixed Capital	1.5	1.4
Moveable Capital	0.6	0.6
“All Other” residual	16.5	19.0

* Figures may not sum to 100.0 due to rounding.

The decrease in the wages and salaries cost weight of 1.2 percentage points and the decrease in the benefits cost weight of 1.3 percentage points is attributable to both employed compensation and direct patient care contract labor costs as reported on the MCR data. Our analysis of the MCR data shows that the decrease in the compensation cost weight of 2.4 percentage points (calculated by combining wages and salaries and benefits) from 2010 to 2016 occurred among for-profit, nonprofit, and government providers and among providers serving only rural beneficiaries, only urban beneficiaries, or both rural and urban beneficiaries.

Over the 2010 to 2016 time period, the average number of FTEs per provider decreased considerably. This corresponds with the HHA claims analysis published on page 35279 of the CY 2018 proposed rule (<https://www.gpo.gov/fdsys/pkg/FR-2017-07-28/pdf/2017-15825.pdf>), which shows that the number of visits per 60-day episode has decreased from 19.8 visits in 2010 to 17.9 visits in 2016 for Medicare PPS. Medicare visits account for approximately 60 percent of total visits.

The direct patient care contract labor costs are contract labor costs for skilled nursing, physical therapy, occupational therapy, speech therapy, and home health aide cost centers. We allocated these direct patient care contract labor costs to the Wages and Salaries and Benefits cost categories based on each provider's relative proportions of both employee wages and salaries and employee benefits costs. For example, the direct patient care contract labor costs that are allocated to wages and salaries is equal to: (1) The employee wages and salaries costs as a percent of

the sum of employee wages and salaries costs and employee benefits costs times; and (2) direct patient care contract labor costs. Nondirect patient care contract labor costs (such as contract labor costs reported in the Administrative and General cost center of the MCR) are captured in the “All Other” residual cost weight and later disaggregated into more detail as described later in this section. This is a similar methodology that was implemented for the 2010-based home health market basket.

We further divided the “All Other” residual cost weight estimated from the 2016 Medicare cost report data into more detailed cost categories. To divide this cost weight we used the 2007 Benchmark I–O “Use Tables/Before Redefinitions/Purchaser Value” for NAICS 621600, Home Health Agencies, published by the BEA. These data are publicly available at http://www.bea.gov/industry/io_annual.htm. The BEA Benchmark I–O data are generally scheduled for publication every 5 years. The most recent data available at the time of rebasing was for 2007. The 2007 Benchmark I–O data are derived from the 2007 Economic Census and are the building blocks for BEA's economic accounts. Therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.⁸ Besides Benchmark I–O estimates, BEA also produces Annual I–O estimates. While based on a similar methodology, the Annual I–O estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data become available.

⁸ http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.

Instead of using the less detailed Annual I–O data, we inflated the detailed 2007 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 that are obtained from the 2007 Benchmark I–O data. We repeated this practice for each year. Then, we calculated the cost shares that each cost category represents of the 2007 data inflated to 2016. These resulting 2016 cost shares were applied to the “All Other” residual cost weight to obtain the detailed cost weights for the 2016-based home health market basket. For example, the cost for Operations and Maintenance represents 8.0 percent of the sum of the “All Other” 2007 Benchmark I–O HHA Expenditures inflated to 2016. Therefore, the Operations and Maintenance cost weight represents 8.0 percent of the 2016-based home health market basket's “All Other” cost category (19.0 percent), yielding an Operations and Maintenance cost weight of 1.5 percent in the 2016-based home health market basket (0.080×19.0 percent = 1.5 percent). For the 2010-based home health market basket, we used the same methodology utilizing the 2002 Benchmark I–O data (aged to 2010).

Using this methodology, we derived nine detailed cost categories from the 2016-based home health market basket “All Other” residual cost weight (19.0 percent). These categories are: (1) Operations and Maintenance; (2) Administrative Support; (3) Financial Services; (4) Medical Supplies; (5) Rubber and Plastics; (6) Telephone; (7) Professional Fees; (8) Other Products; and (9) Other Services. The 2010-based home health market basket included a

separate cost category for Postage; however, due to its small weight for the 2016-based home health market basket, we proposed to eliminate the stand-

alone cost category for Postage and include these expenses in the Other Services cost category.

Table 8 lists the final 2016-based home health market basket cost categories, cost weights, and price proxies.

TABLE 8: COST CATEGORIES, WEIGHTS, AND PRICE PROXIES IN FINAL 2016-BASED HOME HEALTH MARKET BASKET

Cost Categories	Weight	Price Proxy
Compensation, including allocated contract services' labor	76.1	
Wages and Salaries, including allocated contract services' labor	65.1	Home Health Blended Wages and Salaries Index (2016)
Benefits, including allocated contract services' labor	10.9	Home Health Blended Benefits Index (2016)
Operations & Maintenance	1.5	CPI-U for Fuel and utilities
Professional Liability Insurance	0.3	CMS Physician Professional Liability Insurance Index
Administrative & General & Other Expenses including allocated contract services' labor	17.4	
Administrative Support	1.0	ECI for Total compensation for Private industry workers in Office and administrative support
Financial Services	1.9	ECI for Total compensation for Private industry workers in Financial activities
Medical Supplies	0.9	PPI Commodity data for Medical, surgical & personal aid devices
Rubber & Plastics	1.6	PPI Commodity data for Rubber and plastic products
Telephone	0.7	CPI-U for Telephone services
Professional Fees	5.3	ECI for Total compensation for Private industry workers in Professional and related
Other Products	2.8	PPI Commodity data for Finished goods less foods and energy
Other Services	3.2	ECI for Total compensation for Private industry workers in Service occupations
Transportation	2.6	CPI-U for Transportation
Capital-Related	2.1	
Fixed Capital	1.4	CPI-U for Owners' equivalent rent of residences
Movable Capital	0.6	PPI Commodity data for Machinery and equipment
Total	100.0*	

*Figures may not sum due to rounding.

We received no comments on the derivation of the 2016-based Home Health market basket cost categories and weights and therefore are finalizing the categories and weights without modification.

d. 2016-Based Home Health Market Basket Price Proxies

After we computed the CY 2016 cost category weights for the rebased home health market basket, we selected the most appropriate wage and price indexes to proxy the rate of change for each expenditure category. With the exception of the price index for Professional Liability Insurance costs, the price proxies are based on Bureau of Labor Statistics (BLS) data and are grouped into one of the following BLS categories:

- *Employment Cost Indexes:* Employment Cost Indexes (ECIs) measure the rate of change in employee 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. They are not affected by shifts in skill mix. ECIs are superior to average hourly earnings as price proxies for input price indexes for two reasons: (a) They measure pure price change; and (b) they are available by occupational groups, not just by industry.

- *Consumer Price Indexes:* Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by the typical consumer. Consumer price indexes are used when the expenditure is more similar to that of a purchase at the retail level rather than at the wholesale level, or if no appropriate Producer Price Indexes (PPIs) were available.

- *Producer Price Indexes:* PPIs measures average changes in prices received by domestic producers for their goods and services. PPIs are used to measure price changes for goods sold in other than retail markets. For example,

a PPI for movable equipment is used rather than a CPI for equipment. PPIs in some cases are preferable price proxies for goods that HHAs purchase at wholesale levels. These fixed-weight indexes are a measure of price change at the producer or at the intermediate stage of production.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance. 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 way that can be replicated. Low sampling variability is desirable because it indicates that sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because a sample was surveyed rather than the entire population.) 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 the underlying price proxies be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly helps 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 means that the proxy is publicly available. We prefer that our proxies are publicly available because this would 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. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs selected for use in the HH market basket 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.

As part of the revising and rebasing of the home health market basket, we

proposed to rebase the home health blended Wages and Salaries index and the home health blended Benefits index. We proposed to use these blended indexes as price proxies for the Wages and Salaries and the Benefits portions of the proposed 2016-based home health market basket, as we did in the 2010-based home health market basket. A more detailed discussion is provided in this rule.

- *Wages and Salaries:* For measuring price growth in the 2016-based home health market basket, we proposed to apply six price proxies to six occupational subcategories within the Wages and Salaries component, which would reflect the HHA occupational mix. This is the same approach used for the 2010-based index. We used a blended wage proxy because there is not a published wage proxy specific to the home health industry.

We proposed to continue to use the National Industry-Specific Occupational Employment and Wage estimates for North American Industrial Classification System (NAICS) 621600, Home Health Care Services, published by the BLS Office of Occupational Employment Statistics (OES) as the data

source for the cost shares of the home health blended wage and benefits proxy. This is the same data source that was used for the 2010-based HHA blended wage and benefit proxies; however, we proposed to use the May 2016 estimates in place of the May 2010 estimates. 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.

The needed data on HHA expenditures for the six occupational subcategories (Health-Related Professional and Technical, Non Health-Related Professional and Technical, Management, Administrative, Health and Social Assistance Service, and Other Service Workers) for the wages and salaries component were tabulated from the May 2016 OES data for NAICS 621600, Home Health Care Services. Table 9 compares the 2016 occupational assignments to the 2010 occupational assignments of the six CMS designated subcategories. If an OES occupational classification does not exist in the 2010 or 2016 data we use “n/a.”

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TABLE 9: 2016 OCCUPATIONAL ASSIGNMENTS COMPARED TO 2010 OCCUPATIONAL ASSIGNMENTS FOR CMS HOME HEALTH WAGES AND SALARIES BLEND

2016 Occupational Groupings		2010 Occupational Groupings	
Group 1	Health-Related Professional and Technical	Group 1	Health-Related Professional and Technical
n/a	n/a	29-1021	Dentists, General
29-1031	Dietitians and Nutritionists	29-1031	Dietitians and Nutritionists
29-1051	Pharmacists	29-1051	Pharmacists
29-1062	Family and General Practitioners	29-1062	Family and General Practitioners
29-1063	Internists, General	29-1063	Internists, General
29-1065	Pediatricians, General	n/a	n/a
29-1066	Psychiatrists	n/a	n/a
29-1069	Physicians and Surgeons, All Other	29-1069	Physicians and Surgeons, All Other
29-1071	Physician Assistants	29-1071	Physician Assistants
n/a	n/a	29-1111	Registered Nurses
29-1122	Occupational Therapists	29-1122	Occupational Therapists
29-1123	Physical Therapists	29-1123	Physical Therapists
29-1125	Recreational Therapists	29-1125	Recreational Therapists
29-1126	Respiratory Therapists	29-1126	Respiratory Therapists
29-1127	Speech-Language Pathologists	29-1127	Speech-Language Pathologists
29-1129	Therapists, All Other	29-1129	Therapists, All Other
29-1141	Registered Nurses	n/a	n/a
29-1171	Nurse Practitioners	n/a	n/a
29-1199	Health Diagnosing and Treating Practitioners, All Other	29-1199	Health Diagnosing and Treating Practitioners, All Other
Group 2	Non Health Related Professional & Technical	Group 2	Non Health Related Professional & Technical
13-0000	Business and Financial Operations Occupations	13-0000	Business and Financial Operations Occupations
15-0000	Computer and Mathematical Occupations	15-0000	Computer and Mathematical Science Occupations
n/a	n/a	17-0000	Architecture and Engineering Occupations
19-0000	Life, Physical, and Social Science Occupations	19-0000	Life, Physical, and Social Science Occupations
n/a	n/a	23-0000	Legal Occupations
25-0000	Education, Training, and Library Occupations	25-0000	Education, Training, and Library Occupations
27-0000	Arts, Design, Entertainment, Sports, and Media Occupations	27-0000	Arts, Design, Entertainment, Sports, and Media Occupations
Group 3	Management	Group 3	Management
11-0000	Management Occupations	11-0000	Management Occupations
Group 4	Administrative	Group 4	Administrative
43-0000	Office and Administrative Support Occupations	43-0000	Office and Administrative Support Occupations
Group 5	Health and Social Assistance Services	Group 5	Health and Social Assistance Services
21-0000	Community and Social Service Occupations	21-0000	Community and Social Services Occupations
29-2011	Medical and Clinical Laboratory Technologists	29-2011	Medical and Clinical Laboratory Technologists

2016 Occupational Groupings		2010 Occupational Groupings	
29-2012	Medical and Clinical Laboratory Technicians	29-2012	Medical and Clinical Laboratory Technicians
29-2021	Dental Hygienists	29-2021	Dental Hygienists
29-2032	Diagnostic Medical Sonographers	29-2032	Diagnostic Medical Sonographers
29-2034	Radiologic Technologists	29-2034	Radiologic Technologists and Technicians
29-2041	Emergency Medical Technicians and Paramedics	29-2041	Emergency Medical Technicians and Paramedics
29-2051	Dietetic Technicians	29-2051	Dietetic Technicians
29-2052	Pharmacy Technicians	29-2052	Pharmacy Technicians
29-2053	Psychiatric Technicians	n/a	n/a
29-2054	Respiratory Therapy Technicians	29-2054	Respiratory Therapy Technicians
29-2055	Surgical Technologists	n/a	n/a
29-2061	Licensed Practical and Licensed Vocational Nurses	29-2061	Licensed Practical and Licensed Vocational Nurses
29-2071	Medical Records and Health Information Technicians	29-2071	Medical Records and Health Information Technicians
29-2099	Health Technologists and Technicians, All Other	29-2099	Health Technologists and Technicians, All Other
n/a	n/a	29-9012	Occupational Health and Safety Technicians
29-9099	Healthcare Practitioners and Technical Workers, All Other	29-9099	Healthcare Practitioner and Technical Workers, All Other
31-0000	Healthcare Support Occupations	31-0000	Healthcare Support Occupations
Group 6	Other Service Workers	Group 6	Other Service Workers
33-0000	Protective Service Occupations	33-0000	Protective Service Occupations
35-0000	Food Preparation and Serving Related Occupations	35-0000	Food Preparation and Serving Related Occupations
37-0000	Building and Grounds Cleaning and Maintenance Occupations	37-0000	Building and Grounds Cleaning and Maintenance Occupations
39-0000	Personal Care and Service Occupations	39-0000	Personal Care and Service Occupations
41-0000	Sales and Related Occupations	41-0000	Sales and Related Occupations
47-0000	Construction and Extraction Occupations	n/a	n/a
49-0000	Installation, Maintenance, and Repair Occupations	49-0000	Installation, Maintenance, and Repair Occupations
51-0000	Production Occupations	51-0000	Production Occupations
53-0000	Transportation and Material Moving Occupations	53-0000	Transportation and Material Moving Occupations

Total expenditures by occupation were calculated by taking the OES number of employees multiplied by the OES annual average salary for each subcategory, and then calculating the proportion of total wage costs that each

subcategory represents. The proportions listed in Table 10 represent the Wages and Salaries blend weights.

TABLE 10: COMPARISON OF THE 2016-BASED HOME HEALTH WAGES AND SALARIES BLEND AND THE 2010-BASED HOME HEALTH WAGES AND SALARIES BLEND

Cost Subcategory	2016 Weight	2010 Weight	Price Proxy	BLS Series ID
Health-Related Professional and Technical	33.7	33.4	ECI for Wages and salaries for All Civilian workers in Hospitals	CIU1026220000000I
Non Health-Related Professional and Technical	2.3	2.3	ECI for Wages and salaries for Private industry workers in Professional, scientific, and technical services	CIU2025400000000I
Management	7.6	8.3	ECI for Wages and salaries for Private industry workers in Management, business, and financial	CIU2020000110000I
Administrative	6.7	7.7	ECI for Wages and salaries for Private industry workers in Office and administrative support	CIU2020000220000I
Health and Social Assistance Services	35.3	35.8	ECI for Wages and salaries for All Civilian workers in Health care and social assistance	CIU1026200000000I
Other Service Occupations	14.4	12.6	ECI for Wages and salaries for Private industry workers in Service occupations	CIU2020000300000I
Total	100.0*	100.0*		

*Totals may not sum due to rounding.

A comparison of the yearly changes from CY 2016 to CY 2019 for the 2010-based home health Wages and Salaries

blend and the 2016-based home health Wages and Salaries blend is shown in Table 11. The annual increases in the

two price proxies are the same when rounded to one decimal place.

TABLE 11: ANNUAL GROWTH IN 2016 AND 2010 HOME HEALTH WAGES AND SALARIES BLEND

	2016	2017	2018	2019
Wage Blend 2016	2.3	2.5	2.8	3.2
Wage Blend 2010	2.3	2.5	2.8	3.2

Source: IHS Global Insight Inc. 3rd Quarter 2018 forecast with historical data through 2nd Quarter 2018

• *Benefits:* For measuring Benefits price growth in the 2016-based home health market basket, we proposed to apply applicable price proxies to the six

occupational subcategories that are used for the Wages and Salaries blend. The six categories in Table 12 are the same as those in the 2010-based home health

market basket and include the same occupational mix as listed in Table 12.

TABLE 12: COMPARISON OF THE 2016-BASED HOME HEALTH BENEFITS BLEND AND 2010-BASED HOME HEALTH BENEFITS BLEND

Cost Category	2016 Weight	2010 Weight	Price Proxy
Health-Related Professional and Technical	33.9	33.5	ECI for Benefits for All Civilian workers in Hospitals
Non Health-Related Professional and Technical	2.3	2.2	ECI for Benefits for Private industry workers in Professional, scientific, and technical services
Management	7.3	8.0	ECI for Benefits for Private industry workers in Management, business, and financial
Administrative	6.7	7.8	ECI for Benefits for Private industry workers in Office and administrative support
Health and Social Assistance Services	35.5	35.9	ECI for Benefits for All Civilian workers in Health care and social assistance
Other Service Workers	14.2	12.5	ECI for Benefits for Private industry workers in Service occupations
Total	100.0*	100.0*	

*Totals may not sum due to rounding.

There is no available data source that exists for benefit expenditures by occupation for the home health industry. Thus, to construct weights for the home health benefits blend we calculated the ratio of benefits to wages and salaries for CY 2016 for the six ECI series we used in the blended 'wages and salaries' and 'benefits' indexes. To derive the relevant benefits weight, we applied the benefit-to-wage ratios to

each of the six occupational subcategories from the 2016 OES wage and salary weights, and normalized. For example, the ratio of benefits to wages from the 2016 home health wages and salaries blend and the benefits blend for the management category is 0.984. We applied this ratio to the 2016 OES weight for wages and salaries for management, 7.6 percent, and then normalized those weights relative to the

other 5 benefit occupational categories to obtain a benefit weight for management of 7.3 percent.

A comparison of the yearly changes from CY 2016 to CY 2019 for the 2010-based home health Benefits blend and the 2016-based home health Benefits blend is shown in Table 13. The annual increases in the two price proxies are the same when rounded to one decimal place.

TABLE 13: ANNUAL GROWTH IN THE 2016 HOME HEALTH BENEFITS BLEND AND THE 2010 HOME HEALTH BENEFITS BLEND

	2016	2017	2018	2019
Benefits Blend 2016	1.7	1.9	2.2	3.0
Benefits Blend 2010	1.7	1.9	2.2	3.0

Source: IHS Global Insight Inc. 3rd Quarter 2018 forecast with historical data through 2nd Quarter 2018

- *Operations and Maintenance:* We proposed to use CPI U.S. city average for Fuel and utilities (BLS series code #CUUR0000SAH2) to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

- *Professional Liability Insurance:* We proposed to use the CMS Physician Professional Liability Insurance price index to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

To accurately reflect the price changes associated with physician PLI, each year we collect PLI premium data for physicians from a representative sample of commercial carriers and publically available rate filings as maintained by each State's Association of Insurance Commissioners. As we require for our

other price proxies, the PLI price proxy is intended to reflect the pure price change associated with this particular cost category. Thus, the level of liability coverage is held constant from year to year. To accomplish this, we obtain premium information from a sample of commercial carriers for a fixed level of coverage, currently \$1 million per occurrence and a \$3 million annual limit. This information is collected for every State by physician specialty and risk class. Finally, the State-level, physician-specialty data are aggregated to compute a national total, using counts of physicians by State and specialty as provided in the American Medical Association (AMA) publication, *Physician Characteristics and Distribution in the U.S.*

- *Administrative and Support:* We proposed to use the ECI for Total

compensation for Private industry workers in Office and administrative support (BLS series code #CIU2010000220000I) to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

- *Financial Services:* We proposed to use the ECI for Total compensation for Private industry workers in Financial activities (BLS series code #CIU201520A000000I) to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

- *Medical Supplies:* We proposed to use the PPI Commodity data for Miscellaneous products-Medical, surgical & personal aid devices (BLS series code #WPU156) to measure price growth of this cost category. The same

proxy was used for the 2010-based home health market basket.

- *Rubber and Plastics:* We proposed to use the PPI Commodity data for Rubber and plastic products (BLS series code #WPU07) to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

- *Telephone:* We proposed to use CPI U.S. city average for Telephone services (BLS series code #CUUR0000SEED) to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

- *Professional Fees:* We proposed to use the ECI for Total compensation for Private industry workers in Professional and related (BLS series code #CIS2010000120000I) to measure price growth of this category. The same proxy was used for the 2010-based home health market basket.

- *Other Products:* We proposed to use the PPI Commodity data for Final demand-Finished goods less foods and energy (BLS series code #WPUFD4131) to measure price growth of this category. The same proxy was used for the 2010-based home health market basket.

- *Other Services:* We proposed to use the ECI for Total compensation for Private industry workers in Service occupations (BLS series code #CIU2010000300000I) to measure price growth of this category. The same proxy

was used for the 2010-based home health market basket.

- *Transportation:* We proposed to use the CPI U.S. city average for Transportation (BLS series code #CUUR0000SAT) to measure price growth of this category. The same proxy was used for the 2010-based home health market basket.

- *Fixed capital:* We proposed to use the CPI U.S. city average for Owners' equivalent rent of residences (BLS series code #CUUS0000SEHC) to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

- *Movable Capital:* We proposed to use the PPI Commodity data for Machinery and equipment (BLS series code #WPU11) to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

Comment: Several commenters stated they do not believe the CY 2019 home health market basket adequately reflects compensation pressures faced by home health providers. A commenter recommended that CMS build into the 2019 market basket update an increase to reflect general health care wage increases.

Response: We believe the CY 2019 market basket update of 3.0 percent reflects the expected compensation price increases that home health agencies will face in CY 2019. The compensation component of the 2016-

based Home Health market basket is 76.1 percent. The weight for the "Wages and Salaries" cost category is 65.1 percent and the weight for the "Benefits" cost category is 10.9 percent. Each of these two respective cost categories are proxied by price indices that reflect the occupational mix of home health staff for the following categories: Health-related professional and technical; non health-related professional and technical; management; administrative; health and social assistance services; and other service occupations. Full details on these price indices can be found in the CY 2019 HH PPS proposed rule (83 FR 32364 through 32366). For CY 2019, the estimated "Wages and Salaries" inflation is 3.2 percent and the estimated "Benefits" inflation is 3.0 percent. We believe the CY 2019 market basket update adequately reflects these projected price increases associated with wage increases specific to the health and non-health occupations used by the home health industry.

e. Rebasing Results

After consideration of public comments, we are finalizing the proposed 2016-based home health market basket without modification. A comparison of the yearly changes from CY 2014 to CY 2021 for the 2010-based home health market basket and the final 2016-based home health market basket is shown in Table 14.

TABLE 14: COMPARISON OF THE 2010-BASED HOME HEALTH MARKET BASKET AND THE FINAL 2016-BASED HOME HEALTH MARKET BASKET, PERCENT CHANGE, 2014-2021

	Home Health Market Basket, 2010-Based	Home Health Market Basket, 2016-Based	Difference (2016-Based less 2010-Based)
Historical data:			
CY 2014	1.6	1.6	0.0
CY 2015	1.6	1.5	-0.1
CY 2016	2.0	2.0	0.0
CY 2017	2.3	2.3	0.0
Average CYs 2014-2017	1.9	1.9	0.0
Forecast:			
CY 2018	2.7	2.7	0.0
CY 2019	3.0	3.0	0.0
CY 2020	3.2	3.2	0.0
CY 2021	3.2	3.2	0.0
Average CYs 2018-2021	3.0	3.0	0.0

Source: IHS Global Inc. 3rd Quarter 2018 forecast with historical data through 2nd Quarter 2018.

Table 14 shows that the forecasted rate of growth for CY 2019 for the 2016-based home health market basket is 3.0 percent, the same rate of growth as

estimated using the 2010-based home health market basket; other forecasted years also show a similar increase. Similarly, the historical estimates of the

growth in the 2016-based and 2010-based home health market basket are the same except for CY 2015 where the

2010-based home health market basket is 0.1 percentage point higher.

The growth rates in Table 14 are based upon IHS Global Inc.'s (IGI) 3rd quarter 2018 forecast. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets. We noted in the proposed rule that if more recent data were subsequently available (for example, a more recent estimate of the market basket), we would use such data to determine the market basket increases in the final rule. In that proposed rule the forecasted rate of growth for CY 2019, based on IGI's 1st quarter 2018 forecast, for the 2016-based home health market basket was 2.8 percent (83 FR 32368).

Comment: A commenter asked if the 2002 through 2018 increases in the market basket represent the percentage increases in consumer health care costs (defined by the commenter as insurance premiums and cost for services) during the same time period. The commenter further stated the inflationary rates used understated what the actual change to costs would have been during this period.

Response: We believe the commenter may be confusing the concept of the CMS market basket, which is an input price index, with the concept of a consumer price index, which is an output price index. An input price

index measures the change in the prices of goods and services bought by producers or providers as intermediate inputs. An output price index measures the change in the prices of goods and services sold as output by producers.

The 2016-based HHA market basket, along with its predecessors such as the 2010-based HHA market basket, are fixed-weight indices that are intended to measure the input prices used in providing home health care services. The market basket by definition is a price index rather than a cost index and, therefore, only accounts for changes in prices, holding quantities constant. In order to reflect the changes in the mix of input costs over time, CMS rebases the market basket periodically to ensure that the index is reflecting the most up to date relative cost shares for specific categories of expenses. We have found that the relative cost shares for each category do not change substantially from year to year.

The current CY 2019 market basket update factor of 3.0 percent reflects the projected price growth in the input costs to provide home health services. This forecast is based on the IHS Global Inc. (IGI) third quarter 2018 forecast. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets.

We also note that according to the Medicare Payment Advisory Committee,

Medicare home health revenue has greatly exceeded Medicare home health costs since PPS implementation, with the most recent Medicare margins for 2016 estimated to be 15.5 percent (http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch9_sec_rev_0518.pdf)

f. Labor-Related Share

Effective for CY 2019, we revised the labor-related share to reflect the 2016-based home health market basket Compensation (Wages and Salaries plus Benefits) cost weight. The current labor-related share is based on the Compensation cost weight of the 2010-based home health market basket. Based on the 2016-based home health market basket, the labor-related share would be 76.1 percent and the non-labor-related share would be 23.9 percent. The labor-related share for the 2010-based home health market basket was 78.535 percent and the non-labor-related share was 21.465 percent. As explained earlier, the decrease in the compensation cost weight of 2.4 percentage points is attributable to both employed compensation (wages and salaries and benefits for employees) and direct patient care contract labor costs as reported in the MCR data. Table 15 details the components of the labor-related share for the 2010-based and 2016-based home health market baskets.

TABLE 15: LABOR-RELATED SHARE OF 2010-BASED and 2016-BASED HOME HEALTH MARKET BASKETS

Cost Category	2010-Based Market Basket Weight	2016-Based Market Basket Weight
Wages and Salaries	66.3	65.1
Employee Benefits	12.2	11.0
Total Labor-Related	78.5	76.1
Total Nonlabor-Related	21.5	23.9

There are no changes to the labor-related share in this final rule with comment period compared to the labor related share in the proposed rule (83 FR 32368).

We implemented the revision to the labor-related share of 76.1 percent in a budget neutral manner. This proposal would be consistent with our policy of implementing the annual recalibration of the case-mix weights and update of the home health wage index in a budget neutral manner.

Comment: Several commenters disagreed with CMS' proposal to reduce

the labor related share, because such a change could result in less care for patients.

Response: The labor related share is composed of the Wages & Salaries and Benefits cost weights from the 2016-based home health market basket. These cost weights were calculated using the 2016 Medicare cost report data (form CMS-1728-94), which is provided directly by freestanding home health agencies. The 2016 data was the most comprehensive data source available for determining the CY 2019 labor-related share at the time of rulemaking. The CY

2018 labor-related share of 78.535 percent was based on the 2010-based home health market basket Wages and Salaries and Benefit cost weights, which were calculated using the 2010 Medicare cost report data. Therefore, we believe the labor-related share of 76.1 percent is technically appropriate as it is based on more recent Medicare cost report data reported by home health agencies.

Comment: Another commenter agreed with CMS' proposal to reduce the labor related share.

Response: We appreciate the commenter's support and agree that the labor-related share should be reduced from 78.535 percent to 76.1 percent as it reflects the most recent Medicare cost report data for home health agencies available at the time of rebasing.

Final Decision: After consideration of public comments, based on the 2016-based home health market basket, we are finalizing the proposed labor related share of 76.1 percent and the non-labor-related share of 23.9 percent.

g. Multifactor Productivity

In the CY 2015 HHA PPS final rule (79 FR 38384 through 38384), we finalized our methodology for calculating and applying the MFP adjustment. As we explained in that rule, section 1895(b)(3)(B)(vi) of the Act, requires that, in CY 2015 (and in subsequent calendar years, except CY 2018 (under section 411(c) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015)), the market basket percentage under the HHA prospective payment system as described in section 1895(b)(3)(B) of the Act be annually adjusted by changes in economy-wide productivity. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of change 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, calendar year, cost reporting period, or other annual period) (the "MFP adjustment"). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. Please see <http://www.bls.gov/mfp>, to obtain the BLS historical published MFP data.

Based on IHS Global Inc.'s (IGI's) 3rd quarter 2018 forecast with history through the 2nd quarter of 2018, the projected MFP adjustment (the 10-year moving average of MFP for the period ending December 31, 2019) for CY 2019 is 0.8 percent.

We noted in the proposed rule that if more recent data were subsequently available (for example, a more recent estimate of the MFP adjustment), we would use such data to determine the MFP adjustment in the final rule. For comparison purposes, the proposed MFP adjustment for CY 2019 was 0.7 percent (83 FR 32368), and was based on IGI's 1st quarter 2018 forecast.

2. CY 2019 Market Basket Update for HHAs

Using IGI's third quarter 2018 forecast, the MFP adjustment for CY 2019 is projected to be 0.8 percent. In accordance with section 1895(b)(3)(B)(iii) of the Act, we proposed to base the CY 2019 market basket update, which is used to determine the applicable percentage increase for HHA payments, on the most recent estimate of the 2016-based home health market basket. Based on IGI's third quarter 2018 forecast with history through the second quarter of 2018, the projected increase of the 2016-based home health market basket for CY 2019 is 3.0 percent. We then reduce this percentage increase by the current estimate of the MFP adjustment for CY 2019 of 0.8 percentage point in accordance with 1895(b)(3)(B)(vi) of the Act. Therefore, the current estimate of the CY 2019 HHA payment update is 2.2 percent (3.0 percent market basket update, less 0.8 percentage point MFP adjustment).

Section 1895(b)(3)(B)(v) of the Act requires that the home health update be decreased by 2 percentage points for those HHAs that do not submit quality data as required by the Secretary. For HHAs that do not submit the required quality data for CY 2019, the home health payment update would be 0.2 percent (2.2 percent minus 2 percentage points).

Comment: Several commenters agreed with CMS' proposed 2.1 percent payment increase.

Response: We appreciate the commenters' support. The proposed 2.1 percent payment increase was based on IGI Global Inc.'s first quarter 2018 forecast of the 2016-based HHA market basket and the 10-year moving average of annual economy-wide private nonfarm business. As noted in the proposed rule, if a more recent forecast of the market basket and MFP was available, we would use such data to determine the CY 2019 market basket update and MFP adjustment in the final rule. Based on IHS Global Inc.'s (IGI) third quarter 2018 forecast, we determine a payment increase of 2.2 percent for the final update percentage as previously stated.

Based on IGI's third quarter 2018 forecast, we are finalizing the CY 2019 HHA payment update at 2.2 percent (3.0 percent market basket update, less 0.8 percentage point MFP adjustment).

3. CY 2019 Home Health Wage Index

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act require the Secretary to provide appropriate adjustments to the

proportion of the payment amount under the HH PPS that account for area wage differences, using adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of HH services. Since the inception of the HH PPS, we have used inpatient hospital wage data in developing a wage index to be applied to HH payments. We proposed to continue this practice for CY 2019, as we continue to believe that, in the absence of HH-specific wage data that accounts for area differences, using inpatient hospital wage data is appropriate and reasonable for the HH PPS. Specifically, we proposed to continue to use the pre-floor, pre-reclassified hospital wage index as the wage adjustment to the labor portion of the HH PPS rates. For CY 2019, 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). We apply the appropriate wage index value to the labor portion of the HH PPS rates based on the site of service for the beneficiary (defined by section 1861(m) of the Act as the beneficiary's place of residence).

To address those geographic areas in which there are no inpatient hospitals, and thus, no hospital wage data on which to base the calculation of the CY 2019 HH PPS wage index, we proposed to continue to use the same methodology discussed in the CY 2007 HH PPS final rule (71 FR 65884) to address those geographic areas in which there are no inpatient hospitals. For rural areas that do not have inpatient hospitals, we proposed to use the average wage index from all contiguous Core Based Statistical Areas (CBSAs) as a reasonable proxy. 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 do 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 proposed to continue to use the most recent wage index previously available for that area. For urban areas without inpatient hospitals, we use the average wage index of all urban areas within the state as a reasonable proxy for the wage index for that CBSA. For CY 2019, the only urban area without inpatient hospital wage data is Hinesville, GA (CBSA 25980).

On February 28, 2013, OMB issued Bulletin No. 13–01, announcing revisions to the delineations of MSAs, Metropolitan Statistical Areas, and CBSAs, and guidance on uses of the delineation of these areas. In the CY 2015 HH PPS final rule (79 FR 66085 through 66087), we adopted the OMB's new area delineations using a 1-year transition. On August 15, 2017, OMB issued Bulletin No. 17–01 in which it announced that one Micropolitan Statistical Area, Twin Falls, Idaho, now qualifies as a Metropolitan Statistical Area.⁹ The most recent OMB Bulletin (No. 18–03) was published on April 10, 2018 and is available at: <https://www.whitehouse.gov/wp-content/uploads/2018/04/OMB-BULLETIN-NO.-18-03-Final.pdf>. The revisions contained in OMB Bulletin No. 18–03 have no impact on the geographic area delineations that are used to wage adjust HH PPS payments.

The following is a summary of the comments received on the proposed CY 2019 home health wage index and our responses:

Comment: Several commenters shared concerns in how the wage index is calculated and implemented for home health agencies compared to other prospective payment systems within the same CBSAs. A commenter commented that hospitals are given the opportunity to appeal their annual wage index and apply for geographic reclassification while HHAs in the same geographic location are not given that same privilege. The commenter believes that this lack of parity between different health care sectors further exemplifies the inadequacy of CMS' decision to continue to use the pre-floor, pre-reclassified hospital wage index to adjust home health services payment rates. They gave an example of Massachusetts where every hospital in the Worcester CBSA and two hospitals in the Providence-Bristol CBSA have been re-classified to the Boston CBSA, effectively increasing their wage index by approximately 9 percent and 20 percent respectively. They further suggest that CMS use wage index from Critical Access Hospitals in calculating the wage index for HHAs to make the wage index more reflective of actual local wage practices.

Response: We thank the commenters for their comments. We continue to believe that the regulations and statutes that govern the HH PPS do not provide a mechanism for allowing HHAs to seek geographic reclassification or to utilize

the rural floor provision that exists for Hospital Inpatient Prospective Payment System (IPPS) hospitals. Section 4410(a) of the Balanced Budget Act of 1997 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 is the rural floor provision and it is specific to hospitals. The reclassification provision at section 1886(d)(10)(C)(i) of the Act states that the Medicare Geographic Classification Review Board shall consider the application of any subsection (d) hospital requesting the Secretary change the hospital's geographic classification for purposes of payment under the IPPS. This reclassification 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. We continue to believe that using the pre-floor, pre-reclassified hospital wage index as the wage adjustment to the labor portion of the HH PPS rates is appropriate and reasonable. Although the pre-floor, pre-classified hospital wage index does not include data from Critical Access Hospitals (CAHs), we believe that it reflects the relative level of wages and wage-related costs applicable to providing HH services. As we stated in the August 1, 2003 IPPS final rule (68 FR 45397), CAHs represent a substantial number of hospitals with significantly different labor costs in many labor market areas where they exist.

Comment: A commenter expressed concerns with CMS using CY 2015 wage index figures for the CY 2019 wage index since there have been shifts in the labor market in New York State.

Response: As discussed in the CY 2017 HH PPS final rule (81 FR 76721), we believe that the wage index values are reflective of the labor costs in each geographic area as they reflect the costs included on the cost reports of hospitals in those specific labor market areas. The wage index values are based on data submitted on the inpatient hospital cost reports. We utilize efficient means to ensure and review the accuracy of the hospital cost report data and resulting wage index. The home health wage index is derived from the pre-floor, pre-reclassified hospital wage index, which is calculated based on cost report data submitted from hospitals paid under the IPPS. All 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, 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. We believe that our review processes result in an accurate reflection of the applicable wages for each labor market area. The processes and procedures describing how the inpatient hospital wage index is developed are discussed in the IPPS rule each year, with the most recent discussion provided in the FY 2019 IPPS final rule (83 FR 41362 through 41374 and 83 FR 41380 through 41383). Any provider type may submit comments on the hospital wage index during the annual IPPS rulemaking cycle.

Comment: A commenter believes that the CMS decision 10 years ago to switch from Metropolitan Statistical Areas (MSAs) to CBSAs for the wage adjustment to the rates has had negative financial ramifications for HHAs in New York City. The commenter stated that unlike past MSA designations, where all of the counties in the New York City designation were from New York State, the 2006 CBSA wage index designation added Bergen, Hudson, and Passaic counties from New Jersey into the New York City CBSA. The commenter also noted that with the CY 2015 final rule, CMS added three more New Jersey counties (Middlesex, Monmouth, and Ocean) to the CBSA used for New York City.

Response: The MSA delineations as well as the CBSA delineations are determined by the Office of Management and Budget (OMB). The OMB reviews its Metropolitan Area definitions preceding each decennial census to reflect recent population changes. We believe that the OMB's CBSA designations reflect the most recent available geographic classifications and are a reasonable and appropriate way to define geographic areas for purposes of wage index values. Over 10 years ago, in our CY 2006 HH PPS final rule (70 FR 68132), we finalized the adoption of the revised labor market area definitions as discussed in the OMB Bulletin No. 03–04 (June 6, 2003). In the December 27, 2000 **Federal Register** (65 FR 82228 through 82238), the OMB announced its new standards for defining metropolitan and micropolitan statistical areas. According to that notice, the OMB defines a CBSA, beginning in 2003, as “a geographic entity associated with at least one core of 10,000 or more population, plus adjacent territory that has a high degree of social and economic integration with the core as

⁹ <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf>.

measured by commuting ties.” The general concept of the CBSAs is that of an area containing a recognized population nucleus and adjacent communities that have a high degree of integration with that nucleus. The purpose of the standards is to provide nationally consistent definitions for collecting, tabulating, and publishing federal statistics for a set of geographic areas. CBSAs include adjacent counties that have a minimum of 25 percent commuting to the central counties of the area. This is an increase over the minimum commuting threshold for outlying counties applied in the previous MSA definition of 15 percent. Based on the OMB’s current delineations, as described in the July 15, 2015 OMB Bulletin 15–01, the New Jersey counties of Bergen, Hudson, Middlesex, Monmouth, Ocean, and Passaic belong in the New York-Jersey City-White Plains, NY-NJ (CBSA 35614). In addition, for the payment systems of other provider types, such as IPPS hospitals, hospices, skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), and ESRD facilities, we have used CBSAs to define their labor market areas for more than a decade.

Comment: A commenter questioned the validity of the wage index data, especially in the case of the CBSA for Albany-Schenectady-Troy, noting that in the past 5 years, this CBSA has seen its wage index reduced 6.18 percent, going from 0.8647 in 2013 to a proposed CY 2019 wage index of 0.8179.

Response: As discussed in the CY 2017 HH PPS final rule (81 FR 76721), we believe that the wage index values are reflective of the labor costs in each geographic area as they reflect the costs included on the cost reports of hospitals in those specific labor market areas. The area wage index measures differences in hospital wage rates among labor market areas and compares the area wage index of the labor market area to the national average hourly wage. If a hospital or labor market area does not keep pace with the national average hourly wage in a given year, then the labor market area will see a decrease in the area wage index during that year.

Comment: A commenter recommended that providers meeting higher minimum wage standards, such as HHAs, obtain additional supplemental funding to better align payments with cost trends impacting providers.

Response: Regarding minimum wage standards, we note that such increases will be reflected in future data used to create the hospital wage index to the extent that these changes to state

minimum wage standards are reflected in increased wages to hospital staff.

Final Decision: After considering the comments received in response to the CY 2019 HH PPS proposed rule, we are finalizing our proposal to continue to use the pre-floor, pre-reclassified hospital inpatient wage index as the wage adjustment to the labor portion of the HH PPS rates. For CY 2019, the updated wage data are for the hospital cost reporting periods beginning on or after October 1, 2014 and before October 1, 2015 (FY 2015 cost report data). The final CY 2019 wage index is available on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html>.

4. CY 2019 Annual Payment Update

a. Background

The Medicare HH PPS has been in effect since October 1, 2000. As set forth in the July 3, 2000 final rule (65 FR 41128), the base unit of payment under the Medicare HH PPS is a national, standardized 60-day episode payment rate. As set forth in § 484.220, we adjust the national, standardized 60-day episode payment rate by a case-mix relative weight and a wage index value based on the site of service for the beneficiary.

To provide appropriate adjustments to the proportion of the payment amount under the HH PPS to account for area wage differences, we apply the appropriate wage index value to the labor portion of the HH PPS rates. The labor-related share of the case-mix adjusted 60-day episode is 76.1 percent and the non-labor-related share is 23.9 percent for CY 2019. The CY 2019 HH PPS rates use the same case-mix methodology as set forth in the CY 2008 HH PPS final rule with comment period (72 FR 49762) and is adjusted as described in section III.B of this final rule with comment period. The following are the steps we take to compute the case-mix and wage-adjusted 60-day episode rate for CY 2019:

- Multiply the national 60-day episode rate by the patient’s applicable case-mix weight.
- Divide the case-mix adjusted amount into a labor (76.1 percent) and a non-labor portion (23.9 percent).
- Multiply the labor portion by the applicable wage index based on the site of service of the beneficiary.
- Add the wage-adjusted portion to the non-labor portion, yielding the case-mix and wage adjusted 60-day episode rate, subject to any additional applicable adjustments.

In accordance with section 1895(b)(3)(B) of the Act, we proposed the annual update of the HH PPS rates. Section 484.225 sets forth the specific annual percentage update methodology. In accordance with § 484.225(i), for a HHA that does not submit HH quality data, as specified by the Secretary, the unadjusted national prospective 60-day episode rate is equal to the rate for the previous calendar year increased by the applicable HH market basket index amount minus 2 percentage points. Any reduction of the percentage change would apply only to the calendar year involved and would not be considered in computing the prospective payment amount for a subsequent calendar year.

Medicare pays the national, standardized 60-day case-mix and wage-adjusted episode payment on a split percentage payment approach. The split percentage payment approach includes an initial percentage payment and a final percentage payment as set forth in § 484.205(b)(1) and (b)(2). We may base the initial percentage payment on the submission of a request for anticipated payment (RAP) and the final percentage payment on the submission of the claim for the episode, as discussed in § 409.43. The claim for the episode that the HHA submits for the final percentage payment determines the total payment amount for the episode and whether we make an applicable adjustment to the 60-day case-mix and wage-adjusted episode payment. The end date of the 60-day episode as reported on the claim determines which calendar year rates Medicare will use to pay the claim.

We may also adjust the 60-day case-mix and wage-adjusted episode payment based on the information submitted on the claim to reflect the following:

- A low-utilization payment adjustment (LUPA) is provided on a per-visit basis as set forth in §§ 484.205(c) and 484.230.
- A partial episode payment (PEP) adjustment as set forth in §§ 484.205(d) and 484.235.
- An outlier payment as set forth in §§ 484.205(e) and 484.240.

b. CY 2019 National, Standardized 60-Day Episode Payment Rate

Section 1895(b)(3)(A)(i) of the Act requires that the 60-day episode base rate and other applicable amounts be standardized in a manner that eliminates the effects of variations in relative case-mix and area wage adjustments among different home health agencies in a budget neutral manner. To determine the CY 2019 national, standardized 60-day episode payment rate, we apply a wage index

budget neutrality factor and a case-mix budget neutrality factor described in section III.B of this final rule with comment period; and the home health payment update percentage discussed in section III.C.2. of this final rule with comment period.

To calculate the wage index budget neutrality factor, we simulated total payments for non-LUPA episodes using the CY 2019 wage index (including the application of the labor-related share of 76.1 percent and the non-labor-related share of 23.9 percent) applied to CY 2017 utilization (claims) data and compared it to our simulation of total payments for non-LUPA episodes using the CY 2018 wage index (including the application of the current labor-related

share of 78.535 percent and the non-labor-related of 21.465) applied to CY 2017 utilization (claims) data. By dividing the total payments for non-LUPA episodes using the CY 2019 wage index by the total payments for non-LUPA episodes using the CY 2018 wage index, we obtain a wage index budget neutrality factor of 0.9985. We will apply the wage index budget neutrality factor of 0.9985 to the calculation of the CY 2019 national, standardized 60-day episode payment rate.

As discussed in section III.B. of this final rule with comment period, to ensure the changes to the case-mix weights are implemented in a budget neutral manner, we proposed to apply a case-mix weight budget neutrality factor

to the CY 2019 national, standardized 60-day episode payment rate. The case-mix weight budget neutrality factor is calculated as the ratio of total payments when CY 2019 case-mix weights are applied to CY 2017 utilization (claims) data to total payments when CY 2018 case-mix weights are applied to CY 2017 utilization data. The case-mix budget neutrality factor for CY 2019 is 1.0169 as described in section III.B. of this final rule with comment period. Next, we apply the payment rates by the CY 2019 home health payment update percentage of 2.2 percent as described in section III.C.2. of this final rule with comment period. The CY 2019 national, standardized 60-day episode payment rate is calculated in Table 16.

TABLE 16: CY 2019 60-DAY NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT

CY 2018 National, Standardized 60-Day Episode Payment	Wage Index Budget Neutrality Factor	Case-Mix Weights Budget Neutrality Factor	CY 2019 HH Payment Update	CY 2019 National, Standardized 60-Day Episode Payment
\$3,039.64	X 0.9985	X 1.0169	X 1.022	\$3,154.27

The CY 2019 national, standardized 60-day episode payment rate for an HHA that does not submit the required

quality data is updated by the CY 2019 home health payment update of 2.2

percent minus 2 percentage points and is shown in Table 17.

TABLE 17: CY 2019 NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

CY 2018 National, Standardized 60-Day Episode Payment	Wage Index Budget Neutrality Factor	Case-Mix Weights Budget Neutrality Factor	CY 2019 HH Payment Update Minus 2 Percentage Points	CY 2019 National, Standardized 60-Day Episode Payment
\$3,039.64	X 0.9985	X 1.0169	X 1.002	\$3,092.55

c. CY 2019 National Per-Visit Rates

The national per-visit rates are used to pay LUPAs (episodes with four or fewer visits) and are also used to compute imputed costs in outlier calculations. The per-visit rates are paid by type of visit or HH discipline. The six HH disciplines are as follows:

- Home health aide (HH aide).
- Medical Social Services (MSS).
- Occupational therapy (OT).

- Physical therapy (PT).
- Skilled nursing (SN).
- Speech-language pathology (SLP).

To calculate the CY 2019 national per-visit rates, we started with the CY 2018 national per-visit rates. Then we applied a wage index budget neutrality factor to ensure budget neutrality for LUPA per-visit payments. We calculated the wage index budget neutrality factor by simulating total payments for LUPA

episodes using the CY 2019 wage index and comparing it to simulated total payments for LUPA episodes using the CY 2018 wage index. By dividing the total payments for LUPA episodes using the CY 2019 wage index by the total payments for LUPA episodes using the CY 2018 wage index, we obtained a wage index budget neutrality factor of 0.9996. We apply the wage index budget neutrality factor of 0.9996 in order to

calculate the CY 2019 national per-visit rates.

The LUPA per-visit rates are not calculated using case-mix weights. Therefore, no case-mix weights budget neutrality factor is needed to ensure budget neutrality for LUPA payments. Lastly, the per-visit rates for each

discipline are updated by the CY 2019 home health payment update percentage of 2.2 percent. The national per-visit rates are adjusted by the wage index based on the site of service of the beneficiary. The per-visit payments for LUPAs are separate from the LUPA add-on payment amount, which is paid for

episodes that occur as the only episode or initial episode in a sequence of adjacent episodes. The CY 2019 national per-visit rates for HHAs that submit the required quality data are updated by the CY 2019 HH payment update percentage of 2.2 percent and are shown in Table 18.

TABLE 18: CY 2019 NATIONAL PER-VISIT PAYMENT AMOUNTS

HH Discipline	CY 2018 Per-Visit Payment	Wage Index Budget Neutrality Factor	CY 2019 HH Payment Update	CY 2019 Per-Visit Payment
Home Health Aide	\$64.94	X 0.9996	X 1.022	\$ 66.34
Medical Social Services	\$229.86	X 0.9996	X 1.022	\$234.82
Occupational Therapy	\$157.83	X 0.9996	X 1.022	\$161.24
Physical Therapy	\$156.76	X 0.9996	X 1.022	\$160.14
Skilled Nursing	\$143.40	X 0.9996	X 1.022	\$146.50
Speech- Language Pathology	\$170.38	X 0.9996	X 1.022	\$174.06

The CY 2019 per-visit payment rates for HHAs that do not submit the

required quality data are updated by the CY 2019 HH payment update percentage

of 2.2 percent minus 2 percentage points and are shown in Table 19.

TABLE 19: CY 2019 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline	CY 2018 Per-Visit Rates	Wage Index Budget Neutrality Factor	CY 2019 HH Payment Update Minus 2 Percentage Points	CY 2019 Per-Visit Rates
Home Health Aide	\$64.94	X 0.9996	X 1.002	\$ 65.04
Medical Social Services	\$229.86	X 0.9996	X 1.002	\$230.23
Occupational Therapy	\$157.83	X 0.9996	X 1.002	\$158.08
Physical Therapy	\$156.76	X 0.9996	X 1.002	\$157.01
Skilled Nursing	\$143.40	X 0.9996	X 1.002	\$143.63
Speech- Language Pathology	\$170.38	X 0.9996	X 1.002	\$170.65

d. Low-Utilization Payment Adjustment (LUPA) Add-On Factors

LUPA episodes that occur as the only episode or as an initial episode in a sequence of adjacent episodes are adjusted by applying an additional amount to the LUPA payment before adjusting for area wage differences. In the CY 2014 HH PPS final rule (78 FR 72305), we changed the methodology for calculating the LUPA add-on amount by finalizing the use of three LUPA add-on factors: 1.8451 for SN; 1.6700 for PT; and 1.6266 for SLP. We multiply the per-visit payment amount for the first SN, PT, or SLP visit in LUPA episodes

that occur as the only episode or an initial episode in a sequence of adjacent episodes by the appropriate factor to determine the LUPA add-on payment amount. For example, in the case of HHAs that do submit the required quality data, for LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes, if the first skilled visit is SN, the payment for that visit will be \$270.27 (1.8451 multiplied by \$146.48), subject to area wage adjustment.

e. CY 2019 Non-Routine Medical Supply (NRS) Payment Rates

All medical supplies (routine and non-routine) must be provided by the HHA while the patient is under a home health plan of care. Examples of supplies that can be considered non-routine include dressings for wound care, I.V. supplies, ostomy supplies, catheters, and catheter supplies. Payments for NRS are computed by multiplying the relative weight for a particular severity level by the NRS conversion factor. To determine the CY 2019 NRS conversion factor, we updated the CY 2018 NRS conversion

factor (\$53.03) by the CY 2019 home health payment update percentage of 2.2 percent. We did not apply a standardization factor as the NRS

payment amount calculated from the conversion factor is not wage or case-mix adjusted when the final claim payment amount is computed. The NRS

conversion factor for CY 2019 is shown in Table 20.

TABLE 20: CY 2019 NRS CONVERSION FACTOR

CY 2018 NRS Conversion Factor	CY 2019 HH Payment Update	CY 2019 NRS Conversion Factor
\$53.03	X 1.022	\$54.20

Using the CY 2019 NRS conversion factor, the payment amounts for the six severity levels are shown in Table 21.

TABLE 21: CY 2019 NRS PAYMENT AMOUNTS

Severity Level	Points (Scoring)	Relative Weight	CY 2019 NRS Payment Amounts
1	0	0.2698	\$ 14.62
2	1 to 14	0.9742	\$ 52.80
3	15 to 27	2.6712	\$ 144.78
4	28 to 48	3.9686	\$ 215.10
5	49 to 98	6.1198	\$ 331.69
6	99+	10.5254	\$ 570.48

For HHAs that do not submit the required quality data, we updated the CY 2018 NRS conversion factor (\$53.03)

by the CY 2019 home health payment update percentage of 2.2 percent minus 2 percentage points. The CY 2019 NRS

conversion factor for HHAs that do not submit quality data is shown in Table 22.

TABLE 22: CY 2019 NRS CONVERSION FACTOR FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

CY 2018 NRS Conversion Factor	CY 2019 HH Payment Update Percentage Minus 2 Percentage Points	CY 2019 NRS Conversion Factor
\$53.03	X 1.002	\$53.14

The payment amounts for the various severity levels based on the updated conversion factor for HHAs that do not

submit quality data are calculated in Table 23.

TABLE 23: CY 2019 NRS PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

Severity Level	Points (Scoring)	Relative Weight	CY 2019 NRS Payment Amounts
1	0	0.2698	\$14.34
2	1 to 14	0.9742	\$51.77
3	15 to 27	2.6712	\$141.95
4	28 to 48	3.9686	\$210.89
5	49 to 98	6.1198	\$325.21
6	99+	10.5254	\$559.32

The following is a summary of the public comments received on the CY 2019 Annual Payment Update and our responses.

Comment: Several commenters expressed concerns with the reduction in the labor-related shares suggesting such a change will result in less care for patients.

Response: We thank the commenters for expressing their concerns. As noted in the proposed rule (83 FR 32368), the decrease in compensation cost weight of 2.4 percentage points is attributable to both employed compensation (wages

and salaries and benefits for employees) and direct patient care contract labor costs as reported in the MCR data. The decreased labor-related share is implemented in a budget neutral manner, which is consistent with the policies for implementing the annual recalibration of the case-mix weights and update of the home health wage index in a budget neutral manner.

Comment: A commenter stated that HHAs have received only one positive inflation update since 2011 and that this has left them behind in their ability to

attract and retain medically trained personnel.

Response: The home health market basket growth rate measures input price inflation associated with providing home health services. We disagree with the commenter that home health agencies have only received one positive inflation update since 2011 as the market basket update has been approximately 2 percent or higher annually. The table 24 shows the home health market basket updates and productivity adjustments from CY 2011 to CY 2018.

TABLE 24: ACTUAL HOME HEALTH MARKET BASKET UPDATES AND PRODUCTIVITY ADJUSTMENTS

	CY 2011	CY 2012	CY 2013	CY 2014	CY 2015	CY 2016	CY 2017	CY 2018
Home Health Market Basket Update	2.1	2.4	2.3	2.3	2.6	2.3	2.8	2.5
Productivity Adjustment	N/A	N/A	N/A	N/A	0.5	0.4	0.3	0.6
Market Basket Update less Productivity Adjustment	N/A	N/A	N/A	N/A	2.1	1.9	2.5	1.9

Over the 2011 to 2018 time period, the home health market basket update and home health payment rates have been reduced to reflect other statutorily required adjustments (such as the MFP adjustment (required by section 1895(b)(3)(B)(vi) of the Social Security Act), and rebasing adjustments to the national, standardized 60-day episode payment rates (required under section 3131(a) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152)). In some years, this has resulted in the 60-day episode payment rates being less than in prior years. The rationale and methodology regarding these other adjustments, along with CMS response to comments, can be found in prior CY HH PPS proposed and final rules.

We would note, however, that since PPS implementation and particularly over the 2011 to 2016 time period, according to MedPAC, freestanding home health agency margins have averaged roughly 14 percent. Furthermore, as shown in the 2016-based home health market basket, approximately 76 percent of home health costs are compensation costs; therefore, we disagree with the commenter's claims that they are unable to attract and retain medically trained personnel due to insufficient payment updates.

Comment: While several commenters commended and supported CMS on recognizing the need for an increase in home health payments per 60-day episode, MedPAC commented that this increase is not warranted based on their analysis of payment adequacy.

Response: We note that we are statutorily required to update the payment rates under the prospective payment system by the home health payment update percentage in accordance with section 1895(b)(3)(B) of the Act.

Final Decision: After considering all comments received on the proposed payment rate update for CY 2019, we are finalizing the application of the wage index budget neutrality factor (which includes making the change in the labor-related share budget neutral), the case-mix adjustment budget neutrality factor and the home health payment update percentage in updating the home health payment rates for CY 2019 as proposed.

D. Rural Add-On Payments for CYs 2019 Through 2022

1. Background

Section 421(a) of the MMA required, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes or visits ending on or after April 1, 2004, and before April 1, 2005, that the Secretary increase the payment amount that otherwise would have been made under section 1895 of the Act for the services by 5 percent.

Section 5201 of the DRA amended section 421(a) of the MMA. The amended section 421(a) of the MMA required, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), on or after January 1, 2006, and before January 1, 2007, that the Secretary increase the payment amount otherwise made under section 1895 of the Act for those services by 5 percent.

Section 3131(c) of the Affordable Care Act amended section 421(a) of the MMA to provide an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending on or after April 1, 2010, and before January 1, 2016.

Section 210 of the MACRA amended section 421(a) of the MMA to extend the rural add-on by providing an increase of

3 percent of the payment amount otherwise made under section 1895 of the Act for HH services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending before January 1, 2018.

Section 50208(a) of the Bipartisan Budget Act of 2018 amended section 421(a) of the MMA to extend the rural add-on by providing an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for HH services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending before January 1, 2019.

2. Rural Add-On Payments for CYs 2019 Through 2022

Section 50208(a)(1)(D) of the BBA of 2018 adds a new subsection (b) to section 421 of the MMA to provide rural add-on payments for episodes and visits ending during CYs 2019 through 2022. It also mandates implementation of a new methodology for applying those payments. Unlike previous rural add-ons, which were applied to all rural areas uniformly, the extension provides varying add-on amounts depending on the rural county (or equivalent area) classification by classifying each rural county (or equivalent area) into one of three distinct categories: (1) Rural counties and equivalent areas in the highest quartile of all counties and equivalent areas based on the number of

Medicare home health episodes furnished per 100 individuals who are entitled to, or enrolled for, benefits under part A of Medicare or enrolled for benefits under part B of Medicare only, but not enrolled in a Medicare Advantage plan under part C of Medicare (the “High utilization” category); (2) rural counties and equivalent areas with a population density of 6 individuals or fewer per square mile of land area and are not included in the “High utilization” category (the “Low population density” category); and (3) rural counties and equivalent areas not in either the “High utilization” or “Low population density” categories (the “All other” category).

The proposed rule outlined how we categorized rural counties (or equivalent areas) into the three distinct categories outlined in section 50208 of the BBA of 2018 based on CY 2015 claims data and 2015 data from the Medicare Beneficiary Summary File, as well as 2010 Census data. The rural add-on percentages and duration of rural add-on payments outlined in law are shown in Table 25. The HH Pricer module, located within CMS’ claims processing system, will increase the base payment rates provided in Tables 16 through 23 by the appropriate rural add-on percentage prior to applying any case-mix and wage index adjustments.

TABLE 25: HH PPS RURAL ADD-ON PERCENTAGES, CYs 2019-2022

Category	CY 2019	CY 2020	CY 2021	CY 2022
High utilization	1.5%	0.5%		
Low population density	4.0%	3.0%	2.0%	1.0%
All other	3.0%	2.0%	1.0%	

The proposed rule further described the provisions of section 50208(a)(2) of the Bipartisan Budget Act of 2018, which amended section 1895(c) of the Act by adding a new requirement set out at section 1895(c)(3) of the Act. This requirement states that no claim for home health services may be paid unless “in the case of home health services furnished on or after January 1, 2019, the claim contains the code for the county (or equivalent area) in which the home health service was furnished.” This information will be necessary in order to calculate the rural add-on payments. We proposed that HHAs enter the FIPS state and county code, rather than the SSA state and county code, on the claim.

The data used to categorize each county or equivalent area is available in the Downloads section associated with the publication of the proposed rule at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices-Items/CMS-1689-P.html>. In addition, an Excel file containing the rural county or equivalent area names, their FIPS state and county codes, and their designation into one of the three rural add-on categories is available for download.

The following is a summary of the public comments received on the proposal for Rural Add-on Payments for

CYs 2019 through 2022 and our responses:

Comment: A commenter stated that they do not object to the methodology used by CMS in implementing the rural add-on payments for CYs 2019–CY 2022, but they request that CMS ask Congress to modify and reauthorize the three percent rural safeguard for all rural counties to ensure access to home health services by Medicare beneficiaries in rural areas. Some commenters suggested that the cost reports indicate FFS margins are at 5 percent or below, which they suggested reflects the high cost of travel in rural areas and the cost of staffing of visits into rural areas. The commenters indicated that many margins included

the 3 percent rural add-on, thereby further justifying the continuation of the rural-add on payments. Several commenters expressed concern with the reduction and elimination of the rural add-on payments suggesting that without the payments it would make caring for home health patients in rural areas a challenge. Many urged CMS to continue providing rural add-on payments after 2022 so that beneficiaries in rural communities continue to have access to home health services. Several commenters suggested that CMS establish a workgroup to examine rural costs and how best to address those costs with an add-on payment.

Response: Section 421(a) of the MMA, as amended by section 50208 of the BBA of 2018, provides a 3 percent rural add-on for HH services provided in a rural area for episodes and visits ending before January 1, 2019. Section 421(b)(1) of the MMA, as amended by section 50208 of the BBA of 2018, stipulates the percentage of rural add-on payments by rural county (or equivalent area) classification for episodes and visits ending during CYs 2019 through 2022, as provided in Table 25. As these are statutory requirements, we do not have the authority to provide a 3 percent rural add-on for episodes and visits ending on or after January 1, 2019 across all rural areas, or to extend rural add-on payments beyond the duration of the period for which rural add-on payment are in place under section 421(b)(1) of the MMA. However, we plan to continue to monitor the costs associated with providing home health care in rural versus urban areas.

Comment: MedPAC stated that the rural payment add-on policy for 2019 is an improvement that better targets Medicare's scarce resources. They further stated that average utilization is not significantly different between urban and rural areas, but there is some variation around this average, with high-and-low use areas found in counties. They commented that the proposed policy targets payments to areas with lower population density and limits payments to rural areas with higher utilization.

Response: We thank MedPAC for their comments.

Comment: A commenter recommended that CMS research the impact the rural add-on extension will have on low population density areas particularly with the proposal to move to the cost per minute plus non-routine supplies approach in estimating resource use under the PDGM.

Response: We thank the commenter for this suggestion. We will continue

monitoring the impacts due to policy changes, including the changes in rural add-on payments for CYs 2019 through 2022, and will provide the industry with periodic updates on our analysis in rulemaking and/or announcements on the HHA Center web page at: <https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html>.

Comment: Several commenters stated that a HHA may have demographic changes within the four-year period and that they should be able to retract and change their category of rural counties or equivalent areas for the HH rural add-on payment.

Response: Section 421(b)(2)(a) of the MMA provides that the Secretary shall make a determination only for a single time as to which category under sections 421(b)(1)(A) (the "High utilization" category), 421(b)(1)(B) (the "Low population density" category), or 421(b)(1)(C) (the "All other" category) of the MMA that a rural county or equivalent area is classified into, and that the determination applies for the duration of the period for which rural add-on payments are in place under section 421(b) of the MMA. As these are statutory requirements, we do not have the authority to allow the changes to rural county or equivalent area classifications suggested by the commenters.

Final Decision: We are finalizing the policies for the provision of rural add-on payments for CY 2019 through CY 2022 in accordance with section 50208 of the BBA of 2018, which adds a new subsection to section 421 of the MMA. This includes finalizing the designations of rural counties (or equivalent areas) into their respective categories as outlined in the excel files published on the HHA center web page in conjunction with the CY 2019 HH PPS proposed rule: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices-Items/CMS-1689-P.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending>.

E. Payments for High-Cost Outliers Under the HH PPS

1. Background

Section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the home health payment amount otherwise made in the case of outliers because of unusual variations in the type or amount of medically necessary care. Under the HH PPS, outlier payments are made for episodes whose estimated costs exceed a

threshold amount for each Home Health Resource Group (HHRG). The episode's estimated cost was established as the sum of the national wage-adjusted per-visit payment amounts delivered during the episode. The outlier threshold for each case-mix group or Partial Episode Payment (PEP) adjustment is defined as the 60-day episode payment or PEP adjustment for that group plus a fixed-dollar loss (FDL) amount. For the purposes of the HH PPS, the FDL amount is calculated by multiplying the HH FDL ratio by a case's wage-adjusted national, standardized 60-day episode payment rate, which yields an FDL dollar amount for the case. The outlier threshold amount is the sum of the wage and case-mix adjusted PPS episode amount and wage-adjusted FDL amount. The outlier payment is defined to be a proportion of the wage-adjusted estimated cost beyond the wage-adjusted threshold. The proportion of additional costs over the outlier threshold amount paid as outlier payments is referred to as the loss-sharing ratio.

As we noted in the CY 2011 HH PPS final rule (75 FR 70397 through 70399), section 3131(b)(1) of the Affordable Care Act amended section 1895(b)(3)(C) of the Act, and required the Secretary to reduce the HH PPS payment rates such that aggregate HH PPS payments were reduced by 5 percent. In addition, section 3131(b)(2) of the Affordable Care Act amended section 1895(b)(5) of the Act by redesignating the existing language as section 1895(b)(5)(A) of the Act, and revising the language to state that the total amount of the additional payments or payment adjustments for outlier episodes could not exceed 2.5 percent of the estimated total HH PPS payments for that year. Section 3131(b)(2)(C) of the Affordable Care Act also added section 1895(b)(5)(B) of the Act which capped outlier payments as a percent of total payments for each HHA at 10 percent.

As such, beginning in CY 2011, we reduce payment rates by 5 percent and target up to 2.5 percent of total estimated HH PPS payments to be paid as outliers. To do so, we first returned the 2.5 percent held for the target CY 2010 outlier pool to the national, standardized 60-day episode rates, the national per visit rates, the LUPA add-on payment amount, and the NRS conversion factor for CY 2010. We then reduced the rates by 5 percent as required by section 1895(b)(3)(C) of the Act, as amended by section 3131(b)(1) of the Affordable Care Act. For CY 2011 and subsequent calendar years we target up to 2.5 percent of estimated total payments to be paid as outlier

payments, and apply a 10 percent agency-level outlier cap.

In the CY 2017 HH PPS proposed and final rules (81 FR 43737 through 43742 and 81 FR 76702), we described our concerns regarding patterns observed in home health outlier episodes.

Specifically, we noted that the methodology for calculating home health outlier payments may have created a financial incentive for providers to increase the number of visits during an episode of care in order to surpass the outlier threshold; and simultaneously created a disincentive for providers to treat medically complex beneficiaries who require fewer but longer visits. Given these concerns, in the CY 2017 HH PPS final rule (81 FR 76702), we finalized changes to the methodology used to calculate outlier payments, using a cost-per-unit approach rather than a cost-per-visit approach. This change in methodology allows for more accurate payment for outlier episodes, accounting for both the number of visits during an episode of care and also the length of the visits provided. Using this approach, we now convert the national per-visit rates into per 15-minute unit rates. These per 15-minute unit rates are used to calculate the estimated cost of an episode to determine whether the claim will receive an outlier payment and the amount of payment for an episode of care. In conjunction with our finalized policy to change to a cost-per-unit approach to estimate episode costs and determine whether an outlier episode should receive outlier payments, in the CY 2017 HH PPS final rule we also finalized the implementation of a cap on the amount of time per day that would be counted toward the estimation of an episode's costs for outlier calculation purposes (81 FR 76725). Specifically, we limit the amount of time per day (summed across the six disciplines of care) to 8 hours (32 units) per day when estimating the cost of an episode for outlier calculation purposes.

We plan to publish the cost-per-unit amounts for CY 2019 in the rate update change request, which is issued after the publication of the CY 2019 HH PPS final rule. We note that in the CY 2017 HH PPS final rule (81 FR 76724), we stated that we did not plan to re-estimate the average minutes per visit by discipline every year. Additionally, we noted that the per-unit rates used to estimate an episode's cost will be updated by the home health update percentage each year, meaning we would start with the national per-visit amounts for the same calendar year when calculating the cost-per-unit used to determine the cost of an episode of care (81 FR 76727). We note

that we will continue to monitor the visit length by discipline as more recent data become available, and we may propose to update the rates as needed in the future.

2. Fixed Dollar Loss (FDL) Ratio

For a given level of outlier payments, there is a trade-off between the values selected for the FDL ratio and the loss-sharing ratio. A high FDL ratio reduces the number of episodes that can receive outlier payments, but makes it possible to select a higher loss-sharing ratio, and therefore, increase outlier payments for qualifying outlier episodes.

Alternatively, a lower FDL ratio means that more episodes can qualify for outlier payments, but outlier payments per episode must then be lower.

The FDL ratio and the loss-sharing ratio must be selected so that the estimated total outlier payments do not exceed the 2.5 percent aggregate level (as required by section 1895(b)(5)(A) of the Act). Historically, we have used a value of 0.80 for the loss-sharing ratio which, we believe, preserves incentives for agencies to attempt to provide care efficiently for outlier cases. With a loss-sharing ratio of 0.80, Medicare pays 80 percent of the additional estimated costs above the outlier threshold amount.

Simulations based on CY 2015 claims data (as of June 30, 2016) completed for the CY 2017 HH PPS final rule showed that outlier payments were estimated to represent approximately 2.84 percent of total HH PPS payments in CY 2017, and as such, we raised the FDL ratio from 0.45 to 0.55. We stated that raising the FDL ratio to 0.55, while maintaining a loss-sharing ratio of 0.80, struck an effective balance of compensating for high-cost episodes while still meeting the statutory requirement to target up to, but no more than, 2.5 percent of total payments as outlier payments (81 FR 76726). The national, standardized 60-day episode payment amount is multiplied by the FDL ratio. That amount is wage-adjusted to derive the wage-adjusted FDL amount, which is added to the case-mix and wage-adjusted 60-day episode payment amount to determine the outlier threshold amount that costs have to exceed before Medicare would pay 80 percent of the additional estimated costs.

In the CY 2019 proposed rule, we simulated payments using preliminary CY 2017 claims data (as of March 2, 2018) and the CY 2018 HH PPS payment rates (82 FR 51676), and estimated that outlier payments in CY 2018 would comprise 2.30 percent of total payments and approximately 2.32 percent of total HH PPS payments in CY 2019. Our

simulations showed that the FDL ratio would need to be changed from 0.55 to 0.51 to pay up to, but no more than, 2.5 percent of total payments as outlier payments in CY 2019.

Given the statutory requirement that total outlier payments not exceed 2.5 percent of the total payments estimated to be made based under the HH PPS, in the CY 2019 proposed rule, we proposed to lower the FDL ratio for CY 2019 from 0.55 to 0.51 to better approximate the 2.5 percent statutory maximum. However, we noted that we were not proposing a change to the loss-sharing ratio (0.80) for the HH PPS to remain consistent with payment for high-cost outliers in other Medicare payment systems (for example, IRF PPS, IPPS, etc.).

Using updated CY 2017 claims data (as of June 30, 2018) and the final CY 2019 payment rates presented in section III.C of this final rule with comment period, we estimate that outlier payments would continue to constitute approximately 2.47 percent of total HH PPS payments in CY 2019 under the current outlier methodology. Given the statutory requirement to target up to, but no more than, 2.5 percent of total payments as outlier payments, we believe that modifying the FDL ratio from 0.55 to 0.51 with a loss-sharing ratio of 0.80 is appropriate given the percentage of outlier payments projected for CY 2019.

3. Home Health Outlier Payments: Clinical Examples

In the CY 2019 HH PPS proposed rule, we also described clinical examples of how care for a patient with ALS could qualify for an additional outlier payment, which would serve to offset unusually high costs associated with providing home health to a patient with unusual variations in the amount of medically necessary care. (83 FR 32340).

The following is a summary of the comments received on outlier payments under the HH PPS and our responses.

Comment: Several commenters recommended that CMS conduct a more detailed analysis to determine whether the total cap of 2.5 percent of total payments as outlier payments is adequate or whether it needs to be increased for future years, particularly given the expected change in Medicare beneficiary demographics anticipated in the coming years.

Response: As established in section 1895(b)(5) of the Act, both the 2.5 percent target of outlier payments to total home health payments and the 10-percent cap on outlier payments at the home health agency level are statutory

requirements. Therefore, we do not have the authority to adjust or eliminate the 10-percent cap or increase the 2.5-percent target amount. However, we will continue to evaluate for the appropriateness of those elements of the outlier policy that may be modified, including the FDL and the loss-sharing ratio. We note that other Medicare payment systems with outlier payments, such as the IRF PPS and IPPS, annually reassess the fixed-loss cost outlier threshold amount. Adjusting the outlier threshold amount in order to target the statutorily required percentage of total payments as outlier payments is standard practice.

Comment: A commenter recommended that CMS eliminate outlier payments in their entirety.

Response: We believe that section 1895(b)(5)(A) of the Act allows the Secretary the discretion as to whether or not to have an outlier policy under the HH PPS. However, we also believe that outlier payments are beneficial in that they help mitigate the incentive for HHAs to avoid patients that may have episodes of care that result in unusual variations in the type or amount of medically necessary care. The outlier system is meant to help address extra costs associated with extra, and potentially unpredictable, medically necessary care. We note that we plan to continue evaluating whether or not an outlier policy remains appropriate as well as ways to maintain an outlier policy for episodes that incur unusually high costs due to patient care needs.

Comment: Several commenters suggested that we include the cost of supplies in our outlier calculations as the inclusion of the cost of supplies as opposed to the estimated costs would yield more accurate payment totals to be used for determination of outlier payments.

Response: We appreciate the commenters' suggestion regarding the inclusion of supplies in the outlier calculations. In order to incorporate supply costs into the outlier calculation, significant systems modifications would be required. However, we will consider whether to add supply costs to the outlier calculations and evaluate whether such a policy change is appropriate for future rulemaking.

Comment: A commenter expressed concerns about the per-unit outlier approach established in 2017, stating that the assumptions regarding this policy change were not accurate, thereby leading to difficulties in the HHA community. The commenter further suggested that if the outlier provision is to continue for CY2019,

then we should revert to the per-visit approach.

Response: We appreciate the commenter's feedback regarding the revisions to the methodology utilized to calculate outliers in the HH PPS. We maintain that the transition to the per-unit approach advanced our objectives of better aligning payment with the costs of providing care, but we will continue to monitor the impact of this policy change as more recent data become available, and we may propose to modify the outlier policy approaches as needed in the future.

Comment: Several commenters expressed support for the clinical examples provided in the CY 2019 proposed rule and appreciated the descriptions of how an outlier payment may be made for the provision of care for patients living with significant longer-term and debilitating conditions, including ALS.

Response: We appreciate the commenters' support and hope that the examples illustrating how HHAs could be paid by Medicare for providing care to patients with higher resource use in their homes served to highlight that a patient's condition does not need to improve for home health services to be covered by Medicare. We likewise hope that the examples helped to provide a better understanding of Medicare coverage policies and how outlier payments promote access to home health services for such patients under the HH PPS.

Comment: A commenter requested that we identify specific diseases, like ALS, that the commenter asserts are systematically underpaid and exclude outlier payments for such patients from the fixed dollar loss amount and cost sharing percentage up to the full reasonable cost of care at those agencies accepting them for care. Additionally, the commenter suggested that we separately identify those agencies in each area who agree to accept high cost ALS patients under the aforementioned exception. Moreover, the commenter suggested that we undertake a demonstration to test whether an alternative payment mechanism under the home health benefit similar to Disproportionate Share Payments or a Special Needs Plans would provide full access to home health care for ALS and similar patients as well as a demonstration of a bridge program that is a combination of the appropriate features of the Medicare home health and hospice benefits that the commenter asserts would constitute a cost-effective alternative to the use of both benefits and assure access to patients needing "Advanced Disease Management"

(ADM), blending curative treatment approaches of home health and the palliative care benefits of hospice in a manner that allows a seamless transition for persons whose disease process is highly likely to advance and result in death within a two-year period.

Response: We appreciate the commenter's feedback regarding the suggested modifications to the home health outlier calculation as well as the recommendation for possible demonstrations related to home health cases that may qualify for an outlier payment. We maintain that section 1895(b)(5)(A) of the Act allows the Secretary the discretion as to whether or not to have an outlier policy under the HH PPS and we believe that outlier payments are beneficial in that they help mitigate the incentive for HHAs to avoid patients that may have episodes of care that result in unusual variations in the type or amount of medically necessary care. The outlier system is meant to help address extra costs associated with extra, and potentially unpredictable, medically necessary care. The outlier calculation is based upon total payments within the HH PPS and we do not believe it would be appropriate to exclude certain cases from the overall calculation or to make additional payments to certain providers that offer services to home health beneficiaries with a certain clinical profile. Regarding the possibility of a demonstration for those beneficiaries with high resource use, we will consider the comments as we develop new models through the Center for Medicare and Medicaid Innovation. We note that we would need to determine whether such a model would meet the statutory requirements to be expected to reduce Medicare expenditures and preserve or enhance the quality of care for beneficiaries.

Final Decision: We are finalizing the change to the FDL ratio or loss sharing ratio for CY 2019. We are establishing an FDL ratio of 0.51 with a loss-sharing ratio of 0.80 for CY 2019. We will continue to monitor outlier payments and continue to explore ways to maintain an outlier policy for episodes that incur unusually high costs.

F. Implementation of the Patient-Driven Groupings Model (PDGM) for CY 2020

1. Summary of the Proposed PDGM Model, Data, and File Construction

To better align payment with patient care needs and better ensure that clinically complex and ill beneficiaries have adequate access to home health care, we proposed case-mix methodology refinements through the

implementation of the Patient-Driven Groupings Model (PDGM). We proposed to implement the PDGM for home health periods of care beginning on or after January 1, 2020. The PDGM: Uses 30-day periods of care rather than 60-day episodes of care as the unit of payment, as required by section 51001(a)(1)(B) of the BBA of 2018; eliminates the use of the number of therapy visits provided to determine payment, as required by section 51001(a)(3)(B) of the BBA of 2018; and relies more heavily on clinical characteristics and other patient information (for example, diagnosis, functional level, comorbid conditions, admission source) to place patients into clinically meaningful payment categories.

Costs during an episode/period of care are estimated based on the concept of resource use, which measures the costs associated with visits performed during a home health episode/period. For the current HH PPS case-mix weights, we use Wage Weighted Minutes of Care (WWMC), which uses data from the Bureau of Labor Statistics (BLS) reflecting the Home Health Care Service Industry. For the PDGM, we proposed shifting to a Cost-Per-Minute plus Non-Routine Supplies (CPM + NRS) approach, which uses information from the Medicare Cost Report. The CPM + NRS approach incorporates a wider variety of costs (such as transportation) compared to the BLS estimates and the costs are available for individual HHA providers while the BLS costs are aggregated for the Home Health Care Service industry.

Similar to the current payment system, we proposed that 30-day periods under the PDGM would be classified as “early” or “late” depending on when they occur within a sequence of 30-day periods. Under the current HH PPS, the first two 60-day episodes of a sequence of adjacent 60-day episodes are considered early, while the third 60-day episode of that sequence and any subsequent episodes are considered late. Under the PDGM, we proposed that the first 30-day period would be classified as early and all subsequent 30-day periods in the sequence (second or later) would be classified as late. We proposed to adopt this episode timing classification for 30-day periods with the implementation of the PDGM. Similar to the current payment system, we proposed that a 30-day period could not be considered early unless there was a gap of more than 60 days between the end of one period and the start of another. The comprehensive assessment would still be completed within 5 days of the start of care date and completed

no less frequently than during the last 5 days of every 60 days beginning with the start of care date, as currently required by § 484.55, “Condition of participation: Comprehensive assessment of patients.”

Under the PDGM, we proposed that each 30-day period would also be classified into one of two admission source categories—community or institutional—depending on what healthcare setting was utilized in the 14 days prior to home health. The 30-day period would be categorized as institutional if an acute or post-acute care stay occurred within the prior 14 days to the start of the 30-day period of care. The 30-day period would be categorized as community if there was no acute or post-acute care stay in the 14 days prior to the start of the 30-day period of care.

We proposed further grouping 30-day periods into one of six clinical groups based on the principal diagnosis. The principal diagnosis reported would provide information to describe the primary reason for which patients were receiving home health services under the Medicare home health benefit. The proposed six clinical groups, were as follows:

- Musculoskeletal Rehabilitation.
- Neuro/Stroke Rehabilitation.
- Wounds- Post-Op Wound Aftercare and Skin/Non-Surgical Wound Care.
- Complex Nursing Interventions.
- Behavioral Health Care.
- Medication Management, Teaching and Assessment (MMTA).

Under the PDGM, we proposed that each 30-day period would be placed into one of three functional impairment levels. The level would indicate if, on average, given the HHA’s responses on certain functional OASIS questions, a 30-day period was predicted to have higher costs or lower costs. For each of the six clinical groups, we proposed that total periods would be further classified into one of three functional impairment levels with roughly 33 percent of total 30-day periods for all HHAs in each level. We determined how many periods of care would be in each functional impairment level based on the relative number of periods in a potential impairment level, and on the clustering of summed functional scores. The functional impairment level assignment under the PDGM is very similar to the functional level assignment in the current payment system.

Finally, we proposed that 30-day periods would receive a comorbidity adjustment category based on the presence of secondary diagnoses. We proposed that, depending on a patient’s secondary diagnoses, a 30-day period

may receive “no” comorbidity adjustment, a “low” comorbidity adjustment, or a “high” comorbidity adjustment. For low-utilization payment adjustments (LUPAs) under the PDGM, we proposed that the LUPA threshold would vary for a 30-day period under the PDGM depending on the PDGM payment group to which it was assigned. For each payment group, we proposed to use the 10th percentile value of visits to create a payment group specific LUPA threshold with a minimum threshold of at least 2 visits for each group.

The proposed rule further outlined the data file construction process for the PDGM-related analyses, including the claims data used, how the data were cleaned, how OASIS data were matched to claims data, how measures of resource use were constructed, and the total number of 30-day periods used for constructing the PDGM case-mix weights in the proposed rule (82 FR 35297 through 35298).

The following is a summary of general comments received on the proposals and our responses.

Comment: Several commenters supported various elements of PDGM. There was broad support for moving from the current payment system to one that uses a broader clinical profile of the patient. There was also support for the budget neutral implementation of the PDGM and the elimination of the service utilization domain (that is, therapy thresholds). Other commenters indicated they supported the PDGM, but stated that implementation of the PDGM should be delayed until after January 1, 2020 to provide assurances that there is sufficient information and guidance to HHAs, physicians, and Medicare Administrative Contractors (“MACs”) to ensure a smooth transition and no unintended consequences. Commenters also suggested that CMS implement the model incrementally or conduct a small scale demonstration of the model.

Response: We thank the commenters for their support. Section 1895(b)(2)(B) of the Act, as added by section 51001(a)(1) of the BBA of 2018, requires the Secretary to apply a 30-day unit of service (also referred to as unit of payment), effective January 1, 2020. In addition, section 1895(b)(4)(B)(ii) of the Act, as added by section 51001(a)(3)(B) of the BBA of 2018, requires CMS to remove therapy thresholds from the case-mix adjustment methodology used to adjust payments under the HH PPS for CY 2020 and subsequent years. The PDGM was developed in conjunction with a 30-day period of care and should be implemented simultaneously with the change in the length of the unit of

service. Attempting to implement the PDGM piecemeal could cause more burden and confusion, compared to implementing the entire model at the same time. With regards to conducting a demonstration, we note that a demonstration would likely only occur in selected areas with selected participants and therefore would paint a different picture of the effects of the model compared to what would otherwise occur on a national scale. Furthermore, section 1895 of the Act, as amended by the BBA of 2018, requires a change to the unit of payment and the elimination of the therapy thresholds for all payments made under the HH PPS, rather than requiring CMS to conduct a demonstration. While we are finalizing our proposal to implement the PDGM beginning on January 1, 2020, we are sensitive to the concerns expressed by commenters regarding provider outreach, training, billing changes and systems updates needed to implement the PDGM. While we work toward an implementation date of January 1, 2020, we look forward to a continued dialogue with the industry on ways to provide sufficient guidance and training to ensure a smooth transition to the 30-day unit of payment and the PDGM.

Comment: Several commenters asked about what types of training material will be available regarding the PDGM. A commenter asked if and when the claims processing manual will be updated to reflect the PDGM. Additionally, a commenter asked if CMS could develop an email mailbox for patients to offer feedback on the PDGM.

Response: We appreciate comments about the need for guidance and training prior to the implementation of the PDGM. We agree with the commenters that this is an area that deserves attention and we plan to work with HHAs and other stakeholders to ensure a smooth transition between the current payment model and the PDGM. We will update the claims processing manual and we will provide education and support more broadly, which may include MLN articles, program instructions, national provider calls, and open door forums. Once the rule is finalized, we will begin updating the appropriate sections of the Home Health Agency Billing chapter in the Medicare Claims Processing Manual. For questions about the Home Health Prospective Payment System (HH PPS) and the Medicare home health benefit, individuals can email: HomehealthPolicy@cms.hhs.gov.

Comment: Several commenters asked how CMS would monitor the PDGM. Specifically, commenters expressed

concern that the PDGM may result in inappropriate practice patterns and that the PDGM might introduce claims processing issues that could cause delays in payment. A few commenters also indicated that the technical expert panel (TEP) convened in February, 2018 should continue to stay involved with the implementation and roll-out of the PDGM in order to monitor outcomes.

Response: We will continue to monitor the payment system as we have done since the inception of the benefit. We will closely monitor patterns related to utilization, including changes in the composition of patients receiving the home health benefit and the types and amounts of services they are receiving. CMS will also carefully pay attention to claims processing changes needed to implement the 30-day unit of payment and the PDGM in order to mitigate any issues that could cause delays in payment. We appreciated the help of the TEP and, if needed, we will continue to engage the TEP or another set of key stakeholders as we move forward with the implementation of the PDGM for January 1, 2020.

Comment: Commenters stated there was limited involvement with the industry in the development of the PDGM. Some commenters indicated that CMS needs to perform studies and an evaluation of the work related to the PDGM and alternative payment models suggested, like the "Risk-Based Grouper Model".

Response: We thank the commenters' for their willingness to engage in discussion around the PDGM. Through notice and comment rulemaking and other processes, stakeholders always have the opportunity to reach out to CMS and provide suggestions for improvement in the payment methodology under the HH PPS. In the CY 2014 HH PPS final rule, we noted that we were continuing to work on improvements to our case-mix adjustment methodology and welcomed suggestions for improving such methodology as we continued in our case-mix research (78 FR 72287). The analyses and the ultimate development of an alternative case-mix adjustment methodology were shared with both internal and external stakeholders via technical expert panels, clinical workgroups, and special open door forums. We also provided high-level summaries on our case-mix methodology refinement work in the HH PPS proposed rules for CYs 2016 and 2017 (80 FR 39839, and 81 FR 76702). A detailed technical report was posted on the CMS website in December of 2016, additional technical expert panel and clinical workgroup webinars were

held after the posting of the technical report, and a National Provider call occurred in January 2017 to further solicit feedback from stakeholders and the general public. The CY 2018 HH PPS proposed rule further solicited comments on a proposed alternative case-mix adjustment methodology—referred to as the home health groupings model, or HHGM.

On February 1, 2018, CMS convened another TEP to gather perspectives and identify and prioritize recommendations from industry leaders, clinicians, patient representatives, and researchers with experience with home health care and/or experience in home health agency management regarding the case-mix adjustment methodology refinements described in the CY 2018 HH PPS proposed rule (82 FR 35270), and alternative case-mix models submitted during 2017 as comments to the CY 2018 HH PPS proposed rule. During the TEP, there was a description and solicitation of feedback on the components of the proposed case-mix methodology refinement, such as resource use, 30-day periods, clinical groups, functional levels, comorbidity groups, and other variables used to group periods into respective case-mix groups. Also discussed were the comments received from the CY 2018 HH PPS proposed rule, the creation of case-mix weights, and an open discussion to solicit feedback and recommendations for next steps. This TEP satisfied the requirement set forth in section 51001(b)(1) of the BBA of 2018, which requires that at least one session of such a TEP be held between January 1, 2018 and December 31, 2018. In addition, section 51001(b)(3) of the BBA of 2018 requires the Secretary to issue a report to the Committee on Ways and Means and Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate on the recommendations from the TEP members, no later than April 1, 2019. This report has already been completed and is available on the CMS HHA Center web page at: <https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html>. CMS addressed the Risk Based Grouper Model in the report to the Committee on Ways and Means and Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate on the recommendations from the TEP members. Lastly, the CY 2019 HH PPS proposed rule solicited comment on the proposed PDGM.

Comment: Several commenters requested that CMS describe how the

proposed PDGM would impact delivery and payment innovations, such as Accountable Care Organizations (ACOs) and Bundled Payments for Care Improvement (BPCI) Models 2 and 3. Other commenters requested that CMS describe how the proposed PDGM fits in with the IMPACT Act-directed post-acute care PPS and other payment system methodology changes in other settings. Other commenters indicated that the PDGM would hurt HHVBP and the star ratings. A commenter asked if the Review Choice Demonstration was still needed if PDGM was implemented and indicated that would cause additional burden.

Response: BPCI Models 2 and 3 ended September 30, 2018; therefore, BPCI Models 2 and 3 would not be affected by PDGM implementation. CMS will determine whether any refinements are needed to the BPCI Advanced Model, a new payment and service delivery model that began on October 1, 2018, and any ACO programs and models, such as the Medicare Shared Savings Program and the Next Generation ACO Model as a result of PDGM implementation. We note that any changes determined to be necessary to the payment methodology used in the Medicare Shared Savings Program due to implementation of the PDGM would require notice and comment rulemaking.

We believe that the proposed PDGM could assist with meeting the IMPACT Act requirement that the Secretary of Health and Human Services develop a technical prototype for a unified post-acute care (PAC) prospective payment system (PAC PPS). We believe many aspects of the PDGM could be used in a unified PAC PPS prototype so that payments under such a prototype would be based according to individual characteristics, as specified by the IMPACT Act. We do not believe that the PDGM will disrupt the HHVBP Model or the Home Health star ratings. The PDGM is a case-mix adjustment model intended to pay for services more accurately and we believe the HHVBP Model and the Home Health star ratings can continue unchanged when HHA periods of care are paid according to the case-mix adjustments of the PDGM. We do not believe the implementation of the PDGM will eliminate the rationale behind the proposed Review Choice Demonstration for Home Health Services. The PDGM is a case-mix adjustment model with the goal of better aligning home health payments with patient care needs and the cost of care, while the proposed Review Choice Demonstration for Home Health Services would be a demonstration

aimed at assisting in the development of improved procedures to identify, investigate, and prosecute potential Medicare fraud occurring among HHAs providing services to Medicare beneficiaries.

Comment: A commenter asked CMS to provide greater detail about the appeals process that will be available to help patients address any shortcomings in their care and/or coverage. In addition, the commenter stated that providers also should be able to appeal any inaccurate assignments to payment classifications.

Response: The Advance Beneficiary Notice of Noncoverage (ABN) is issued by providers (including home health agencies and hospices), physicians, practitioners, and other suppliers to Original Medicare (fee-for-service) beneficiaries in situations where Medicare payment is expected to be denied for some or all services. When a home health patient gets an ABN, the ABN gives clear directions for getting an official decision from Medicare about payment for home health services and supplies and for filing an appeal. An HHA must also furnish a "Home Health Change of Care Notice" (HHCCN) to beneficiaries when the beneficiary's home health plan of care is changing because the Agency reduces or stops providing home health services or supplies for business-related reasons or because the beneficiary's physician changed orders for such services or supplies. An HHA must also furnish a "Notice of Medicare Non-Coverage" (NOMNC) at least 2 days before all covered services end. When home health services are ending, beneficiaries may have the right to an expedited appeal if they believe the services are ending too soon. During an expedited appeal, a Beneficiary and Family Centered Care Quality Improvement Organization (BFCC-QIO) will examine the case and decide whether home health services need to continue. If the beneficiary is dissatisfied with the determination by the QIO, in accordance with § 405.1204, the beneficiary has the right to an expedited reconsideration by a Qualified Independent Contractor (QIC). If the beneficiary is dissatisfied with the determination by the QIC, the beneficiary then has the right to request an Administrative Law Judge hearing or review of a dismissal, Medicare Appeals Council review, and judicial review by a federal district court, so long as jurisdictional requirements are met (as outlined by 42 CFR part 405, subpart I).

With regards to inaccurate assignments to payment classifications under the PDGM, corrections to

payment classifications on claims will not require appealing the initial determination. Because the assignment of the payment classification will be performed by the claims system based on data reported by the HHA on the claim or the corresponding patient assessment, the provider could correct this information to change the assignment. The HHA could submit a correction OASIS assessment and subsequently adjust their claim after the corrected assessment is accepted, or simply correct the payment-related items on the claim (occurrence code, diagnosis code, etc.) and submit the adjusted claim.

Comment: Another commenter asked CMS to review the current therapy assessment burden for providers and the time points in which those assessments need to be completed given that the PDGM does not use a service utilization domain.

Response: Prior to January 1, 2015, therapy reassessments were required to be performed on or "close to" the 13th and 19th therapy visits and at least once every 30 days (75 FR 70372). As a reminder, in the CY 2015 HH PPS final rule, CMS eliminated the requirement for reassessments to be performed on or "close to" the 13th and 19th visits. Instead, the current regulations at § 409.44(c)(2)(B) require a qualified therapist (instead of an assistant) to provide the needed therapy service and functionally reassess the patient at least every 30 days. Where more than one discipline of therapy is being provided, a qualified therapist from each of the disciplines must provide the needed therapy service and functionally reassess the patient.

Comment: A commenter indicated that under the PDGM those HHAs with lower margins will be paid less and those HHAs with higher margins will be paid more. Another commenter indicated that there should be a site of service adjustment for patients in assisted living as their needs are greater.

Response: The goal of the PDGM is to more closely align payments with costs based on patient characteristics. The PDGM was not designed to help agencies achieve any particular margin. While a commenter noted that patients in assisted living facilities may have greater needs, we also note that an HHA may have lower costs when treating multiple patients within the same assisted living facility due to economies of scale (lower per visit costs due to transportation and other overhead costs spread over more visits). We will analyze data after implementation of the PDGM to determine whether a site of

service adjustment may be warranted in the future.

Comment: Another commenter asked if CMS would reimburse 30-day periods without a skilled visit when a skilled visit exists for the 60-day episode and certification period.

Response: Current regulation at § 409.45(a) does not permit coverage of dependent services (home health aide services, medical social services, occupational therapy, durable medical equipment, medical supplies, or intern and resident services) furnished after the final qualifying skilled service (skilled nursing; physical therapy; speech-language pathology; or a continuing occupational therapy after the need for skilled nursing, physical therapy and/or speech-language pathology services have ceased), except when the dependent service was not followed by a qualifying skilled service as a result of the unexpected inpatient admission or death of the beneficiary, or due to some other unanticipated event. We did not propose to change the regulation regarding coverage of dependent services after qualifying skilled services have ceased in this rule. Therefore, we would not pay 30-day periods without a qualifying skilled service. Furthermore, HHAs should not be billing for dependent services that occur after the last qualifying skilled service, unless such services occurred due to an unexpected inpatient admission or death of the beneficiary, or due to some other unanticipated event.

Comment: A commenter asked whether CMS would give guidance to MA plans to implement the PDGM. Another commenter asked how Medicare as a secondary payer would be impacted by the PDGM.

Response: We acknowledge that some Medicare Advantage plans could change their payment models to mirror PDGM, while others may not change their payment models in relation to the changes finalized in this rule. It should be noted that, as private plans, Medicare Advantage plans do not have to use the FFS payment methodology. Medicare Advantage payment models for home health currently take a wide variety of forms and some may already be approximating the structure of PDGM, using patient characteristics rather than service utilization as the basis for payment. We will work generally with stakeholders, including these private plans, to help ensure that adequate education and resources are available for all parties. The implementation of the PDGM will have no impact on the Medicare as a secondary payer process.

Final Decision: We are finalizing the change in the unit of payment from 60

days to 30 days, effective for 30-day periods of care that start on or after January 1, 2020, as proposed and in accordance with the provisions in the BBA of 2018. In addition, we are finalizing the PDGM, with modification, also effective for 30-day periods of care that start on or after January 1, 2020. We are also finalizing the corresponding regulations text changes as described in section III.F.13 of this final rule with comment period. We will provide responses to more detailed comments regarding the PDGM and the calculation of the 30-day budget neutral payment amount for CY 2020 further in this final rule with comment period.

2. Methodology Used To Calculate the Cost of Care

To construct the case-mix weights for the PDGM proposal, the costs of providing care needed to be determined. A Wage-Weighted Minutes of Care (WWMC) approach is used in the current payment system based on data from the BLS. However, we proposed to adopt a Cost-per-Minute plus Non-Routine Supplies (CPM+NRS) approach, which uses information from HHA Medicare cost reports and home health claims. Under the proposed PDGM, we group periods of care into their case-mix groups taking into account admission source, timing, clinical group, functional level, and comorbidity adjustment. From there, the average resource use for each case-mix group dictates the group's case-mix weight. We proposed that resource use is the estimated cost of visits recorded on the home health claim plus the cost of NRS recorded on the claims. The cost of NRS is generated by taking NRS charges on claims and converting them to costs using a NRS cost to charge ratio that is specific to each HHA. When NRS is factored into the average resource use, NRS costs are reflected in the average resource use that establishes the case-mix weights. Similar to the current system, NRS would still be paid prospectively under the PDGM, but the PDGM eliminates the separate case-mix adjustment model for NRS. See the proposed rule for more detail on the steps used to generate the measure of resource use under the proposed CPM+NRS approach (83 FR 32385 through 32388).

The following is a summary of the public comments received on the "Methodology Used to Calculate the Cost of Care" proposal and our responses.

Comment: Several commenters objected to the use of Medicare cost report data rather than Wage-Weighted Minutes of Care (WWMC) in the

methodology used to calculate the cost of care. Commenters indicated that HHAs' inputs, as demonstrated through cost reports, are not accurately reflecting the effects of changes in utilization, provider payments, and provider supply that have occurred over the past decade. They argue that the strength and utility of episode-specific cost depends on the accuracy and consistency of agencies' reported charges, cost-to-charge ratios, and episode minutes and that there are no incentives for ensuring the accuracy of their cost reports; and therefore the data are presumptively inaccurate. Several commenters also indicated that the use of cost report data in lieu of WWMC favors facility-based agencies because they have the ability to allocate indirect overhead costs from their parent facilities to their service cost and argue that the PDGM will reward inefficient HHAs with historically high costs. Finally, a few commenters indicated that they would support the CPM+NRS approach only if HHA cost reports were audited.

Response: We believe that the use of HHA Medicare cost reports better reflects changes in utilization, provider payments, and supply amongst Medicare-certified HHAs that occur over time. Under the WWMC approach, using the BLS average hourly wage rates for the entire home health care service industry does not reflect changes in Medicare home health utilization that impact costs, such as the allocation of overhead costs when Medicare home health visit patterns change. Using data from HHA Medicare cost reports better represents the total costs incurred during a 30-day period (including, but not limited to, direct patient care contract labor, overhead, and transportation costs), while the WWMC method provides an estimate of only the labor costs (wage and fringe benefit costs) related to direct patient care from patient visits that are incurred during a 30-day period. We note the correlation coefficient between the two approaches to calculating resource use is equal to 0.8537 (n=8,521,924). Correlation coefficients are used in statistics to measure how strong the relationship is between two variables. The closer to 1 the stronger the relationship (zero means no relationship). Therefore, the relationship between using the CPM+NRS approach compared to the WWMC approach is very similar. In conjunction with this final rule with comment period, we posted an excel file on the HHA Center page that includes the case-mix weights produced using the proposed CPM+NRS approach and those produced using the current

WWMC approach in calculating resource use.¹⁰ The correlation coefficient between the two sets of weights (CPM+NRS versus WWMC using BLS data) is 0.9806, meaning the two methods produce very similar case-mix weights.

In response to comments regarding the accuracy of HHA Medicare cost report data, as we indicated in the proposed rule, we applied the trimming methodology described in detail in the “Analyses in Support of Rebased & Updating Medicare Home Health Payment Rates” Report available at: <https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20osxf.pdf>. This is also the trimming methodology outlined in the CY 2014 HH PPS proposed rule (78 FR 40284) in determining the rebased national, standardized 60-day episode payment amount. For each discipline and for NRS, we also followed the methodology laid out in the “Rebasing Report” by trimming out values that fall in the top or bottom 1 percent of the distribution across all HHAs. This included the cost per visit values for each discipline and NRS cost-to-charge ratios that fall in the top or bottom 1 percent of the distribution across all HHAs. Normalizing data by trimming out missing or extreme values is a widely accepted methodology both within CMS and amongst the health research community. In eliminating missing or questionable data with extreme values from the data we obtain a more robust measure of average costs per visit that is reliable for the purposes of establishing base payment amounts and case-mix weights under the HH PPS. Using HHA Medicare cost report data to establish the case-mix relative weight aligns with the use of this data in determining the base payment amount under the HH PPS.

Furthermore, we would note that each HHA Medicare cost report is required to be certified by the Officer or Director of the home health agency as being true, correct, and complete, with potential penalties should any information in the cost report be a misrepresentation or falsification of information. The HHA Medicare Cost Report (MCR) Form (CMS-1728-94) with this certification statement is available at <https://www.cms.gov/Regulations-and-Guidance/Legislation/Paperwork-ReductionActof1995/PRA-Listing-Items/CMS-1728-94.html>.

As always, we encourage providers to fill out the Medicare cost reports as accurately as possible. We remind the

industry again that each home health cost report is required to be certified by the Officer or Director of the home health agency. We also welcome suggestions for improving compliance and accuracy on cost reports within the current cost reporting forms. We will explore whether it is feasible to provide some sort of national, mandatory training on completing the Medicare HHA cost report form and whether and to what extent CMS can conduct more desk reviews and audits of Medicare HHA cost reports in the future.

With regards to the case-mix weights rewarding inefficient providers with high costs or facility-based HHAs, each HHA's costs impact only a portion of the calculation of the weights and costs are blended together across all HHAs. To put it simply, the payment regression was estimated using 8,521,924 30-day periods from 10,522 providers. On average, each provider contributed 841 30-day periods to the payment regression, which is only 0.010 percent of all 30-day periods. Therefore, including or excluding any single HHA on average would not dramatically impact the results of the payment regression. Additionally, in the PDGM, we estimate the payment regression using provider-level fixed effects; therefore we are looking at the within provider variation in resource use. That is, we may find there are two HHAs with different cost structures (for example, HHA “A”) has costs that are on average 1.5 times as high as HHA “B”) but both HHAs can still have similar patterns in resource use across their 30-day periods. Since the PDGM is controlling for the variation in the general costs for HHAs with high and lower costs, including those that have variation in costs due to being facility-based versus freestanding, we do not agree that using the CPM+NRS approach in estimating resource use introduces a bias that favors inefficient or facility-based HHAs.

Comment: Several commenters stated that Non-Routine Supplies (NRS) should not be incorporated into the base rate and then wage-index adjusted. The industry stated that HHAs' supply costs are approximately the same nationally, regardless of rural or urban locations and regardless of the wage-index. Commenters stated that including NRS in the base rate will penalize rural providers and unnecessarily overpay for NRS in high wage-index areas. Another commenter indicated that CMS should lower the labor-related share to account for NRS in the base payment rate.

Response: As we noted in the CY 2008 HH PPS final rule with comment, use of NRS is unevenly distributed

across episodes of care in home health. In addition, the majority of episodes do not incur any NRS costs and, at that time, the current payment system overcompensated for episodes with no NRS costs. We found that patients with certain conditions, many of them related to skin conditions, were more likely to require high non-routine medical supply utilization (72 FR 49850). We noted in the CY 2008 HH PPS proposed rule that, in particular, commenters were concerned about the adequacy of payment for some patients with pressure ulcers, stasis ulcers, other ulcers, wounds, burns or trauma, cellulitis, and skin cancers (72 FR 25427). At that time (and currently), the clinical levels for the HH PPS did not group patients with similar supply needs together; therefore, for CY 2008 we created a separate case-mix adjustment process for NRS based on a NRS conversion factor and six severity levels. We noted that the NRS case-mix adjustment process did not have a high degree of predictive accuracy, possibly due to the limited data available to model NRS costs and the likelihood that OASIS does not have any measures available for some kinds of NRS. We stated in the CY 2008 HH PPS final rule that we would continue to look for ways to improve our approach to account for NRS by exploring alternative methods for accounting for NRS costs and payments in the future (72 FR 25428). We believe that the PDGM offers an alternative method for accounting for NRS costs and payments by grouping patients more likely to require high NRS utilization into two groups—the Wound group and the Complex Nursing Interventions group. For example, while the Wound group and Complex Nursing Interventions groups comprise about 10 percent and 4 percent of all 30-day periods of care, respectively; roughly 30 percent of episodes where NRS was supplied was for Wound and Complex Nursing Interventions groups and 47 percent of NRS charges fall into the Wound and Complex Nursing Interventions groups. We note that CY 2017 claims data indicates that about 71 percent of 60-day episodes did not provide any NRS.

As noted by the commenters, in the CY 2008 HH PPS proposed rule we stated that because the market for most NRS is national, we proposed not to have a geographic adjustment to the conversion factor (72 FR 25430). More accurately, because the NRS conversion factor reflected supplies and not wage and wage-related costs, we did not subject NRS payments to the geographic wage adjustment process. However, we

¹⁰ <https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html>.

note that we did not revise the labor-related share to reflect the exclusion of NRS payments from the national, standardized 60-day episode payment amount. The labor-related share (LRS), effective for CY 2013 to CY 2018 home health payments of 78.535 percent is based on the 2010-based HHA market basket where the LRS is equal to the compensation cost weight, including salaries, benefits, and direct patient care contract labor. The non-labor-related share of 21.465 includes the relative costs for the NRS supplies. For comparison purposes, if we had removed NRS supplies from the calculations in the 2010-based Home Health market basket, the LRS would have been 79.7 percent and the non-labor-related share would have been 20.4 percent. Again, the LRS of 78.535 percent did not include NRS costs and therefore, NRS was not subjected to the geographic adjustment as it does not reflect wage and wage related costs. Similarly, the CY 2019 LRS of 76.1 percent, based on the 2016-based HHA market basket, also does not include NRS.

Comment: A few commenters stated that based on their operational experiences with clinical staffing labor costs, HHA cost report data suggests more parity exists between skilled nursing (“SN”) versus physical therapist (“PT”) costs than in fact exists. Commenters stated that BLS data showing a 40 percent difference between SN and PT costs are more reflective of the commenters’ human resources/staffing experiences in the markets where they operate. As such, commenters believe the use of cost report data would cause the PDGM model to overpay for nursing services and underpay for therapy services. A commenter indicated that contract staff are more expensive than staff that are hired and indicated this will widen the gap between nursing and therapy costs.

Response: The HHA Medicare cost report data reflects all costs and, most importantly, it reflects all labor costs, including contract labor costs. The BLS data only reflects employed staff. This may at least partially explain why a 40 percent variation between SN and PT costs is not evident in the cost report data. The HHA Medicare cost report data shows about a 20 percent difference between PT and SN compensation costs (wages and salaries, employee benefits and contract labor) per visit, which is consistent with the difference between PT and SN total costs per visit. Moreover, in aggregate, about 15 percent of compensation costs are contract labor costs and this varies among type of visit with contract labor

costs accounting for a much higher proportion of therapy visit compensation costs compared to skilled nursing visit compensation cost. Utilization also varies among freestanding providers with smaller providers having a higher proportion of contract labor costs, particularly for therapy services compared to larger providers. It also seems to vary by region. The decision of whether to/or what proportion of contract labor to use is at the provider’s discretion. In regards to the comment on expense of contracted services, we note that using cost report data allows those types of relationships to be fully measured. Finally, we note that in order to be eligible for Medicare HH PPS payments, providers must complete the HHA Medicare cost report; therefore, if providers are required to complete the cost report, then we believe such data are appropriate to use for payment purposes.

Comment: Several commenters indicated that WWMC and CPM+NRS results should be blended together to minimize disruptions.

Response: CMS appreciates this suggestion. However, there are difficulties in blending due to the WWMC and CPM+NRS approaches measuring different outcomes. WWMC is focused on cost of labor while CPM+NRS takes a more diverse approach and accounts for labor, overhead, and NRS. As discussed previously, there is very high correlation between the two approaches, meaning they produce very similar weights.

Comment: Another commenter indicated costs related to enrollment should be included in the calculation of resource use.

Response: These costs may be included in staffing and overhead costs and, if so, would be captured by the CPM+NRS approach.

Comment: A commenter cited a report that indicated for “on-the-job activities undertaken by employees, HHS Guidelines recommend using estimates of pre-tax wages for the particular industry and affected occupation, to the extent possible, and adding estimate of benefits and indirect costs.”

Response: The goal of the CPM+NRS methodology is to not simply measure costs related to on-the-job activities. In order to account for a broader array of costs, which is necessary to assign accurate payment rates, we instead used information from cost reports which is more detailed than information on wages, benefits, and indirect cost.

Final Decision: We are finalizing our proposal to adopt a Cost-per-Minute

plus Non-Routine Supplies (CPM+NRS) approach in estimating resource use, which uses information from HHA Medicare cost reports. The following steps would be used to generate the measure of resource use under the CPM+NRS approach:

(1) From the cost reports, obtain total costs for each of the six home health disciplines for each HHA.

(2) From the cost reports, obtain the number of visits by each of the six home health disciplines for each HHA.

(3) Calculate discipline-specific cost per visit values by dividing total costs [1] by number of visits [2] for each discipline for each HHA. For HHAs that do not have a cost report available (or a cost report that was trimmed from the sample), imputed values are used as follows:

- A state-level mean is used if the HHA was not hospital-based. The state-level mean is computed using all non-hospital based HHAs in each state.
- An urban nationwide mean is used for all hospital-based HHAs located in a Core-based Statistical Area (CBSA). The urban nation-wide mean is computed using all hospital-based HHAs located in any CBSA.
- A rural nationwide mean is used for all hospital-based HHAs not in a CBSA. The rural nation-wide mean is computed using all hospital-based HHAs not in a CBSA.

(4) From the home health claims data, obtain the average number of minutes of care provided by each discipline across all episodes for a HHA.

(5) From the home health claims data, obtain the average number of visits provided by each discipline across all episodes for each HHA.

(6) Calculate a ratio of average visits to average minutes by discipline by dividing average visits provided [5] by average minutes of care [4] by discipline for each HHA.

(7) Calculate costs per minute by multiplying the HHA’s cost per visit [3] by the ratio of average visits to average minutes [6] by discipline for each HHA.

(8) Obtain 30-day period costs by multiplying costs per minute [7] by the total number of minutes of care provided during a 30-day period by discipline. Then, sum these costs across the disciplines for each period.

NRS costs are added to the resource use calculated in [8] in the following way:

(9) From the cost reports, determine the NRS cost-to-charge ratio for each HHA. Imputation for missing or trimmed values is done in the same manner as it was done for cost per visit (see [3] as previously indicated).

(10) From the home health claims data, obtain NRS charges for each period.

(11) Obtain NRS costs for each period by multiplying charges from the home health claims data [10] by the cost-to-charge ratio from the cost reports [9] for each HHA.

Resource use is then obtained by:

(12) Summing costs from [8] with NRS costs from [11] for each 30-day period.

3. Change From a 60-Day to a 30-Day Unit of Payment

a. Background

Currently, HHAs are paid for each 60-day episode of home health care provided. By examining the resources used within a 60-day episode of care, we identified differences in resources used between the first 30-day period within a 60-day episode and the second 30-day period within a 60-day episode. Episodes have more visits, on average, during the first 30 days compared to the last 30 days. Costs are much higher earlier in the episode and lesser later on, therefore, dividing a single 60-day episode into two 30-day periods more accurately apportions payments. In addition, with the removal of therapy thresholds from the case-mix adjustment methodology under the HH PPS, a shorter period of care reduces the variation and improves the accuracy of the case-mix weights generated under the PDGM.

Section 1895(b)(2)(B) of the Act, as added by section 51001(a)(1) of the BBA of 2018, requires the Secretary to apply a 30-day unit of service for purposes of implementing the HH PPS, effective January 1, 2020. We note that we interpret the term “unit of service” to be synonymous with “unit of payment” and will henceforth refer to “unit of payment” in this final rule with comment period with regards to payment under the HH PPS. Therefore, in accordance with section 1895(b)(2)(B) of the Act, we proposed changing the unit of payment from a 60-day episode of care to 30-day unit of payment, effective January 1, 2020.

Comment: Many commenters understood the requirement for CMS to change from a 60-day episode to a 30-day unit of payment. Several commenters appreciated that CMS was maintaining the existing 60-day timing for comprehensive assessments, certifications and recertifications, and plans of care. Some commenters expressed concern that the 30-day payment period was more confusing because it is on a different a timeline than for other home health requirements

such as the certification/recertification, OASIS assessments and updates to the plan of care.

Response: CMS thanks commenters for recognizing that the change from a 60-day unit of payment to a 30-day unit of payment is required by law and we do not have the discretion to implement a different policy. We believe that changing to a 30-day unit of payment will more accurately pay for services in accordance with patient characteristics and is a better approach to focus on patient care needs. We believe maintaining the existing timeframes for updates to the comprehensive assessment, updates to the plan of care, and recertifications will help make the transition to a new case-mix adjustment methodology more seamless for HHAs. Under the PDGM, the initial certification of patient eligibility, plan of care, and comprehensive assessment are valid for two 30-day periods of care (that is, for 60 days of home health care) in accordance with the home health regulations at 42 CFR 409.43 and 424.22, and the home health CoPs at 42 CFR 484.55. Each recertification, care plan update, and comprehensive assessment update will also be valid for two 30-day periods of care, also in accordance with the home health regulations at 42 CFR 409.43(e) and 424.22(b), and the home health CoPs at 484.60(c).

We also note that not all home health requirements have a 60-day timeframe. For example, OASIS reporting regulations require the OASIS to be completed within 5 days and transmitted within 30 days of completing the assessment of the beneficiary. In addition, physical, occupational, and speech therapists must provide the needed therapy service and functionally reassess the patient at least every 30 calendar days. Home health is not the only care setting where billing and certifications are not done in the same timeframe. For example, hospices must certify and recertify patients every 60–90 days and they bill on a monthly basis. Previous to the inception of the HH PPS, HHAs also billed on a monthly basis even though the plan of care and certifications were completed every 60 days.

Comment: Many commenters described the burden that would exist in switching to a 30-day period. Some commenters indicated their overhead costs would increase because they would have to double their billing and CMS should account for those costs. Some commenters believe that switching to 30-days would result in documentation errors and increased administrative burdens to both

providers and to CMS due to an increase in claim submissions, resubmissions, and appeals. Some commenters indicated that switching to a 30-day billing cycle would result in a need to change current software and would require additional training for the providers. Commenters remarked they did not have the manpower to implement this change and that it goes against the Secretary’s goal of reducing burden. Many commenters expressed concern that switching to a 30-day period would cause undue burden because of the current difficulty in getting physicians to sign the plan of care in a timely manner.

Response: Under section 1895(b)(2)(B) of the Act, we are required to apply a 30-day unit of service for purposes of implementing the HH PPS, effective January 1, 2020. We appreciate the commenters’ concern regarding burden surrounding the change in the unit of payment from a 60-day episode to a 30-day period. While the change from a 60-day episode to a 30-day period may increase the billing frequency for final claims, we note that this change should not result in a measurable increase in burden, as many of the data elements that are used to populate an electronic claims submission will remain the same from one 30-day period to the next. HHAs are required to line-item bill each visit performed and whether each visit is recorded on a single 60-day claim or the visits are recorded on two different 30-day claims should not result in a measurable burden increase. Also, current data for CY 2017 suggests that nearly 1/3 of all 60-day periods would not produce a second 30-day period and would not require a second bill to be submitted. The proposed elimination of unnecessary items from the OASIS, especially those items no longer needed on follow-up assessments under the PDGM, would result in a decrease in regulatory burden, as discussed in section V. of this final rule with comment period. We remind commenters that prior to the inception of the HH PPS, HHAs also billed on a monthly basis even though the plan of care and certifications were completed every 60 days. We believe that the 30-day period is appropriate even if some requirements in home health have 60-day timeframes as a 30-day period of care under the PDGM better aligns home health payments with the costs of providing care. While we do not anticipate any increases in the numbers of appeals because of the implementation of the PDGM, we plan to conduct training and education for both HHAs and the MACs on the

operational aspects of the PDGM to mitigate any issues with claims submissions, resubmissions, and appeals.

Just like in the current system, under the PDGM, before a provider submits a final claim, the HHA will need to have a completed OASIS assessment, signed certification, orders, and plan of care. Our expectation is that the HHA will obtain the signed physician certification and plan of care timely. As we have reiterated in previous rulemaking and in sub-regulatory guidance, the certification must be complete prior to when an HHA bills Medicare for payment; however, physicians should complete the certification when the plan of care is established, or as soon as possible thereafter. This is longstanding CMS policy as referenced in Pub 100–01, Medicare General Information, Eligibility, and Entitlement Manual, chapter 4, section 30.1.¹¹ As stated in sub-regulatory guidance in the Pub. 100–02, Medicare Benefit Policy Manual, chapter 7, section, section 30.5.1, “it is not acceptable for HHAs to wait until the end of a 60-day episode of care to obtain a completed certification/recertification.” Per the regulations at § 409.43(c), if the HHA does not have detailed orders for the services to be rendered, the plan of care must either be signed or immediately sent to the physician for signature at the time that the agency submits its request for anticipated payment (submitted at the start of care after the first visit is performed). The Conditions of Participation (CoPs) require the Outcome and Assessment Information Set (OASIS) to be completed within 5 days and submitted within 30 days of completion. Under the PDGM, the initial certification of patient eligibility, plan of care, and comprehensive assessment are valid for two 30-day periods of care. Each recertification, care plan update, and comprehensive assessment update will also be valid for two 30-day periods of care.

Comment: Another commenter indicated that if there was a 30-day period then the face-to-face encounter requirement provision could be eliminated. Another commenter asked if all physicians’ orders must be signed and returned before the HHA can bill the first 30-day period. A commenter questioned what would occur with episodes where a portion of the payment started prior to the implementation date of January 1, 2020. Another commenter questioned what

would happen if a patient’s diagnosis changes for the second 30-day period, as no additional comprehensive assessment is required before the second payment period.

Response: The face-to-face requirement is statutorily required under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act as part of the certification for home health services. As a condition of payment for Medicare home health benefits, a face-to-face encounter must meet the requirements as set forth at § 424.22(a)(1)(v). The intent of the face-to-face encounter requirement is to achieve greater physician accountability in certifying a patient’s home health eligibility and in establishing a patient’s plan of care. As such, this requirement is unrelated to the switch from a 60-day episode to a 30-day period. Likewise, the requirements for submission of home health claims have not changed. The regulations at § 409.43 state that in order to submit a final claim for payment, the plan of care and any physician’s orders must be signed and dated by the physician before the HHA bills for the care.

For implementation purposes, the 30-day payment amount would be paid for home health services that start on or after January 1, 2020. More specifically, for 60-day episodes that begin on or before December 31, 2019 and end on or after January 1, 2020 (episodes that would span the January 1, 2020 implementation date), payment made under the Medicare HH PPS would be the CY 2020 national, standardized 60-day episode payment amount. For home health periods of care that begin on or after January 1, 2020, the unit of payment would now be a 30-day period and payment made under the Medicare HH PPS would be the CY 2020 national, standardized prospective 30-day payment amount. For home health periods of care that begin on or after December 2, 2020 through December 31, 2020 and end on or after January 1, 2021, the HHA would be paid the CY 2021 national, standardized prospective 30-day payment amount.

As we have stated, the requirements for when to update the comprehensive assessment remain unchanged. For example, if the HHA does not need to update the comprehensive assessment prior to recertifying the patient (for which the comprehensive assessment would be completed within the last 5 days of every 60 days beginning with the start of care date), then responses from the start of care OASIS would be used for determining the functional impairment level for both the first and second 30-day periods. The follow-up

OASIS completed near the time of recertification would be used for the third and fourth 30-day periods of care. If, for example, the HHA needs to complete a resumption of care OASIS within 48 hours of the patient returning to home health after being transferred and admitted to the hospital for 24 hours or more and this occurs during the first 30-day period of care, then the responses for functional items from the resumption of care assessment would be used to determine the functional impairment level for the second 30-day period of care.

With regards to diagnosis codes, the PDGM uses the diagnoses from the home health claim to group a 30-day home health period of care into a clinical group and to determine if there is a comorbidity adjustment. If a home health patient has any changes in diagnoses (either the principal or secondary), this would be reflected on the home health claim and the case-mix weight could change accordingly. However, we would expect that the HHA clinical documentation would also reflect these changes and any communication/coordination with the certifying physician would also be documented. The home health CoPs at § 484.60(c) require that the HHA must promptly alert the relevant physician(s) to any changes in the patient’s condition or needs that suggest that outcomes are not being achieved and/or that the plan of care should be altered.

b. 30-Day Unit of Payment

Section 1895(b)(3)(A)(iv) of the Act, requires CMS to calculate a 30-day payment amount for CY 2020 in a budget neutral manner such that estimated aggregate expenditures under the HH PPS during CY 2020 are equal to the estimated aggregate expenditures that otherwise would have been made under the HH PPS during CY 2020 in the absence of the change to a 30-day unit of payment. As also required by 1895(b)(3)(A)(iv) of the Act, to calculate a 30-day payment amount in a budget-neutral manner, we are required to make assumptions about, and take into account behavior changes that could occur as a result of the implementation of the 30-day unit of payment and case-mix adjustment factors in CY 2020. We are also required to calculate a budget-neutral 30-day payment amount before the provisions of section 1895(b)(3)(B) of the Act are applied, that is, before application of the home health applicable percentage increase, the adjustment for case-mix changes, the adjustment if quality data is not reported, and the productivity adjustment.

¹¹ <https://www.cms.gov/Regulations-and-Guidance/Manuals/downloads/ge101c04.pdf>.

To calculate the 30-day budget-neutral payment amount, we proposed three assumptions about behavior change that could occur in CY 2020 as a result of the implementation of the 30-day unit of payment and the implementation of the PDGM case-mix adjustment methodology:

- **Clinical Group Coding:** This is based on the principal diagnosis code for the patient as reported by the HHA on the home health claim. Our proposed assumption was that HHAs will change their documentation and coding practices and put the highest paying diagnosis code as the principal diagnosis code in order to have a 30-day period be placed into a higher-paying clinical group.

- **Comorbidity Coding:** The PDGM further adjusts payments based on patients' secondary diagnoses as reported by the HHA on the home health claim. OASIS only allows HHAs to designate 1 principal diagnosis and 5 secondary diagnoses while the home health claim allows HHAs to designate 1 principal diagnosis and 24 secondary diagnoses. Our proposed assumption was that by taking into account additional ICD-10-CM diagnosis codes listed on the home health claim (beyond the 6 allowed on the OASIS), more 30-day periods of care will receive a comorbidity adjustment

- **LUPA Threshold:** Under the proposed PDGM, our proposed assumption was that for one-third of LUPAs that are 1 to 2 visits away from the LUPA threshold HHAs will provide 1 to 2 extra visits to receive a full 30-day payment.

If no behavioral assumptions were made, we estimated that the 30-day payment amount needed to achieve budget neutrality would be \$1,873.91. The clinical group and comorbidity coding assumptions would result in the need to decrease the budget-neutral 30-day payment amount to \$1,786.54 (a 4.66 percent decrease from \$1,873.91). Adding the LUPA assumption would require us to further decrease that amount to \$1,753.68 (a 6.42 percent decrease from \$1,873.91). Because we proposed to implement the 30-day unit of payment and the PDGM for CY 2020, we would propose the actual 30-day payment amount in the CY 2020 HH PPS proposed rule calculated using CY 2018 home health utilization data and we would calculate this amount before application of the proposed home health update percentage required for CY 2020 (as required by section 1895(b)(3)(B)(i) of the Act). In the proposed rule, we noted that we are also required under section 1895(b)(3)(D)(i) of the Act, as added by section 51001(a)(2)(B) of the

BBA of 2018, to analyze data for CYs 2020 through 2026, after implementation of the 30-day unit of payment and new case-mix adjustment methodology, to annually determine the impact of differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures. We interpret actual behavior change to encompass both behavior changes that were previously outlined, as assumed by CMS when determining the budget-neutral 30-day payment amount for CY 2020, and other behavior changes not identified at the time the 30-day payment amount for CY 2020 is determined.

We solicited comments on the proposed behavior change assumptions previously outlined to be used in determining the 30-day payment amount for CY 2020.

The following is a summary of the public comments received on the "30-day Unit of Payment" proposals and our responses.

Comment: Some commenters expressed support for the inclusion of behavioral assumptions in calculating the budget-neutral 30-day payment amount. Some commenters stated that using these behavioral assumptions may help mitigate potential program integrity issues which could cause disruptions in patient care.

Response: We thank commenters for their remarks supporting the behavioral assumptions. The purpose of these behavioral assumptions is not to incorporate a built-in program integrity measure, but rather CMS is required by law to make behavioral assumptions when calculating a 30-day budget-neutral payment amount for CY 2020. Also as required by section 1895(b)(3)(D)(i) of the Act, as added by section 51001 of the BBA of 2018, we will analyze the impact of the assumed versus the actual behavior change after the implementation of the PDGM and the 30-day unit of payment to determine if any payment adjustment, either upward or downward, is warranted. We will monitor utilization trends after implementation of the PDGM in CY 2020 to identify any aberrant behavior or significant changes in practice patterns that may signal potential program integrity concerns and investigate such occurrences accordingly.

Comment: The majority of commenters stated that CMS should not apply behavioral assumptions industry-wide as it punishes all HHAs for the performance of small set of agencies and these commenters expressed concern over what they describe as an adversarial approach to assumed

behavior changes. Many of the commenters were concerned with the broad assumption by CMS that HHAs would indulge in "gaming" and unethical behavior to compensate for the changes within the PDGM model. It was stated that CMS should instead do more targeted program integrity efforts, such as creating a system of audits and significant monetary or other punishments, or adjust payments only for HHAs whose reimbursement falls outside normal variations. It was also suggested that HHAs that do not actually change their behavior in response to the PDGM should have a different payment rate structure compared to HHAs that do change their behavior.

Response: By including behavior change assumptions in the proposed calculation of the 30-day payment amount, as required by statute, we did not intend to imply that HHAs would engage in unethical behavior; therefore, these assumptions are not meant to be punitive. We acknowledge that in making assumptions about provider behavior, no matter if required by law or well-supported by evidence, there will be those who will disagree with this type of approach to adjusting payment. We have addressed in the CY 2016 HH PPS final rule why we do not believe targeted program integrity efforts would mitigate behavioral changes resulting from a case-mix system (80 FR 68421). As we stated in the CY 2016 HH PPS final rule (80 FR 68421 through 68422), for a variety of reasons, we have not proposed targeted reductions for nominal case-mix growth, meaning the portion of case-mix growth that cannot be explained by changes in patient characteristics. The foremost reason is that we believe changes and improvements in coding have been widespread, so that such targeting would likely not separate agencies clearly into high and low coding-change groups. In that same rule, we referenced an independent review of our case-mix measurement methodology conducted by Dr. David Grabowski, Ph.D., a professor of health care policy at Harvard Medical School, and his team agreed with our reasons for not proposing targeted reductions, stating their concerns about the small sample size of many agencies and their findings of significant nominal case-mix across different classes of agencies (please see the "Home Health Study Report—Independent Review of the Models to

Assess Nominal Case-Mix Growth”, dated June 21, 2011.)¹²

While certain commenters seem to assume that CMS can precisely identify those agencies practicing abusive coding, we do not agree that agency specific case-mix levels can precisely distinguish the agencies that engage in abusive coding from all others. System wide, case-mix levels have risen over time throughout the country, while patient characteristics data indicate little real change in patient severity over time. That is, the main issue is not the level of case-mix billed by any specific HHA over a period of time, but the amount of change in the billed case-mix weights not attributable to underlying changes in actual patient severity. Therefore, while commenters provided specific suggestions for targeted efforts, we are unable to implement such actions for the reasons described. We note that we have taken various measures to reduce payment vulnerabilities and the federal government has launched actions to directly identify fraudulent and abusive activities. Commenters should be aware of tip lines available that can help support investigative efforts of the federal government. The Office of the Inspector General, Department of Health and Human Services website at: <http://oig.hhs.gov/fraud/report-fraud/index.asp>, provides information about how to report fraud. Another website, <http://www.stopmedicarefraud.gov/index.html>, is oriented to Medicare patients and their families and provides information about recognizing fraud.

Finally, we remind commenters that section 1895(b)(3)(A)(iv) of the Act requires that in calculating a 30-day budget-neutral payment amount, we are required to make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of payment and a change to the case-mix adjustment methodology; therefore, we do not have the discretion to apply different policies. Likewise, we are required to analyze data for CYs 2020 through 2026, after implementation of the 30-day unit of payment and the alternate case-mix adjustment methodology, to annually determine the impact of the differences between assumed behavioral changes and actual behavioral changes on estimated aggregate expenditures and adjust the payment amount either upwards or downwards accordingly.

Comment: Several commenters disagreed with the three behavioral

assumptions made and remarked that the assumptions appear to be randomly determined, inappropriate and that there is no evidence to support them. A commenter specifically stated that the assumptions lack any foundation in actual evidence-based data and therefore penalize providers in an arbitrary and capricious fashion in violation of the Administrative Procedures Act (APA). A few remarked that the assumptions are “mere guesses” and appear to be used solely to reduce home health payments. Other commenters remarked that the proposed behavioral assumptions appear to be overly complex and unsubstantiated. Some commenters stated the assumptions are illogical because the broad assumptions in the proposed rule basically construct a completely new payment system that is predicated on a presumption that HHAs will attempt to manipulate the system and recommended that the behavioral assumptions be tested before they are implemented. Many commenters asked for additional documentation on how the reductions derived from the three behavioral assumptions were calculated and wanted to know the specific calculations that were made and the rationale behind those calculations.

Response: We disagree that the three behavioral assumptions made are arbitrary, inappropriate, illogical, mere guesses, overly complex, meant to penalize providers, or that there is no evidence to support them. Likewise, we disagree that these assumptions are in violation of the APA given that CMS is required by statute to apply behavioral assumptions in calculating the 30-day budget-neutral payment amount; we described such assumptions in notice and comment rulemaking as required by section 1895(b)(3)(A)(iv) of the Act. Additionally, we examined relevant data and believe we have a satisfactory explanation for these assumptions, including a substantive connection between the data and the behavioral assumptions made. We believe that there is both evidence for and precedent for adjusting the home health prospective payment based on assumed behavioral changes.

With regards to our assumption that HHAs would code the highest-paying diagnosis code as primary for the clinical grouping assignment, this assumption was based on decades of past experience under the case-mix system for the HH PPS and other case-mix systems for other payment systems, such as the implementation of the diagnosis-related groups (DRGs) and the Medicare Severity (MS)-DRGs under the inpatient prospective payment system.

In the FY 2008 IPPS final rule (72 FR 47176), we noted that case-mix refinements can lead to substantial unwarranted increase in payments. To address this issue when CMS transitioned from DRGs to MS-DRGs, MedPAC recommended that the Secretary project the likely effect of reporting improvements on total payments and make an offsetting adjustment to the national average base payment amounts (72 FR 47176). In the FY 2008 IPPS final rule (72 FR 47181), we summarized instances where case-mix increases resulted from documentation and coding-induced changes for the first year of the IRF PPS and in Maryland hospitals’ transition to APR DRGs (estimated at around 5 percent in both instances). Therefore, we estimated that a total adjustment of 4.8 percent would be necessary to maintain budget neutrality for the transition to the MS-DRGs (72 FR 47178).

In both the FY 2010 and FY 2011 IPPS final rules, subsequent analysis of claims data, using FYs 2008 and 2009 claims, supported the prospective payment adjustments to account for the documentation and coding effects (74 FR 43770 and 75 FR 50356). Specifically, we stated that based on our retrospective evaluation of claims, our actuaries determined that the implementation of the MS-DRG system resulted in a 2.5 percent change and a 5.4 percent change in case-mix not due to actual changes in patient characteristics, but due to documentation and coding changes for discharges occurring during FYs 2008 and 2009, respectively. We stated that the coding assumption is appropriate because, in the absence of such adjustments, the effect of the documentation and coding changes resulting from the adoption of the MS-DRGs results in inappropriately high payments because that portion of the increase in aggregate payments is not due to an increase in patient severity of illness (and costs).

With regards to experience under the HH PPS, we note that effective for CY 2008, CMS finalized changes to the HH PPS case-mix model to reflect different resource costs for early home health episodes versus later home health episodes and expanded the case-mix variables and therapy thresholds included in the payment model (72 FR 49764). These changes resulted in the 153 home health resource groups (HHRGs) currently used to case-mix adjust payment in the HH PPS. Since the CY 2008 proposed rule, we have stated in HH PPS rulemaking that we would continue to monitor case-mix

¹² https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/HHPPS_HHAcase-mix-growth-Final-Report.pdf.

changes in the HH PPS and to update our analysis to measure change in case-mix, both nominal and real. As discussed in the CY 2010 HH PPS rule (74 FR 40958), the analysis then indicated approximately 9.77 percent of the 15.03 percent increase in the overall observed case-mix between the IPS baseline and 2007 was real, that is, due to actual changes in patient characteristics. Our estimate was that a 13.56 percent nominal increase ($15.03 - (15.03 \times 0.0977)$) in case-mix was due to changes in coding procedures and documentation rather than to treatment of more resource-intensive patients (that is, nominal case mix growth). In the CY 2011 HH PPS proposed rule, we stated from 2000 to 2007, we observed about a 1 percent per year increase in total average case-mix. However, that annual change increased to slightly more than 4 percent [4.37 percent] between 2007 and 2008 (75 FR 43238). Our analyses at that time indicated a 19.40 percent increase in the overall observed case-mix since 2000 with approximately 10.07 percent attributed to actual changes in patient characteristics. Our estimate was that a 17.45 percent nominal increase ($19.40 - (19.40 \times 0.1007)$) in case-mix was due to changes in coding practices and documentation rather than to treatment of more resource-intensive patients. In the CY 2012 HH PPS proposed rule we stated that our analysis indicated another large increase in the average case-mix weight between CY 2008 and CY 2009 of 2.6 percent (76 FR 40990), attributable to the CY 2008 refinements. Therefore, analysis of case-mix growth between the two years immediately after implementation of the CY 2008 refinements demonstrated that average case-mix increased by nearly 7 percent. Our latest analysis continues to support the payment adjustments as outlined in the CY 2018 HH PPS proposed rule (82 FR 35274), which shows that between CY 2000 and 2010, total case-mix change was 23.90 percent, with 20.08 considered nominal case-mix growth, an average of approximately 2 percent nominal case-mix growth per year, including changes due to the CY 2008 case-mix adjustment methodology refinements. Therefore, we believe that there is ample evidence supporting the behavioral assumptions relating to changes, including improvements, in coding.

Our analysis shows that only about a third of 30-day periods move into a different clinical group as a result of the clinical group coding assumption, meaning that the reported secondary diagnosis(es) would place a period of

care into a higher case-mix group under the PDGM if reported as the principal diagnosis. Clinically, there are circumstances in which it would be appropriate to report a higher paying code as the principal diagnosis. For example, if medical documentation notes that a patient was recently hospitalized for exacerbation of congestive heart failure (which, if reported as the principal diagnosis, would group a period of care into the clinical group, MMTA) and there is expected teaching by the HHA associated with the recent exacerbation, but the patient also has a stage 2 pressure ulcer (which, if reported as the principal diagnosis, would group a period of care into the clinical group, Wounds) that requires wound care, we believe it would be appropriate to report the pressure ulcer as the principal diagnosis as the pressure ulcer would likely take priority as the primary reason for home health care in terms of increased resource utilization. However, the teaching associated with the exacerbation of heart failure would be a secondary reason, but still an important additional reason for home health care, and congestive heart failure would be reported as an additional diagnosis on the home health claim. In the current HH PPS, the assignment of points as part of the clinical level in the case-mix methodology is dependent upon the reporting of diagnoses. However, the points assigned are not generally dependent on whether the diagnosis is reported as the primary diagnosis or other diagnosis, except for a few exceptions. This means, that for most of the clinical point assignments, the ordering of the diagnosis does not matter as much as whether the diagnosis is present or not. For example, if a cancer diagnosis is reported, there are the same number of associated clinical points regardless of whether the cancer diagnosis is reported as a principal diagnosis or as a secondary diagnosis. However, under the PDGM, the ordering of diagnoses is important in determining the clinical group and the comorbidity adjustment, so we do expect that HHAs will improve the ordering of diagnosis codes to ensure that the home health period of care is representative of patient characteristics and paid accordingly. Furthermore, the implementation of ICD-10-CM has expanded the diagnosis code set significantly, making it possible for HHAs to more accurately and specifically code conditions present in the home health patient population.

With regards to the comorbidity coding assumption, using the home

health claim for the comorbidity adjustment as opposed to OASIS provides more opportunity to report all comorbid conditions that may affect the home health plan of care. The OASIS item set only allows HHAs to designate up to 5 secondary diagnoses, while the home health claim (837I institutional claim format-electronic version of the paper UB-04) allows HHAs to report up to 24 secondary diagnoses. Additionally, because ICD-10 coding guidelines require reporting of all secondary diagnoses that affect the plan of care, we would expect that more secondary diagnoses would be reported on the home health claim given the increased number of secondary diagnosis fields on the home health claim compared to the OASIS item set. Therefore, we assume that by taking into account additional ICD-10-CM diagnosis codes listed on the home health claim, more 30-day periods of care will receive a comorbidity adjustment than periods otherwise would have received if we only used the OASIS diagnosis codes for payment. Furthermore, because the comorbidity adjustment in the PDGM can increase payment by up to 20 percent, we assume that HHAs will ensure that secondary diagnoses affecting the home health plan of care would be reported to more accurately identify the conditions affecting resource use.

Regarding the LUPA threshold assumption, as noted in the FY 2001 HH PPS final rule, the episode file showed that approximately 16 percent of episodes would have received a LUPA (65 FR 41162). However, currently, only about 7 percent of all 60-day episodes receive a LUPA. In other words, it appears HHAs changed practice patterns such that more than half of 60-day episodes that would have been LUPAs upon implementation of the HH PPS are now non-LUPAs. Current data for CY 2017 suggest that what would be about one-third of the LUPA episodes with visits near the LUPA threshold would move up to become non-LUPA episodes as we currently see clustering of episodes at and around the current LUPA threshold of 5 visits. Under the current 60-day episode structure, there is a natural breaking point in the distribution of episodes between those with 4 or fewer visits (LUPAs) and those with 5 or more visits (non-LUPAs). The distribution around this breaking point of episodes as a percent of total episodes has remained fairly constant over the last few years. In particular, the episodes with 2, 3, or 4 visits are similar, with each comprising about 2.4 percent of total episodes. Likewise, the

episodes with 5, 6, or 7 visits each represent about 4.6 percent of total episodes. We assume this same phenomenon will be observed in the PDGM, except that, to account for the different threshold structure, it will occur for periods that otherwise would be 1 or 2 visits away from becoming non-LUPA.

We disagree with those commenters who state that the behavioral assumptions basically construct a completely new payment system that is predicated on gaming of the system. The goal of the proposed PDGM is to more accurately pay for home health services based on patient characteristics. As previously noted, section 1895(b)(3)(A)(iv) of the Act requires that behavioral assumptions be made in calculating the payment amount for CY 2020 so that the estimated aggregate amount of expenditures under the HH PPS in CY 2020 is equal to the estimate aggregate amount of expenditures in CY 2020 that otherwise would have been made under the HH PPS if the change to a 30-day unit of payment had not been enacted. Furthermore, we remind commenters that the law requires that CMS analyze data for CYs 2020 through 2026, after implementation of the 30-day unit of payment and the alternate case-mix adjustment methodology, to annually determine the impact of the differences between assumed and actual behavioral changes on estimated aggregate expenditures and adjust the payment amount either upwards or downwards accordingly. As such, we do not believe the law provides the latitude to test behavioral assumptions prior to implementation of the 30-day unit of payment and the PDGM for CY 2020 given these requirements, in law, to make behavioral assumptions in calculating a 30-day budget-neutral payment amount for CY 2020 and to determine the impact on estimated aggregate expenditures of differences between the assumed and actual behavior changes once the data for CYs 2020 through 2026 become available to determine whether temporary and permanent adjustments are needed.

We believe that, as described in the CY 2019 HH PPS proposed rule and throughout this final rule with comment period, we have provided sufficient detail for these behavioral assumptions as well as referenced past rules in which nominal case-mix change has been evaluated. The reconciliation process involving temporary and permanent adjustments required by law should assure HHAs that any over or underestimate of the payment amount will be adjusted accordingly. However, to support HHAs in evaluating the

effects of the proposed PDGM, CMS provides, upon request, a Home Health Claims-OASIS Limited Data Set (LDS) to accompany the proposed and final rules. The Home Health Claims-OASIS LDS file can be requested by following the instructions on the following CMS website: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures/Data-Agreements/DUA-NewLDS.html>.

Comment: In its public comments to the proposed CY 2019 HH PPS rule, MedPAC stated that the past experience of the home health PPS demonstrates that HHAs have changed coding, utilization, and the mix of services provided in reaction to new payment incentives. MedPAC remarked that CMS continued to find nominal increases in case mix unrelated to patient severity in later years and reduced payment by an average of 1.8 percent a year in 2008 through 2017 to account for this trend. MedPAC remarked that the proposed home health payment reduction of 6.42 percent appears to be consistent with past coding trends but that they do not expect that the reduction would create payment adequacy issues for most HHAs. As MedPAC has noted previously, the average margin of Medicare HHAs is 15.5%.

Response: We thank MedPAC for their comments and we agree that there is sufficient evidence of HHA behavioral responses in reaction to payment incentives. We believe that HHA margins are adequate and that the 30-day budget-neutral payment amount should not cause revenue concerns for the majority of HHAs.

Comment: Some commenters asked CMS to clarify their interpretation of the BBA of 2018 as it relates to budget neutrality. Specifically, Another commenter indicated that CMS should clarify that Congress intended to replace the existing budget neutrality requirement under the HH PPS with a temporary one-year budget neutrality requirement for CY 2020 that would be limited to maintaining equal aggregate expenditures associated with the transition between 60-day to 30-day units of service.

Response: The law does not require CMS to replace the current budget neutrality requirements as set forth in section 1895(b)(3)(A) of the Act. However, under section 1895(b)(3)(A)(iv) of the Act, we are required to calculate a 30-day payment amount for CY 2020 in a budget neutral manner such that estimated aggregate expenditures under the HH PPS during CY 2020 are equal to the estimated aggregate expenditures that otherwise would have been made under the HH

PPS during CY 2020 in the absence of the change to a 30-day unit of payment. We are also required to calculate a budget-neutral 30-day payment amount before the provisions of section 1895(b)(3)(B) of the Act are applied, that is, the home health applicable percentage increase, the adjustment for case-mix changes, the adjustment if quality data is not reported, and the productivity adjustment. However, this does not mean that the 30-day budget-neutral payment amount only pertains to payments made in CY 2020 as we remind commenters that we are required to annually determine the impact of differences between assumed and actual behavior changes on estimated aggregate expenditures for CY 2020 through CY 2026 and adjust the payment amount upwards or downwards accordingly. Because we are proposing to implement the 30-day unit of payment and proposed PDGM for CY 2020, we would propose the actual 30-day payment amount in the CY 2020 HH PPS proposed rule calculated using CY 2018 home health utilization data, and we would calculate this amount before application of the proposed home health update percentage required for CY 2020 (as required by section 1895(b)(3)(B)(ii)(V) of the Act).

Comment: Several commenters asked how CMS will make the reconciliation between assumed and actual behavioral changes upon implementation of the PDGM. A commenter indicated that CMS should fully display the reconciliation process with public notice and an opportunity to comment in advance of its application. Another commenter wanted to know if CMS would update its behavioral assumptions using CY 2020 data to compare actual behavior to assumed behavior. Several commenters were concerned that CMS was placing a cap on the growth in home health services and in the event of growth, future payments would be reduced to match a payment amount from a prior year. A few commenters indicated that the behavioral assumptions are already accounted for in the current PPS and stated that HHAs already are incentivized to report the highest paying clinical diagnosis code on the claim, and also to develop and deliver plans of care that exceed the LUPA threshold.

Response: We provided a detailed explanation as to how we calculated the 30-day budget-neutral payment amount in the CY 2019 HH PPS proposed rule (83 FR 32389) Specifically, we described how we calculated the budget-neutral 30-day payment amounts, both with and without behavioral assumptions and using CY

2019 payment parameters (for example, proposed 2019 payment rates, proposed 2019 case-mix weights, and outlier fixed-dollar loss ratio) to determine the expenditures that would occur under the current case-mix adjustment methodology. As with all elements of the PDGM, we would update the impacts of the proposed behavioral assumptions using CY 2018 claims data in CY 2020 proposed rulemaking. This would be described in the CY 2020 HH PPS proposed rule to ensure HHAs are fully aware of the behavioral assumption impacts on the payment amount for CY 2020 using the most recent data available for CY 2020 implementation.

In accordance with the BBA of 2018, we will annually determine the impact of differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures for CYs 2020 through 2026. We interpret actual behavior change to encompass both behavior changes that were previously outlined, as assumed by CMS when determining the budget-neutral 30-day payment amount for CY 2020, and other behavior changes not identified at the time the 30-day payment amount for CY 2020 is determined.

In the CY 2015 HH PPS final rule (79 FR 66072), we finalized our proposal to recalibrate the case-mix weights every year with more current data. Therefore, we refer commenters to previous HH PPS rules (for example, CY 2016 HH PPS final rule, (80 FR 68629)), where we recalibrate case-mix weights to account for nominal case-mix change. We anticipate a similar methodology when making any required permanent and temporary adjustments to payments, as required under sections 1895(b)(3)(D)(ii) and (iii) of the Act, to address the impact of the assumed versus actual behavioral change after implementation of the PDGM and the 30-day budget-neutral payment amount. Section 1895(b)(3)(D)(ii) of the Act requires notice and comment rulemaking for any permanent adjustments. Section 1895(b)(3)(D)(iii) of the Act similarly requires notice and comment rulemaking for any temporary adjustments. As a result, any reconciliation methodology for permanent and/or temporary adjustments would be subject to rulemaking, with the opportunity for the public to provide comments prior to the finalization of any policies. The data from CYs 2020 through 2026 will be available to determine whether temporary adjustments and/or permanent adjustments (increase or

decrease) are needed no earlier than in years 2022 through 2028 rulemaking.

We believe that the temporary and prospective adjustments outlined in the statute are not meant to act as a cap on overall home health expenditures. CMS is required by section of 1895(b)(3)(A)(iv) of the Act to calculate a 30-day payment amount for CY 2020 in a budget neutral manner so that estimated aggregate expenditures under the HH PPS during CY 2020 made under the new 30-day unit of payment would be equal to the estimated aggregate expenditures that otherwise would have been made in the absence of the 30-day unit of payment. Likewise, any permanent or temporary adjustments made, as required by the BBA of 2018, would be made to address the impact of differences between assumed and actual behavior changes on estimated aggregate expenditures with respect to years beginning with 2020 and ending with 2026. Any adjustment to the payment amount resulting from differences between assumed versus actual behavior changes would not be related to increases in the number of beneficiaries utilizing Medicare home health services. The purpose of the required behavioral assumptions is to calculate the 30-day budget-neutral payment amount and not to limit payment for home health services or access to needed care.

We disagree with comments that state that the behavioral assumptions made under the PDGM are already accounted for in the current HH PPS case-mix system given the assumptions made under the proposed PDGM are based on a shorter unit of payment, 30 days as opposed to the current 60 days. As described throughout this final rule with comment period and the proposed rule, the variation in resource utilization is most notable in the first versus second and subsequent 30-day periods of care. Consequently, the behavioral assumptions are based on the 30-day unit of payment and the unique case-mix variables that are present under the PDGM, but not under the current HH PPS case-mix system.

Comment: A few commenters remarked that it would be difficult to change their behavior in response to the PDGM. For example, these commenters referenced the LUPA thresholds that vary by case-mix group and stated that these are difficult to understand and that it would be extremely difficult for a front line care provider to know for a specific patient whether they were close to a LUPA threshold.

Response: As we have described in detail in the CY 2019 HH PPS proposed rule and other rules, the evidence supports a pattern of “practicing to the

payment”. Specifically, there is ample evidence that there are notable behavior changes as they relate to payment thresholds. The findings from the Report to Congress on the “Medicare Home Health Study: An Investigation on Access to Care and Payment for Vulnerable Patient Populations”, note that concerns have been raised about the use of therapy thresholds in the current HH PPS. Under the current payment system, HHAs receive higher payments for providing more therapy visits once certain thresholds are reached. As a result, the average number of therapy visits per 60-day episode of care have increased since the implementation of the HH PPS, while the number of skilled nursing and home health aide visits have decreased over the same time period as shown in Figure 3 of the CY 2018 HH PPS proposed rule (82 FR 35276). The study demonstrates that the percentage of episodes, and the average episode payment by the number of therapy visits for episodes with at least one therapy visit in 2013 increased sharply in therapy provision just over payment thresholds at 6, 7, and 16. Similarly, between 2008 and 2013, MedPAC reported a 26 percent increase in the number of episodes with at least 6 therapy visits, compared with a 1 percent increase in the number of episodes with five or fewer therapy visits.¹³ CMS analysis demonstrates that the average share of therapy visits across all 60-day episodes of care increased from 9 percent of all visits in 1997, prior to the implementation of the HH PPS (see 64 FR 58151), to 39 percent of all visits in 2015 (82 FR 35277). Furthermore, as noted in the FY 2001 HH PPS final rule, the episode file showed that approximately 16 percent of episodes would have received a LUPA (65 FR 41162). However, currently, only about 7 percent of all 60-day episodes receive a LUPA. In other words, it appears HHAs changed practice patterns such that more than half of 60-day episodes that would have been LUPAs upon implementation of the HH PPS are now non-LUPAs.

Therefore, past analysis confirms that there are noted changes in provider behavior resulting from the presence of thresholds that affect payment. As such, we believe that the presence of thresholds, regardless of whether they are therapy or LUPA thresholds, provides the incentive for providers to

¹³ Medicare Payment Advisory Commission (MedPAC). “Home Health Care Services.” *Report to Congress: Medicare Payment Policy*. Washington, DC, March 2015. P. 223. Accessed on September 9, 2018 at <http://www.medpac.gov/docs/default-source/reports/chapter-9-home-health-care-services-march-2015-report-.pdf?sfvrsn=0>.

adopt business practices that encourage the provision of visits to meet and exceed these thresholds to receive higher payment.

Comment: A few commenters noted language in the FY 2019 Skilled Nursing Facility Prospective Payment System (SNF PPS) Final Rule (83FR 39162), which included a payment and case-mix redesign known as the Patient-Driven Payment Model (PDPM) and noted that CMS declined to make any behavioral adjustments in the PDPM. These commenters stated that because the PDPM did not implement behavioral adjustments then the PDGM also should not implement behavioral adjustments.

Response: We remind commenters that section 1895(b)(3)(A)(iv) of the Act requires CMS to make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of payment and changes to the case-mix adjustment methodology when calculating the 30-day budget-neutral payment amount for CY 2020. Furthermore, as previously described in detail, we believe we have ample experience and data regarding changes in provider behavior made in response to payment changes that support the proposed behavioral assumptions. Additionally, the law requires us to annually determine the impact of differences between assumed and actual behavior changes on estimated aggregate expenditures for CY 2020 through CY 2026 and adjust the payment amount upwards or downwards accordingly. We will analyze any actual, observed behavioral changes with respect to CYs 2020 through 2026 to make any payment adjustments beginning in CY 2022 at the earliest.

Comment: Some commenters indicated that the behavioral assumptions were too high and out of line with case-mix adjustments made in recent years. Commenters indicated that CMS should phase in reductions over multiple years if they exceeded a certain amount (for example, 2 percent). Commenters indicated that adjustments should be based on actual behavior change and not based on assumed behavioral change. Several commenters recommended delaying implementation of the behavioral assumptions until actual data on provider behavior is available.

Response: As detailed throughout this final rule with comment period, we believe there is sufficient evidence supporting the behavioral assumptions and payment impacts. Therefore, we disagree that the impacts of the assumptions are too high or not in alignment with previous analysis of nominal case-mix growth. Likewise,

MedPAC commented that they believe the 6.42 percent reduction to the payment amount from the behavioral assumptions was appropriate and does not expect that this percent reduction would create payment adequacy issues for most HHAs.

We acknowledge that there have been previous phase-ins of other payment adjustments to account for nominal case mix growth. We remind commenters that the statute requires that in calculating the 30-day budget-neutral payment amount, for home health units of service furnished that end during the 12-month period beginning January 1, 2020, the Secretary shall make assumptions about behavior changes that could occur as a result of the implementation of a 30-day unit of payment and the alternate case-mix adjustment methodology. Therefore, we do not have the discretion to implement a different policy. However, because the statute requires that we must analyze data for CYs 2020 through 2026 after implementation of the 30-day unit of payment and new case-mix adjustment methodology to annually determine the impact of differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures, and to make payment amount adjustments accordingly, we believe there is already a mechanism in place to assure HHAs that payment amount will be adjusted to accurately account for actual behavior.

We remind commenters that the 30-day unit of payment and the PDGM will not be implemented until CY 2020 and CMS will analyze claims data from CY 2018 to determine any changes to the payment amount for CY 2020 and will propose the amount in the CY 2020 HH PPS proposed rule. Finally, we are required to make the adjustments at a later date when we have actual data. Therefore, we can ensure that the 30-day payment amounts are set at the level they would have been had changes in case mix due to behavior adjustments been known. Therefore, we do not believe it is necessary to phase-in the impacts of the behavioral assumptions. By providing updated analysis and payment rates in the CY 2020 HH PPS proposed rule, this will allow stakeholders additional opportunity to comment on the behavioral assumption impacts. While many commenters wanted CMS to delay implementation of the behavioral assumption impacts until actual data are available, CMS is required under section 1895(b)(3)(A)(iv) of the Act to take into account behavior changes that could occur as a result of the implementation of a 30-day unit of payment and the case-mix adjustment

factors that are implemented in CY 2020 when calculating the 30-day budget neutral payment amount for CY 2020. Deferring until actual data are available would delay implementation of the behavioral assumption impacts until CY 2022, which would not meet the requirements of the statute. Data from CY 2020 to 2026 will be available to determine whether temporary or permanent adjustments to the payment amounts are needed.

Comment: Several commenters encouraged CMS to closely monitor utilization patterns, billing trends, and other associated behaviors following implementation of the PDGM, to ensure that beneficiary access is not negatively impacted as a result of the new case-mix system, particularly the switch from a 60-day episode to a 30-day unit of payment. There was also concern that agencies may inappropriately extend 30-day periods that previously would have ended within 30 days in order to receive additional payment. There were other commenters who indicated that 30-day periods would cause beneficiaries to be discharged from home health earlier than they otherwise would be. Some commenters were concerned that certain visits would be frontloaded under a 30-day system as opposed to being spread out over a longer period of time, whereas another commenter indicated that have a 30-day period would discourage frontloading.

Response: The goal of the PDGM is to more accurately align payment with the cost of providing care and is not meant to penalize or harm providers or beneficiaries. We recognize that changes in payment generally have an effect on the provision of services and we believe we have accounted for those assumed behavioral changes in calculating the 30-day budget-neutral payment amount. To address concerns regarding patient access and safety, we remind commenters that the home health CoPs are to help ensure the health and safety of Medicare beneficiaries. The home health CoPs have requirements as they relate to the content of the plan of care. Specifically, the CoPs at § 484.60 state that the individualized plan of care must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including identification of the responsible discipline(s), and the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. Services must be furnished in accordance with accepted standards of practice. Therefore, upon implementation of the PDGM, we expect that HHAs will

continue to provide the services in accordance with the existing requirements. As such, we would not expect HHAs to inappropriately discharge home health patients or extend unnecessary home health services.

CMS does not intend to prescribe how home health agencies provide care to their patients. As reiterated throughout this section, services provided, including the disciplines providing the care and the frequency of those services, are done so in accordance with an individualized plan of care, established and periodically reviewed by the certifying physician. We recognize that some beneficiaries may benefit from the frontloading of visits and there has been research to indicate that the frontloading of skilled visits is beneficial to some patients and may reduce hospitalization.¹⁴ However, there may be other beneficiaries that may benefit from visits that are provided over a longer period of time. In accordance with the plan of care requirements at § 484.60, we expect the provision of services to be made to best meet the patient's care needs. After implementation of the PDGM and a change to the 30-day unit of payment, CMS will closely monitor utilization patterns, beneficiary impact and provider behavior to see if any refinements to the PDGM are warranted, or if any concerns are identified that may signal the need for appropriate program integrity measures.

Comment: MedPAC recommended that CMS include an additional behavioral assumption to account for responses to the shorter unit of payment that would result in increased aggregate payments (that is, HHAs changing visit patterns such that instead of having a single 30-day period of care, they would provide just enough visits to get payment for a second 30-day period of care).

Response: Public comments received in response to both the CY 2018 and CY 2019 HH PPS proposed rules presented conflicting predictions regarding anticipated provider behavior in response to the timing element of the PDGM with regards to 30-day periods of care. Several commenters stated that they expected providers to discharge patients after the first 30-days of care given that the case-mix weights are, on average, higher for the first 30-days of care. Other commenters expressed

concern that providers may attempt to keep home health beneficiaries on service for as long as possible. We do not believe it is necessary to add any additional behavioral assumptions at this time and we note that CMS is required to make future payment amount adjustments based on the difference between assumed and actual behavioral changes.

Comment: A couple of commenters raised the question of whether CMS removed LUPA payments from the numerator when calculating the budget-neutral 30-day payment amount with and without behavioral assumptions.

Response: CMS did not remove the LUPA payments from the numerator when calculating the budget-neutral 30-day payment amounts. Including LUPA payments provides a broader picture when looking at impacts. In order to calculate the 30-day budget-neutral payment amount, both with and without the behavioral assumptions, we first calculated the total, aggregate amount of expenditures that would occur under the current case-mix adjustment methodology. Because estimated aggregate expenditures under the 30-day unit of payment must be budget neutral to estimated aggregate expenditures made if the 30-day unit of payment was not implemented, we must look at the aggregate payments made under the current HH PPS. This means we must look at all payments made, including LUPA payments.

Comment: Another commenter indicated that according to CMS' 2017 Fee-for-Service Supplemental Improper Payment Data report, the projected amount of improper payments made to HHAs for incorrect coding was \$0 and that this zero dollar figure stands in stark contrast to CMS' assumption that all HHAs will use improper codes to bill Medicare for higher payments under PDGM. Conversely, other commenters indicated that the behavioral assumptions will cause a perverse incentive to "upcode" when previously agencies wouldn't have engaged in this practice.

Response: CMS uses the Comprehensive Error Rate Testing (CERT) Program to estimate the Medicare Fee-For-Service (FFS) improper payment rate. The purpose of the CERT Program is to identify payments that should not have been made or payments made in an incorrect amount. Specifically, "improper payments" include: Both overpayments and underpayments; payments to an ineligible recipient; payments for an ineligible service duplicate payments; payments for services not received; or, payments for an incorrect amount.

Conversely, as we have noted throughout this section, the purpose of the behavioral assumptions is to take into account assumed behavioral changes resulting from a change in the unit of payment from 60 to 30 days and the change to the case-mix adjustment methodology in order to calculate a 30-day budget neutral prospective payment amount, and not to determine whether improper payments were or will be made. We have also stated that the purpose of the behavioral assumptions is not to be punitive or to indicate that HHAs are engaging in unethical or inappropriate behavior, but to anticipate those behavioral changes when calculating a prospective payment. We expect coding changes to occur given the expansion of the ICD-10 code set and the PDGM using the diagnoses reported on the claim as opposed to the OASIS. This provides HHAs with an opportunity to report conditions supported in the medical documentation for which home health services are being provided. We remind commenters that "upcoding" is a fraudulent billing practice where a healthcare provider assigns an inaccurate billing code to a medical procedure or treatment to increase payment and where the actual service(s) provided are not supported by the codes reported. We do not view reporting diagnoses that are supported in the medical documentation and which reflect the home health care and services provided to be "upcoding". We do expect, however, that HHAs will establish the individualized plan of care in accordance with the needs identified in the initial and comprehensive assessments to address all pertinent and supported diagnoses.

Final Decision: We are finalizing the three behavioral assumptions as previously described in calculating a 30-day budget-neutral payment amount. We will update the CY 2020 30-day budget-neutral payment amount in the CY 2020 proposed rule using the most recent data available.

c. Split Percentage Payment Approach for a 30-Day Unit of Payment

In the current HH PPS, there is a split percentage payment approach to the 60-day episode. The first bill, a Request for Anticipated Payment (RAP), is submitted at the beginning of the initial episode for 60 percent of the anticipated final claim payment amount. The second, final bill is submitted at the end of the 60-day episode for the remaining 40 percent. For all subsequent episodes for beneficiaries who receive continuous home health care, the episodes are paid at a 50/50 percentage payment split.

¹⁴ O'Connor M, Bowles KH, Feldman PH, St Pierre M, Jarrin O, Shah S, Murtaugh CM. Frontloading and intensity of skilled home health visits: A state of the science. Home Health Care Services Quarterly. 2014; 33(3):159-75. doi: 10.1080/01621424.2014.931768.

The BBA of 2018 requires a change to the unit of payment from a 60-day episode to a 30-day period of care, effective January 1, 2020. As described in the CY 2018 HH PPS proposed rule (82 FR 35270) and in the CY 2019 HH PPS proposed rule (83 FR 32391), we believe that as a result of the reduced timeframe for the unit of payment, that a split percentage approach to payment may not be needed for HHAs to maintain adequate cash flow. Currently, about 5 percent of requests for anticipated payment are not submitted until the end of a 60-day episode of care and the median length of days for RAP submission is 12 days from the start of the 60-day episode. As such, we are reevaluating the necessity of RAPs for existing and newly-certified HHAs versus the risks they pose to the Medicare program.

In the CY 2019 HH PPS proposed rule, we described in detail, potential program integrity vulnerabilities as they relate to RAP payments (83 FR 32391). We stated that given the program integrity concerns and the reduced timeframe for the unit of payment (30 days rather than 60 days), we proposed not to allow newly-enrolled HHAs, that is HHAs certified for participation in Medicare effective on or after January 1, 2019, to receive RAP payments beginning in CY 2020. We proposed that HHAs, that are certified for participation in Medicare effective on or after January 1, 2019, would still be required to submit a “no pay” RAP at the beginning of care in order to establish the home health period of care, as well as every 30-days thereafter.

We proposed that existing HHAs, that is HHAs certified for participation in Medicare with effective dates prior to January 1, 2019, would continue to receive RAP payments upon implementation of the 30-day unit of payment and the proposed PDGM case-mix adjustment methodology in CY 2020.

We solicited comments as to whether the split payment approach would still be needed for HHAs to maintain adequate cash flow if the unit of payment changes from 60-day episodes to 30-day periods of care under our proposal. In addition, we solicited comments on ways to phase-out the split percentage payment approach in the future. Specifically, we solicited comments on reducing the percentage of the upfront payment over a period of time. We also solicited comments on requiring for HHAs to submit a notice of admission within 5 days of the start of care to alert the claims processing system that a beneficiary is under a home health period of care, if in the

future the split percentage approach was eliminated, to assure being established as the primary HHA for the beneficiary and so that the claims processing system is alerted that a beneficiary is under a HH period of care to enforce the consolidating billing edits required by law.

The following is a summary of the public comments received on the “Split Percentage Payment Approach for a 30-day Unit of Payment” proposal and our responses:

Comment: Many commenters supported all or parts of CMS’s changes to the RAP policy. Some commenters indicated that the elimination of the split percentage would align better with a 30-day payment and would simplify claims submission. Other commenters stated they do not want any type of phase-out of RAPs and remarked that RAPs should continue under the PDGM to ensure no disruption in cash flow. There was some commenter support to phase out the split percentage payment over a multi-year period starting at least one year after the implementation of the PDGM in order to allow agencies to adapt to PDGM. Some commenters indicated that RAPs for late periods could be phased out, but that RAPs for early periods should remain in place to ensure an upfront payment for newly admitted home health patients. Some commenters supported the reduction in the split percentage payment but wanted to allow RAPs for newly enrolled HHAs.

Response: We thank commenters for their careful review and suggestions regarding the proposals regarding a potential phase-out of RAPs. We continue to believe that as a result of a reduced timeframe for the unit of payment from a 60-day episode to a 30-day period, that a split percentage approach to payment may not be needed for HHAs to maintain an adequate cash flow. We also believe that by eventually phasing-out the submission of RAPs with each 30-day period, that this will significantly streamline claims processing for HHAs. Likewise, by eliminating RAP payments for newly-enrolled HHAs, we believe this would allow these HHAs to structure their operations without becoming dependent on a partial advanced payment and take advantage of receiving full payments every 30 days. We will continue to monitor the need for RAPs after the implementation of the PDGM. We understand that HHAs may need time to adapt to the PDGM so any phase-out of RAP payments for existing HHAs would be addressed in future rulemaking.

Comment: Many commenters had concerns that CMS was modifying its

RAP policy due to abuse by certain agencies. Commenters suggested that CMS should utilize their ability to restrict RAPs for agencies that abuse it instead of modifying the current RAP policy. Some commenters indicated that not all cases where a final claim isn’t submitted after a RAP are abusive. Commenters encouraged CMS to identify the agencies that are abusing the system and to impose more oversight through accrediting organizations and the MACs.

Response: While one of the reasons for the elimination of the RAP is to potentially stem program integrity vulnerabilities, it is not the sole reason. We remind commenters that the current median length of days for RAP submission is 12 days from the start of the 60-day episode. With a change to a 30-day unit of payment, if this median length of days for RAP submissions remains constant, there is the possibility that HHAs could be simultaneously submitting a RAP and a final claim for each 30-day period of care. We believe that this defeats the purpose of the RAP to maintain adequate cash flow and only increases complexity for HHAs in their claims processing. With monthly billing, HHAs have the ability to receive an ongoing cash flow which we believe would mitigate concerns over having adequate funds for the provision of care.

We acknowledge and appreciate the concerns commenters have with regards to abuse of the RAP policy by certain HHAs. We plan to continue to closely monitor RAP submissions, service utilization, payment, and quality trends which may change as a result of implementing of the PDGM and a 30-day unit of payment. If changes in practice and/or coding patterns or RAPs submissions arise, we may take further action, which may include administrative action against providers as appropriate and/or proposing changes in policy. We will also continue to work with the HHS Office of Inspector General in case any cases of provider abuse are identified.

We would like to reiterate that in the CY 2019 HH PPS proposed rule, we proposed existing HHAs, that is HHAs that are certified for participation in Medicare with effective dates prior to January 1, 2019, would continue to receive RAP payments upon implementation of the PDGM in CY 2020. Only newly-enrolled HHAs, that is HHAs certified for participation in Medicare effective on or after January 1, 2019, would not receive RAP payments beginning in CY 2020.

Comment: Several commenters believe that newly enrolled HHAs have the same or more cash flow concerns as

existing HHAs and that split-percentage payments should also be made to newly enrolled HHAs. Some commenters expressed concern about HHAs acquired or opened on or after January 1, 2019 under a HHA chain organization and whether these newly enrolled HHAs that are part of a chain would be “grandfathered” in and would be allowed to receive RAP payments beginning in CY 2020. These commenters remarked that not allowing these HHAs to be grandfathered in would disrupt operations.

Response: While we appreciate commenter concerns, in the CY 2019 HH PPS proposed rule, when referring to not allowing newly-enrolled HHAs (that is, those certified for Medicare participation effective on or after January 1, 2019) to receive RAP payments beginning in CY 2020, we did not distinguish between solely-owned HHAs and HHAs that are owned by a parent or chain company. For payment purposes, a CMS Certification Number (CCN) is required to be included on the Medicare claim and the RAP. Upon Medicare enrollment, a CCN is issued. This policy is applicable to newly enrolled HHAs and thus this policy would apply to those HHAs with a CCN that is effective on and after January 1, 2019, regardless of whether they are solely-owned or owned by a parent or chain company. We believe that having the opportunity to receive full payment every 30 days may mitigate cash flow concerns for newly enrolled HHAs.

Comment: Some commenters expressed support for the Notice of Admission (NOA) and recognized that the NOA would be necessary to alert the claims processing system of a home health period of care because of the consolidated billing requirements. Other commenters opposed the use of a NOA and the requirement to submit a NOA within 5 days of the home health start of care. These commenters referenced some of the operational and processing issues with the hospice Notice of Election and expressed concern that there could be delay in needed care. Other questioned the burden associated with a NOA process.

Response: We remind commenters that existing HHAs, meaning those certified for participation in Medicare with effective dates prior to January 1, 2019, would continue with the same RAP submission process as they currently follow under the current HH PPS except that a RAP would have to be submitted at the beginning of each 30-day period of care. Likewise, we proposed that newly-enrolled HHAs (that is, those certified for participation in Medicare effective on and after

January 1, 2019) would have to submit a “no-pay” RAP at the beginning of care in order to establish the home health period of care, as well as every 30-days thereafter. RAP submissions are significant as the RAP establishes the HHA as the primary HHA for the beneficiary during the timeframe and alerts the claims processing system that the beneficiary is under the care of the HHA. A Notice of Admission (NOA) would only be required if the split-percentage payment approach is eliminated in the future. However, we did not propose to eliminate RAP payments for existing providers and newly-enrolled providers would only have to submit a “no-pay” RAP in order to establish a home health period of care within the claims processing system. If we do propose elimination of the split-percentage approach, we would do so in future rulemaking and would solicit comments at that time about the process that would be established in regards to the submission of a Notice of Admission.

Final Decision: We are finalizing the split-percentage proposal as proposed with an effective date of January 1, 2020. This means that newly-enrolled HHAs, that is HHAs certified for participation in Medicare effective on or after January 1, 2019, would not receive RAP payments beginning in CY 2020. HHAs that are certified for participation in Medicare effective on or after January 1, 2019, would still be required to submit a “no pay” RAP at the beginning of care in order to establish the home health period of care, as well as every 30-days thereafter. Existing HHAs, meaning those HHAs that are certified for participation in Medicare effective prior to January 1, 2019, will continue to receive RAP payments upon implementation of the PDGM in CY 2020. For split-percentage payments to be made, existing HHAs would have to submit a RAP at the beginning of each 30-day period of care and a final claim would be submitted at the end of each 30-day period of care. For the first 30-day period of care, the split percentage payment would be 60/40 and all subsequent 30-day periods of care would be a split percentage payment of 50/50. We are also finalizing the corresponding regulations text changes as described in section III.F.13 of this final rule with comment period related to the split percentage payment approach.

4. Timing Categories

In the CY 2019 HH PPS proposed rule, we described analysis showing the impact of timing on home health resource use and proposed to classify

the 30-day periods under the proposed PDGM as “early” or “late” depending on when they occur within a sequence of 30-day periods. For the purposes of defining “early” and “late” periods for the PDGM, we proposed that only the first 30-day period in a sequence of periods be defined as “early” and all other subsequent 30-day periods would be considered “late”. Additionally, we proposed that the definition of a “home health sequence” (as currently described in § 484.230) would remain unchanged relative to the current system; that is, 30-day periods are considered to be in the same sequence as long as no more than 60 days pass between the end of one period and the start of the next, which is consistent with the definition of a “home health spell of illness” described at section 1861(tt)(2) of the Act. We further noted that because section 1861(tt)(2) of the Act is a definition related to eligibility for home health services as described at section 1812(a)(3) of the Act, it does not affect or restrict our ability to implement a 30-day unit of payment.

We solicited public comments on the timing categories under the proposed PDGM and the associated regulations text changes discussed in section III.F.13 of the proposed rule. The following is a summary of the public comments received and our responses:

Comment: Several commenters supported the inclusion of the timing category in the PDGM, stating that this differentiation reflects that HHA costs are typically highest during the first 30 days of care and supports HHA efforts to follow clinical evidence on the importance of “frontloading” resources in the home care setting in order to facilitate improved patient outcomes.

Response: We appreciate the commenters’ support regarding the inclusion of the timing element within the PDGM framework, as we believe that the early and late designations will serve to better align payments with the existing resource use pattern observed in home health data. The utilization of increased resources in early periods is demonstrated in the data analyzed during the development of the PDGM, as described in the CY 2019 HH PPS proposed rule (83 FR 32340). We believe that ultimately this component of the PDGM will help to account for the increase in intensity of resources often required at the start of home health care.

Comment: Several commenters expressed concern regarding the change in the definition of “early” and “late” 30-day periods from the current payment model, stating that many patients need more than 30 days of intense care due to their medically

complex, chronic conditions and their multiple, serious diagnoses requiring skilled assessment and interventions. The commenters asserted that HHAs may ration care to those beneficiaries in “late” 30-day periods and that the new timing category would serve to penalize those HHAs that do enroll clinically-complex beneficiaries with ongoing care needs. Several commenters stated that categorizing 30-day home health periods into “early” and “late” would serve to “devalue” later care during a home health period of care. A commenter also stated that categorizing only the first 30 days as “early” would potentially put beneficiaries at risk because they state that more costly therapy services become most appropriate as a beneficiary begins to stabilize, which the commenter stated typically occurs around week three of a home health care. Another commenter also stated that caregiver availability also varies in the weeks following an acute event, with support diminishing in the weeks following admission to home health, leading to an increased need for additional support during those 30-day periods that would now be categorized as “late.” Several commenters expressed concern that the definition of the “late” category would not account for any additional costs that would be associated with a new set of resource-intensive health needs for a patient that may occur after the “early” 30-day period.

Response: As described in detail in the CY 2019 HH PPS proposed rule, our proposal regarding the timing element of the PDGM was intended to refine and to better fit costs incurred by agencies for patients with differing characteristics and needs under the HH PPS (83 FR 32340). The resource cost estimates are derived from a very large, representative dataset. Therefore, we expect that the proposal reflects agencies’ average costs for all home health beneficiaries, including medically-complex patients with ongoing needs. We have constructed the revised payment model based upon the actual resources expended by home health agencies for Medicare beneficiaries, which show that typically HHAs provide more visits during the first 30 days of care and utilize less resources thereafter. We reiterate that the timing categories are reflective of the utilization patterns observed in the data analyzed for the purposes of constructing the PDGM, and we have not manipulated the resource utilization or weighting to encourage certain patterns of care for the first 30-day period within the PDGM. The weights of

the two timing categories are driven by the mix of services provided, the costs of services provided as determined by cost report data, the length of the visits, and the number of visits provided. The categorization of 30-day periods as “early” and “late” serves to better align payments with already existing resource use patterns. This alignment of payment with resource use is not to be interpreted as placing a value judgment on particular care patterns or patient populations.

Additionally, in our CY 2008 HH PPS final rule, we implemented an “early” and “late” distinction in the HH PPS in which the late episode groupings were weighted more heavily than those episodes designated as early due to heavier resource use during later episodes (72 FR 49770). At that time, commenters expressed concerns that this heavier weighting for later episodes could lead to gaming by providers, with patients on service longer than would be appropriate, and that providers may not discharge patients when merited. During our analysis in support of subsequent refinements to the HH PPS in 2015, as described in the CY 2015 HH PPS proposed rule (79 FR 38366), we analyzed the utilization patterns observed in the CY 2013 claims data and observed that the resource use for later episodes had indeed shifted such that later episodes had less resource use than earlier periods, which was the opposite of the pattern observed prior to CY 2008. Furthermore, in its 2016 Report to Congress, MedPAC noted that, between 2002 and 2014, a pattern in home health emerged where the number of episodes of care provided to home health beneficiaries trended upwards, with the average number of episodes per user increasing by 18 percent, rising from 1.6 to 1.9 episodes per user.¹⁵ MedPAC noted that this upward trajectory coincided with, among other changes, higher payments for the third and later episodes in a consecutive spell of home health episodes. Given the longitudinal variation in terms of resource use during home health episodes, we believe that restricting the “early” definition to the first 30-day is most appropriate for this facet of the PDGM. Our analysis of home health resource use, our review of the literature on “frontloading,” as well as comments from the public that confirm that more resources are used in the first 30 days, provide compelling evidence to limit the definition of early to the first 30-day period. As we receive and evaluate new

data related to utilization patterns in Medicare home health care, specifically under the PDGM, we will reassess the appropriateness of the payment levels for “early” and “late” periods in a sequence of periods, and we will evaluate whether changes are needed once the model has been implemented.

Comment: Several commenters described concerns regarding the potential for problematic provider behavior due to financial incentives. Several commenters stated that the timing element of the PDGM has the potential to create an incentive to increase overall patient volume, to discourage providers from accepting community referrals, to extend home health lengths of stay so as to include at least two 30-day periods, and to promote lower quality home health care in order to maximize reimbursements. Several commenters stated that the timing variable in the PDGM payment model would increase the incentive to prematurely discharge patients while other commenters stated that the timing variable may incentivize HHAs to avoid patients who require care over the span of multiple periods of care.

Response: We fully intend to monitor provider behavior in response to the new PDGM. As we receive and evaluate new data related to the provision of Medicare home health care under the PDGM, we will reassess the appropriateness of the payment levels for “early” and “late” periods in a sequence of periods. Additionally, we will share any concerning behavior or patterns with the MACs and/or other program integrity contractors. We plan to monitor for and identify any variations in the patterns of care provided to home health patients, including both increased and decreased provision of care to Medicare beneficiaries. We note that an increase in the volume of Medicare beneficiaries receiving home health care may, in fact, represent a positive outcome of the PDGM, signaling increased access to care for the Medicare population, so long as said increase in volume of beneficiaries is in keeping with eligibility guidelines for the Medicare home health benefit.

Moreover, the public comments we received in response to both the CY 2018 and CY 2019 HH PPS proposed rules presented conflicting predictions regarding anticipated provider behavior in response to the implementation of the PDGM. Several commenters stated that they expected providers to discharge patients after the first 30-days of care given that the case-mix weights are, on average, higher for the first 30-days of care. Other commenters expressed

¹⁵ <http://www.medpac.gov/docs/default-source/reports/chapter-8-home-health-care-services-march-2016-report.pdf>.

concern that providers may attempt to keep home health beneficiaries on service for as long as possible. We note the PDGM case-mix weights reflect existing patterns of resource use observed in our analyses of home health claims data. Since we proposed to recalibrate the PDGM case-mix weights on an annual basis to ensure that the case-mix weights reflect the most recent utilization data available at the time of rulemaking, future recalibrations of the PDGM case-mix weights may result in changes to the case-mix weights for early versus late 30-day periods of care as a result of changes in utilization patterns. Finally, we expect that HHAs will furnish care in accordance with each beneficiary's HH plan of care as required by the HH CoPs at § 484.60.

Comment: Several commenters requested that we modify the definition of an "early" 30-day period to either the first two 30-day periods or the first four 30-days of care, stating that those definitions would more closely mirror the current payment system's definition of "early" and that HHAs would otherwise experience a payment decrease when compared to the current 60-day episode payment amount because of the differentiated payment amounts for "early" and "late" 30-day periods. The commenters also stated that there is concern that the PDGM definitions of "early" and "late" may hurt agencies due to the decrease in overall payment because of the lower reimbursement for periods categorized as "late." Another commenter stated that the PDGM inaccurately ties payment to time in home health care, with very little regard to actual care needs.

Response: With regard to a potential reduction in overall payment due to the revised designations of "early" and "late" periods under the PDGM, as we described in the CY 2019 HH PPS proposed rule, our analysis of the related data indicates that there is significant difference in the resource utilization between early and late 30-day periods as demonstrated in Table 34 of the proposed rule (83 FR 32392). One of the driving goals in the development of the PDGM was to better align payments with costs incurred by agencies for patients with differing characteristics and needs under the HH PPS. We continue to believe that a PDGM that accounts for the actual, demonstrated increase in resource utilization in the first 30-day period better captures the variations in resource utilization. We believe that the PDGM further promotes the goal of payment accuracy within the HH PPS and Medicare overall. However, we note

that we will continue to monitor for any changes in trends as evidenced by home health data reflecting the change to the HH PPS and make modifications to the PDGM as necessary.

Comment: Several commenters suggested that we revise the payment model such that a readmission to home health within the 60-day gap period results in an "early" instead of a "late" 30-day period. They suggested that we should consider altering the definition of sequences of 30-day periods to include home health re-admissions following acute institutionalization as a condition of determining a new sequence of home health periods of care, in addition to the 60-day gap in home health services, stating that this would be akin to the proposal defining admission source for the purposes of determining institutional payment status.

Response: We appreciate the commenter's suggestion regarding the consideration of a readmission to home health within the 60-day gap be treated as an "early" stay. However, we note that the PDGM also includes a category for source of admission, which would account for a readmission to home health within 14 days of an acute care hospital stay. The admission source category is discussed in detail in Section III.E.5 of this final rule with comment period. Under the PDGM we already account for the differentiating features of institutional stays, including inpatient stays that occur within 14 days of the commencement of a home health period. Our proposal was intended to refine and to better fit costs incurred by agencies for patients with differing characteristics and needs under the prospective payment system. Therefore, we expect that the addition of both the source of admission as well as the timing categories would reflect agencies' average costs for home health patients. We believe that crafting a multi-pronged model, which includes adjustments based both on timing within a home health sequence as well as the source of the beneficiary's admission, will serve to more accurately account for resources required for Medicare beneficiaries and similarly provide a differentiated payment amount for care.

Comment: A commenter stated that the timing categories create disincentives for home health care providers to prevent hospital readmissions because a resumption of care would then generate higher revenues. Another commenter stated that HHAs often front load visits post hospitalization or admission to a SNF, including the "resumption of care

period." The commenter expressed concern that the proposed timing categories for the PDGM do not capture the resources required for a resumption of care and asks that we expand the definition of sequencing of "early" periods to include home health readmissions following acute hospital or SNF stays.

Response: For the purposes of the timing category of the PDGM, an intervening hospital stay would not trigger re-categorization to an "early" 30-day period of care unless there was more than a 60-day gap in home health care. Therefore, we do not believe that the timing element of the PDGM would create a financial incentive to inappropriately encourage the admission of home health patients to an acute care setting in order to receive a subsequent home health referral in the higher-paid "early" category. Additionally, we note that the admission source category within the PDGM serves to capture the increased resource needs in the home health population referred from an inpatient hospital stay, occurring within 14 days of home health admission, creating differentiated case-mix weights that align payment with the resource use for that subpopulation of home health beneficiaries.

Comment: Several commenters expressed concern regarding the operational aspects of the timing element of the PDGM. Another commenter asked how patient transfers would be addressed, asserting that the second agency should not receive lower payment if they were unaware that the patient was being served by another home health agency. A commenter expressed concern regarding the identification of the timing of the 30-day period, stating that the OASIS in particular does not provide enough information to determine timing for a 30-day period.

Response: As we described in the CY 2019 HH PPS proposed rule, we will use Medicare claims data and not the OASIS assessment in order to determine if a 30-day period is considered "early" or "late" (83 FR 32393). Regarding transfers, we note that 30-day periods are considered to be adjacent if they are contiguous, meaning they are separated by no more than a 60-day period between 30-day periods of care. This would mean that if a patient transfers from one HHA to another HHA after the first 30-day period of care, all adjacent 30-day periods of care would be considered "late". In order for any 30-day period of care to be considered "early", there would have to be a gap in home health services of more than 60

days. We have developed claims processing procedures to reduce the amount of administrative burden associated with the implementation of the PDGM. Providers will not have to determine whether a 30-day period is early (the first 30-day period) or later (all adjacent 30-day periods beyond the first 30-day period) if they choose not to. Information from Medicare systems will be used during claims processing to automatically assign the appropriate timing category. Details regarding these processes are outlined in the CY 2019 HH PPS proposed rule (83 FR 32394). We reiterate that we plan to develop materials regarding the timing categories, including such topics as claims adjustments and resolution of claims processing issues. We will also update guidance in the Medicare Claims Processing Manual as well as the Medicare Benefit Manual as appropriate with detailed procedures. We will also work with the MACs to address any concerns regarding the processing of home health claims as well as develop training materials to facilitate all aspects of the transition from the current payment system to the PDGM, including the unique aspects of the timing categories.

Final Decision: We are finalizing our proposal to classify 30-day periods of care under the PDGM as “early” or “late” depending on when they occur within a sequence of 30-day periods. The first 30-day period would be classified as early and all subsequent 30-day periods in the sequence (second or later) would be classified as late and 30-day periods of care cannot be considered early unless there is a gap of more than 60 days between the end of one period and the start of another.

5. Admission Source Categories

In the CY 2019 HH PPS proposed rule, we described analysis showing the impact of the source of admission on home health resource use and proposed to establish two admission source categories for grouping 30-day periods of care under the PDGM—institutional and community—as determined by the healthcare setting utilized in the 14 days prior to home health admission (83 FR 32340). We proposed that 30-day periods for beneficiaries with any inpatient acute care hospitalizations, skilled nursing facility (SNF) stays, inpatient rehabilitation facility (IRF) stays, or long term care hospital (LTCH) stays within the 14 days prior to a home health admission would be designated as institutional admissions. We also proposed that the institutional admission source category would also include patients that had an acute care

hospital stay during a previous 30-day period of care and within 14 days prior to the subsequent, contiguous 30-day period of care and for which the patient was not discharged from home health and readmitted (that is, the admission date and from date for the subsequent 30-day period of care do not match) as we acknowledge that HHAs have discretion as to whether they discharge the patient due to a hospitalization and then readmit the patient after hospital discharge. However, we also proposed that we would not categorize PAC stays (SNF, IRF, LTCH stays) that occur during a previous 30-day period and within 14 days of a subsequent, contiguous 30-day period of care (that is, the admission date and from date for the subsequent 30-day period of care do not match) as institutional, as we would expect the HHA to discharge the patient if the patient required PAC in a different setting and then readmitted the patient, if necessary, after discharge from such setting. If the patient was discharged and then readmitted to home health, the admission date and “from” date on the 30-day claim would match and the claims processing system will look for an acute or a PAC stay within 14 days of the home health admission date. We proposed that this admission source designation process would be applicable to institutional stays both paid by Medicare or another payer. All other 30-day periods would be designated as community admissions. For the purposes of a RAP, we proposed that we would only adjust the final home health claim submitted for source of admission. Additionally, we also proposed that HHAs would only indicate the proposed admission source occurrence codes on the final claim and not on any RAPs submitted. The proposed admission source category was discussed in detail in the proposed rule.

We solicited public comments on the admission source component of the proposed PDGM. The following is a summary of the public comments and our responses:

Comment: Several commenters expressed their support for the admission categories within the framework of the PDGM, as they believe patient needs significantly differ between these groups and payment differences are warranted in order to better reflect the cost of Medicare home health care, thus improving the accuracy of payments in the revised system.

Response: We appreciate the commenters’ support with regard to the admission source element of the PDGM. The intention of the PDGM proposal,

including the admission source component, is to refine and to better fit costs incurred by agencies for patients with differing characteristics and needs under the prospective payment system, and we believe that the differing weights for source of admission will facilitate more appropriate alignment within the HH PPS.

Comment: Several commenters stated that the source of a home health admission may not always correspond with home health beneficiary needs and corresponding provider costs, as some community entrants sometimes require more intensive resources than their institutional counterparts, presenting with complex conditions such as psychiatric and neurological conditions, pressure and stasis ulcers, and a history of falls. Several commenters also stated that we are “devaluing” community entrants by providing lower reimbursement for those beneficiaries when compared with institutional entrants.

Response: As described in detail in the CY 2019 HH PPS proposed rule, our analytic findings demonstrate that institutional admissions have higher average resource use when compared with community admissions, which ultimately led to the inclusion of the admission source category within the framework of the PDGM (83 FR 32340). We do not seek to “devalue” or show preference to any particular patient profile, but rather aim to better align home health payment with the costs observed in providing care. Additionally, as discussed in our CY 2019 HH PPS proposed rule, current research around those patients who are discharged from acute and PAC settings shows that these beneficiaries tend to be sicker upon admission, are being discharged rapidly back to the community, and are more likely to be re-hospitalized after discharge due to the acute nature of their illness (83 FR 32396). As further described in the CY 2019 HH PPS proposed rule, research studies indicate that patients admitted to home health from institutional settings are vulnerable to adverse effects and injury because of the functional decline that occurs due to their institutional stay, indicating that the patient population referred from an institutional setting requires more concentrated resources and supports to account for and mitigate this functional decline (83 FR 32397). We continue to believe that accounting for the material differences in the care needs of the home health beneficiary population admitted from institutional settings and their resulting, differentiated resource use, will serve to better align payments

with actual costs incurred by HHAs when providing care. We will carefully monitor the outcomes of this change, including any impacts to community entrants, and make further refinements as necessary. We also note that a component of the PDGM is the classification of periods of care into clinical groups according to the principal diagnosis reported. This component of the PDGM serves to capture the different resource needs of different conditions in the home health population, including complex conditions such as neurological conditions.

Comment: Several commenters noted that the admission source component of the PDGM has strong explanatory power in the model, outweighing clinical and functional factors. Several commenters believe the inclusion of admission source in the PDGM is akin to the use of therapy thresholds in HHRGs, as the commenters assert that it has the potential to create inappropriate incentives. Some commenters suggested that admission source not be utilized used in the model; instead, only patient clinical and functional status should be considered. Other commenters believe that the payment differences by admission source is too great. A commenter recommended that additional analysis be conducted regarding the payment adjustment for admission source and that we determine if other elements of the case-mix system would more adequately account for differences in payments when compared to the admission source variable. Another commenter stated that the admission source component of the PDGM is inaccurate and will likely push patients into the institutional setting and suggested that we instead utilize a “risk of readmission” measure, which could serve to gauge patient severity and promote value-based care.

Response: We appreciate the commenters’ feedback regarding the admission source component of the PDGM. However, we reiterate that the analytic findings presented in the CY 2019 HH PPS proposed rule point to clear differences in resources utilized by beneficiaries with differing sources of admission. In developing the various elements of the PDGM, we sought to focus on variables that predicted care needed by the patient (83 FR 32340). We disagree that using an admission source variable is equivalent to therapy thresholds. The data supports that resource utilization is higher among those with beneficiaries who have had a previous institutional stay prior to admission to home health, which accounts for the explanatory power of

this particular variable. Conversely, increased payment associated with the therapy thresholds is directly correlated with the number of therapy visits provided. Regarding the suggestion that we instead utilize a “risk of readmission” measure, we remind commenters that the PDGM does include an OASIS item for “Risk for Hospitalization” in its construction at the functional level to further account for patient characteristics that could translate into resource use. We note that we will continue to analyze the inclusion of other variables in the PDGM case-mix adjustment and will consider such additional components for future refinement.

Comment: Commenters stated that inpatient settings would become the primary patient referral target for HHAs and that community referral beneficiaries may find HHAs less willing to admit them to home health care if CMS were to finalize the admission source categories in the PDGM as proposed.

Response: We appreciate the commenters’ concern regarding possible behavioral changes by providers given the perceived incentives created by the admission source categories within the PDGM. We continue to expect that HHAs will provide the appropriate care needed by all beneficiaries who are eligible for the home health benefit, including those beneficiaries with medically-complex conditions who are admitted from the community. We recognize that providers may shift practices based upon strategies meant to maximize payment; therefore, we plan to closely monitor for any concerning trends in provider behavior, including such metrics as proportion of cases in a provider’s caseload referred from both the community and institutional settings. We also note that in previous analysis related to the solicitation of home health referrals, research has shown that many agencies seek referrals from any setting, institutional or otherwise. In the FY 2001 HH PPS proposed rule, evaluators assessing the HH PPS demonstration came to the conclusion that agencies did not alter their behavior in response to payment changes in the home health demonstration in such a way that impacted beneficiary access or quality of care, nor did they employ practices in order to avoid costly patients or recruit lower-care cases (64 FR 58140). Many agencies wanted to maintain a steady stream of referrals and were therefore not in a position to avoid a specific referral source, and, as a result, did not do so. We expect that HH providers will continue to seek referrals

from all sources under the PDGM system, resulting in continued access to home health care for Medicare beneficiaries.

Comment: Several commenters suggested the inclusion of inpatient psychiatric facility (IPF) stays in the institutional category for the purposes of the PDGM.

Response: We appreciate the commenters’ feedback and agree that inpatient psychiatric facility (IPF) stays should be included in the institutional category for the payment system under the PDGM. We agree that admission to an inpatient psychiatric facility would merit inclusion as an institutional source under the PDGM and therefore, we will include this site of service as part of the institutional category case-mix variable.

Comment: Several commenters recommended that CMS consider incorporating other clinical settings into the definition of the institutional category, including hospices and outpatient facilities, including emergency rooms. The commenters asserted that the criteria for inpatient hospital admission versus outpatient and other non-acute/PAC services are not always clear and that the differences between patients admitted as inpatient versus as outpatient are minimal. The commenters also stated that observation stays, which are not considered institutional stays by CMS, should be considered as such for the purposes of the PDGM, in part because beneficiaries and their families will have the “perception” of an inpatient stay and inform the HHA of what they perceive to have been an institutional stay. Another commenter stated that patients who utilize emergency room services either need a higher level of home health services once they transition to home health care or they require a lot of education to encourage them to utilize options other than the ER when issues arise. The commenter moreover asserted that hospitals have become adept at using observation stays for purposes of avoiding re-hospitalization penalties but maintains that these patients have just as high acuity as those referred to home health from a typical inpatient hospital stay. A commenter stated that joint replacement surgery continues to evolve, and patients are having surgery and are being treated as an “observation stay” rather than a hospital admission despite requiring a high level of service once they return home. A commenter noted concern that categorization could limit access to home care for joint replacements that may occur in ambulatory surgery centers and other outpatient facilities,

settings not currently considered institutional for the purposes of the PDGM. Another commenter stated that the exclusion of observation stays and ED visits from the institutional category would create an incentive for HHAs to potentially encourage hospitalizations for potentially higher reimbursement.

Response: We appreciate the commenters' concerns regarding potential impacts to those patients who may have experienced an event in a setting that is not defined as acute or post-acute, including visits to emergency departments. However, for the purposes of the PDGM, we will only include those stays in the institutional category that are considered institutional stays in other Medicare settings. As described in detail in the CY 2019 HH PPS proposed rule, we analyzed the resource use of admission source categories, including ED visits and observational stays, as well as corresponding payment weights based upon the resource use demonstrated in existing home health data (83 FR 32340). Our findings indicate that the volume of patients utilizing such settings prior to a home health episode is very low. Given that the proportion of home health periods with admissions from ED visits and observational stays is low relative to community and institutional counterparts, we believe that creating a third community admission source category for observational stays and ED visits could potentially introduce added complexity into the payment system in order to address a small portion of home health stays, which could in turn lead to the creation of payment groups that contain very few stays with very little difference in case-mix weights across the landscape of groups. Moreover, we remain concerned that a third admission source category for observational stays and ED visits could potentially create an incentive for HHAs to encourage outpatient encounters both prior to a 30-day period of care or within a 30-day period of care within 14 days of the start of the next 30-day period, thereby potentially increasing costs to the Medicare program overall. For all of these reasons, we believe that incorporating HH stays with preceding observational stays and ED visits into the community admission category is most appropriate at this time.

While we recognize that there is more recent use of Ambulatory Surgery Centers (ASCs) for certain joint replacement surgeries, we do not have sufficient data at this time to determine the impact on home health resource use for beneficiaries coming from an ASC facility after these types of surgeries. As

mentioned previously, we will only include those stays that are considered institutional stays in other Medicare settings and where "institutional" refers to discharges from acute-care hospitals, IRFs, LTCHs, IPFs, and SNFs. Therefore, a discharge from an ASC does not meet the definition of "institutional". Likewise, discharge from hospice care would not be considered an institutional discharge, nor would we expect large enough numbers of beneficiaries discharging from hospice to home health to warrant such an inclusion.

However, we note that as we receive and evaluate new data related to the provision of Medicare home health care under the PDGM, we will continue to assess the payment levels for admission source within a home health period and give consideration to any cost differentiation evidenced by the resources required by those home health patients with a preceding outpatient event.

Comment: Several commenters stated that the addition of the admission source category and potential payment differential could negatively affect agencies' ability to provide the care for beneficiaries in the community and that the admission source categories placed a higher value on care provided to a beneficiary referred to home health care from an acute setting. Several commenters stated that home health community entrants are provided education and oversight as well as preventative and maintenance therapy and care, citing the Jimmo Settlement Agreement.¹⁶ Commenters assert that such maintenance care ultimately prevents beneficiaries from requiring an admission to a more expensive hospital setting. Several commenters stated that the admission source element of the PDGM would lead to reduced access to home-based care, which may, in turn, result in an increase in emergency department visits, an increase in hospital admissions, and increased use of high cost institutional care for patients. The commenters further suggested that the maintenance interventions provided produce value for the Medicare system and that these savings should be reflected through higher payment to HHAs for the care of community entrants.

Response: HHAs should continue to provide the most appropriate care to Medicare home health beneficiaries, regardless of admission source or any other category related to home health

payment in accordance with the home health CoP requirements at § 484.60. As we noted in the CY 2019 HH PPS proposed rule, the primary goal of home health care is to provide restorative care when improvement is expected, maintain function and health status if improvement is not expected, slow the rate of functional decline to avoid institutionalization in an acute or post-acute care setting, and/or facilitate transition to end-of-life care as appropriate (83 FR 32375). The primary goal of the HH PPS is to align payment with the costs of providing home health care. As described in the CY 2019 HH PPS proposed rule, we have developed the PDGM categories and corresponding payment weights based upon the resource use demonstrated in existing home health data, which shows that differentiated amounts are merited between the two admission sources (83 FR 32375). Furthermore, in our CY 2000 HH PPS final rule, commenters asserted that patients admitted to home health from the hospital were often more acutely ill and resource-intensive than other patients, particularly when compared with beneficiaries who had no institutional care prior to admission (64 FR 41147). Commenters further noted that home health beneficiaries referred from institutional settings typically required more visits and more intensive teaching. Given our analyses as well as clinical observations regarding the resource needs of the institutional entrants to home health, we believe that differentiated admission source categories are merited. We will continue to monitor home health data for impacts of this payment policy change, potentially evaluating for increases in hospital admissions during home health stays, poorer quality outcomes, and increases in costs for the overall Medicare program, and we will make refinements to the payment system as appropriate.

Comment: Several commenters expressed concern regarding the operational aspects of the admission source category, requesting guidance for retroactive adjustments, plans for the claims readjustment process due to institutional claim issues, definitions for timely filing, and guidance regarding when occurrence codes may be utilized (for example, for both non-Medicare and Medicare institutional stays). Several commenters expressed concern that the usage of occurrence codes for institutional admissions will increase burden on providers, cause difficulties for HHAs when having to rely on institutional providers to submit timely claims to Medicare, and create

¹⁶ <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPSP/Downloads/Jimmo-Settlement-Agreement.pdf>.

challenges when modifications to home health payments are made retroactively due to the re-categorization of a community stay when an institutional claim was not submitted correctly. Several commenters requested that CMS clarify the length of time that a HHA would have to resubmit a home health claim when it learns of a non-Medicare institutional stay occurring within 14 days of the home health admission. A commenter expressed concern regarding the usage of the OASIS for identification of institutional admission sources.

Response: As described in the CY 2019 HH PPS proposed rule, we have developed automated claims processing procedures with the goal of reducing the amount of administrative burden associated with the admission source category of the PDGM (83 FR 32375). For example, Medicare systems will automatically determine whether a beneficiary has been discharged from an institutional setting for which Medicare paid the claim, using information used during claims processing to systematically identify admission source and address this issue. When the Medicare claims processing system receives a Medicare home health claim, the systems will check for the presence of a Medicare acute or PAC claim for an institutional stay. If such an institutional claim is found, and the institutional stay occurred within 14 days of the home health admission, our systems will trigger an automatic adjustment of the corresponding HH claim to the appropriate institutional category. Similarly, when the Medicare claims processing system receives a Medicare acute or PAC claim for an institutional stay, the systems will check for the presence of a subsequent HH claim with a community payment group. If such a HH claim is found, and the institutional stay occurred within 14 days of the home health admission, our systems will trigger an automatic adjustment of the HH claim to the appropriate institutional category. This process may occur any time within the 12-month timely filing period for the acute or post-acute claim. The OASIS assessment will not be utilized in evaluating for admission source information.

Moreover, we proposed that newly-created occurrence codes would also be established, allowing HHAs to manually indicate on Medicare home health claims that an institutional admission had occurred prior to the processing of an acute/post-acute Medicare claim, if any, by Medicare systems in order to receive the higher payment associated with the institutional admission source sooner (83 FR 35312). However, the

usage of the occurrence codes is limited to situations in which the HHA has information about the acute or PAC stay. We also noted that the use of these occurrence codes would not be limited to home health beneficiaries for whom the acute/post-acute claims were paid by Medicare. HHAs would also use the occurrence codes for beneficiaries with acute/post-acute care stays paid by other payers, such as the Veterans Administration (VA).

If a HHA does not include the occurrence code on the HH claim indicating that a home health patient had a previous institutional stay, processed either by Medicare or other institutions such as the VA, such an admission will be categorized as “community” and paid accordingly. However, if later a Medicare acute/post-acute claim for an institutional stay occurring within 14 days of the home health admission is submitted within the timely filing deadline and processed by the Medicare systems, the HH claim would be automatically adjusted and re-categorized as an institutional admission and appropriate payment modifications would be made. If there was a non-Medicare institutional stay occurring within 14 days of the home health admission but the HHA was not aware of such a stay, upon learning of such a stay, the HHA would be able to resubmit the HH claim that included an occurrence code, subject to the timely filing deadline, and payment adjustments would be made accordingly.

Again, however, we note that the Medicare claims processing system will check for the presence of an acute/post-acute Medicare claim for an institutional stay occurring within 14 days of the home health admission on an ongoing basis and automatically assign the home health claim as “community” or “institutional” appropriately. As a result, with respect to a HH claim with a Medicare institutional stay occurring within 14 days of home health admission, we will not require the submission of an occurrence code in order to appropriately categorize the HH claim to the applicable admission source. With respect to a HH claim with a non-Medicare institutional stay occurring with 14 days of home health admission, a HHA would need to submit an occurrence code on the HH claim in order to have the HH claim categorized as “institutional” and paid the associated higher amount.

Additionally, we plan to provide education and training regarding all aspects of the admission source process and to develop materials for guidance

on claims adjustments, for resolution of claims processing issues, for defining timely filing windows, and for appropriate usage of occurrence codes through such resources as the Medicare Learning Network. We will also update guidance in the Medicare Claims Processing Manual as well as the Medicare Benefit Policy Manual as appropriate with detailed procedures. We will also work with the MACs to address any concerns regarding the processing of home health claims as well as develop training materials to facilitate all aspects of the transition to the PDGM, including the unique aspects of the admission source categories.

With regards to the length of time for resubmission of home health claims that reflect a non-Medicare institutional claim, all appropriate Medicare rules regarding timely filing of claims will still apply. Procedures required for the resubmission of home health claims will apply uniformly for those claims that require editing due to the need to add or remove occurrence codes. Details regarding the timely filing guidelines for the Medicare program are available in the Medicare Claims Processing Manual, Chapter 1—General Billing Requirements, which is available at the following website: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c01.pdf>. Additionally, adjustments to any resubmitted home health claims will be processed in the same manner as other edited Medicare home health claims. Additionally, we plan to perform robust testing within the Medicare claims processing system to optimize and streamline the payment process.

Comment: Another commenter requested details regarding the process by which HHAs should verify a non-Medicare institutional stay.

Response: As we noted in in the CY 2019 HH PPS proposed rule, we expect home health agencies would utilize discharge summaries from all varieties of institutional providers (that is, Medicare and non-Medicare) to inform the usage of these occurrence codes, and these discharge documents should already be part of the beneficiary’s home health medical record used to support the certification of patient eligibility as outlined in § 424.22(c) (83 FR 32340). Providers should utilize existing strategies and techniques for verification of such stays and incorporate relevant clinical information into the plan of care, as is already required by the Medicare CoPs.

Comment: Several commenters expressed concern that the use of occurrence codes will lead to claims

denials by MACs and stated that MAC staff will require training in order to ensure appropriate application of the admission source policy as well as avoid any unintended consequences.

Response: We intend to provide education and training regarding the usage of the admission source occurrence codes to providers through such tools as Medicare Learning Network articles. We are also working closely with the MACs to ensure proper processing of home health claims under the new PDGM. Additionally, as we noted in the CY 2019 HH PPS proposed rule, while a home health claim with a non-Medicare institutional admission source can be categorized by the HHA as an institutional admission and paid accordingly, we may conduct medical review if deemed appropriate (83 FR 35312).

Comment: Several commenters expressed concern regarding our proposal to potentially conduct post-payment medical review of home health claims in order to assess whether a home health admission was preceded by an institutional stay, asserting that HHAs should not be held responsible for other providers' claim activity. The commenters stated that post-payment medical review for instances in which HHAs manually indicate on the claim an institutional admission source, and the institution's claim for an acute/post-acute stay is subsequently denied or not filed in a timely manner could be problematic. The commenters stated that a denial for the acute/post-acute stay could be due to a number of reasons of which the HHA has no knowledge or involvement and noted that any denial of an institutional claim or non-timely filing of a claim, would be outside of the control of the HHAs.

Response: Our evaluation process within the Medicare claims processing system will check for the presence of an acute/post-acute Medicare claim for an institutional stay occurring within 14 days of the home health admission on an ongoing basis. Under this approach, the Medicare systems would only evaluate for whether an acute/post-acute Medicare claim for an institutional stay occurring within 14 days of the home health admission was processed by Medicare, not whether it was paid. Therefore, we do not expect that a home health claim will be denied due to unpaid Medicare claims for preceding acute/post-acute admissions. Moreover, we note that providers would have the option to submit the occurrence code indicating a preceding institutional stay in order to categorize the home health admission as "institutional." If in the case of a Medicare institutional stay,

upon review after finding no Medicare acute or post-acute care claims in the National Claims History, and there is documentation of a Medicare acute or post-acute care stay within the 14 days prior to the home health admission, but the institutional setting did not submit its claim in a timely fashion or at all, we would permit the institutional categorization for the payment of the home health claim through appropriate administrative action. Similarly, in the case of a non-Medicare institutional stay, if documentation of a non-Medicare acute or post-acute care stay within the 14 days prior to the home health admission, is found, we would permit the categorization of the home health claim as "institutional". However, if upon medical review after finding no acute or post-acute care Medicare claims in the National Claims History, and there is no documentation of an acute or post-acute care stay, either a Medicare or non-Medicare stay, within 14 days of the home health admission, we would correct the overpayment and re-categorize the stay as community. If upon medical review after finding no Medicare acute or post-acute care claims in the National Claims History and we find that an HHA is systematically including occurrence codes that indicate the patient's admission source was "institutional," but no documentation exists in the medical record of Medicare or non-Medicare stays, we would refer the HHA to the zone program integrity contractor (ZPIC) for further review, including any potential administrative action.

Comment: A commenter suggested that we only conduct post-payment review for HHAs that have claims that are consistently associated with acute/post-acute claim denials, or whose utilization pattern of acute/post-acute occurrence codes is aberrant when compared with their peers, which the commenter asserts would ensure a more equitable approach toward conducting post-payment medical review of home health claims.

Response: We appreciate the commenter's suggestions regarding targeted approaches for medical review after the implementation of the admission source element of the PDGM, and we will consider such metrics in the development of any targeted reviews.

Comment: Another commenter expressed concerns regarding operational aspects of the admission source portion of the PDGM, stating that if the institutional stay were billed very late in the timely filing period, the HHA might not receive an appropriate admission source adjustment within the

PDGM. The commenter also expressed concern regarding the timely filing window for HHAs, asking if we will increase the timely filing period for home health agencies. The commenter also wanted to understand how home health agencies will know if institutional providers are submitting their claim correctly and meeting the necessary criteria. Additionally, the commenter asked why we were not allowing payment to the home health agency if the agency's billing is submitted appropriately based on the information currently at hand and later recalculate and adjust payment if necessary. The commenter also asked if discharge summaries received by home health from external institutions will serve as "proof" in the event of medical review. The commenter also asked what would transpire if an institutional provider decided post-discharge that the inpatient admission did not meet inpatient criteria when discharge summary documents still indicate the patient was being discharged to home health following a qualifying inpatient stay.

Response: We appreciate the commenter's questions regarding the operational aspects of the admission source category within the PDGM. With respect to any issues around a Medicare institutional claim submitted near the end of the timely filing period, if the institutional stay is billed very late in the timely filing period, that institutional stay claim would trigger an automatic adjustment to the HH claim whenever it is received by CMS's claims processing system and the HHA would be paid appropriately. If there was a non-Medicare institutional stay occurring within 14 days of the home health admission but the HHA was not aware of such a stay, upon learning of such a stay, the HHA would be able to resubmit the HH claim that included an occurrence code to indicate an institutional admission source, subject to the timely filing deadline, and payment adjustments would be made accordingly. Regarding timely filing timeframes, we do not have the authority to extend timely filing timeframes as they are mandated by statute. However, the HHA may utilize the newly-established occurrence codes to indicate an institutional admission source without dependency on the claims submission by the institutional provider.

Additionally, we reiterate that the HHA is not dependent on the institutional provider's "correct" submission of the institutional claim for appropriate admission source categorization, as HHAs will have the

option of including the relevant occurrence codes to indicate an HH admission from an institutional provider separate and apart from any claims submission by the institutional provider. In the case of a Medicare institutional stay, if the institutional setting did not submit its claim in a timely fashion, or at all, but there is documentation of a Medicare acute or PAC stay within the 14 days prior to the home health admission, we would permit the institutional categorization for the payment of the home health claim through appropriate administrative action. Similarly, in the case of a non-Medicare institutional stay, if documentation of a non-Medicare acute or post-acute care stay within the 14 days prior to the home health admission, is found, we would permit the categorization of the home health claim as “institutional”. Regarding the usage of discharge summaries as evidence of a prior institutional stay, such summaries may be considered in the assessment of the appropriateness of the usage of an occurrence code indicating admission to HH from an institutional setting and determinations will be made based upon the evidence gathered. Regarding a scenario where an institutional provider determines post-discharge that an admission did not meet inpatient criteria but the discharge summary utilized by an HHA indicated that the patient was being discharged to home health following a qualifying inpatient stay, the home health agency would not be left with a non-covered claim. However, the home health claim may be paid as non-institutional rather than institutional, given the source of the admission. Furthermore, we note that details regarding the claims processing instructions for Medicare home health claims will be updated in our Medicare Claims Processing Manual. We plan to provide education and training regarding all aspects of the admission source process and to develop materials for guidance on claims adjustments, and for appropriate usage of occurrence codes.

Final Decision: We are finalizing our proposal to establish two admission source categories for grouping 30-day periods of care under the PDGM—institutional and community—as determined by the healthcare setting utilized in the 14 days prior to home health admission. Thirty-day periods for beneficiaries with any inpatient acute care hospitalizations, inpatient psychiatric facility (IPF) stays, skilled nursing facility (SNF) stays, inpatient rehabilitation facility (IRF) stays, or long

term care hospital (LTCH) stays within the 14 days prior to a home health admission will be designated as institutional admissions. The institutional admission source category will also include patients that had an acute care hospital stay during a previous 30-day period of care and within 14 days prior to the subsequent, contiguous 30-day period of care and for which the patient was not discharged from home health and readmitted (that is, the admission date and from date for the subsequent 30-day period of care do not match) as we acknowledge that HHAs have discretion as to whether they discharge the patient due to a hospitalization and then readmit the patient after hospital discharge. However, we will not categorize post-acute care stays (SNF, IRF, or LTCH) or IPF stays that occur during a previous 30-day period and within 14 days of a subsequent, contiguous 30-day period of care (that is, the admission date and from date for the subsequent 30-day period of care do not match) as institutional, as we would expect the HHA to discharge the patient if the patient required post-acute care in a different setting or inpatient psychiatric care and then readmit the patient, if necessary, after discharge from such setting. If the patient was discharged and then readmitted to home health, the admission date and “from” date on the 30-day claim would match and the claims processing system will look for an acute or a post-acute care stay within 14 days of the home health admission date. This admission source designation process would be applicable to institutional stays paid by Medicare or another payer. All other 30-day periods would be designated as community admissions. For the purposes of a RAP, we would only adjust the final home health claim submitted for source of admission. For example, if a RAP for a community admission was submitted and paid, and then an acute or PAC Medicare claim was submitted for that patient before the final home health claim was submitted, we would not adjust the RAP and would only adjust the final home health claim so that it reflected an institutional admission. Additionally, HHAs would only indicate admission source occurrence codes on the final claim and not on any RAPs submitted. As noted previously, we plan to provide future training and guidance of operational aspects of claims processing under the PDGM especially regarding the admission source case-mix variable.

6. Clinical Groupings

In the CY 2019 HH PPS proposed rule (83 FR 32340), we proposed grouping 30-day periods of care into six clinical groups: Musculoskeletal Rehabilitation, Neuro/Stroke Rehabilitation, Wounds—Post-Op Wound Aftercare and Skin/Non-Surgical Wound Care, Behavioral Health Care (including Substance Use Disorder), Complex Nursing Interventions, and Medication Management, Teaching, and Assessment (MMTA). We stated that by placing periods of care into clinical groups reflecting the primary reason the patient is receiving home health, as determined by the principal diagnosis on the claim, we would capture the most common types of care provided and more accurately align payments with the cost of providing care (that is, resource use).

In response to comments on the CY 2018 HH PPS proposed rule (82 FR 35317) and a Technical Expert Panel (TEP) held in February 2018, we conducted further analysis on the division of the MMTA clinical group into subgroups. We conducted a thorough review of all the diagnosis codes grouped into the MMTA group and we grouped codes into MMTA subgroups based on feedback from public comments, which mainly focused on cardiac, oncology, infectious, and respiratory diagnoses. We created the additional subgroups (Surgical Aftercare, Cardiac/Circulatory, Endocrine, GI/GU, Infectious Diseases/Neoplasms/Blood Forming Diseases, Respiratory, and Other) based on data that showed above-average resource use for the codes in those groups, and then combined certain groups that had a minimal number of codes.

Similar to the initial Home Health Groupings Model (HHGM) analysis conducted in 2016 that was discussed in the CY 2018 HH PPS proposed rule, results showed that the change in case-mix weights, as well as impacts to the other case-mix variables (admission source/timing, comorbidity adjustment) was minimal for the 30-day periods assigned to these subgroups compared to the case-mix weights without the subgroups. We showed that overall, using the MMTA subgroup model would result in more payment groups but no significant differences in case-mix weights across those groups. For that reason, in the CY 2019 HH PPS proposed rule, we proposed to retain the six clinical groups as shown in Table 26, and not divide the MMTA clinical group into subgroups. A complete list of ICD-10-CM codes and their assigned clinical groupings is posted on the CMS HHA Center web page (<https://>

www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html). More information on the analysis and development of the groupings can be found in the CY 2019 HH PPS proposed rule as well as the Summary of the Home Health Technical

Expert Panel Meeting.¹⁷ However, we solicited comments from the public on whether there may be other compelling reasons why the MMTA clinical group should be broken out into subgroups, despite analysis indicating that additional subgroups do not result in

significant differences in case-mix weights. We noted that we also planned to continue to examine trends in reporting and resource utilization to determine if future changes to the clinical groupings are needed after implementation of the PDGM.

Table 26: PROPOSED CLINICAL GROUPS USED IN THE PDGM

Clinical Groups	The Primary Reason for the Home Health Encounter is to Provide:
Musculoskeletal Rehabilitation	Therapy (physical, occupational or speech) for a musculoskeletal condition
Neuro/Stroke Rehabilitation	Therapy (physical, occupational or speech) for a neurological condition or stroke
Wounds – Post-Op Wound Aftercare and Skin/Non-Surgical Wound Care	Assessment, treatment & evaluation of a surgical wound(s); assessment, treatment & evaluation of non-surgical wounds, ulcers, burns, and other lesions
Behavioral Health Care	Assessment, treatment & evaluation of psychiatric conditions, including substance use disorder
Complex Nursing Interventions	Assessment, treatment & evaluation of complex medical & surgical conditions including IV, TPN, enteral nutrition, ventilator, and ostomies
Medication Management, Teaching and Assessment (MMTA)	Assessment, evaluation, teaching, and medication management for a variety of medical and surgical conditions not classified in one of the previously listed groups.

The following is a summary of the public comments received on the proposed clinical groups under the PDGM and our responses:

Comment: Many commenters supported the patient-centered approach to grouping patients by clinical characteristics, and appreciated that additional codes were added to the PDGM in comparison to the HHGM.

Response: We appreciate these comments and thank the commenters for their support of the clinical groupings as defined in the CY 2019 HH PPS proposed rule.

Comment: Many commenters reiterated concern that the MMTA group was too large (that is, too many 30-day periods group into the MMTA clinical group under the PDGM) and stated preference for more specificity within this group despite analysis showing a lack of variation in resource use across subgroups. A commenter specifically noted that the groupings exclude heart failure and pulmonary clinical groups,

which are two medically complex categories that result in significant time and resource use in order to prevent hospital readmissions.

Response: As discussed in the CY 2019 HH PPS proposed rule, health teaching; guidance and counseling; case management, treatments and procedures; and surveillance are integral in the care of the majority of home health patients. Additionally, these important interventions are often the primary reason for home health services. However, because these interventions cross the spectrum of diagnoses, the MMTA clinical group included the largest number of 30-day periods among the proposed clinical groups in the PDGM. Despite additional analysis showing very little variation in resource use after sub-dividing MMTA into smaller subgroups, we understand stakeholder preference to capture the distinctions in care provided to patients within this group. The majority of commenters still expressed concern

with the high number of diagnoses that grouped into the MMTA and preferred greater specificity over having fewer HHRGs.

Therefore, we will create 7 additional clinical groups to replace the comprehensive MMTA group. These subgroups were selected based on public comments in response to the CY 2018 HH PPS proposed rule and these comments mainly focused on cardiac, oncology, infectious disease, and respiratory diagnoses.¹⁸ We created the additional subgroups based on data that showed above-average resource use for codes in those groups, and then combined certain groups that had a minimal number of codes. These subgroups were presented to the TEP convened in February, 2018 and were detailed in the CY 2019 HH PPS proposed rule; commenters were generally supportive of these seven subgroup designations. As such, these MMTA subgroups will be called:

- MMTA—Surgical Aftercare

¹⁷ <https://www.cms.gov/center/provider-type/home-health-agency-HHA-center.html>.

¹⁸ Public comments can be viewed at: [Regulations.gov](https://www.regulations.gov), ID: CMS-2017-0100-0002:

Medicare and Medicaid Programs: Home Health Prospective Payment System Rate Update, etc.

- MMTA—Cardiac/Circulatory
- MMTA—Endocrine
- MMTA—GI/GU
- MMTA—Infectious Disease/Neoplasms/Blood-forming Diseases
- MMTA—Respiratory
- MMTA—Other

The addition of these 7 new groups generated a new table of case-mix weights for the model. The PDGM will now contain 432 case-mix groups. We agree with commenters that greater specificity in the MMTA clinical group will help distinguish differences in care and allow for greater transparency in resource use. We also believe that with the elimination of therapy thresholds, having more discrete subgroups within this clinical group may result in more variation in resource use over time.

Comment: Several commenters submitted specific diagnosis codes that they believe should be reassigned to different clinical groups or added to the grouper tool. Another commenter stated that any existing ICD-10-CM diagnosis code should be considered when assigning a clinical group. Several commenters submitted new codes effective for October 1, 2018 that were not in the grouper tool released with the proposed rule on July 2, 2018.

Response: We thank commenters for thoroughly reviewing the PDGM Grouper tool and providing questions and detailed examples regarding the grouping of specific codes. As discussed in the CY 2019 HH PPS proposed rule, one of the main goals of the PDGM is to clearly account for resource use by highlighting the main reason for home health services. The ICD-10-CM code list is an exhaustive list that contains many codes that do not support the need for home health services and so are not appropriate as principal diagnosis codes for grouping home health periods into clinical groups. Dental codes, for example, are included in the ICD-10-CM code list, but are not Medicare covered services. Others are Medicare covered codes, but are not relevant to home health, for example, codes that indicate death as the outcome. Another reason a code is not appropriate for grouping home health periods into clinical groups is because of coding guidelines. For example, this would include codes listed out of sequence when ICD-10 coding conventions indicate certain codes in which the underlying condition must be listed first (that is, Parkinson's disease must be listed prior to Dementia if both codes were listed on a claim).

In addition to coding guidelines, we also looked at clinical practice guidelines and the interventions and

skilled care involved in managing the diagnosis at home. We believe these guidelines provide valuable information for establishing a plan of care and support home health resource use. For instance, an infection of an amputation stump may only require treatment with antibiotics, whereas management of necrotic tissue always involves debridement and subsequent wound care in order to allow wound healing to take place. Thus, necrosis of an amputation stump clearly denotes wound care. For a period to be grouped into the wound category, the diagnosis on the claim must reflect a break in skin integrity for which clinical practice guidelines involve wound care necessitating skilled nursing services. A diagnosis simply indicating infection may or may not necessitate wound care.

We also expect that whenever possible, the most specific code that describes a medical disease, condition, or injury should be documented. For instance many codes contain the word "unspecified." Generally, "unspecified" codes are used when there is lack of information about location or severity of medical conditions in the medical record. However, we would expect a provider to use a precise code whenever more specific codes are available. Furthermore, if additional information regarding the diagnosis is needed, we would expect the HHA to follow-up with the referring provider in order to ensure the care plan is sufficient in meeting the needs of the patient. We believe that a vague principal diagnosis does not clearly identify the primary reason for home health, and subsequently leads to ambiguous resource use. For example, T14.90 "Injury, unspecified", lacks clarity regarding the type and extent of injury and therefore, fails to indicate and support the needed resources. Additionally, the ICD-10-CM code set includes laterality. We believe a home health clinician should not report an "unspecified" code if that clinician can identify the side or site of a condition. For example, a home health clinician should be able to state whether a fracture of the arm is the right or left arm.

Similarly, many of the codes that indicate pain or contractures as the primary diagnosis, for example M54.5, Low back pain or M62.422, Contracture of muscle, right hand, although site specific, do not indicate the cause of the pain or contracture. We would expect a more definitive diagnosis indicating the cause of the pain or contracture, as the reason for the skilled care, in order to appropriately group the home health period.

We also believe that the majority of the R codes (codes that describe signs and symptoms, as opposed to diagnoses) are not appropriate as principal diagnosis codes for grouping home health periods into clinical groups. While we recognize that the coding guidelines allow for the reporting of signs, symptoms, and less well-defined conditions, HHAs are required to establish an individualized plan of care in accordance with the home health CoPs at § 484.60. The plan of care must specify the services necessary to meet the patient-specific needs as identified during the comprehensive assessment. This includes identification of the responsible discipline(s), and anticipated measurable outcomes as a result of implementing and coordinating the plan of care. We believe that the use of symptoms, signs, and abnormal clinical and laboratory findings would make it difficult to meet the requirements of an individualized plan of care. Likewise, we believe that clinically it is important for home health clinicians to have a clearer understanding of the patients' diagnoses in order to safely and effectively furnish home health services. Interventions and treatment aimed at mitigating signs and symptoms of a condition may vary depending on the cause. For example, if a patient has been referred to home health with a diagnosis of "other abnormalities of gait and mobility" (R26.89), we believe it is important for the home health clinician to know what is precipitating the abnormality. For instance, a plan of care for a gait abnormality related to a neurological diagnosis is likely to be different from a plan of care for a gait abnormality due to a fracture or injury. Anecdotally, we have heard that the home health referral may be non-specific or that the physician may be in the process of determining a more definitive diagnosis. However, with respect to patient safety and quality of care, we believe it is important for a clinician to investigate the cause of the signs and/or symptoms for which the referral was made. This may involve calling the referring physician to gather more information regarding the gait abnormality. We note that HHAs are required under the home health CoPs at § 484.60 to participate in care coordination to assure the identification of patient needs and factors that could affect patient safety and treatment efficacy. Coding guidelines are clear that R codes are to be used when no more specific diagnosis can be made even after all the facts bearing on the case have been investigated. Therefore, these codes

should not be used as a primary diagnosis for the provision of home health services while a physician may still be in the diagnostic process. By the time the patient is referred to home health and meets the qualifications of eligibility, we would expect that a more definitive code exists to substantiate the need for services. Furthermore, commenters have indicated a preference for greater specificity in the clinical groups, therefore, we believe this should extend to the codes within the clinical groups as well.

Another commonly reported diagnosis, M62.81, "Muscle weakness, generalized" is extremely vague. Generalized muscle weakness, while obviously a common condition among recently hospitalized patients does not clearly support a rationale for skilled services and does not lend itself to a comprehensive plan of care. In § 409.44(c)(1)(ii) we state that "the patient's clinical record must include documentation describing how the course of therapy treatment for the patient's illness or injury is in accordance with accepted professional standards of clinical practice." If there is not an identified cause of muscle weakness, then it would be questionable as to whether the course of therapy treatment would be in accordance with accepted professional standards of clinical practice. Additionally, in the 2008 HH PPS final rule, we identified "muscle weakness (generalized)" as a nonspecific condition that represents general symptomatic complaints in the elderly population. We stated that inclusion of this code "would threaten to move the case-mix model away from a foundation of reliable and meaningful diagnosis codes that are appropriate for home care" (72 FR 49774). Specifically, the 2008 HH PPS final rule stipulated that the case-mix system avoid, to the fullest extent possible, non-specific or ambiguous ICD-9-CM codes, codes that represent general symptomatic complaints in the elderly population, and codes that lack consensus for clear diagnostic criteria within the medical community. We believe that diagnostic approaches to determining the cause of muscle weakness, polyneuropathy, and other vague conditions, combined with the expanded ICD-10 list, ensure that codes exist that more clearly describe a patient's need for home health. With respect to commenter rationale for coding "Muscle weakness, generalized" in response to severe deconditioning and weakness due to extended hospitalization, we believe a more appropriate code would be one of the muscle wasting and atrophy codes as

grouped into the musculoskeletal group. Muscle wasting and atrophy would indicate the reason for the generalized muscle weakness and provide more clarity for the necessity of skilled services.

Using these guidelines, we worked with certified coders to review all of the codes submitted with commenter feedback. We included the new codes added with respect to Fiscal Year 2018 (for use beginning October 1, 2017) and with respect to Fiscal Year 2019 (for use beginning October 1, 2018) and grouped the MMTA diagnosis codes into the appropriate sub-groups. We remind commenters that the ICD 10-CM code list is updated each fiscal year with an effective date of October 1st. Because of an annual October effective date for updated ICD 10-CM codes, the HH PPS is subject to two Grouper releases, one in October and one in January, to ensure that claims are submitted with the most current code set available. Additionally, we re-grouped many of the codes submitted by commenters based on feedback we received and changed the clinical grouping of many additional codes based on commenter rationale. For example, we agree with commenters regarding many of the S and T codes where the fracture and/or injury is unspecified, but the site is specified. We maintain that the site of injury and/or fracture should be identified; however, we believe that, as the treatment or intervention would likely not change based on the exact type of injury or fracture, many of these codes are appropriate to group the period into a clinical group. These codes were changed to either the musculoskeletal group or the wounds group. We also agreed with commenters regarding some of the combination diagnosis/symptom codes. For example, we re-grouped I13.2, Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease into MMTA-Cardiac/Circulatory, as despite the likelihood that the patient is covered under the End Stage Renal Disease (ESRD) benefit, the patient may also be receiving home health services for hypertension. We also agree that Z46.6, Encounter for fitting and adjustment of urinary device should be grouped into the Complex Nursing Interventions group.

Regarding A41.0, Sepsis due to *Staphylococcus aureus* and A40.0, Sepsis due to streptococcus, group A, as guidelines state that a sepsis diagnosis should be assigned the appropriate code for the underlying systemic infection, these codes will be classified under MMTA—Infectious Disease/Neoplasms/

Blood-forming Diseases. With regards to Z45.2, Encounter for adjustment and management of VAD, per coding guidelines, Z45.2 can be reported as the principal diagnosis and will remain in the Complex Nursing Interventions group. However, we recognize that coding guidelines indicate that if treatment is directed at current, acute disease, then the disease diagnosis code should be reported first, followed by the Z aftercare codes. Therefore, in a case where the patient is receiving an IV antibiotic for sepsis, as the HHA is required to code sepsis as the primary diagnosis, the Z code must be listed as the first secondary diagnosis code listed on the claim in order to group the period into the Complex Nursing Interventions group.

Ultimately we believe that precise coding allows for more meaningful analysis of home health resource use and ensures that patients are receiving appropriate home health services as identified on an individualized plan of care. We thank the commenters for their in-depth review and suggested changes to the ICD-10-CM code assignments for the clinical groups under the PDGM. We note that we did regroup additional codes to the ones identified in this section, based on the reasons previously discussed, and we encourage HHAs to continue to review the list of diagnosis codes in the PDGM Grouper Tool posted with the final rule on the HHA Center web page (<https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html>). Commenters are encouraged to continue to submit comments to the home health policy mailbox (HomehealthPolicy@cms.hhs.gov) regarding diagnosis coding under the PDGM. We will continue to review ICD-10-CM code assignments for the clinical groups under the PDGM and make future refinements as necessary, including refinements to reflect new codes added to the ICD 10-CM code list.

Comment: Another commenter expressed concern about patients grouped into the MMTA group who experience a change of condition that warrants additional resources during a period of care that is not properly accounted for under the PDGM. The commenter gave the example of an MMTA patient who experiences a fall and thereafter requires therapy services which are not accounted for in the case-mix weight based on the HHRG. The commenter suggested that "it may be necessary for CMS to reinstate a payment adjustment similar to the Significant Change in Condition ("SCIC") adjustment when HHGM is

implemented to address these patients' needs."

Response: If the primary diagnosis changes between the first and the second 30-day periods, then the claim for the second 30-day period would reflect the new diagnosis, and providers would not change the claim for the first 30-day period. We note that if a patient experienced a significant change in condition before the start of a subsequent, contiguous 30-day period, for example due to a fall, in accordance with § 484.55(d)(1)(ii), the HHA is required to update the comprehensive assessment. Furthermore, in accordance with § 484.18(b) the total plan of care is reviewed by the attending physician and HHA personnel as often as the severity of the patient's condition requires, but at least once every 60 days or more frequently when there is a beneficiary elected transfer; a significant change in condition resulting in a change in the case-mix assignment; or a discharge and return to the same HHA during the 60-day episode. A follow-up assessment would be submitted at the start of the second 30-day period to reflect the change in the functional level and the second 30-day claim would be grouped into its appropriate case-mix group accordingly. In this respect, two 30-day periods can have two different case-mix groups to reflect any changes in patient condition. This is different from the current payment system where the case-mix group does not change in the middle of a 60-day episode. However, similar to the current system, the case mix group cannot be adjusted within each 30-day period. HHAs must be sure to update the assessment completion date on the second 30-day claim if a follow-up assessment changes the case-mix group to ensure the claim can be matched to the follow-up assessment. HHAs can submit a claims adjustment if the assessment is received after the claim has been submitted, if the assessment items would change the payment grouping.

Comment: A few commenters questioned what will happen when a provider who has a claim returned for a principal diagnosis code that does not group into one of the six clinical groups and the provider corrects the claim by changing the principal diagnosis to one that corresponds to a clinical category. The commenter expressed concern that this may be regarded as "up-coding" and wanted to know how CMS would prevent this.

Response: As we are posting a complete list of ICD-10-CM codes that are available at the time of this final rule with comment period and their assigned clinical groupings on the CMS HHA

Center web page, HHAs should have ample time to become familiar with codes that would be used to group 30-day periods of care into the 12 clinical groupings, therefore we believe the number of returned claims should be minimal as HHAs will avoid listing codes as the principal diagnosis code on the home health claim knowing in advance that such claims will be returned to the provider for more appropriate or specific coding. Returning a claim for more appropriate or specific coding would not be considered as "up-coding" assuming the documentation clearly supports the need for services. Furthermore, it is required per § 409.43(c)(4) that any changes in the plan of care must be signed and dated by a physician. If a claim is returned for more specific coding, then it is expected that the diagnosis on the plan of care will be corrected as well.

Under the PDGM, case-mix assignment is based, in part, on certain items in patient assessments completed by home health agencies and the diagnoses reported on the home health claim. Thus, if the average case-mix weight of Medicare home health patients increases over time, the extent to which case-mix increases reflect real changes in patient characteristics versus nominal case-mix changes attributable to changes in coding practices (more commonly referred to as "up-coding") has been examined. CMS examines the proportion of total case-mix change that is nominal versus real across all HHAs on an annual basis as this has important implications for determining home health payment rates that are accurate and reasonable. We do not determine nominal case-mix changes on a case-by-case basis.

Comment: A commenter indicated that SNFs and HHAs should use the same diagnosis classification system. Another commenter noted that providers do not generally determine their treatment based on a patient's clinical diagnosis, but rather "treat the body structure and impairments derived from the diagnosis within each patient's unique environment." This commenter also suggested building a "Diagnosis-Driven Groupings Model."

Response: We stated in the CY 2019 HH PPS proposed rule that we agree that diagnosis alone does not provide the entire clinical picture of the home health patient. However, we maintain that a diagnosis is important to the overall care of a patient, as it crosses disciplines when identifying signs and symptoms of a disease or condition that may impact care planning. We stated that we believe that different healthcare

disciplines use the signs and symptoms associated with a diagnosis to apply their own approach and skill set to treat the patient. We also reiterated that the clinical group is only one aspect of the PDGM, and that the combination of the clinical group with the other aspects of the PDGM, such as functional level and comorbidity adjustment, provide a more complete picture of the patient, allowing a thorough understanding of the resources needed for treatment. Payment would, in turn, be aligned with the more clearly defined resource use. It is unclear why the commenter suggested a "Diagnosis-Driven Groupings Model," as the preceding comment indicates a rejection of the concept of grouping patients by diagnosis, but rather favors grouping patients by impairment. We would argue that, as the clinical group is determined by the patient's primary diagnosis, this aspect of the PDGM is diagnosis-driven. While CMS is making strides in aligning the patient assessment instruments, and in some cases aligning the case-mix adjustment methodology by virtue of removing therapy visit/minute thresholds, across the four post-acute care settings; we note that the SNF and HH benefits do not include the same set of services. For example, while not covered under the Medicare home health benefit, SNF covered services include room and board, medications, and ambulance transportation. Based on differences in setting of care and coverage between the SNF and Home Health benefits, we believe that there are appropriate reasons for the case-mix adjustment methodology to differ between the two settings.

Comment: Some commenters stated that patients who are not categorized into either the musculoskeletal or neuro rehabilitation groups, but who require physical therapy, occupational therapy, or speech-language pathology services may be at risk for receiving an inordinately low level of rehabilitation due to the allocation of resources to address those patients' other conditions. Another commenter indicated this undermined Jimmo Settlement Agreement and the provision of maintenance therapy. A commenter suggested removing therapy thresholds in stages. Another commenter also requested that CMS institute a mechanism within the PDGM to hold providers accountable for the delivery of appropriate, medically necessary care and provide safeguards to ensure how the delivery of therapy services aligns with individual patient characteristics and clinical needs.

Response: With respect to the provision of therapy services as they

relate to the home health period's clinical group, we should emphasize that although the principal diagnosis is a contributing factor in the PDGM and determines the clinical group, it is not the only consideration in determining what home health services are needed in a patient's care plan. We stated in the CY 2019 HH PPS proposed rule that it is the responsibility of the patient's treating physician to determine if and what type of therapy (that is, maintenance or otherwise) the patient needs regardless of clinical grouping. As such, we continue to expect the ordering physician in conjunction with the therapist to develop and follow a plan of care for any home health patient, regardless of clinical group, as outlined in the skilled service requirements when therapy is deemed reasonable and necessary. Therefore, a home health period's clinical group should not solely determine the type and extent of therapy needed for a particular patient.

Ultimately, case-mix adjustment takes into account the resource use of different groups of home health patients, and although not the sole determinant, diagnosis has always been a factor. Highlighting the principal diagnosis in the case-mix model helps to define the primary reason for home health, but does not in any way dictate what services should be included in the plan of care. Therefore, if the primary reason for home health care is for maintenance purposes with the primary need being therapy, this would be indicated on the plan of care and the patient would likely be grouped into one of the therapy groups.

The home health benefit is a bundled payment. It allows home health agencies the discretion to allocate resources based on their knowledge of the patient and the services needed to meet the goals of the individualized home health plan of care. This would mean that the HHA would consider the most appropriate and efficient use of home health services based on patient needs. Therefore, therapy may be an important service in any of the clinical groups; however, it may not necessarily be the primary reason for home health care, which is what the clinical group is intended to capture. Similarly, we expect that skilled nursing, home health

aide, and medical social services would likely be included in the care plan for patients in the rehabilitation clinical groups.

While implementing the use of safeguards to ensure comprehensive evaluation of therapy needs is out of scope for this rule, we note that the home health CoPs establish the health and safety standards for care given to Medicare home health beneficiaries. As such, the CoPs would include such safeguards such as the type and frequency of patient assessments. Finally, section 1895(b)(4)(B)(ii) of the Act, as added by section 51001 of the BBA of 2018 requires elimination of therapy thresholds as part of the case-mix adjustment methodology, effective for January 1, 2020.

Comment: Another commenter expressed concern with the lower reimbursement assigned to the musculoskeletal rehabilitation clinical group, stating that home health providers may not have the same incentives to admit and treat these patients under PDGM. Another commenter suggested the addition of a complex therapy clinical group.

Response: We believe that it is important to look at the entire structure of the model, not only the clinical grouping, in order to understand how a patient with different skilled therapy or nursing needs are placed into a payment group. The clinical grouping is only one step in establishing a home health payment for a period of care. Again, this group is based on the principal diagnosis listed on the claim as well as specific OASIS items that indicate the need for more complex interventions that correlate with higher resource use. The clinical group is intended to capture the main reason the patient is receiving home health, but as we state in the CY 2019 HH PPS proposed rule, we understand that not all care needs can be identified by a diagnosis alone. Therefore, after the primary reason for the 30-day period is captured by the clinical grouping, the PDGM then takes into account the functional impairment level of the patient. Decreasing functional status, as indicated by a specific set of OASIS items, is associated with increased resource use. We believe that the functional

impairment level of patients, when combined with the clinical grouping, would capture additional resource use from any multi-disciplinary therapy patients, or patients with "complex-therapy" needs. For instance, a patient grouped into the Neuro-Rehabilitation clinical grouping with a high Functional Impairment Level indicates increased therapy needs, potentially utilizing all skilled therapy disciplines. Additionally, the comorbidity adjustment further case mixes the period and increases payment to capture the additional resource use for a patient regardless of whether the services are skilled nursing or therapy based. Therefore, a patient with complex needs, including multiple therapy services and medical management, is captured by the combination of the different levels of the model. Furthermore, we note that the current payment model does not differentiate between utilization of therapy disciplines and whether or not all three therapy disciplines are utilized for the same patient. We believe that the PDGM's functional impairment level when combined with the clinical grouping provides a much clearer picture of the patient's needs, particularly in relation to therapy services.

Final Decision: We are finalizing, with modification, our approach to grouping 30-day periods of care into clinical groups that represent the primary reason for home health care. We are finalizing twelve clinical groups, as shown in Table 27, which capture the most common primary reasons for home health care. The additional groups are a result of dividing the MMTA clinical group into 7 sub-groups. We note that although we are categorizing patients into twelve groups according to the principal diagnosis, these groups do not reflect all the care being provided to the home health patient during a 30-day period of care. Home health care remains a multidisciplinary benefit. Additionally, as stated in the CY 2019 HH PPS proposed rule, we will continue to examine trends in reporting and resource utilization to determine if future changes to the clinical groupings are needed after implementation of the PDGM in CY 2020.

TABLE 27: FINAL CLINICAL GROUPS USED IN THE PDGM

Clinical Groups	The Primary Reason for the Home Health Encounter is to Provide:
Musculoskeletal Rehabilitation	Therapy (physical, occupational or speech) for a musculoskeletal condition
Neuro/Stroke Rehabilitation	Therapy (physical, occupational or speech) for a neurological condition or stroke
Wounds – Post-Op Wound Aftercare and Skin/Non-Surgical Wound Care	Assessment, treatment & evaluation of a surgical wound(s); assessment, treatment & evaluation of non-surgical wounds, ulcers, burns, and other lesions
Behavioral Health Care	Assessment, treatment & evaluation of psychiatric conditions
Complex Nursing Interventions	Assessment, treatment & evaluation of complex medical & surgical conditions including IV, TPN, enteral nutrition, ventilator, and ostomies
Medication Management, Teaching and Assessment (MMTA)	
MMTA –Surgical Aftercare	Assessment, evaluation, teaching, and medication management for surgical aftercare
MMTA – Cardiac/Circulatory	Assessment, evaluation, teaching, and medication management for cardiac or other circulatory related conditions
MMTA – Endocrine	Assessment, evaluation, teaching, and medication management for endocrine related conditions
MMTA – GI/GU	Assessment, evaluation, teaching, and medication management for gastrointestinal or genitourinary related conditions
MMTA – Infectious Disease/Neoplasms/Blood-forming Diseases	Assessment, evaluation, teaching, and medication management for conditions related to infectious diseases, neoplasms, and blood-forming diseases
MMTA –Respiratory	Assessment, evaluation, teaching, and medication management for respiratory related conditions
MMTA – Other	Assessment, evaluation, teaching, and medication management for a variety of medical and surgical conditions not classified in one of the previously listed groups

7. Functional Impairment Levels and Corresponding OASIS Items

As part of the overall case-mix adjustment under the PDGM, we proposed in the CY 2019 HH PPS proposed rule to include a functional impairment adjustment to account for the resource costs associated with providing home health care to those patients with functional impairments. Research has shown a relationship exists between functional status, rates of hospital readmission, and the overall costs of health care services.¹⁹ Functional status is defined in a number of ways, but generally, functional status reflects an individual's ability to carry out activities of daily living (ADLs) and to participate in various life situations and in society.²⁰ CMS currently requires the collection of data on functional status in home health through a standardized assessment instrument: the

¹⁹ Burke, R. MD, MS, Whitfield, E. Ph.D., Hittle, D. Ph.D., Min, S. Ph.D., Levy, C. MD, Ph.D., Prochazka, A. MD, MS, Coleman, E. MD, MPH, Schwartz, R. MD, Ginde, A. (2016). "Hospital Readmission From Post-Acute Care Facilities: Risk Factors, Timing, and Outcomes". *The Journal of Post-Acute Care and Long Term Care Medicine*. (17), 249–255.

²⁰ Clauser, S. Ph.D., and Arlene S. Bierman, M.D., M.S. (2003). "Significance of Functional Status Data for Payment and Quality". *Health Care Financing Review*. 24(3), 1–12.

Outcome and Assessment Information Set (OASIS).

Including functional status in the case-mix adjustment methodology allows for higher payment for those patients with higher service needs. As functional status is commonly used for risk adjustment in various payment systems, including in the current HH PPS, we proposed that the PDGM would also adjust payments based on responses to selected functional OASIS items that have demonstrated higher resource use. Generally, worsening functional status is associated with higher resource use, indicating that the responses to functional OASIS items may be useful as adjusters to construct case-mix weights for an alternative case-mix adjustment methodology.

Each proposed OASIS item included in the PDGM has a positive relationship with resource use, meaning as functional status declines (as measured by a higher response category), home health periods have more resource use, on average. In the CY 2019 HH PPS proposed rule, we proposed that the following OASIS items would be included as part of the functional impairment level adjustment under the PDGM:

- M1800: Grooming.

- M1810: Current Ability to Dress Upper Body.
- M1820: Current Ability to Dress Lower Body.
- M1830: Bathing.
- M1840: Toilet Transferring.
- M1850: Transferring.
- M1860: Ambulation/Locomotion.
- M1033 Risk of Hospitalization (at least four responses checked, excluding responses #8, #9, and #10).²¹

Due to the lack of variation in resource use across certain responses and because certain responses were infrequently chosen, we combined some responses into larger response categories to better capture the relationship between worsening functional status and resource use. The resulting combinations of responses for the OASIS items previously discussed are found at Exhibit 7–2 in the technical report, "Overview of the Home Health Groupings Model," on the HHA Center web page.²²

Under the PDGM, a home health period of care receives points based on each of the responses associated with

²¹ Exclusions of the OASIS C–1 Item M1033 include, response #8: "currently reports exhaustion"; response #9: "other risk(s) not listed in 1–8; response #10: None of the above.

²² <https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf>.

the proposed functional OASIS items which are then converted into a table of points corresponding to increased resource use. That is, the higher the points, the higher the functional impairment. The sum of all of these points' results in a functional impairment score which is used to group home health periods into a functional level with similar resource use. We proposed three functional impairment levels of low, medium, and high with approximately one-third of home health periods from each of the clinical groups within each level. This means home health periods in the low impairment level have responses for the proposed functional OASIS items that are associated with the lowest resource use on average. Home health periods in the high impairment level have responses for the proposed functional OASIS items that are associated with

the highest resource use on average. We also proposed that the functional impairment level thresholds would vary between the clinical groups to account for the patient characteristics within each clinical group associated with increased resource costs affected by functional impairment. In the CY 2019 HH PPS proposed rule, we also discussed the potential, future inclusion of the IMPACT Act section GG functional items, which will be collected on the OASIS starting January 1, 2019. A detailed analysis of the development of the functional points and the functional impairment level thresholds by clinical group can be found in the technical report on the HHA Center web page.

As noted in section III.F.6 of this final rule with comment period, we are subdividing the MMTA clinical group into seven sub-groups (MMTA-aftercare;

cardiac/circulatory; endocrine; gastrointestinal/genitourinary; infectious disease/neoplasms/blood-forming diseases; respiratory; and other) to more accurately capture unique patient characteristics associated with patients receiving home health services for medication management, teaching, and assessment. As such, we recalculated the functional points and the thresholds for the functional impairment levels by clinical group. This also resulted in a few minor changes to the functional thresholds compared to the thresholds in the CY 2019 HH PPS proposed rule (Table 42, 83 FR 32406). The updated OASIS points table for the functional items and the table of functional impairment level thresholds for by clinical group are found in Tables 28 and 29.

TABLE 28: OASIS POINTS TABLE FOR THOSE ITEMS ASSOCIATED WITH INCREASED RESOURCE USE USING A REDUCED SET OF OASIS ITEMS, CY 2017

	Response Category	Points (2017)	Percent of Periods in 2017 with this Response Category
M1800: Grooming	1	4	56.9%
M1810: Current Ability to Dress Upper Body	1	6	60.0%
M1820: Current Ability to Dress Lower Body	1	5	59.3%
	2	11	20.9%
M1830: Bathing	1	3	18.0%
	2	13	53.1%
	3	21	23.7%
M1840: Toilet Transferring	1	4	32.1%
M1850: Transferring	1	4	37.7%
	2	8	59.3%
M1860: Ambulation/Locomotion	1	10	25.1%
	2	12	52.9%
	3	24	14.8%
M1032: Risk of Hospitalization	4 or more items checked	11	17.8%

TABLE 29: THRESHOLDS FOR FUNCTIONAL LEVELS BY CLINICAL GROUP, CY 2017

Clinical Group	Level of Impairment	Points (2017 Data)
Behavioral Health	Low	0-36
	Medium	37-52
	High	53+
Complex Nursing Interventions	Low	0-38
	Medium	39-58
	High	59+
Musculoskeletal Rehabilitation	Low	0-38
	Medium	39-52
	High	53+
Neuro Rehabilitation	Low	0-44
	Medium	45-60
	High	61+
Wound	Low	0-42
	Medium	43-61
	High	62+
MMTA - Surgical Aftercare	Low	0-24
	Medium	25-37
	High	38+
MMTA - Cardiac and Circulatory	Low	0-36
	Medium	37-52
	High	53+
MMTA - Endocrine	Low	0-51
	Medium	52-67
	High	68+
MMTA - Gastrointestinal tract and Genitourinary system	Low	0-27
	Medium	28-44
	High	45+
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	Low	0-32
	Medium	33-49
	High	50+
MMTA - Respiratory	Low	0-29
	Medium	30-43
	High	44+
MMTA - Other	Low	0-32
	Medium	33-48
	High	49+

In the CY 2019 HH PPS proposed rule, we solicited comments on the proposed functional OASIS items, the associated points, and the thresholds by clinical group used to group patients into three functional impairment levels under the PDGM, as previously outlined. The majority of comments received were very similar to those received on the alternate case-mix adjustment methodology (HHGM), in the CY 2018 HH PPS proposed rule. The

comments received are summarized in this section.

Comment: Most commenters agreed that the level of functional impairment should be included as part of the overall case-mix adjustment in a revised case-mix model. Commenters stated that including a robust functional level variable in the home health payment system will eliminate the incentive to provide unnecessary therapy services to reach higher classifications for payment but will also move the HH PPS toward

greater consistency with other post-acute care PPS.

Response: We thank commenters for their careful review of all variables contributing to the overall case-mix adjustment in the PDGM. We agree that functional status is an important component in understanding patient characteristics to help facilitate the development of an individualized home health plan of care based on identified needs and to help ensure that payment

is in alignment with the costs of providing care.

Comment: Several commenters supported the examination and possible inclusion of the IMPACT Act's section GG, Functional Abilities and Goals, as part of the functional level case-mix adjustment in the PDGM. A commenter remarked that by adding the section GG functional items to the HH VBP model and the HH QRP, CMS would be able to better monitor provider behavior to detect inappropriate responses to implementation of the PDGM, including withholding therapy services that could result in poor outcomes; selecting patients who are likely to be relatively more profitable; generating unnecessary periods of care; or prematurely discharging patients. However, a few commenters recommended that CMS study and validate the predictive capability of such items prior to pursuing any refinements to the PDGM's functional level category. This commenter remarked that it is critical that CMS is confident in the capability of Section GG functional items to sufficiently predict functional impairment level and associated resource use.

Response: We appreciate the commenter feedback on the potential use of the GG functional items as part of the functional impairment level case-mix adjustment in the PDGM. We remind commenters that because these GG functional items are not required to be collected on the OASIS until January 1, 2019, we do not have the data at this time to determine the effect, if any, of these newly added items on resource costs during a home health period of care. Therefore, the GG functional items would not be used immediately upon implementation of the PDGM in CY 2020. We will continue to analyze all OASIS items, including the newly added GG functional items, after the implementation of the PDGM, to determine if the data supports any refinements to the case-mix adjustments. The goal is to keep only those items that are reliable, validated, have an impact on resource utilization, and address quality outcomes in order to ultimately decrease the number of OASIS items and reduce burden. Likewise, while the GG functional items may be able to play an important role in the HHVBP Model and HH QRP in monitoring for quality outcomes, their consideration for use in the PDGM would be to identify their relationship to resource utilization to more accurately align payment with home health costs.

Comment: Commenters stated that the functional impairment level thresholds

do not fully capture the functional impairments that translate to the actual resources needed on the home health plan of care. Many commenters believe that the functional impairment level adjustment is relatively small and inadequate to reimburse for patients with chronic care needs potentially creating access issues for people who are chronically ill and may require a prolonged period of home health care. Many commenters remarked that HHAs would not admit these types of patients or would cut back on the number of therapy visits provided, especially now that therapy thresholds will be removed in CY 2020. Several commenters stated that the PDGM favors only patients who are expected to improve and not those who require ongoing, maintenance therapy but do not group into one of the predominantly therapy groups and therefore is counter to the provisions in the Jimmo Settlement Agreement.

Response: We believe that the functional impairment level adjustment would adequately capture the level of functional impairment based on patient characteristics reported on the OASIS. The PDGM not only uses the same five OASIS items used in the current HH PPS to determine the functional case-mix adjustment (M1810, M1820, M1830, M1830, M1850, and M1860), but adds two additional OASIS items (M1800 and M1033) to determine the level of functional impairment. The structure of categorizing functional impairment into Low, Medium, and High levels has been part of the home health payment structure since the implementation of the HH PPS. The current HH PPS groups home health episodes using functional scores based on functional OASIS items with similar average resource use within the same functional level, with approximately a third of episodes classified as low functional score, a third of episodes are classified as medium functional score, and a third of episodes are classified as high functional score. Likewise, the PDGM groups' home health periods of care using functional impairment scores based on functional OASIS items with similar resource use and has three levels of functional severity: low, medium and high. However, the PDGM differs from the current HH PPS functional variable in that the three functional impairment level thresholds in the PDGM vary between the clinical groups. The PDGM functional impairment level structure accounts for the patient characteristics within that clinical group associated with increased resource costs affected by functional impairment. This is to further ensure that payment is more

accurately aligned with actual patient characteristics and resource needs. As such, we believe the more granular structure of these functional levels provides the information needed on functional impairment and allows greater flexibility for therapists to tailor a more patient-centered home health plan of care to meet the individualized needs of their patients.

We disagree that the functional impairment level case-mix payment adjustment is inadequate and that the PDGM would inhibit access to care for those with patients with complex and/or chronic care needs and high functional impairments. The absence of discipline-related therapy thresholds allows for a more equitable distribution of services based on patient needs, including needs for chronically ill patients. We note that the PDGM is structured to capture patient characteristics, including functional impairment status, similar to the functional case-mix adjustment in the current HH PPS. As HHA-reported OASIS information determines the payment amounts for each of the functional levels, accurate reporting on the OASIS by HHAs will help to ensure that the case-mix adjustment is in alignment with the actual level of functional impairment.

We also disagree with the comment that the PDGM favors only those home health patients who are expected to improve, does not take into account patients with longer term maintenance therapy needs, and is counter to the provisions of the Jimmo Settlement Agreement. We remind commenters that the structure of the home health benefit requires a multidisciplinary approach, and the PDGM promotes the provision of not only therapy services, but skilled nursing, home health aide, and medical social services as well. The clinical groups, as well as the functional impairment level case-mix adjustment, account for the full range of services available under the Medicare home health benefit. We believe that the functional impairment level adjustment compensates for the resource needs of those with functional impairment and ongoing therapy needs, and therefore does not endorse one type of patient over another. There has never been an expectation that only patients who demonstrate the ability to improve are eligible for the Medicare home health benefit. We have educated the MACs extensively to ensure that any medical review of claims for cognitively or functionally impaired patients who are receiving maintenance therapy to prevent further deterioration, are doing

so according to the parameters within the *Jimmo* Settlement Agreement.

We believe adding a more robust and granular functional impairment level adjustment should preserve, and potentially increase access to therapy services for vulnerable patients who may not otherwise have received needed therapy services, including those with complex and/or chronic care needs. As such, we would expect continued admissions of these patient populations with therapy visits provided in accordance with physician orders as documented on the plan of care, including the frequency and duration of these orders. We remind HHAs that the PDGM case-mix adjusters work in tandem to reflect a patient's resource needs. The overall payment for a home health period of care under the PDGM is determined by the cumulative effect of all of the variables used in the case-mix adjustments. Ultimately, the goal of the PDGM is to provide more accurate payment based on the identified resource use of different patient groups.

The PDGM is not limiting or prohibiting the provision of therapy services or the number of home health periods of care, nor is there a reduction to the overall base rate of home health payment. The commenters imply that HHAs would "cherry pick" the type of patients to admit primarily based on Medicare payment under the PDGM and that care decisions, including the number of therapy visits, are determined solely on profitability of patients. As such, any potential access issues would be the result of a change in HHA behavior in response to the removal of therapy thresholds to maximize margins of a bundled payment rather than the result of a case-mix adjustment model that seeks to more accurately pay for home health services. Manipulating visit patterns, including the type and number of visits provided, and/or admitting only certain patient populations to maximize payment is counter to the purpose of a prospective payment system and the intent of a patient-driven Medicare home health benefit. Furthermore, this could result in a violation of the home health CoPs and may signal program integrity issues. We will continue to monitor the impact of all of the case-mix adjustments in the PDGM to determine if any changes to utilization are occurring, especially as they relate to the provision of therapy. This may involve, but is not limited to, comparative analysis of utilization patterns prior to and after the implementation of the PDGM and could result in additional enforcement actions

as a result of any program integrity concerns. Likewise, the BBA of 2018 requires that we calculate the 30-day budget-neutral payment amount based on assumed behavior changes resulting from the implementation of a 30-day unit of payment and the PDGM. The law also requires that we annually analyze the impact of differences between the assumed and actual behavioral changes on estimated aggregate expenditures for CYs 2020 through 2026 and to make any payment amount adjustments, either upwards or downwards, accordingly.

Comment: Some commenters remarked that the PDGM diminishes and devalues the role physical, occupational, and speech language pathology therapists play in quality outcomes by alleviating risks of increased falls, emergency room visits, re-hospitalizations, improving or maintaining functional level, and keeping patients in their homes. Other commenters stated that minimization of the importance of the home health therapy disciplines would cause therapists to lose their jobs in home health. Commenters said that access to home therapy will be significantly curtailed as a result and functional outcomes would be negatively impacted. These commenters remarked that the PDGM appears to be counter to the Triple Aim: improving the patient experience of care (including quality and satisfaction); improving the health of populations; and reducing the per capita cost of health care.

Response: We disagree that the PDGM diminishes or devalues the clinical importance of therapy. The musculoskeletal and neurological rehabilitation groups under the PDGM recognize the unique needs of patients with musculoskeletal or neurological conditions who require therapy as the primary reason for home health services. For the other clinical groups, we note that the 30-day base payment amount includes therapy services, even if the primary reason for home health is not for the provision of therapy. The functional impairment level adjustment in conjunction with the other case-mix adjusters under the PDGM, aligns payment with the costs of providing services, including therapy.

We agree with commenters that the role of the physical, occupational, and speech language pathology therapists is important in quality outcomes and the prevention of adverse events, such as falls and emergency room visits, and that these disciplines are important in helping patients remain in their own homes. However, we note that the goal of the PDGM is to provide appropriate payment based on the identified

resource use of different patient groups; not to encourage, discourage, value, devalue, or promote one type of skilled care over another.

We do not expect HHAs to make personnel decisions solely based on a change to the HH PPS case-mix methodology as the requirements for providing home health services have not been changed. Under the Medicare home health benefit, skilled professional services include skilled nursing services, physical therapy, speech-language pathology services, and occupational therapy, as specified in § 409.44, and dependent services include home health aide services and medical social work services, as specified in § 409.45. Skilled professionals who provide services to HHA patients directly or under arrangement must participate in the coordination of care. Additionally, we note that the home health CoPs at § 484.60 require that each patient receive an individualized written plan of care that must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including identification of the responsible discipline(s).

Concerns regarding HHAs changing the way they provide services to eligible beneficiaries, specifically therapy services, should be mitigated by the more granular functional impairment level adjustment (for example, functional thresholds which vary between each of the clinical groups). The functional impairment level case-mix adjustment is reflective of the resource costs associated with the reported OASIS items and therefore ensures greater payment accuracy based on patient characteristics. We believe that this approach will help to maintain and could potentially increase access to needed therapy services. We remind HHAs that the provision of home health services should be based on patient characteristics and identified care needs. This could include those patients with complex and/or chronic care needs, or those patients requiring home health services over a longer period of time or for which there is no measureable or expected improvement.

Finally, we believe that the PDGM is in alignment with the tenants of the CMS Triple Aim to provide better care for individuals; promote better health outcomes for populations; and lower health care costs. The PDGM does so by taking a patient-driven approach over a volume-based approach by using patient characteristics, rather than arbitrary thresholds of visits that do not necessarily equate to better outcomes or

lower costs. The PDGM seeks to better define the services needed by home health beneficiaries. We believe that developing a case-mix system that provides a clearer picture as to the services provided under the Medicare home health benefit can help promote efficiencies in achieving desired patient outcomes.

Comment: Several commenters expressed concern over how CMS would ensure that necessary therapy visits are provided to home health beneficiaries. These commenters remarked that it is unclear how CMS intends to capture an accurate assessment of the services delivered during the home health period of care, particularly physical therapy, occupational therapy, and/or speech-language pathology services. Other comments stated that they fail to see how medical review is a sufficient option to remedy the consequences associated with delivering inadequate care, as they said that medical review does nothing that would allow care delivery to be modified during the period of care. A few commenters urged CMS to use “accountability mechanisms,” such as medical review, and recommended that the agency analyze the medical review findings and publically report any observed patient care trends via Home Health Compare.

Response: The purpose of the changes to the case-mix adjustment methodology is to more accurately align home health payments with the costs of providing care. Other accountability mechanisms, such as survey and certification of HHAs, are the most appropriate ways to ensure quality and safety for Medicare home health recipients. Quality is also determined through other mechanisms, such as the HH QRP and the HHVBP Model.

The new home health CoPs are more detailed in the expectations of the provision of needed home health services. Specifically, the CoPs at § 484.60 require that patients are accepted for treatment on the reasonable expectation that an HHA can meet the patient’s medical, nursing, rehabilitative, and social needs in his or her place of residence. Services are required to be identified in an individualized written plan of care, including any revisions or additions. The individualized plan of care must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including identification of the responsible discipline(s), and the measurable outcomes that the HHA anticipates will occur as a result of

implementing and coordinating the plan of care.

It is difficult to proactively determine that care is “inadequate” or “of poor quality” given that we do not know the type, frequency or quality of services until after those services are provided. The volume of services provided does not necessarily equate with higher quality of care.

We believe that the home health CoPs provide the requirements to promote and ensure quality home health care. However, as we indicated in the CY 2019 HH PPS proposed rule, we will continue to analyze utilization trends, including therapy visits as reported on home health claims, to identify any issues that may warrant any quality or program integrity intervention.

Comment: Some commenters expressed concerns that Medicare beneficiaries’ functional outcomes may significantly decline following PDGM implementation because the provision of the therapy services would be reduced without the extra payment for increased therapy services. These commenters stated that research has shown a significant correlation between volume of therapy and improvement in outcomes. Some commenters stated adoption of the PDGM could reverse the progress in patient outcomes that was seemingly ignited by a “financial incentive” to increase therapy visits versus skilled nursing visits.

Response: We disagree that patients’ functional outcomes would significantly decline following PDGM implementation. We reference a study conducted by RAND contrasting the effects of two payment reforms for home health agencies, specifically comparing the Interim Prospective Payment System (IPS) and the Prospective Payment System (PPS). This study did not show worsening patient outcomes (that is, increased hospitalizations or mortality) when there was a transition from one payment system to another (that is, from the IPS to the PPS). In this particular study, the analysis also showed both payment reforms had limited effects on costs in other post-acute settings, and limited effects on patient outcomes as the study noted that there was not any substantial increase in hospital readmissions or patient mortality after the implementation of the PPS.²³ Furthermore, in its March, 2010 report, MedPAC stated that higher home health spending is not yielding better

outcomes. In this report, MedPAC stated that undesirable outcomes (for example, unnecessary complications) may result in additional payments, and sectors with more than adequate payments may have little incentive to improve quality.²⁴

We believe that the structure of the PDGM is more patient-driven than the current case-mix system and more accurately represents the patient characteristics that will correspond to an appropriate individualized care plan to provide those needed services. We believe that the PDGM will allow for more tailored, appropriate quality of care and removes the financial incentive to focus on the volume of care and not patient needs. By keeping patient characteristics at the center of the case-mix adjustment methodology, we believe that patient needs will be more accurately addressed and that this has the potential to result in care plan goal achievement and desired patient outcomes.

Comment: Another commenter remarked that using the term “Functional Level” with a score of low-medium-high is confusing. This commenter stated that this will confuse providers into believing the reference is to low, medium, or high functional level. It would be clearer to refer to this measure as a “Functional Impairment Level” in which case a low, medium, or high functional impairment would be properly indicated.

Response: As explained in the CY 2019 HH PPS proposed rule, a home health period of care receives points based on each of the responses associated with the proposed functional OASIS items which are then converted into a table of points corresponding to increased resource use. That is, the higher the points, the higher the functional impairment. As such, we agree that adding the term “impairment” when referring to the functional level adjustment is appropriate.

Comment: A few commenters stated that the PDGM case-mix variables, including the functional impairment level adjustment would make it more difficult to manage costs and revenues for patients with high functional impairments. Some commenters disagreed with the removal of therapy thresholds as they asserted that the increased payments with the thresholds allowed for the provision of adequate therapy services. These commenters indicated that the reductions in payment for therapy visits would result

²³ Huckfeldt, P., Sooda, N., Escarcea, J., Grabowski, D., Newhouse, J. *Effects of Medicare payment reform: Evidence from the home health interim and prospective payment systems.* Journal of Health Economics (34) 1–18. March, 2014. <https://doi.org/10.1016/j.jhealeco.2013.11.005>.

²⁴ http://www.medpac.gov/docs/default-source/reports/Mar10_EntireReport.pdf.

in a decrease in HHA viability and would force many HHAs to go out of business.

Response: We remind commenters that the removal of therapy thresholds for CY 2020 and subsequent years is required by section 1895(b)(4)(B)(ii) of the Act, as added by section 51001 of the BBA of 2018, and therefore we are statutorily mandated to exclude therapy thresholds in the development of an alternate case-mix adjustment methodology effective January 1, 2020. We note that since 2000, under the Medicare home health benefit, HHAs receive a bundled payment for the provision of care to include skilled nursing; physical, occupational, and speech-language pathology therapy; medical social work; home health aides; and medical supplies. Under the PDGM, home health payments remain prospective payments similar to the current payment system, meaning an overall national, standardized base rate with case-mix adjustments. The structure of a prospective payment system is such that payment is based on a predetermined base rate regardless of the volume, frequency, or intensity of the actual service(s) provided. The case-mix adjustments provide additional payment to account for patient characteristics. As such, the overall payment amount is known to the HHA at the beginning of each home health episode and this fixed home health rate necessitates better management and estimation of costs and payments, and helps to motivate providers to be more efficient in the provision of quality care. Therefore, a home health bundled payment allows HHAs the discretion to allocate resources based on their knowledge of the patient and the services needed to meet the goals of the individualized home health plan of care. This would mean that the HHA would consider the most appropriate and efficient use of home health services based on patient needs. A bundled payment reduces the uncertainty in payment, affording the HHA more information to help manage revenues and costs in order to allocate resources accordingly.

Additionally, the Medicare home health benefit requires a multidisciplinary approach to care and the expectation is that HHAs provide the full range of services under the benefit to all eligible beneficiaries, and not solely therapy services. As such, developing a business model designed to target only those patients requiring therapy in order to maximize Medicare payment is counter to the requirements under the benefit. It also places the HHA at financial risk if payment is

reliant only on a specific patient population. For those HHAs who do provide the full range of services and do not target only those patients for whom they can maximize payment based on therapy thresholds, we believe that the functional impairment level adjustment provides sufficient additional payment across all clinical groups. This would include those patients who are receiving home health services primarily for other skilled needs but who may also require therapy services as part of their home health plan of care. The PDGM is clinically-based, meaning it relies more heavily on patient characteristics to place home health periods of care into clinically meaningful payment categories. These patient characteristics also help home health clinicians differentiate between the services needed by home health patients. We believe that a patient-driven approach to case-mix adjusting payment better clarifies the services provided under the Medicare home health benefit. Therefore, we believe this patient-driven approach better promotes efficiencies in the provision of care based on actual patient needs and will make it easier for HHAs to manage revenues and costs.

Finally, to support HHAs in evaluating the effects of the proposed PDGM, CMS is providing, upon request, a Home Health Claims-OASIS Limited Data Set (LDS).²⁵ Additionally, CMS has posted an interactive PDGM Grouper Tool on the HHA Center web page that will allow HHAs to determine case-mix weights for their patient populations.²⁶

Comment: Several commenters stated that inclusion of caregiver availability and support should be part of the functional level payment adjustment in the PDGM because they report that a lack of caregiver support plays a significant role in a patient's overall functional level and resource needs especially as they relate to ADLs and IADLs. Another commenter remarked that research has shown non-compliance and readmission risk is higher when other psychosocial factors are present. Several commenters recommended that the functional level include OASIS items related to social determinants of health, such as those associated with caregiver support.

Response: We understand the value of caregiver support for home health patients and its potential to affect resource utilization and the inclusion of

caregiver variables has been examined several times since the development of the current HH PPS. As explained in the FY 2001 HH PPS final rule (65 FR 41145), we examined the usefulness of caregiver factors but found them to be only minimally helpful in explaining or predicting resource use. We found that variables on the availability of a caregiver had no impact on average resource cost and only a modest impact after controlling for other patient characteristics. We stated that we recognized that adjusting payment in response to the presence or absence of a caregiver may be seen as inequitable by patients and their families. To the extent the availability of caregiver services, particularly privately paid services, reflects socioeconomic status differences, reducing payment for patients who have caregiver assistance may be particularly sensitive. Furthermore, adjusting payment for caregiver factors may introduce new and negative incentives into family and patient behavior. It is questionable whether Medicare should adopt a payment policy that could weaken informal familial supports currently benefiting patients at times when they are most vulnerable (65 FR 41145). Similarly, when we re-examined caregiver assistance as a potential case-mix variable in the CY 2008 HH PPS proposed rule to analyze the payment adequacy of the current four-equation model, we found that for patients without a caregiver, on average, episodes would be "underpaid" (72 FR 25361). However, the score to be gained by adding the variable was not large and the overall ability of the four-equation model to explain resource costs was improved only minimally by adding this variable. As such, we did not propose that a caregiver variable be added to the case-mix model at that time.

When we re-examined the OASIS caregiver items for possible inclusion in the functional impairment level case-mix adjustment in the PDGM, we found inverse patterns in resource use (82 FR 35319). We examined OASIS items associated with types and sources of caregiver assistance and frequency of ADL/IADL assistance. These items assess the ability and willingness of non-agency caregivers (such as family members, friends, or privately paid caregivers) to provide categories of assistance needed by the patient, including ADL/IADL assistance, medication administration, and management of equipment. As responses to these items generally are not based on direct observation by the clinician conducting the assessment,

²⁵ https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures-Data-Agreements/DUA_-_NewLDS.html.

²⁶ <https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html>.

this presents a limitation for use in a case-mix adjustment as the accuracy of the responses cannot be easily validated. Patients or caregivers may overestimate or underestimate their ability or willingness to assist in the patient's care. Likewise, analysis of these items generally showed that an increased need for assistance had a negative impact on resource costs, meaning that as need for assistance increased, costs decreased. We believe this is clinically counterintuitive and, as outlined in both the Medicare Home Health Prospective Payment System: Case-Mix Methodology Refinements Overview of the Home Health Groupings Model technical report²⁷ and the CY 2018 and CY 2019 HH PPS proposed rules (82 FR 35270 and 83 FR 32340), we excluded any OASIS items that had a negative relationship with resource costs. Including these items would only serve to reduce the home health period of care payment. As such, the current data analysis findings we conducted on caregiver variables weaken the assertion that failure to adjust for caregiver factors could render payments inadequate.

Finally, we continue to believe that including this kind of variable in the case-mix system raises significant policy concerns. We maintain that a case-mix adjustment should not discourage assistance from family members of home care patients, nor should it make patients believe there is some financial stake in how they report their familial supports during their convalescence. We have concerns that adjusting payment in response to the absence of a caregiver would introduce negative incentives with adverse effects on home health Medicare beneficiaries.

Comment: Several commenters recommended that cognition, pain and dyspnea should be included as functional level determinants as they affect functional performance and trajectory for improvement. Many commenters supported the inclusion of cognitive items as part of the functional case-mix adjustment, and noted that there is a correlation between cognitive status and functional impairment. A few commenters suggested that OASIS item M1242, Frequency of Pain interfering with Activity, should be included as part of the functional level items in the PDGM. These commenters stated that pain directly impacts functional performance. These same commenters remarked that PT and OT can directly reduce pain thus improving the patient's quality of life.

²⁷ <https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf>.

Response: The current HH PPS does not use OASIS items associated with IADLs or cognition. We agree with commenters that the relationship between cognition and functional status is important and well-documented in health care literature. We discussed our analysis and rationale for evaluating all of the OASIS items related to function, including the relationship between cognitive functioning and resource use, extensively in both the technical report²⁸ and the CYs 2018 and 2019 HH PPS proposed rules (82 FR 35319, 83 FR 32404). Empirically, it appears that cognition does impact functionality, and initially these items were included in the PDGM. Counterintuitively, however, resource use declined as cognitive status worsened. This negative relationship with resource use was consistent throughout all levels of cognitive functioning as assessed on the OASIS, including mild impairment. While we cannot explain this phenomenon from OASIS or home health claims alone, anecdotally we have heard that while cognitive impairment may intuitively signal increased resource use, the cognitive items are not currently payment items and therefore do not receive the same attention as the payment items when completing the OASIS. Likewise, we have received reports that as cognition declines, individuals often become more dependent on caregivers for functional tasks and thus the home health clinician is not performing those tasks during a visit. We frequently hear from clinicians that as it becomes increasingly difficult to teach the cognitively impaired patient how to perform ADLs/IADLs, teaching the caregiver to perform the functional tasks is more efficient or beneficial. Additionally, we have been told it that generally takes more time to teach and train the cognitively impaired patient to perform a functional task so the clinician may simply perform the functional task him or herself as the patient's ability to independently perform these tasks progressively declines. All of these anecdotes potentially could explain the inverse relationship between cognitive impairment and resource use.

As discussed previously, the OASIS cognitive items are not used for a payment adjustment under the current HH PPS, but most of the proposed functional items are. As commenters have stated, there is potentially more HHA focus on the OASIS payment items, which could explain why the functional items show a positive

²⁸ <https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf>.

relationship to resource use while the cognitive items do not. As many commenters have stated and as supported in the research, there is a relationship between cognition and functional status. As such, we believe that the functional items included in the functional impairment level case-mix adjustment provide a reasonable proxy for cognitive status given their interrelatedness. Because of the negative relationship between the OASIS cognitive items and resource use, we decided not to include the items as part of the functional adjustment in the PDGM but will continue to analyze their inclusion once the PDGM is implemented.

Similarly, we also examined pain and dyspnea OASIS items for inclusion in the case-mix adjustment methodology including OASIS items M1242, Pain and M1400, Shortness of Breath. While M1242, Pain, is used in the current HH PPS, this was shown to have only a minimal relationship with resource use in the current payment model. Additionally, we believe that this one item alone may not be robust enough to fully capture the pain presentation of the patient and its impact on resource utilization and therefore it was dropped from consideration. While M1400, Shortness of Breath, is also used in the current HH PPS, it too shows minimal impact on resource use. We did not include M1400 in the PDGM case-mix adjustment methodology because we believe the more granular ICD-10 codes that describe respiratory conditions, more accurately capture this patient characteristic. Again, we refer commenters to the more detailed discussion on why certain OASIS items were included or excluded from the model, the "Overview of the Home Health Groupings Model Technical Report"²⁹ and the CY 2018 HH PPS proposed rule (82 FR 35307).

Comment: The majority of commenters agreed that the elimination of therapy thresholds is appropriate because of the current financial incentive to overprovide therapy services. However, these commenters believe that the functional impairment level adjustment is not an adequate proxy to ensure the provision of therapy services needed for patients requiring multiple disciplines of therapy or the frail elderly with multiple chronic conditions and associated functional impairment. A few commenters questioned whether CMS has evidence

²⁹ "Overview of the Home Health Groupings Model" technical report, Appendix Exhibit A7-1 on the HHA Center web page (<https://www.com.gov/center/provider-type/home-health-agency-hha-center.html>).

that Medicare beneficiaries have received “too much” therapy, or that the functional outcomes of Medicare beneficiaries receiving home health services have suffered, under the current payment system. These commenters stated that given the ever-increasing effort to promote the delivery of care in the home and community settings, it is imperative that the Medicare program continue to incentivize providers to deliver care in non-facility-based settings while also ensuring that patients may continue to receive the highest quality of care that aligns with their preferences, desires, and needs.

Response: We agree that the therapy thresholds have created an incentive to overprovide therapy services that are not in alignment with patient characteristics and care needs. Section 1895(b)(4)(B)(ii), as added by section 51001 of the BBA of 2018, requires that CMS eliminate the use of therapy thresholds as part of the case-mix adjustment methodology beginning in CY 2020. We note that the purpose of the functional impairment level case-mix adjustment is not meant to act as a direct proxy to replace the current therapy thresholds. As noted, the presence of the therapy thresholds provided an incentive to overprovide services and their removal deflates that financial incentive to help ensure that therapy services are based on actual patient needs. However, we recognized that in order to account for levels of functional impairment and to help ensure that necessary therapy services are provided, the development of a functional impairment level case-mix adjustment with more granularity was necessary. We believe that the three PDGM functional impairment levels in each of the 12 clinical groups are designed to encourage therapists to determine the appropriate services for their patients in accordance with identified needs rather than an arbitrary threshold of visits.

The PDGM has other case-mix adjustments in addition to the functional impairment level to adjust payment for those patients requiring multiple therapy disciplines or those chronically ill patients with significant functional impairment. We believe that also accounting for timing, source of admission, clinical group (meaning the primary reason the patient requires home health services), and the presence of comorbidities will provide the necessary adjustments to payment to ensure that care needs are met based on actual patient characteristics.

To address comments about evidence regarding “too much” therapy, we

remind commenters that analysis has repeatedly shown that the current HH PPS therapy thresholds promote the provision of care based on increased payment associated with each of these thresholds as opposed to actual patient needs. In the CY 2018 HH PPS proposed rule, analysis of home health claims shows that the average episode payment by the number of therapy visits for episodes with at least one therapy visit increases sharply just over payment thresholds at 6, 7, and 16 (82 FR 35276).

Furthermore, CMS analysis demonstrates that the average share of therapy visits across all 60-day episodes of care increased from 9 percent of all visits in 1997, prior to the implementation of the HH PPS (see 64 FR 58151), to 39 percent of all visits in 2015 (82 FR 35276). We note that the therapy thresholds have been widely criticized by MedPAC who has recommended the removal of therapy thresholds for the past 5 years, as their analysis has repeatedly shown that Medicare payments for home health services have substantially exceeded costs. Additionally, the Senate Committee on Finance conducted an investigation and issued a report on therapy practices of four of the largest publically-traded home health agencies where three out of the four companies investigated encouraged therapists to target the most profitable number of therapy visits, even when patient need alone may not have justified such patterns. The Senate investigation also highlighted the abrupt and dramatic responses the home health industry has taken to maximize payment under the therapy threshold models (both the original 10-visit threshold model and under the revised thresholds implemented in the CY 2008 HH PPS final rule (72 FR 49762)). The report noted that, under the current HH PPS, HHAs have broad discretion over the number of therapy visits provided, and therefore have control of the single-largest variable in determining reimbursement and overall margins. The report recommended that CMS closely examine a future payment approach that focuses on patient wellbeing and health characteristics, rather than the numerical utilization measures.

We agree that most patients would prefer to receive services in their own home whenever feasible and the Medicare home health benefit affords a comprehensive range of services for eligible beneficiaries. However, we are cognizant that payment may affect practice patterns and our analysis has shown that visits vary in response to financial incentives. While the goal of the PDGM case-mix adjustments is to

align payment with actual patient characteristics, we are aware that practice patterns may shift upon implementation of a new case-mix methodology. Our goal is to protect patient choice and preferences as well as promote the provision of high quality, appropriate home care. As we have reiterated throughout this final rule with comment period, upon implementation of the PDGM, we will continue to examine the impact of all OASIS items on resource costs. Likewise, we will also examine any changes in the number of therapy visits provided that could indicate HHAs stunting on needed therapy services to determine whether any impacts warrant additional refinements to the case-mix adjustments under the PDGM.

Comment: Some commenters expressed concern that eliminating the therapy thresholds, which dominate the current HH PPS, would cause the unintended consequence of shifting patients to other home health disciplines, specifically nursing and home health aides, which would steer patients away from restorative therapies and ultimately increase Medicare costs. Some expressed concern about other disciplines providing therapy services outside of the scope of their practice. Some expressed reservations about possible misuse of aides to provide what should be skilled therapy, such as providing exercise programs or evaluating self-care needs and safety as a substitute for skilled therapy. These commenters state that both substitutions are inappropriate and may violate state licensure law, for example, the provision of therapy services by unqualified personnel.

Response: Regarding the comment that the removal of therapy thresholds would shift patients to other home health disciplines, we note that in the CY 2001 HH PPS final rule, we expressed concern over using a therapy utilization measure to determine home health payment because it could be susceptible to manipulation and may cause a shift away from home health nursing and other services. In this same rule, commenters expressed concern that implementing a therapy threshold would divert utilization of the home health benefit away from the frail elderly and in favor of the short-term patient (65 FR 41149). These concerns about the impact of the introduction of the therapy thresholds are the same concerns now expressed by commenters regarding the impact of the elimination of the therapy thresholds. In the CY 2001 rule, we stated that we would continue to review the use of a utilization variable in the payment

system over the long-term. As discussed previously in this section, there was a noted shift to increased therapy services after the implementation of the HH PPS with the therapy thresholds. We believe that the elimination of the therapy thresholds will remove the financial incentive to provide therapy solely for increased payment. As we are not adding any service utilization measure for nursing or home health aides, this would mitigate the financial incentive to provide more of those services solely for increased payment as well. Essentially, this would mean that no one home health discipline is favored or paid differently than any other discipline within the home health bundled payment and the plan of care would be patient-centered as opposed to payment-centered. We believe that elimination of the therapy thresholds is more in alignment with the intent of the home health benefit to be patient-centered and based on patient characteristics, such as functional status, and actual patient needs. Likewise, we expect that any services provided would be in accordance with all Federal and State laws, including all licensure requirements. The provision of skilled therapy services as part of a home health plan of care must also adhere to the home health CoPs, and substituting a home health aide to provide those skilled therapy services would be a violation of the CoPs (42 CFR 484.32).

We note that the goal of the PDGM is to provide appropriate payment based on the identified resource use of different patient groups; not to encourage, discourage, value, devalue, or promote one type of skilled care over another. Because there are no service utilization thresholds in the PDGM, we expect that HHAs will respond by adapting a business model based on more patient-centered care as opposed to payment-driven care.

Comment: Several commenters stated that the PDGM would reward inefficiency but not high quality outcomes by redistributing payments away from services such as physical, occupational and speech therapy. They remarked that this shift would make it harder for patients with high functional impairment to achieve quality outcomes.

Response: The intent of the PDGM is to more accurately apportion payment with the costs of providing care. We disagree that the redistribution of payments would reward inefficiency as the home health agency is already tasked with developing efficiencies within the current home health bundled payment. Additionally, the home health

quality reporting program (HH QRP), and the HH VBP Model contain outcome measures which are used, respectively, for the Home Health star ratings and a total performance score used to tie payments to quality performance for HHAs in certain states. As such, we believe that both the HH QRP and the HH VBP Model help to promote and ensure quality outcomes, whereas the PDGM is the mechanism for payment for services provided. Furthermore, regardless of level of functional impairment, we expect that HHAs always strive for efficiency and high quality outcomes for their patients. This is achieved through the appropriate provision of services in accordance with patient characteristics and physician orders as documented on the home health plan of care.

Final Decision: After review of public comments, we are finalizing the use of OASIS items: M1800, M1810, M1820, M1830, M1840, M1850, M1860 and M1033 for the functional impairment level case-mix adjustment under the PDGM. We are finalizing that a home health period of care receives points based on each of the responses associated with the functional OASIS items which are then converted into a table of points corresponding to increased resource use (see Table 28). The sum of all of these points results in a functional score which is used to group home health periods into a functional level with similar resource use. We are finalizing three functional levels of low impairment, medium impairment, and high impairment with approximately one third of home health periods from each of the clinical groups within each functional impairment level (see Table 29). For the implementation of the PDGM in CY 2020, we will update the functional points and functional thresholds as previously described based on analysis of CY 2018 home health claims, and using the most current version of the OASIS data set, to reflect any changes in resource use associated with these variables. Likewise, as articulated in the proposed rule and throughout this final rule with comment period, once the PDGM is implemented in CY 2020, we will continue to analyze the impact of all of the PDGM case mix variables to determine if any additional refinements need to be made to ensure that all variables used as part of the overall case-mix adjustment appropriately align home health payment with the actual cost of providing home health care services.

8. Comorbidity Adjustment

The proposed PDGM groups home health periods based on the primary

reason for home health care (principal diagnosis), functional level, admission source, and timing. To further account for differences in resource use based on patient characteristics, we proposed to use the presence of home health specific comorbidities as part of the overall case-mix adjustment under the PDGM. The home health-specific comorbidity list is based on the principles of patient assessment by body systems and their associated diseases, conditions, and injuries to develop larger categories of conditions that identified clinically relevant relationships associated with increased resource use. These broad, body system-based categories we proposed to use to group comorbidities within the PDGM included the following:

- Heart Disease.
- Respiratory Disease.
- Circulatory Disease and Blood Disorders.
- Cerebral Vascular Disease.
- Gastrointestinal Disease.
- Neurological Disease and Associated Conditions.
- Endocrine Disease.
- Neoplasms.
- Genitourinary and Renal Disease.
- Skin Disease.
- Musculoskeletal Disease or Injury.
- Behavioral Health (including Substance Use Disorders).
- Infectious Disease.

These broader categories were further refined into comorbidity subcategories to more accurately capture differences in resource use. All of the comorbidity diagnoses grouped into these comorbidity categories and subcategories are posted on the Home Health Agency web page and listed in the HHGM technical report, "Medicare Home Health Prospective Payment System: Case-Mix Methodology Refinements Overview of the Home Health Groupings Model", at the following link: <https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html>.

We originally proposed in the CY 2018 HH PPS proposed rule that if a period had at least one secondary diagnosis reported on the home health claim that fell into one of the proposed body-system based subcategories listed in that rule, the period would receive a comorbidity adjustment to account for higher costs associated with the comorbidity (82 FR 35309). A period would receive only one comorbidity adjustment regardless of the number of secondary diagnoses reported on the home health claim that fell into one of the subcategories. We received comments supporting the inclusion of a comorbidity adjustment, but the

majority of commenters also stated that the presence of multiple comorbidities has more of an effect on home health resource use than a single comorbidity. We agreed with commenters that the relationship between comorbidities and resource use can be complex and that a single adjustment, regardless of type or number of comorbidities, may be insufficient to fully capture the resource use of a varied population of home health beneficiaries. A TEP was convened and we conducted additional analyses on methodologies for incorporating multiple comorbidity adjustments into the PDGM. There was general agreement that most home health patients have multiple conditions which increase the complexity of their care and affects the ability to care for one's self at home (83 FR 32375).

Taking these comments into consideration, CMS conducted additional analysis on the effect of comorbidities on resource utilization during a home health period of care. The goal of our analyses was to identify those clinically and statistically significant comorbidities and interactions that could be used to further case-mix adjust a 30-day home health period of care. In the CY 2019 HH PPS proposed rule, we described the methodology used to identify, group, and appropriately weight comorbidity subgroups and interactions between subgroups (83 FR 32375). As a result of these analyses, we identified that there were certain individual comorbidity subgroups and interactions of the comorbidity subgroups (for example,

having diagnoses associated with two of the comorbidity subgroups) which could be used as part of the comorbidity case-mix adjustment in the PDGM. This meant that patients with certain comorbidities and interactions of certain comorbid conditions have home health periods of care with higher resource use than home health periods of care without those comorbidities or interactions. Specifically, we identified individual comorbidity subgroups that were statistically and clinically significant for case-mix adjustment and these are identified in Table 30. From the individual comorbidity subgroups, we then identified a subset of statistically and clinically significant comorbidity interactions for case-mix adjustment and these are identified in Table 31.

In the CY 2019 HH PPS proposed rule, we proposed three mutually exclusive levels of comorbidity case-mix adjustment that depend on the presence of certain secondary diagnoses codes: No Comorbidity Adjustment, Low Comorbidity Adjustment, and High Comorbidity adjustment. We proposed that home health 30-day periods of care can receive a comorbidity payment adjustment under the following circumstances:

- *Low comorbidity adjustment:* A 30-day period of care would receive a low comorbidity adjustment if there is a reported secondary diagnosis that falls within one of the home-health specific individual comorbidity subgroups, as listed in Table 30, for example, Heart 11, Cerebral 4, etc., associated with higher resource use, or;

- *High comorbidity adjustment:* A 30-day period of care would receive a high comorbidity adjustment if a 30-day period has two or more secondary diagnoses reported that fall within one or more of the comorbidity subgroup interactions, as listed in Table 31, for example, Heart 11 plus Neuro 5, that are associated with higher resource use.

A 30-day period would receive no comorbidity adjustment if no secondary diagnoses exist or none meet the criteria. A 30-day period of care can receive only one comorbidity adjustment—low or high—regardless of the number of subgroups or subgroup interactions. We proposed that the low comorbidity adjustment amount would be the same across the individual subgroups and the high comorbidity adjustment would be the same across the subgroup interactions. Table 46 in the CY 2019 HH PPS proposed rule showed the average resource use by comorbidity adjustment (83 FR 32411).

With dividing the MMTA clinical group into subgroups as finalized in section III.E.6 of this final rule with comment period, we note that the number of comorbidity subgroups in both the low and high comorbidity adjustment is higher than as described in the CY 2019 HH PPS proposed rule. This more recent analysis of CY 2017 home health claims results in 13 comorbidity subgroups which would receive the low comorbidity adjustment and 34 comorbidity subgroup interactions which would receive the high comorbidity adjustment (see Tables 30 and 31).

TABLE 30: LOW COMORBIDITY ADJUSTMENT SUBGROUPS

Comorbidity Subgroup	Description
Cerebral 4	Includes sequelae of cerebral vascular diseases
Circulatory 10	Includes varicose veins with ulceration
Circulatory 9	Includes acute and chronic embolisms and thrombosis
Heart 10	Includes cardiac dysrhythmias
Heart 11	Includes heart failure
Neoplasms 1	Includes oral cancers
Neuro 10	Includes peripheral and polyneuropathies
Neuro 11	Includes diabetic retinopathy and other blindness
Neuro 5	Includes Parkinson's disease
Neuro 7	Includes hemiplegia, paraplegia, and quadriplegia
Skin 1	Includes cutaneous abscess, cellulitis, lymphangitis
Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of June 30, 2018).

TABLE 31: HIGH COMORBIDITY ADJUSTMENT INTERACTION SUBGROUPS

Comorbidity Subgroup Interaction	Comorbidity Subgroup	Description	Comorbidity Subgroup	Description
1	Behavioral 2	Includes depression and bipolar disorder	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
2	Cerebral 4	Includes sequelae of cerebral vascular diseases	Circulatory 4	Includes hypertensive chronic kidney disease
3	Cerebral 4	Includes sequelae of cerebral vascular diseases	Heart 10	Includes cardiac dysrhythmias
4	Cerebral 4	Includes sequelae of cerebral vascular diseases	Heart 11	Includes heart failure
5	Cerebral 4	Includes sequelae of cerebral vascular diseases	Neuro 10	Includes peripheral and polyneuropathies
6	Circulatory 10	Includes varicose veins with ulceration	Endocrine 3	Includes diabetes with complications
7	Circulatory 10	Includes varicose veins with ulceration	Heart 11	Includes heart failure
8	Circulatory 4	Includes hypertensive chronic kidney disease	Skin 1	Includes cutaneous abscess, cellulitis, lymphangitis
9	Circulatory 4	Include hypertensive chronic kidney disease	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
10	Circulatory 4	Include hypertensive chronic kidney disease	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
11	Circulatory 7	Includes atherosclerosis	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
12	Endocrine 3	Includes diabetes with complications	Neuro 5	Includes Parkinson's disease
13	Endocrine 3	Includes diabetes with complications	Neuro 7	Includes hemiplegia, paraplegia, and quadriplegia
14	Endocrine 3	Includes diabetes with complications	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
15	Endocrine 3	Diabetes with complications	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
16	Heart 10	Includes cardiac dysrhythmias	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
17	Heart 11	Includes heart failure	Neuro 10	Includes peripheral and polyneuropathies
18	Heart 11	Includes heart failure	Neuro 5	Includes Parkinson's disease
19	Heart 11	Includes heart failure	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
20	Heart 11	Includes heart failure	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
21	Heart 12	Includes other heart diseases	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
22	Heart 12	Includes other heart diseases	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
23	Neuro 10	Includes peripheral and polyneuropathies	Neuro 5	Includes Parkinson's disease
24	Neuro 3	Includes dementias	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
25	Neuro 3	Includes dementias	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
26	Neuro 5	Includes Parkinson's disease	Renal 3	Includes nephrogenic diabetes insipidus
27	Neuro 7	Includes hemiplegia, paraplegia, and quadriplegia	Renal 3	Includes nephrogenic diabetes insipidus

28	Renal 1	Includes Chronic kidney disease and ESRD	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
29	Renal 1	Includes Chronic kidney disease and ESRD	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
30	Renal 3	Includes nephrogenic diabetes insipidus	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
31	Resp 5	Includes COPD and asthma	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
32	Resp 5	Includes COPD and asthma	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
33	Skin 1	Includes cutaneous abscess, cellulitis, lymphangitis	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
34	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of June 30, 2018).

We solicited comments on the comorbidity case-mix adjustment in the PDGM, which includes three comorbidity levels: No Comorbidity, Low Comorbidity, and High Comorbidity Adjustment. We also invited comment on the payments associated with the Low and High Comorbidity Adjustment to account for increased resource utilization resulting from the presence of certain comorbidities and comorbidity interactions. These comments are summarized in this section along with our responses.

Comment: The majority of commenters were generally supportive of the change in the comorbidity adjustment in the PDGM to include both a low and high comorbidity adjustment and believe that adding the Low and High Comorbidity adjustment will yield a more accurate and robust payment that accounts for the additional resource intensity needed to care for patients with multiple comorbidities. Commenters stated that it is appropriate to examine the relationship of reported comorbidities on resource utilization to ensure that payment is in alignment with the actual costs of providing care. Several commenters encourage ongoing monitoring to ensure that subcategories of diagnoses and associated comorbidity payment adjustments remain appropriate and adequate. Several commenters believe the comorbidity adjustment should be expanded since as proposed it would only apply to only a small proportion of patients compared to the number of home health patients with multiple chronic conditions. This would result in providers facing financial difficulty in caring for medically complex patients. A commenter urged us to expand the Low Comorbidity Adjustment criteria. Another commenter believe the comorbidity adjustment was overly simplistic and that it should incorporate

social determinants of health. The commenter also suggested inclusion additional comorbidity adjustments levels, including moderate and very high.

Response: We thank the commenters for their support regarding a comorbidity case-mix adjustment that accounts for the interaction between multiple comorbid conditions. We believe that this change for the PDGM (compared to the comorbidity adjustment proposed under the HHGM) addresses stakeholder comments regarding the impact of the presence of multiple comorbidities and their interactions on resource utilization. This change also helps to ensure that payment is more in alignment with the actual costs of providing care.

We agree that continued monitoring is needed to understand how the PDGM, including the comorbidity adjustment, affects home health patients and providers and inform future refinements. While we are aware of the prevalence of comorbidities in the Medicare home health population, we note that the average number of comorbidities in the aggregate becomes the standard within that population for the purpose of payment. For example, if the Medicare home health patient population has an average of three comorbidities then this is already factored into the base rate given that this rate represents the average home health payment for the average patient. The case-mix adjustment process recognizes increased resource use beyond the average. If the “average” patient under home health is multi-morbid, then additional resource use is not evident as the data reflects this average.

As noted in the CY 2019 HH PPS proposed rule, the comorbidity subgroups were selected through a stepwise process that identified clinically and statistically meaningful diagnosis-based comorbidity groups that

were associated with higher resource use than the average or that would be indicated by examining clinical and functional groups, admission source, and timing characteristics. As such, the comorbidity subgroups were meant to identify only those cases when resource use was higher than the median when accounting for other attributions of the patient. A similar process was used to identify the comorbidity subgroup interactions that would result in a high comorbidity adjustment. We agree that social determinants of health is an important consideration in providing effective patient-centered health care, and we thank the commenter for raising this point. However, the comorbidity adjustment in the PDGM is meant to capture clinical conditions that are present that affect resource utilization under a home health plan of care.

We anticipate that we would annually recalibrate the PDGM case-mix weights, which would include the comorbidity adjustment. This would be similar to the annual recalibration of case mix weights under the current HH PPS. Therefore, this could mean additions or subtractions of comorbidity subgroups and/or comorbidity subgroup interactions in the low and/or high comorbidity adjustment groups in the future. We will continue to analyze and monitor reported secondary diagnoses to inform the need for any future refinements to the comorbidity adjustment under the PDGM.

Comment: Some commenters remarked that the comorbidity adjustment would provide insufficient payment for providers and that not enough periods of care would receive a comorbidity adjustment even though the treatment of home health patients with comorbidities is commonplace. Another commenter stated that the average amount of \$35 for low comorbidity adjustment and \$350 for high comorbidity adjustment is out of sync

with the costs of serving these complex beneficiaries. Another commenter stated that the comorbidity adjustment is not adequate to cover ancillary services. These same commenters wrote that this would expose a high proportion of HHAs to additional risk and recommended that CMS return to its' comorbidity payment adjustment as proposed under the HHGM in the CY 2018 HH PPS proposed rule or to expand both the application and the value of the PDGM's low comorbidity adjustment so that it would more fully cover the frequent instances in which more complex care is provided to those beneficiaries with comorbid conditions.

Response: The payments associated with the low and high comorbidity adjustment are the result of actual resource utilization as reported on home health claims. As detailed in both the CY 2018 HH PPS proposed rule (82 FR 35322) and the CY 2019 HH PPS proposed rule (83 FR 32407), we analyzed home health claims to determine the actual resource utilization associated with the presence of certain comorbid conditions. We remind commenters that the additional diagnoses used for analysis are reported by the HHAs themselves and therefore we could only analyze those comorbidities reported, whether or not beneficiaries receiving home health care had other, unreported conditions that potentially could have affected resource utilization. Regardless, the payment amount proposed for the low and high comorbidity adjustment is driven by the actual resource utilization as identified on home health claims and therefore we believe to be sufficient to align the comorbidity adjustment to the costs of providing care. Likewise, the difference in payment between the low and the high comorbidity adjustment is reflective of the resource use between those patients with individual comorbid conditions and those with multiple comorbid conditions. This is also in alignment with what commenters and the TEP that was convened in February 2018 stated in regards to the more complex needs of patients who have multiple comorbidities.

We disagree with commenters who stated that not enough periods of care would receive the comorbidity adjustment. To better ensure that reported conditions represented an actual impact on resource use, the proposed comorbidities include those conditions that represent more than 0.1 percent of periods and have at least as high as the median resource use as they indicate a direct relationship between the comorbidity and resource utilization. Under the PDGM, this

approach increases the 30-day periods of care that would receive a comorbidity adjustment compared to the approach proposed in the CY 2018 HH PPS proposed rule. Under the proposed PDGM, almost 40 percent of home health periods of care would receive a low or high comorbidity adjustment compared to approximately 15 percent of home health periods under the HHGM. We believe a more granular approach to the comorbidity adjustment more accurately represents patient characteristics and more accurately aligns payments with the cost of providing care. Again, we remind commenters that the comorbidity adjustment is just one of the case-mix variables in the PDGM made in addition to the base payment and adjustments made for clinical and functional status, admission source, and timing. These variables work in tandem to account for the complexity of patient care needs and to make payment for home health services accordingly. Similarly, the HH PPS is a bundled payment to cover all home health services, including ancillary services such as home health aides. HHAs are expected to provide the services, including the disciplines responsible for providing those services, in accordance with the home health plan of care.

We disagree that this approach to a comorbidity adjustment exposes HHAs to additional risk. In the CY 2001 HH PPS final rule, commenters stated that patients with multiple diagnoses should be credited with additional points in their clinical dimension measurement given the impact of comorbidities on resource use (65 FR 41153). We stated that time constraints and the data available during the development of the HH PPS was not robust enough for the inclusion of a comorbidity variable as part of the HH PPS case-mix adjustment (65 FR 41153). We also reiterated that we would consider comorbidities for future case-mix analyses and that such an effort would be significantly aided by complete four-digit and 5-digit diagnosis coding on the OASIS record. In the CY 2008 HH PPS final rule (72 FR 49772), we added secondary diagnoses and their interactions with the principal diagnosis as part of the clinical dimension in the overall case-mix adjustment. However, analysis since that time has shown that nominal case-mix growth became an ongoing issue resulting from the incentive in the current HH PPS to code only those conditions associated with clinical points even though the data did not show an associated increase in resource utilization. For CY 2018, there was a

0.97 percent reduction to the national, standardized 60-day payment rate to account for nominal case-mix growth between CY 2012 and CY 2014. Therefore, during the development of the PDGM, we sought to mitigate nominal case-mix growth and looked at different ways to account for comorbidities in the overall case-mix adjustment. The description of the initial comorbidity analysis for an alternate case-mix methodology is included in the technical report, "Overview of the Home Health Groupings Model" found on the HHA Center web page.³⁰

Comment: A commenter expressed concern that underlying mood disorders, cognitive impairments and other behavioral issues may be underreported and therefore not prevalent enough to be represented in a comorbidity subgroup. The commenter further noted that current guidelines state that clinicians should list diagnoses that support the disciplines and services provided, which appears contrary to current guidance to report any and all diagnoses the patient has whether or not they are related to treatment indicated in the plan of care.

Response: Behavioral Health Care is one of the PDGM clinical groupings, and as such, principal diagnoses related to these conditions are already incorporated into the case-mix weight. HHAs already should be reporting any and all secondary diagnoses on the plan of care that affect resource use, including diagnoses related to cognitive and behavioral issues. We agree that coding guidelines are clear that additional (secondary) diagnoses are only to be reported if they are conditions that affect patient care in terms of requiring clinical evaluation; or therapeutic treatment; or diagnostic procedures; or extended length of hospital stay; or increased nursing care and/or monitoring. We do not expect that HHAs would report comorbid conditions that are not being addressed in the individualized plan of care. The home health CoPs at § 484.60 state that the plan of care must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, which would include all pertinent diagnoses.

Comment: A commenter stated patients with comorbidities frequently require multiple episodes of home health care and instead of the comorbidity adjustment, the PDGM should have more payment groups to

³⁰ <https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sf.pdf>.

more accurately predict resource use among patients.

Response: We remind commenters that the subdivision of the MMTA clinical group into subgroups, as finalized in section III.F.6 of this final rule with comment period, results in 432 payment groups in the PDGM. Therefore, we believe that the presence of more clinical groups better describes patient characteristics and care needs which will translate to more accurate payment. Likewise, adjusting a home health period of care payment to account for the presence of comorbidities will help to more accurately pay for those patients with chronic, comorbid conditions who require multiple periods of home health care.

Comment: We received a specific comment on the comorbidity subgroups where a commenter recommended that instead of having Skin 3 and Skin 4 should be in their own separate clinical group instead of including them as part of the comorbidity adjustment.

Response: The diagnoses that are in the Skin 3 and Skin 4 comorbidity subgroups are already included in the Wounds clinical group and therefore are already accounted for in a separate clinical group. We believe it is important, clinically, to retain these two subgroups in the comorbidity adjustment as these can be conditions found in patients who are primarily receiving home health services for other reasons. For example, a patient who has recently suffered from a stroke with significant functional deficits and developed a pressure ulcer would likely be appropriately grouped into the Neuro Rehab group. Having these comorbidity subgroups which represent the presence of chronic wounds and/or pressure ulcers would provide additional payment to account for the complex care needs of a patient receiving Neuro Rehab services and who also has a wound. However, we will continue to reexamine reported secondary diagnoses upon implementation of the PDGM to see which conditions are associated with increased resource use and will make any refinements, as necessary, to more accurately align payment with patient characteristics and costs.

Comment: Another commenter stated that with the adoption of ICD 10-CM, HHAs have been instructed through coding guidance to code all diagnoses that impact the patient's care and that it is not uncommon to fill all 25 code fields on the claim. This commenter remarked that Direct Data Entry (DDE) only considers the first 9 codes on the patient's claim and therefore would limit payment for those periods of care

if there are any comorbidities listed beyond the first 9 diagnosis fields on the claim.

Response: We remind commenters that the DDE supports 25 diagnoses just like the electronic 837I claim format. The difference between the DDE and the electronic formats is that for the DDE format, the reporting of diagnosis codes is split between two screens, meaning the first 9 diagnosis codes are entered on the first screen, and diagnosis codes 10–25 are entered on the second screen. To reach the second screen to enter these codes, the person entering the claim information would hit the F6 key to move from the first screen to the second screen.

Final Decision: After considering the public comments, we are finalizing the comorbidity adjustment as part of the overall case mix in the PDGM. To summarize, this includes the home health specific list of comorbidity subgroups and comorbidity subgroup interactions. One of the three mutually exclusive categories of comorbidity adjustment will be applied to each period: No Comorbidity Adjustment, Low Comorbidity Adjustment, and High Comorbidity Adjustment. A 30-day period of care can receive payment for a low comorbidity adjustment or a high comorbidity adjustment, but not both. A 30-day period of care can receive only one low comorbidity adjustment regardless of the number of secondary diagnoses reported on the home health claim that fell into one of the individual comorbidity subgroups or one high comorbidity adjustment regardless of the number of comorbidity group interactions, as applicable. The low comorbidity adjustment amount would be the same across the subgroups and the high comorbidity adjustment would be the same across the subgroup interactions. Upon implementation of the PDGM in CY 2020, we will analyze the most recently available claims to update the comorbidity list to include those comorbid conditions and interaction subgroups that represent more than 0.1 percent of periods and have at least as high as the median resource use. Likewise, we will continue to evaluate reported secondary diagnoses and interactions between comorbidities to identify their impact on resource costs to determine if any additional refinements to this case-mix adjustment variable are warranted.

9. Change in the Low-Utilization Payment Adjustment (LUPA) Threshold

Currently, a 60-day episode with four or fewer visits is paid the national per visit amount by discipline, adjusted by the appropriate wage index based on the

site of service of the beneficiary, instead of the full 60-day episode payment amount. Such payment adjustments are called Low Utilization Payment Adjustments (LUPAs). While the proposed PDGM system in the CY 2019 HH PPS proposed rule would still include LUPA payments, the approach to calculating the LUPA thresholds needed to change due to the proposed change in the unit of payment to 30-day periods of care from 60-day episodes. We note that in the current payment system, approximately 8 percent of episodes are LUPAs. Under the PDGM, the 30-day periods of care have substantially more periods with four or fewer visits than 60-day episodes. Therefore, to create LUPA thresholds under the PDGM, in the CY 2019 proposed rule (82 FR 32411), we proposed to set the LUPA threshold at the 10th percentile value of visits or 2 visits, whichever is higher, for each payment group in order to target approximately the same percentage of LUPAs. This resulted in approximately 7.1 percent of 30-day periods that would be LUPAs (assuming no behavior change) under the PDGM. We also proposed that the LUPA thresholds for each PDGM payment group would be re-evaluated every year based on the most current utilization data available.

We received several comments on the LUPA threshold methodology proposed for the PDGM and these are summarized in this section with our responses:

Comment: Several commenters agreed in concept with the proposed changes to the LUPA threshold, but stated that additional time is necessary to fully evaluate the model's impact, especially in conjunction with the transition from a 60-day to a 30-day payment period. Several commenters requested a more cautious approach of delayed implementation, to allow providers and software vendors an opportunity to prepare for implementation of the new thresholds.

Response: We appreciate commenters agreeing that LUPA thresholds should vary by clinical group. LUPA thresholds that vary by case-mix group level take into account different resource use patterns based on clinical characteristics and is a more patient-driven approach. We note that we will implement the PDGM for home health periods of care starting on or after January 1, 2020, giving HHAs and vendors sufficient time to evaluate the impact of the PDGM and make necessary changes to their software systems to accommodate a 30-day unit of payment and the varying LUPA threshold approach.

Comment: Many commenters expressed concern that creating

different LUPA thresholds, in which the thresholds vary from 2–6 minimum visits, depending on the home health grouping, will greatly increase the complexity of the payment system, administrative burden, and costs to agencies. Several commenters suggested maintaining the use of a single LUPA threshold. Other commenters suggested a system of varying LUPA thresholds (that is, more than one), but more simplified to include a narrower range of thresholds than the proposed 2–6 thresholds. Commenters recommended that any LUPA threshold options should be fully evaluated for potential impacts, including behavioral changes that could affect patient access to care.

Response: The concept of case-mix adjusted LUPA thresholds is not new. In the FY 2001 HH PPS final rule (42 FR 41143), when the LUPA threshold of four or fewer visits was introduced, commenters suggested that CMS instead use specific LUPA thresholds for each HHRG. We are unsure why case-mix-specific LUPA thresholds would result in additional administrative burden and costs. We note that under the current HH PPS, LUPA episodes are billed the same as a non-LUPA episodes and this will not change under the PDGM where LUPA periods of care will be billed the same way as non-LUPA 30-day periods of care. We are unsure why case-mix group specific LUPA thresholds would impact patient access and commenters did not provide any additional information to inform such assertions. While some commenters suggested a system of varying LUPA thresholds (that is, more than one), but more simplified to include a narrower range of thresholds than the proposed 2–6 thresholds, they did not provide specifics on their recommendation nor any rationale for this suggestion. However, we remind commenters that we set the LUPA threshold at the 10th percentile value of visits or 2 visits, whichever is higher, for each payment group in order to target approximately the same percentage of LUPAs as under the current system. Therefore, we believe this approach to be the most reasonable. However, we will analyze this methodology once the PDGM is implemented in CY 2020 to determine whether any changes to the LUPA thresholds are warranted.

Comment: Several commenters expressed concern that this policy change could increase the number of LUPAs, which present a financial loss for agencies. A commenter remarked that a 60-day episode under the current system with 14 visits would potentially become two 30-day LUPAs under the proposed PDGM.

Response: As explained in the CY 2019 HH PPS proposed rule (83 FR 32412), our methodology for determining LUPA assignment was calibrated to target approximately the same rate of LUPA occurrences as under the current HH PPS case-mix system. Based on our analysis of CY 2017 home health utilization data, under the PDGM, a slightly lower rate of 30-periods would be assigned as LUPAs (approximately 7%) than 60-day episodes under the current payment system (approximately 8%). We believe that targeting approximately the same percentage of LUPA periods under the PDGM as the current HH PPS should mitigate HHA concerns of an increased number of LUPA periods of care and we do not believe this approach would create a financial hardship for HHAs.

Comment: A commenter questioned the methodology of the LUPA threshold calculation. They suggested that low counts of visits due to the patient's death or transfer to another agency are not comparable with counts of low visits due to patient needs and thereby these two situations at least should be excluded when determining the thresholds.

Response: While we appreciate the commenter's suggestion, when we examined the data, we found the combined occurrences of patient deaths or transfers to another agency did not impact the threshold numbers.

Comment: Another commenter expressed concern about how the change to the LUPA thresholds under the PDGM would affect the provision and payment of Non-Routine Supplies (NRS). The commenter cited an example of periods of care classified under the Wound clinical group for which the commenter noted use disproportionately greater amounts of NRS, and questioned whether the per-visit rates alone would be sufficient to recoup costs. Another commenter noticed that, with some groupings and

all else equal, the threshold amounts can be seen to rise and then fall with functional level and thereby the thresholds were not consistent with patient needs.

Response: We remind commenters that payment for NRS has been included in the per-visit LUPA rates since the implementation of the HH PPS (65 FR 41128). At that time, commenters expressed concern that the per-visit LUPA rates would not adequately compensate for NRS and the per visit payment rates were updated to reflect those concerns (65 FR 41138). In the CY 2014 HH PPS final rule (72 FR 72280), we rebased the national, per-visit payment amounts the highest amounts allowed by law. Under the PDGM, the LUPA thresholds are data-driven and determined based on the visit patterns reflected in each of the case-mix groups. Any noted patterns of LUPA thresholds varying with functional level is the result of provider reported information on the OASIS. Accurate reporting on the OASIS is imperative to fully account for the level of impairment at the time of the assessment and to be reflective of the services provided. We reiterate, that in order to maintain approximately the same proportion of LUPA periods under the PDGM with a 30-day unit of payment compared to the current HH PPS with a 60-day episode of payment, the LUPA thresholds were set at the 10th percentile of visits or 2 visits, whichever is higher.

Final Decision: We are finalizing our proposal to vary the LUPA threshold for each 30-day period of care depending on the PDGM payment group to which it is assigned. Likewise, we are finalizing that the LUPA thresholds for each PDGM payment group will be re-evaluated every year based on the most current utilization data available. The LUPA thresholds for the PDGM payment groups with the corresponding HIPPS codes based on CY 2017 home health data are listed in Table 32. Since we propose to implement the PDGM on January 1, 2020, LUPA thresholds for the PDGM payment groups with the corresponding HIPPS codes for CY 2020 will be updated in the CY 2020 HH PPS proposed rule using CY 2018 home health data.

TABLE 32—LUPA THRESHOLDS FOR THE PDGM PAYMENT GROUPS

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10th percentile or 2 - whichever is higher)
1FC11	Behavioral Health - High	Early - Community	0	4
1FC21	Behavioral Health - High	Early - Community	1	4
1FC31	Behavioral Health - High	Early - Community	2	4
2FC11	Behavioral Health - High	Early - Institutional	0	4
2FC21	Behavioral Health - High	Early - Institutional	1	4
2FC31	Behavioral Health - High	Early - Institutional	2	4
3FC11	Behavioral Health - High	Late - Community	0	2
3FC21	Behavioral Health - High	Late - Community	1	2
3FC31	Behavioral Health - High	Late - Community	2	3
4FC11	Behavioral Health - High	Late - Institutional	0	3

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10th percentile or 2 - whichever is higher)
4FC21	Behavioral Health - High	Late - Institutional	1	3
4FC31	Behavioral Health - High	Late - Institutional	2	2
1FA11	Behavioral Health - Low	Early - Community	0	3
1FA21	Behavioral Health - Low	Early - Community	1	3
1FA31	Behavioral Health - Low	Early - Community	2	4
2FA11	Behavioral Health - Low	Early - Institutional	0	3
2FA21	Behavioral Health - Low	Early - Institutional	1	3
2FA31	Behavioral Health - Low	Early - Institutional	2	4
3FA11	Behavioral Health - Low	Late - Community	0	2
3FA21	Behavioral Health - Low	Late - Community	1	2
3FA31	Behavioral Health - Low	Late - Community	2	2
4FA11	Behavioral Health - Low	Late - Institutional	0	2
4FA21	Behavioral Health - Low	Late - Institutional	1	2
4FA31	Behavioral Health - Low	Late - Institutional	2	2
1FB11	Behavioral Health - Medium	Early - Community	0	4
1FB21	Behavioral Health - Medium	Early - Community	1	4
1FB31	Behavioral Health - Medium	Early - Community	2	4
2FB11	Behavioral Health - Medium	Early - Institutional	0	4
2FB21	Behavioral Health - Medium	Early - Institutional	1	4
2FB31	Behavioral Health - Medium	Early - Institutional	2	4
3FB11	Behavioral Health - Medium	Late - Community	0	2
3FB21	Behavioral Health - Medium	Late - Community	1	2
3FB31	Behavioral Health - Medium	Late - Community	2	2
4FB11	Behavioral Health - Medium	Late - Institutional	0	3
4FB21	Behavioral Health - Medium	Late - Institutional	1	3
4FB31	Behavioral Health - Medium	Late - Institutional	2	4
1DC11	Complex - High	Early - Community	0	2
1DC21	Complex - High	Early - Community	1	2
1DC31	Complex - High	Early - Community	2	2
2DC11	Complex - High	Early - Institutional	0	4
2DC21	Complex - High	Early - Institutional	1	4
2DC31	Complex - High	Early - Institutional	2	4
3DC11	Complex - High	Late - Community	0	2
3DC21	Complex - High	Late - Community	1	2
3DC31	Complex - High	Late - Community	2	2
4DC11	Complex - High	Late - Institutional	0	3
4DC21	Complex - High	Late - Institutional	1	3
4DC31	Complex - High	Late - Institutional	2	3
1DA11	Complex - Low	Early - Community	0	2
1DA21	Complex - Low	Early - Community	1	2
1DA31	Complex - Low	Early - Community	2	2
2DA11	Complex - Low	Early - Institutional	0	3
2DA21	Complex - Low	Early - Institutional	1	3
2DA31	Complex - Low	Early - Institutional	2	4
3DA11	Complex - Low	Late - Community	0	2
3DA21	Complex - Low	Late - Community	1	2
3DA31	Complex - Low	Late - Community	2	2
4DA11	Complex - Low	Late - Institutional	0	2

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10th percentile or 2 - whichever is higher)
4DA21	Complex - Low	Late - Institutional	1	3
4DA31	Complex - Low	Late - Institutional	2	3
1DB11	Complex - Medium	Early - Community	0	3
1DB21	Complex - Medium	Early - Community	1	3
1DB31	Complex - Medium	Early - Community	2	3
2DB11	Complex - Medium	Early - Institutional	0	4
2DB21	Complex - Medium	Early - Institutional	1	4
2DB31	Complex - Medium	Early - Institutional	2	5
3DB11	Complex - Medium	Late - Community	0	2
3DB21	Complex - Medium	Late - Community	1	2
3DB31	Complex - Medium	Late - Community	2	2
4DB11	Complex - Medium	Late - Institutional	0	3
4DB21	Complex - Medium	Late - Institutional	1	3
4DB31	Complex - Medium	Late - Institutional	2	3
1GC11	MMTA - Surgical Aftercare - High	Early - Community	0	4
1GC21	MMTA - Surgical Aftercare - High	Early - Community	1	4
1GC31	MMTA - Surgical Aftercare - High	Early - Community	2	4
2GC11	MMTA - Surgical Aftercare - High	Early - Institutional	0	4
2GC21	MMTA - Surgical Aftercare - High	Early - Institutional	1	5
2GC31	MMTA - Surgical Aftercare - High	Early - Institutional	2	5
3GC11	MMTA - Surgical Aftercare - High	Late - Community	0	2
3GC21	MMTA - Surgical Aftercare - High	Late - Community	1	2
3GC31	MMTA - Surgical Aftercare - High	Late - Community	2	2
4GC11	MMTA - Surgical Aftercare - High	Late - Institutional	0	3
4GC21	MMTA - Surgical Aftercare - High	Late - Institutional	1	4
4GC31	MMTA - Surgical Aftercare - High	Late - Institutional	2	4
1GA11	MMTA - Surgical Aftercare - Low	Early - Community	0	3
1GA21	MMTA - Surgical Aftercare - Low	Early - Community	1	3
1GA31	MMTA - Surgical Aftercare - Low	Early - Community	2	3
2GA11	MMTA - Surgical Aftercare - Low	Early - Institutional	0	3
2GA21	MMTA - Surgical Aftercare - Low	Early - Institutional	1	4
2GA31	MMTA - Surgical Aftercare - Low	Early - Institutional	2	4
3GA11	MMTA - Surgical Aftercare - Low	Late - Community	0	2
3GA21	MMTA - Surgical Aftercare - Low	Late - Community	1	2
3GA31	MMTA - Surgical Aftercare - Low	Late - Community	2	2
4GA11	MMTA - Surgical Aftercare - Low	Late - Institutional	0	3
4GA21	MMTA - Surgical Aftercare - Low	Late - Institutional	1	3
4GA31	MMTA - Surgical Aftercare - Low	Late - Institutional	2	3
1GB11	MMTA - Surgical Aftercare - Medium	Early - Community	0	4
1GB21	MMTA - Surgical Aftercare - Medium	Early - Community	1	4
1GB31	MMTA - Surgical Aftercare - Medium	Early - Community	2	5
2GB11	MMTA - Surgical Aftercare - Medium	Early - Institutional	0	4
2GB21	MMTA - Surgical Aftercare - Medium	Early - Institutional	1	5
2GB31	MMTA - Surgical Aftercare - Medium	Early - Institutional	2	5
3GB11	MMTA - Surgical Aftercare - Medium	Late - Community	0	2
3GB21	MMTA - Surgical Aftercare - Medium	Late - Community	1	2
3GB31	MMTA - Surgical Aftercare - Medium	Late - Community	2	2
4GB11	MMTA - Surgical Aftercare - Medium	Late - Institutional	0	3

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10th percentile or 2 - whichever is higher)
4GB21	MMTA - Surgical Aftercare - Medium	Late - Institutional	1	3
4GB31	MMTA - Surgical Aftercare - Medium	Late - Institutional	2	4
1HC11	MMTA - Cardiac - High	Early - Community	0	5
1HC21	MMTA - Cardiac - High	Early - Community	1	4
1HC31	MMTA - Cardiac - High	Early - Community	2	4
2HC11	MMTA - Cardiac - High	Early - Institutional	0	4
2HC21	MMTA - Cardiac - High	Early - Institutional	1	4
2HC31	MMTA - Cardiac - High	Early - Institutional	2	4
3HC11	MMTA - Cardiac - High	Late - Community	0	2
3HC21	MMTA - Cardiac - High	Late - Community	1	2
3HC31	MMTA - Cardiac - High	Late - Community	2	3
4HC11	MMTA - Cardiac - High	Late - Institutional	0	3
4HC21	MMTA - Cardiac - High	Late - Institutional	1	4
4HC31	MMTA - Cardiac - High	Late - Institutional	2	4
1HA11	MMTA - Cardiac - Low	Early - Community	0	4
1HA21	MMTA - Cardiac - Low	Early - Community	1	4
1HA31	MMTA - Cardiac - Low	Early - Community	2	4
2HA11	MMTA - Cardiac - Low	Early - Institutional	0	4
2HA21	MMTA - Cardiac - Low	Early - Institutional	1	4
2HA31	MMTA - Cardiac - Low	Early - Institutional	2	4
3HA11	MMTA - Cardiac - Low	Late - Community	0	2
3HA21	MMTA - Cardiac - Low	Late - Community	1	2
3HA31	MMTA - Cardiac - Low	Late - Community	2	3
4HA11	MMTA - Cardiac - Low	Late - Institutional	0	3
4HA21	MMTA - Cardiac - Low	Late - Institutional	1	3
4HA31	MMTA - Cardiac - Low	Late - Institutional	2	3
1HB11	MMTA - Cardiac - Medium	Early - Community	0	5
1HB21	MMTA - Cardiac - Medium	Early - Community	1	4
1HB31	MMTA - Cardiac - Medium	Early - Community	2	5
2HB11	MMTA - Cardiac - Medium	Early - Institutional	0	4
2HB21	MMTA - Cardiac - Medium	Early - Institutional	1	4
2HB31	MMTA - Cardiac - Medium	Early - Institutional	2	5
3HB11	MMTA - Cardiac - Medium	Late - Community	0	2
3HB21	MMTA - Cardiac - Medium	Late - Community	1	2
3HB31	MMTA - Cardiac - Medium	Late - Community	2	3
4HB11	MMTA - Cardiac - Medium	Late - Institutional	0	3
4HB21	MMTA - Cardiac - Medium	Late - Institutional	1	3
4HB31	MMTA - Cardiac - Medium	Late - Institutional	2	4
1IC11	MMTA - Endocrine - High	Early - Community	0	5
1IC21	MMTA - Endocrine - High	Early - Community	1	5
1IC31	MMTA - Endocrine - High	Early - Community	2	4
2IC11	MMTA - Endocrine - High	Early - Institutional	0	4
2IC21	MMTA - Endocrine - High	Early - Institutional	1	4
2IC31	MMTA - Endocrine - High	Early - Institutional	2	4
3IC11	MMTA - Endocrine - High	Late - Community	0	3
3IC21	MMTA - Endocrine - High	Late - Community	1	3
3IC31	MMTA - Endocrine - High	Late - Community	2	3
4IC11	MMTA - Endocrine - High	Late - Institutional	0	3

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10th percentile or 2 - whichever is higher)
4IC21	MMTA - Endocrine - High	Late - Institutional	1	3
4IC31	MMTA - Endocrine - High	Late - Institutional	2	4
1IA11	MMTA - Endocrine - Low	Early - Community	0	4
1IA21	MMTA - Endocrine - Low	Early - Community	1	4
1IA31	MMTA - Endocrine - Low	Early - Community	2	4
2IA11	MMTA - Endocrine - Low	Early - Institutional	0	3
2IA21	MMTA - Endocrine - Low	Early - Institutional	1	4
2IA31	MMTA - Endocrine - Low	Early - Institutional	2	4
3IA11	MMTA - Endocrine - Low	Late - Community	0	2
3IA21	MMTA - Endocrine - Low	Late - Community	1	2
3IA31	MMTA - Endocrine - Low	Late - Community	2	2
4IA11	MMTA - Endocrine - Low	Late - Institutional	0	3
4IA21	MMTA - Endocrine - Low	Late - Institutional	1	3
4IA31	MMTA - Endocrine - Low	Late - Institutional	2	3
1IB11	MMTA - Endocrine - Medium	Early - Community	0	5
1IB21	MMTA - Endocrine - Medium	Early - Community	1	5
1IB31	MMTA - Endocrine - Medium	Early - Community	2	5
2IB11	MMTA - Endocrine - Medium	Early - Institutional	0	4
2IB21	MMTA - Endocrine - Medium	Early - Institutional	1	4
2IB31	MMTA - Endocrine - Medium	Early - Institutional	2	4
3IB11	MMTA - Endocrine - Medium	Late - Community	0	2
3IB21	MMTA - Endocrine - Medium	Late - Community	1	3
3IB31	MMTA - Endocrine - Medium	Late - Community	2	3
4IB11	MMTA - Endocrine - Medium	Late - Institutional	0	3
4IB21	MMTA - Endocrine - Medium	Late - Institutional	1	3
4IB31	MMTA - Endocrine - Medium	Late - Institutional	2	3
1JC11	MMTA - GI/GU - High	Early - Community	0	4
1JC21	MMTA - GI/GU - High	Early - Community	1	4
1JC31	MMTA - GI/GU - High	Early - Community	2	3
2JC11	MMTA - GI/GU - High	Early - Institutional	0	4
2JC21	MMTA - GI/GU - High	Early - Institutional	1	4
2JC31	MMTA - GI/GU - High	Early - Institutional	2	4
3JC11	MMTA - GI/GU - High	Late - Community	0	2
3JC21	MMTA - GI/GU - High	Late - Community	1	2
3JC31	MMTA - GI/GU - High	Late - Community	2	2
4JC11	MMTA - GI/GU - High	Late - Institutional	0	3
4JC21	MMTA - GI/GU - High	Late - Institutional	1	3
4JC31	MMTA - GI/GU - High	Late - Institutional	2	3
1JA11	MMTA - GI/GU - Low	Early - Community	0	3
1JA21	MMTA - GI/GU - Low	Early - Community	1	3
1JA31	MMTA - GI/GU - Low	Early - Community	2	4
2JA11	MMTA - GI/GU - Low	Early - Institutional	0	3
2JA21	MMTA - GI/GU - Low	Early - Institutional	1	4
2JA31	MMTA - GI/GU - Low	Early - Institutional	2	4
3JA11	MMTA - GI/GU - Low	Late - Community	0	2
3JA21	MMTA - GI/GU - Low	Late - Community	1	2
3JA31	MMTA - GI/GU - Low	Late - Community	2	2
4JA11	MMTA - GI/GU - Low	Late - Institutional	0	3

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10th percentile or 2 - whichever is higher)
4JA21	MMTA - GI/GU - Low	Late - Institutional	1	3
4JA31	MMTA - GI/GU - Low	Late - Institutional	2	3
1JB11	MMTA - GI/GU - Medium	Early - Community	0	4
1JB21	MMTA - GI/GU - Medium	Early - Community	1	4
1JB31	MMTA - GI/GU - Medium	Early - Community	2	5
2JB11	MMTA - GI/GU - Medium	Early - Institutional	0	4
2JB21	MMTA - GI/GU - Medium	Early - Institutional	1	4
2JB31	MMTA - GI/GU - Medium	Early - Institutional	2	5
3JB11	MMTA - GI/GU - Medium	Late - Community	0	2
3JB21	MMTA - GI/GU - Medium	Late - Community	1	2
3JB31	MMTA - GI/GU - Medium	Late - Community	2	2
4JB11	MMTA - GI/GU - Medium	Late - Institutional	0	3
4JB21	MMTA - GI/GU - Medium	Late - Institutional	1	3
4JB31	MMTA - GI/GU - Medium	Late - Institutional	2	4
1KC11	MMTA - Infectious - High	Early - Community	0	3
1KC21	MMTA - Infectious - High	Early - Community	1	3
1KC31	MMTA - Infectious - High	Early - Community	2	3
2KC11	MMTA - Infectious - High	Early - Institutional	0	3
2KC21	MMTA - Infectious - High	Early - Institutional	1	3
2KC31	MMTA - Infectious - High	Early - Institutional	2	4
3KC11	MMTA - Infectious - High	Late - Community	0	2
3KC21	MMTA - Infectious - High	Late - Community	1	2
3KC31	MMTA - Infectious - High	Late - Community	2	2
4KC11	MMTA - Infectious - High	Late - Institutional	0	3
4KC21	MMTA - Infectious - High	Late - Institutional	1	3
4KC31	MMTA - Infectious - High	Late - Institutional	2	3
1KA11	MMTA - Infectious - Low	Early - Community	0	3
1KA21	MMTA - Infectious - Low	Early - Community	1	3
1KA31	MMTA - Infectious - Low	Early - Community	2	3
2KA11	MMTA - Infectious - Low	Early - Institutional	0	3
2KA21	MMTA - Infectious - Low	Early - Institutional	1	3
2KA31	MMTA - Infectious - Low	Early - Institutional	2	4
3KA11	MMTA - Infectious - Low	Late - Community	0	2
3KA21	MMTA - Infectious - Low	Late - Community	1	2
3KA31	MMTA - Infectious - Low	Late - Community	2	2
4KA11	MMTA - Infectious - Low	Late - Institutional	0	2
4KA21	MMTA - Infectious - Low	Late - Institutional	1	3
4KA31	MMTA - Infectious - Low	Late - Institutional	2	3
1KB11	MMTA - Infectious - Medium	Early - Community	0	3
1KB21	MMTA - Infectious - Medium	Early - Community	1	3
1KB31	MMTA - Infectious - Medium	Early - Community	2	4
2KB11	MMTA - Infectious - Medium	Early - Institutional	0	3
2KB21	MMTA - Infectious - Medium	Early - Institutional	1	4
2KB31	MMTA - Infectious - Medium	Early - Institutional	2	4
3KB11	MMTA - Infectious - Medium	Late - Community	0	2
3KB21	MMTA - Infectious - Medium	Late - Community	1	2
3KB31	MMTA - Infectious - Medium	Late - Community	2	2
4KB11	MMTA - Infectious - Medium	Late - Institutional	0	3

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10th percentile or 2 - whichever is higher)
4KB21	MMTA - Infectious - Medium	Late - Institutional	1	3
4KB31	MMTA - Infectious - Medium	Late - Institutional	2	3
1AC11	MMTA - Other - High	Early - Community	0	5
1AC21	MMTA - Other - High	Early - Community	1	5
1AC31	MMTA - Other - High	Early - Community	2	5
2AC11	MMTA - Other - High	Early - Institutional	0	4
2AC21	MMTA - Other - High	Early - Institutional	1	5
2AC31	MMTA - Other - High	Early - Institutional	2	5
3AC11	MMTA - Other - High	Late - Community	0	2
3AC21	MMTA - Other - High	Late - Community	1	3
3AC31	MMTA - Other - High	Late - Community	2	3
4AC11	MMTA - Other - High	Late - Institutional	0	3
4AC21	MMTA - Other - High	Late - Institutional	1	3
4AC31	MMTA - Other - High	Late - Institutional	2	4
1AA11	MMTA - Other - Low	Early - Community	0	4
1AA21	MMTA - Other - Low	Early - Community	1	4
1AA31	MMTA - Other - Low	Early - Community	2	4
2AA11	MMTA - Other - Low	Early - Institutional	0	3
2AA21	MMTA - Other - Low	Early - Institutional	1	4
2AA31	MMTA - Other - Low	Early - Institutional	2	4
3AA11	MMTA - Other - Low	Late - Community	0	2
3AA21	MMTA - Other - Low	Late - Community	1	2
3AA31	MMTA - Other - Low	Late - Community	2	3
4AA11	MMTA - Other - Low	Late - Institutional	0	3
4AA21	MMTA - Other - Low	Late - Institutional	1	3
4AA31	MMTA - Other - Low	Late - Institutional	2	3
1AB11	MMTA - Other - Medium	Early - Community	0	5
1AB21	MMTA - Other - Medium	Early - Community	1	5
1AB31	MMTA - Other - Medium	Early - Community	2	5
2AB11	MMTA - Other - Medium	Early - Institutional	0	4
2AB21	MMTA - Other - Medium	Early - Institutional	1	5
2AB31	MMTA - Other - Medium	Early - Institutional	2	5
3AB11	MMTA - Other - Medium	Late - Community	0	2
3AB21	MMTA - Other - Medium	Late - Community	1	2
3AB31	MMTA - Other - Medium	Late - Community	2	3
4AB11	MMTA - Other - Medium	Late - Institutional	0	3
4AB21	MMTA - Other - Medium	Late - Institutional	1	4
4AB31	MMTA - Other - Medium	Late - Institutional	2	4
1LC11	MMTA - Respiratory - High	Early - Community	0	4
1LC21	MMTA - Respiratory - High	Early - Community	1	4
1LC31	MMTA - Respiratory - High	Early - Community	2	5
2LC11	MMTA - Respiratory - High	Early - Institutional	0	4
2LC21	MMTA - Respiratory - High	Early - Institutional	1	4
2LC31	MMTA - Respiratory - High	Early - Institutional	2	4
3LC11	MMTA - Respiratory - High	Late - Community	0	2
3LC21	MMTA - Respiratory - High	Late - Community	1	2
3LC31	MMTA - Respiratory - High	Late - Community	2	2
4LC11	MMTA - Respiratory - High	Late - Institutional	0	3

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10th percentile or 2 - whichever is higher)
4LC21	MMTA - Respiratory - High	Late - Institutional	1	3
4LC31	MMTA - Respiratory - High	Late - Institutional	2	4
1LA11	MMTA - Respiratory - Low	Early - Community	0	4
1LA21	MMTA - Respiratory - Low	Early - Community	1	4
1LA31	MMTA - Respiratory - Low	Early - Community	2	4
2LA11	MMTA - Respiratory - Low	Early - Institutional	0	3
2LA21	MMTA - Respiratory - Low	Early - Institutional	1	4
2LA31	MMTA - Respiratory - Low	Early - Institutional	2	4
3LA11	MMTA - Respiratory - Low	Late - Community	0	2
3LA21	MMTA - Respiratory - Low	Late - Community	1	2
3LA31	MMTA - Respiratory - Low	Late - Community	2	2
4LA11	MMTA - Respiratory - Low	Late - Institutional	0	3
4LA21	MMTA - Respiratory - Low	Late - Institutional	1	3
4LA31	MMTA - Respiratory - Low	Late - Institutional	2	3
1LB11	MMTA - Respiratory - Medium	Early - Community	0	4
1LB21	MMTA - Respiratory - Medium	Early - Community	1	4
1LB31	MMTA - Respiratory - Medium	Early - Community	2	5
2LB11	MMTA - Respiratory - Medium	Early - Institutional	0	4
2LB21	MMTA - Respiratory - Medium	Early - Institutional	1	4
2LB31	MMTA - Respiratory - Medium	Early - Institutional	2	5
3LB11	MMTA - Respiratory - Medium	Late - Community	0	2
3LB21	MMTA - Respiratory - Medium	Late - Community	1	2
3LB31	MMTA - Respiratory - Medium	Late - Community	2	2
4LB11	MMTA - Respiratory - Medium	Late - Institutional	0	3
4LB21	MMTA - Respiratory - Medium	Late - Institutional	1	3
4LB31	MMTA - Respiratory - Medium	Late - Institutional	2	4
1EC11	MS Rehab - High	Early - Community	0	5
1EC21	MS Rehab - High	Early - Community	1	5
1EC31	MS Rehab - High	Early - Community	2	5
2EC11	MS Rehab - High	Early - Institutional	0	6
2EC21	MS Rehab - High	Early - Institutional	1	6
2EC31	MS Rehab - High	Early - Institutional	2	6
3EC11	MS Rehab - High	Late - Community	0	2
3EC21	MS Rehab - High	Late - Community	1	2
3EC31	MS Rehab - High	Late - Community	2	3
4EC11	MS Rehab - High	Late - Institutional	0	4
4EC21	MS Rehab - High	Late - Institutional	1	4
4EC31	MS Rehab - High	Late - Institutional	2	4
1EA11	MS Rehab - Low	Early - Community	0	5
1EA21	MS Rehab - Low	Early - Community	1	5
1EA31	MS Rehab - Low	Early - Community	2	5
2EA11	MS Rehab - Low	Early - Institutional	0	5
2EA21	MS Rehab - Low	Early - Institutional	1	5
2EA31	MS Rehab - Low	Early - Institutional	2	5
3EA11	MS Rehab - Low	Late - Community	0	2
3EA21	MS Rehab - Low	Late - Community	1	2
3EA31	MS Rehab - Low	Late - Community	2	2
4EA11	MS Rehab - Low	Late - Institutional	0	4

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10th percentile or 2 - whichever is higher)
4EA21	MS Rehab - Low	Late - Institutional	1	4
4EA31	MS Rehab - Low	Late - Institutional	2	3
1EB11	MS Rehab - Medium	Early - Community	0	5
1EB21	MS Rehab - Medium	Early - Community	1	5
1EB31	MS Rehab - Medium	Early - Community	2	5
2EB11	MS Rehab - Medium	Early - Institutional	0	6
2EB21	MS Rehab - Medium	Early - Institutional	1	6
2EB31	MS Rehab - Medium	Early - Institutional	2	6
3EB11	MS Rehab - Medium	Late - Community	0	2
3EB21	MS Rehab - Medium	Late - Community	1	2
3EB31	MS Rehab - Medium	Late - Community	2	3
4EB11	MS Rehab - Medium	Late - Institutional	0	4
4EB21	MS Rehab - Medium	Late - Institutional	1	4
4EB31	MS Rehab - Medium	Late - Institutional	2	4
1BC11	Neuro - High	Early - Community	0	4
1BC21	Neuro - High	Early - Community	1	5
1BC31	Neuro - High	Early - Community	2	5
2BC11	Neuro - High	Early - Institutional	0	5
2BC21	Neuro - High	Early - Institutional	1	5
2BC31	Neuro - High	Early - Institutional	2	5
3BC11	Neuro - High	Late - Community	0	2
3BC21	Neuro - High	Late - Community	1	3
3BC31	Neuro - High	Late - Community	2	3
4BC11	Neuro - High	Late - Institutional	0	4
4BC21	Neuro - High	Late - Institutional	1	4
4BC31	Neuro - High	Late - Institutional	2	4
1BA11	Neuro - Low	Early - Community	0	4
1BA21	Neuro - Low	Early - Community	1	5
1BA31	Neuro - Low	Early - Community	2	4
2BA11	Neuro - Low	Early - Institutional	0	5
2BA21	Neuro - Low	Early - Institutional	1	5
2BA31	Neuro - Low	Early - Institutional	2	5
3BA11	Neuro - Low	Late - Community	0	2
3BA21	Neuro - Low	Late - Community	1	2
3BA31	Neuro - Low	Late - Community	2	2
4BA11	Neuro - Low	Late - Institutional	0	3
4BA21	Neuro - Low	Late - Institutional	1	4
4BA31	Neuro - Low	Late - Institutional	2	3
1BB11	Neuro - Medium	Early - Community	0	5
1BB21	Neuro - Medium	Early - Community	1	5
1BB31	Neuro - Medium	Early - Community	2	6
2BB11	Neuro - Medium	Early - Institutional	0	6
2BB21	Neuro - Medium	Early - Institutional	1	6
2BB31	Neuro - Medium	Early - Institutional	2	6
3BB11	Neuro - Medium	Late - Community	0	2
3BB21	Neuro - Medium	Late - Community	1	2
3BB31	Neuro - Medium	Late - Community	2	3
4BB11	Neuro - Medium	Late - Institutional	0	4

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10th percentile or 2 - whichever is higher)
4BB21	Neuro - Medium	Late - Institutional	1	4
4BB31	Neuro - Medium	Late - Institutional	2	5
1CC11	Wound - High	Early - Community	0	4
1CC21	Wound - High	Early - Community	1	5
1CC31	Wound - High	Early - Community	2	4
2CC11	Wound - High	Early - Institutional	0	4
2CC21	Wound - High	Early - Institutional	1	5
2CC31	Wound - High	Early - Institutional	2	4
3CC11	Wound - High	Late - Community	0	3
3CC21	Wound - High	Late - Community	1	3
3CC31	Wound - High	Late - Community	2	3
4CC11	Wound - High	Late - Institutional	0	3
4CC21	Wound - High	Late - Institutional	1	3
4CC31	Wound - High	Late - Institutional	2	4
1CA11	Wound - Low	Early - Community	0	5
1CA21	Wound - Low	Early - Community	1	4
1CA31	Wound - Low	Early - Community	2	4
2CA11	Wound - Low	Early - Institutional	0	4
2CA21	Wound - Low	Early - Institutional	1	4
2CA31	Wound - Low	Early - Institutional	2	4
3CA11	Wound - Low	Late - Community	0	2
3CA21	Wound - Low	Late - Community	1	3
3CA31	Wound - Low	Late - Community	2	3
4CA11	Wound - Low	Late - Institutional	0	3
4CA21	Wound - Low	Late - Institutional	1	3
4CA31	Wound - Low	Late - Institutional	2	3
1CB11	Wound - Medium	Early - Community	0	5
1CB21	Wound - Medium	Early - Community	1	5
1CB31	Wound - Medium	Early - Community	2	5
2CB11	Wound - Medium	Early - Institutional	0	5
2CB21	Wound - Medium	Early - Institutional	1	5
2CB31	Wound - Medium	Early - Institutional	2	5
3CB11	Wound - Medium	Late - Community	0	3
3CB21	Wound - Medium	Late - Community	1	3
3CB31	Wound - Medium	Late - Community	2	3
4CB11	Wound - Medium	Late - Institutional	0	4
4CB21	Wound - Medium	Late - Institutional	1	4
4CB31	Wound - Medium	Late - Institutional	2	4

10. HH PPS Case-Mix Weights Under the PDGM

Section 1895(b)(4)(B) requires the Secretary to establish appropriate case mix adjustment factors for home health services in a manner that explains a significant amount of the variation in cost among different units of services. In the CY 2019 HH PPS proposed rule (83 FR 32415), we proposed an alternative case-mix adjustment methodology to better align payment with patient care needs. The proposed alternative case-

mix adjustment methodology places patients into meaningful payment categories based on patient characteristics (principal diagnosis, functional level, comorbid conditions, referral source and timing). As outlined in previous sections of this final rule with comment period, we are finalizing this alternative case-mix adjustment methodology, called the PDGM. This new methodology results in 432 unique case-mix groups. These 432 unique case-mix payment groups are called

Home Health Resource Groups (HHRGs).

To generate PDGM case-mix weights, we utilized a data file based on home health 30-day periods of care, as reported in Medicare home health claims linked to OASIS assessment data to obtain patient characteristics. The claims data provides visit-level data and data on whether non-routine supplies (NRS) was provided during the period and the total charges for NRS. We determined the case-mix weight for each

of the different PDGM payment groups by regressing resource use on a series of indicator variables for each of the categories using a fixed effects model. The regression measures resource use with the Cost per Minute (CPM) + NRS approach outlined in section III.F.2 of this final rule with comment period. The model used in the PDGM payment regression generates outcomes that are statistically significant.

After best fitting the model on CY 2017 home health data, we used the estimated coefficients of the model to predict the expected average resource

use of each 30-day period based on the five PDGM categories. In order to normalize the results, we divided the regression predicted resource use of each 30-day period by the overall average resource use used to estimate the model in order to calculate the case mix weight of all periods within a particular payment group, where each payment group is defined as the unique combination of the subgroups within the five PDGM categories (admission source, timing of the 30-day period, clinical grouping, functional impairment level, and comorbidity

adjustment). The case-mix weight is then used to adjust the base payment rate to determine each period's payment. Table 48 shows the coefficients of the payment regression used to generate the weights, and the coefficients divided by average resource use. Information can be found in section III.F.6 of this rule for the clinical groups, section III.F.7 of this rule for the functional impairment levels, section III.F.5 for admission source, section III.F.4 for timing, and section III.F.8 for the comorbidity adjustment.

TABLE 33 – COEFFICIENT OF PAYMENT REGRESSION AND COEFFICIENT DIVIDED BY AVERAGE RESOURCE USE FOR PDGM PAYMENT GROUP

Variable	Coefficient	Coefficient Divided by Average Resource Use
Clinical Group and Functional Impairment Level (MMTA - Other - Low is excluded)		
MMTA - Other - Medium Functional Impairment	\$220.79	0.1400
MMTA - Other - High Functional Impairment	\$418.85	0.2656
MMTA - Surgical Aftercare - Low Functional Impairment	-\$175.69	-0.1114
MMTA - Surgical Aftercare - Medium Functional Impairment	\$83.62	0.0530
MMTA - Surgical Aftercare - High Functional Impairment	\$329.50	0.2089
MMTA - Cardiac and Circulatory - Low Functional Impairment	-\$34.25	-0.0217
MMTA - Cardiac and Circulatory - Medium Functional Impairment	\$207.73	0.1317
MMTA - Cardiac and Circulatory - High Functional Impairment	\$388.49	0.2463
MMTA - Endocrine - Low Functional Impairment	\$153.49	0.0973
MMTA - Endocrine - Medium Functional Impairment	\$413.53	0.2622
MMTA - Endocrine - High Functional Impairment	\$606.21	0.3843
MMTA - Gastrointestinal tract and Genitourinary system - Low Functional Impairment	-\$97.99	-0.0621
MMTA - Gastrointestinal tract and Genitourinary system - Medium Functional Impairment	\$159.99	0.1014
MMTA - Gastrointestinal tract and Genitourinary system - High Functional Impairment	\$307.84	0.1952
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Low Functional Impairment	-\$46.85	-0.0297
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Medium Functional Impairment	\$166.31	0.1054
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - High Functional Impairment	\$341.89	0.2168
MMTA - Respiratory - Low Functional Impairment	-\$70.73	-0.0448
MMTA - Respiratory - Medium Functional Impairment	\$156.22	0.0990
MMTA - Respiratory - High Functional Impairment	\$328.24	0.2081
Behavioral Health - Low Functional Impairment	-\$139.38	-0.0884
Behavioral Health - Medium Functional Impairment	\$140.70	0.0892
Behavioral Health - High Functional Impairment	\$280.07	0.1776
Complex - Low Functional Impairment	-\$66.09	-0.0419
Complex - Medium Functional Impairment	\$260.06	0.1649
Complex - High Functional Impairment	\$319.72	0.2027
MS Rehab - Low Functional Impairment	\$128.07	0.0812
MS Rehab - Medium Functional Impairment	\$329.00	0.2086
MS Rehab - High Functional Impairment	\$554.71	0.3517
Neuro - Low Functional Impairment	\$303.21	0.1922
Neuro - Medium Functional Impairment	\$572.80	0.3632
Neuro - High Functional Impairment	\$729.03	0.4622
Wound - Low Functional Impairment	\$356.42	0.2260
Wound - Medium Functional Impairment	\$596.96	0.3785
Wound - High Functional Impairment	\$785.46	0.4980
Admission Source with Timing (Community - Early is excluded)		
Community - Late	-\$637.39	-0.4041
Institutional - Early	\$287.01	0.1820
Institutional - Late	\$67.51	0.0428
Comorbidity Adjustment (No Comorbidity Adjustment - is excluded)		
Comorbidity Adjustment - Has at least one comorbidity from comorbidity list, no interaction from interaction list	\$94.05	0.0596
Comorbidity Adjustment - Has at least one interaction from interaction list	\$291.27	0.1847
Constant	\$1,567.71	0.9939
Average Resource Use	\$1,577.26	
N	8,851,924	
Adj. R-Squared	0.2937	

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of June 30, 2018) for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded.

Table 34 presents the case-mix weight for each Home Health Resource Group (HHRG) in the regression model. LUPA episodes, outlier episodes, and episodes

with PEP adjustments were excluded. Weights are determined by first calculating the predicted resource use for episodes with a particular

combination of admission source, episode timing, clinical grouping, functional impairment level, and comorbidity adjustment. This

combination specific calculation is then divided by the average resource use of all the episodes that were used to estimate the standard 30-day payment rate. The resulting ratio represents the case-mix weight for that particular combination of a HHRG payment group. The adjusted R-squared value provides a measure of how well observed

outcomes are replicated by the model, based on the proportion of total variation of outcomes explained by the model.

Similar to the annual recalibration of the case-mix weights under the current HH PPS, we proposed to annually recalibrate the PDGM case-mix weights. We note that this includes a re-

calculation of the proposed PDGM case-mix weights for CY 2020 in the CY 2020 HH PPS proposed rule using CY 2018 home health claims data linked with OASIS assessment data since we will implement the PDGM for 30-day periods of care beginning on or after January 1, 2020.

TABLE 34 - CASE MIX WEIGHTS FOR EACH HHRG PAYMENT GROUP

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	CY 2019 Weight
1AA11	MMTA - Other - Low	Early - Community	0	0.9939
1AA21	MMTA - Other - Low	Early - Community	1	1.0536
1AA31	MMTA - Other - Low	Early - Community	2	1.1786
1AB11	MMTA - Other - Medium	Early - Community	0	1.1339
1AB21	MMTA - Other - Medium	Early - Community	1	1.1936
1AB31	MMTA - Other - Medium	Early - Community	2	1.3186
1AC11	MMTA - Other - High	Early - Community	0	1.2595
1AC21	MMTA - Other - High	Early - Community	1	1.3191
1AC31	MMTA - Other - High	Early - Community	2	1.4442
1BA11	Neuro - Low	Early - Community	0	1.1862
1BA21	Neuro - Low	Early - Community	1	1.2458
1BA31	Neuro - Low	Early - Community	2	1.3708
1BB11	Neuro - Medium	Early - Community	0	1.3571
1BB21	Neuro - Medium	Early - Community	1	1.4167
1BB31	Neuro - Medium	Early - Community	2	1.5418
1BC11	Neuro - High	Early - Community	0	1.4562
1BC21	Neuro - High	Early - Community	1	1.5158
1BC31	Neuro - High	Early - Community	2	1.6408
1CA11	Wound - Low	Early - Community	0	1.2199
1CA21	Wound - Low	Early - Community	1	1.2795
1CA31	Wound - Low	Early - Community	2	1.4046
1CB11	Wound - Medium	Early - Community	0	1.3724
1CB21	Wound - Medium	Early - Community	1	1.4321
1CB31	Wound - Medium	Early - Community	2	1.5571
1CC11	Wound - High	Early - Community	0	1.4919
1CC21	Wound - High	Early - Community	1	1.5516
1CC31	Wound - High	Early - Community	2	1.6766
1DA11	Complex - Low	Early - Community	0	0.9520
1DA21	Complex - Low	Early - Community	1	1.0117
1DA31	Complex - Low	Early - Community	2	1.1367
1DB11	Complex - Medium	Early - Community	0	1.1588
1DB21	Complex - Medium	Early - Community	1	1.2185
1DB31	Complex - Medium	Early - Community	2	1.3435
1DC11	Complex - High	Early - Community	0	1.1966
1DC21	Complex - High	Early - Community	1	1.2563
1DC31	Complex - High	Early - Community	2	1.3813
1EA11	MS Rehab - Low	Early - Community	0	1.0751
1EA21	MS Rehab - Low	Early - Community	1	1.1348
1EA31	MS Rehab - Low	Early - Community	2	1.2598
1EB11	MS Rehab - Medium	Early - Community	0	1.2025
1EB21	MS Rehab - Medium	Early - Community	1	1.2622
1EB31	MS Rehab - Medium	Early - Community	2	1.3872
1EC11	MS Rehab - High	Early - Community	0	1.3456
1EC21	MS Rehab - High	Early - Community	1	1.4053

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	CY 2019 Weight
1EC31	MS Rehab - High	Early - Community	2	1.5303
1FA11	Behavioral Health - Low	Early - Community	0	0.9056
1FA21	Behavioral Health - Low	Early - Community	1	0.9652
1FA31	Behavioral Health - Low	Early - Community	2	1.0902
1FB11	Behavioral Health - Medium	Early - Community	0	1.0832
1FB21	Behavioral Health - Medium	Early - Community	1	1.1428
1FB31	Behavioral Health - Medium	Early - Community	2	1.2678
1FC11	Behavioral Health - High	Early - Community	0	1.1715
1FC21	Behavioral Health - High	Early - Community	1	1.2311
1FC31	Behavioral Health - High	Early - Community	2	1.3562
1GA11	MMTA - Surgical Aftercare - Low	Early - Community	0	0.8826
1GA21	MMTA - Surgical Aftercare - Low	Early - Community	1	0.9422
1GA31	MMTA - Surgical Aftercare - Low	Early - Community	2	1.0672
1GB11	MMTA - Surgical Aftercare - Medium	Early - Community	0	1.0470
1GB21	MMTA - Surgical Aftercare - Medium	Early - Community	1	1.1066
1GB31	MMTA - Surgical Aftercare - Medium	Early - Community	2	1.2316
1GC11	MMTA - Surgical Aftercare - High	Early - Community	0	1.2029
1GC21	MMTA - Surgical Aftercare - High	Early - Community	1	1.2625
1GC31	MMTA - Surgical Aftercare - High	Early - Community	2	1.3875
1HA11	MMTA - Cardiac - Low	Early - Community	0	0.9722
1HA21	MMTA - Cardiac - Low	Early - Community	1	1.0319
1HA31	MMTA - Cardiac - Low	Early - Community	2	1.1569
1HB11	MMTA - Cardiac - Medium	Early - Community	0	1.1256
1HB21	MMTA - Cardiac - Medium	Early - Community	1	1.1853
1HB31	MMTA - Cardiac - Medium	Early - Community	2	1.3103
1HC11	MMTA - Cardiac - High	Early - Community	0	1.2403
1HC21	MMTA - Cardiac - High	Early - Community	1	1.2999
1HC31	MMTA - Cardiac - High	Early - Community	2	1.4249
1IA11	MMTA - Endocrine - Low	Early - Community	0	1.0913
1IA21	MMTA - Endocrine - Low	Early - Community	1	1.1509
1IA31	MMTA - Endocrine - Low	Early - Community	2	1.2759
1IB11	MMTA - Endocrine - Medium	Early - Community	0	1.2561
1IB21	MMTA - Endocrine - Medium	Early - Community	1	1.3158
1IB31	MMTA - Endocrine - Medium	Early - Community	2	1.4408
1IC11	MMTA - Endocrine - High	Early - Community	0	1.3783
1IC21	MMTA - Endocrine - High	Early - Community	1	1.4379
1IC31	MMTA - Endocrine - High	Early - Community	2	1.5630
1JA11	MMTA - GI/GU - Low	Early - Community	0	0.9318
1JA21	MMTA - GI/GU - Low	Early - Community	1	0.9914
1JA31	MMTA - GI/GU - Low	Early - Community	2	1.1165
1JB11	MMTA - GI/GU - Medium	Early - Community	0	1.0954
1JB21	MMTA - GI/GU - Medium	Early - Community	1	1.1550
1JB31	MMTA - GI/GU - Medium	Early - Community	2	1.2800
1JC11	MMTA - GI/GU - High	Early - Community	0	1.1891
1JC21	MMTA - GI/GU - High	Early - Community	1	1.2487
1JC31	MMTA - GI/GU - High	Early - Community	2	1.3738
1KA11	MMTA - Infectious - Low	Early - Community	0	0.9642
1KA21	MMTA - Infectious - Low	Early - Community	1	1.0239
1KA31	MMTA - Infectious - Low	Early - Community	2	1.1489

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	CY 2019 Weight
1KB11	MMTA - Infectious - Medium	Early - Community	0	1.0994
1KB21	MMTA - Infectious - Medium	Early - Community	1	1.1590
1KB31	MMTA - Infectious - Medium	Early - Community	2	1.2841
1KC11	MMTA - Infectious - High	Early - Community	0	1.2107
1KC21	MMTA - Infectious - High	Early - Community	1	1.2703
1KC31	MMTA - Infectious - High	Early - Community	2	1.3954
1LA11	MMTA - Respiratory - Low	Early - Community	0	0.9491
1LA21	MMTA - Respiratory - Low	Early - Community	1	1.0087
1LA31	MMTA - Respiratory - Low	Early - Community	2	1.1338
1LB11	MMTA - Respiratory - Medium	Early - Community	0	1.0930
1LB21	MMTA - Respiratory - Medium	Early - Community	1	1.1526
1LB31	MMTA - Respiratory - Medium	Early - Community	2	1.2777
1LC11	MMTA - Respiratory - High	Early - Community	0	1.2021
1LC21	MMTA - Respiratory - High	Early - Community	1	1.2617
1LC31	MMTA - Respiratory - High	Early - Community	2	1.3867
2AA11	MMTA - Other - Low	Early - Institutional	0	1.1759
2AA21	MMTA - Other - Low	Early - Institutional	1	1.2355
2AA31	MMTA - Other - Low	Early - Institutional	2	1.3606
2AB11	MMTA - Other - Medium	Early - Institutional	0	1.3159
2AB21	MMTA - Other - Medium	Early - Institutional	1	1.3755
2AB31	MMTA - Other - Medium	Early - Institutional	2	1.5006
2AC11	MMTA - Other - High	Early - Institutional	0	1.4415
2AC21	MMTA - Other - High	Early - Institutional	1	1.5011
2AC31	MMTA - Other - High	Early - Institutional	2	1.6261
2BA11	Neuro - Low	Early - Institutional	0	1.3681
2BA21	Neuro - Low	Early - Institutional	1	1.4278
2BA31	Neuro - Low	Early - Institutional	2	1.5528
2BB11	Neuro - Medium	Early - Institutional	0	1.5391
2BB21	Neuro - Medium	Early - Institutional	1	1.5987
2BB31	Neuro - Medium	Early - Institutional	2	1.7237
2BC11	Neuro - High	Early - Institutional	0	1.6381
2BC21	Neuro - High	Early - Institutional	1	1.6978
2BC31	Neuro - High	Early - Institutional	2	1.8228
2CA11	Wound - Low	Early - Institutional	0	1.4019
2CA21	Wound - Low	Early - Institutional	1	1.4615
2CA31	Wound - Low	Early - Institutional	2	1.5865
2CB11	Wound - Medium	Early - Institutional	0	1.5544
2CB21	Wound - Medium	Early - Institutional	1	1.6140
2CB31	Wound - Medium	Early - Institutional	2	1.7391
2CC11	Wound - High	Early - Institutional	0	1.6739
2CC21	Wound - High	Early - Institutional	1	1.7335
2CC31	Wound - High	Early - Institutional	2	1.8586
2DA11	Complex - Low	Early - Institutional	0	1.1340
2DA21	Complex - Low	Early - Institutional	1	1.1936
2DA31	Complex - Low	Early - Institutional	2	1.3187
2DB11	Complex - Medium	Early - Institutional	0	1.3408
2DB21	Complex - Medium	Early - Institutional	1	1.4004
2DB31	Complex - Medium	Early - Institutional	2	1.5255
2DC11	Complex - High	Early - Institutional	0	1.3786

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	CY 2019 Weight
2DC21	Complex - High	Early - Institutional	1	1.4382
2DC31	Complex - High	Early - Institutional	2	1.5633
2EA11	MS Rehab - Low	Early - Institutional	0	1.2571
2EA21	MS Rehab - Low	Early - Institutional	1	1.3167
2EA31	MS Rehab - Low	Early - Institutional	2	1.4418
2EB11	MS Rehab - Medium	Early - Institutional	0	1.3845
2EB21	MS Rehab - Medium	Early - Institutional	1	1.4441
2EB31	MS Rehab - Medium	Early - Institutional	2	1.5692
2EC11	MS Rehab - High	Early - Institutional	0	1.5276
2EC21	MS Rehab - High	Early - Institutional	1	1.5872
2EC31	MS Rehab - High	Early - Institutional	2	1.7123
2FA11	Behavioral Health - Low	Early - Institutional	0	1.0875
2FA21	Behavioral Health - Low	Early - Institutional	1	1.1472
2FA31	Behavioral Health - Low	Early - Institutional	2	1.2722
2FB11	Behavioral Health - Medium	Early - Institutional	0	1.2651
2FB21	Behavioral Health - Medium	Early - Institutional	1	1.3247
2FB31	Behavioral Health - Medium	Early - Institutional	2	1.4498
2FC11	Behavioral Health - High	Early - Institutional	0	1.3535
2FC21	Behavioral Health - High	Early - Institutional	1	1.4131
2FC31	Behavioral Health - High	Early - Institutional	2	1.5381
2GA11	MMTA - Surgical Aftercare - Low	Early - Institutional	0	1.0645
2GA21	MMTA - Surgical Aftercare - Low	Early - Institutional	1	1.1241
2GA31	MMTA - Surgical Aftercare - Low	Early - Institutional	2	1.2492
2GB11	MMTA - Surgical Aftercare - Medium	Early - Institutional	0	1.2289
2GB21	MMTA - Surgical Aftercare - Medium	Early - Institutional	1	1.2886
2GB31	MMTA - Surgical Aftercare - Medium	Early - Institutional	2	1.4136
2GC11	MMTA - Surgical Aftercare - High	Early - Institutional	0	1.3848
2GC21	MMTA - Surgical Aftercare - High	Early - Institutional	1	1.4444
2GC31	MMTA - Surgical Aftercare - High	Early - Institutional	2	1.5695
2HA11	MMTA - Cardiac - Low	Early - Institutional	0	1.1542
2HA21	MMTA - Cardiac - Low	Early - Institutional	1	1.2138
2HA31	MMTA - Cardiac - Low	Early - Institutional	2	1.3389
2HB11	MMTA - Cardiac - Medium	Early - Institutional	0	1.3076
2HB21	MMTA - Cardiac - Medium	Early - Institutional	1	1.3672
2HB31	MMTA - Cardiac - Medium	Early - Institutional	2	1.4923
2HC11	MMTA - Cardiac - High	Early - Institutional	0	1.4222
2HC21	MMTA - Cardiac - High	Early - Institutional	1	1.4818
2HC31	MMTA - Cardiac - High	Early - Institutional	2	1.6069
2IA11	MMTA - Endocrine - Low	Early - Institutional	0	1.2732
2IA21	MMTA - Endocrine - Low	Early - Institutional	1	1.3329
2IA31	MMTA - Endocrine - Low	Early - Institutional	2	1.4579
2IB11	MMTA - Endocrine - Medium	Early - Institutional	0	1.4381
2IB21	MMTA - Endocrine - Medium	Early - Institutional	1	1.4977
2IB31	MMTA - Endocrine - Medium	Early - Institutional	2	1.6228
2IC11	MMTA - Endocrine - High	Early - Institutional	0	1.5603
2IC21	MMTA - Endocrine - High	Early - Institutional	1	1.6199
2IC31	MMTA - Endocrine - High	Early - Institutional	2	1.7449
2JA11	MMTA - GI/GU - Low	Early - Institutional	0	1.1138
2JA21	MMTA - GI/GU - Low	Early - Institutional	1	1.1734

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	CY 2019 Weight
2JA31	MMTA - GI/GU - Low	Early - Institutional	2	1.2985
2JB11	MMTA - GI/GU - Medium	Early - Institutional	0	1.2773
2JB21	MMTA - GI/GU - Medium	Early - Institutional	1	1.3370
2JB31	MMTA - GI/GU - Medium	Early - Institutional	2	1.4620
2JC11	MMTA - GI/GU - High	Early - Institutional	0	1.3711
2JC21	MMTA - GI/GU - High	Early - Institutional	1	1.4307
2JC31	MMTA - GI/GU - High	Early - Institutional	2	1.5558
2KA11	MMTA - Infectious - Low	Early - Institutional	0	1.1462
2KA21	MMTA - Infectious - Low	Early - Institutional	1	1.2058
2KA31	MMTA - Infectious - Low	Early - Institutional	2	1.3309
2KB11	MMTA - Infectious - Medium	Early - Institutional	0	1.2814
2KB21	MMTA - Infectious - Medium	Early - Institutional	1	1.3410
2KB31	MMTA - Infectious - Medium	Early - Institutional	2	1.4660
2KC11	MMTA - Infectious - High	Early - Institutional	0	1.3927
2KC21	MMTA - Infectious - High	Early - Institutional	1	1.4523
2KC31	MMTA - Infectious - High	Early - Institutional	2	1.5773
2LA11	MMTA - Respiratory - Low	Early - Institutional	0	1.1311
2LA21	MMTA - Respiratory - Low	Early - Institutional	1	1.1907
2LA31	MMTA - Respiratory - Low	Early - Institutional	2	1.3157
2LB11	MMTA - Respiratory - Medium	Early - Institutional	0	1.2750
2LB21	MMTA - Respiratory - Medium	Early - Institutional	1	1.3346
2LB31	MMTA - Respiratory - Medium	Early - Institutional	2	1.4596
2LC11	MMTA - Respiratory - High	Early - Institutional	0	1.3840
2LC21	MMTA - Respiratory - High	Early - Institutional	1	1.4436
2LC31	MMTA - Respiratory - High	Early - Institutional	2	1.5687
3AA11	MMTA - Other - Low	Late - Community	0	0.5898
3AA21	MMTA - Other - Low	Late - Community	1	0.6495
3AA31	MMTA - Other - Low	Late - Community	2	0.7745
3AB11	MMTA - Other - Medium	Late - Community	0	0.7298
3AB21	MMTA - Other - Medium	Late - Community	1	0.7894
3AB31	MMTA - Other - Medium	Late - Community	2	0.9145
3AC11	MMTA - Other - High	Late - Community	0	0.8554
3AC21	MMTA - Other - High	Late - Community	1	0.9150
3AC31	MMTA - Other - High	Late - Community	2	1.0401
3BA11	Neuro - Low	Late - Community	0	0.7821
3BA21	Neuro - Low	Late - Community	1	0.8417
3BA31	Neuro - Low	Late - Community	2	0.9667
3BB11	Neuro - Medium	Late - Community	0	0.9530
3BB21	Neuro - Medium	Late - Community	1	1.0126
3BB31	Neuro - Medium	Late - Community	2	1.1377
3BC11	Neuro - High	Late - Community	0	1.0520
3BC21	Neuro - High	Late - Community	1	1.1117
3BC31	Neuro - High	Late - Community	2	1.2367
3CA11	Wound - Low	Late - Community	0	0.8158
3CA21	Wound - Low	Late - Community	1	0.8754
3CA31	Wound - Low	Late - Community	2	1.0005
3CB11	Wound - Medium	Late - Community	0	0.9683
3CB21	Wound - Medium	Late - Community	1	1.0279
3CB31	Wound - Medium	Late - Community	2	1.1530

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	CY 2019 Weight
3CC11	Wound - High	Late - Community	0	1.0878
3CC21	Wound - High	Late - Community	1	1.1475
3CC31	Wound - High	Late - Community	2	1.2725
3DA11	Complex - Low	Late - Community	0	0.5479
3DA21	Complex - Low	Late - Community	1	0.6076
3DA31	Complex - Low	Late - Community	2	0.7326
3DB11	Complex - Medium	Late - Community	0	0.7547
3DB21	Complex - Medium	Late - Community	1	0.8143
3DB31	Complex - Medium	Late - Community	2	0.9394
3DC11	Complex - High	Late - Community	0	0.7925
3DC21	Complex - High	Late - Community	1	0.8522
3DC31	Complex - High	Late - Community	2	0.9772
3EA11	MS Rehab - Low	Late - Community	0	0.6710
3EA21	MS Rehab - Low	Late - Community	1	0.7307
3EA31	MS Rehab - Low	Late - Community	2	0.8557
3EB11	MS Rehab - Medium	Late - Community	0	0.7984
3EB21	MS Rehab - Medium	Late - Community	1	0.8581
3EB31	MS Rehab - Medium	Late - Community	2	0.9831
3EC11	MS Rehab - High	Late - Community	0	0.9415
3EC21	MS Rehab - High	Late - Community	1	1.0012
3EC31	MS Rehab - High	Late - Community	2	1.1262
3FA11	Behavioral Health - Low	Late - Community	0	0.5015
3FA21	Behavioral Health - Low	Late - Community	1	0.5611
3FA31	Behavioral Health - Low	Late - Community	2	0.6861
3FB11	Behavioral Health - Medium	Late - Community	0	0.6790
3FB21	Behavioral Health - Medium	Late - Community	1	0.7387
3FB31	Behavioral Health - Medium	Late - Community	2	0.8637
3FC11	Behavioral Health - High	Late - Community	0	0.7674
3FC21	Behavioral Health - High	Late - Community	1	0.8270
3FC31	Behavioral Health - High	Late - Community	2	0.9521
3GA11	MMTA - Surgical Aftercare - Low	Late - Community	0	0.4784
3GA21	MMTA - Surgical Aftercare - Low	Late - Community	1	0.5381
3GA31	MMTA - Surgical Aftercare - Low	Late - Community	2	0.6631
3GB11	MMTA - Surgical Aftercare - Medium	Late - Community	0	0.6429
3GB21	MMTA - Surgical Aftercare - Medium	Late - Community	1	0.7025
3GB31	MMTA - Surgical Aftercare - Medium	Late - Community	2	0.8275
3GC11	MMTA - Surgical Aftercare - High	Late - Community	0	0.7987
3GC21	MMTA - Surgical Aftercare - High	Late - Community	1	0.8584
3GC31	MMTA - Surgical Aftercare - High	Late - Community	2	0.9834
3HA11	MMTA - Cardiac - Low	Late - Community	0	0.5681
3HA21	MMTA - Cardiac - Low	Late - Community	1	0.6277
3HA31	MMTA - Cardiac - Low	Late - Community	2	0.7528
3HB11	MMTA - Cardiac - Medium	Late - Community	0	0.7215
3HB21	MMTA - Cardiac - Medium	Late - Community	1	0.7812
3HB31	MMTA - Cardiac - Medium	Late - Community	2	0.9062
3HC11	MMTA - Cardiac - High	Late - Community	0	0.8361
3HC21	MMTA - Cardiac - High	Late - Community	1	0.8958
3HC31	MMTA - Cardiac - High	Late - Community	2	1.0208
3IA11	MMTA - Endocrine - Low	Late - Community	0	0.6871

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	CY 2019 Weight
3IA21	MMTA - Endocrine - Low	Late - Community	1	0.7468
3IA31	MMTA - Endocrine - Low	Late - Community	2	0.8718
3IB11	MMTA - Endocrine - Medium	Late - Community	0	0.8520
3IB21	MMTA - Endocrine - Medium	Late - Community	1	0.9116
3IB31	MMTA - Endocrine - Medium	Late - Community	2	1.0367
3IC11	MMTA - Endocrine - High	Late - Community	0	0.9742
3IC21	MMTA - Endocrine - High	Late - Community	1	1.0338
3IC31	MMTA - Endocrine - High	Late - Community	2	1.1588
3JA11	MMTA - GI/GU - Low	Late - Community	0	0.5277
3JA21	MMTA - GI/GU - Low	Late - Community	1	0.5873
3JA31	MMTA - GI/GU - Low	Late - Community	2	0.7124
3JB11	MMTA - GI/GU - Medium	Late - Community	0	0.6913
3JB21	MMTA - GI/GU - Medium	Late - Community	1	0.7509
3JB31	MMTA - GI/GU - Medium	Late - Community	2	0.8759
3JC11	MMTA - GI/GU - High	Late - Community	0	0.7850
3JC21	MMTA - GI/GU - High	Late - Community	1	0.8446
3JC31	MMTA - GI/GU - High	Late - Community	2	0.9697
3KA11	MMTA - Infectious - Low	Late - Community	0	0.5601
3KA21	MMTA - Infectious - Low	Late - Community	1	0.6198
3KA31	MMTA - Infectious - Low	Late - Community	2	0.7448
3KB11	MMTA - Infectious - Medium	Late - Community	0	0.6953
3KB21	MMTA - Infectious - Medium	Late - Community	1	0.7549
3KB31	MMTA - Infectious - Medium	Late - Community	2	0.8799
3KC11	MMTA - Infectious - High	Late - Community	0	0.8066
3KC21	MMTA - Infectious - High	Late - Community	1	0.8662
3KC31	MMTA - Infectious - High	Late - Community	2	0.9913
3LA11	MMTA - Respiratory - Low	Late - Community	0	0.5450
3LA21	MMTA - Respiratory - Low	Late - Community	1	0.6046
3LA31	MMTA - Respiratory - Low	Late - Community	2	0.7297
3LB11	MMTA - Respiratory - Medium	Late - Community	0	0.6889
3LB21	MMTA - Respiratory - Medium	Late - Community	1	0.7485
3LB31	MMTA - Respiratory - Medium	Late - Community	2	0.8735
3LC11	MMTA - Respiratory - High	Late - Community	0	0.7979
3LC21	MMTA - Respiratory - High	Late - Community	1	0.8576
3LC31	MMTA - Respiratory - High	Late - Community	2	0.9826
4AA11	MMTA - Other - Low	Late - Institutional	0	1.0367
4AA21	MMTA - Other - Low	Late - Institutional	1	1.0964
4AA31	MMTA - Other - Low	Late - Institutional	2	1.2214
4AB11	MMTA - Other - Medium	Late - Institutional	0	1.1767
4AB21	MMTA - Other - Medium	Late - Institutional	1	1.2364
4AB31	MMTA - Other - Medium	Late - Institutional	2	1.3614
4AC11	MMTA - Other - High	Late - Institutional	0	1.3023
4AC21	MMTA - Other - High	Late - Institutional	1	1.3619
4AC31	MMTA - Other - High	Late - Institutional	2	1.4870
4BA11	Neuro - Low	Late - Institutional	0	1.2290
4BA21	Neuro - Low	Late - Institutional	1	1.2886
4BA31	Neuro - Low	Late - Institutional	2	1.4136
4BB11	Neuro - Medium	Late - Institutional	0	1.3999
4BB21	Neuro - Medium	Late - Institutional	1	1.4595

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	CY 2019 Weight
4BB31	Neuro - Medium	Late - Institutional	2	1.5846
4BC11	Neuro - High	Late - Institutional	0	1.4990
4BC21	Neuro - High	Late - Institutional	1	1.5586
4BC31	Neuro - High	Late - Institutional	2	1.6836
4CA11	Wound - Low	Late - Institutional	0	1.2627
4CA21	Wound - Low	Late - Institutional	1	1.3223
4CA31	Wound - Low	Late - Institutional	2	1.4474
4CB11	Wound - Medium	Late - Institutional	0	1.4152
4CB21	Wound - Medium	Late - Institutional	1	1.4749
4CB31	Wound - Medium	Late - Institutional	2	1.5999
4CC11	Wound - High	Late - Institutional	0	1.5347
4CC21	Wound - High	Late - Institutional	1	1.5944
4CC31	Wound - High	Late - Institutional	2	1.7194
4DA11	Complex - Low	Late - Institutional	0	0.9948
4DA21	Complex - Low	Late - Institutional	1	1.0545
4DA31	Complex - Low	Late - Institutional	2	1.1795
4DB11	Complex - Medium	Late - Institutional	0	1.2016
4DB21	Complex - Medium	Late - Institutional	1	1.2613
4DB31	Complex - Medium	Late - Institutional	2	1.3863
4DC11	Complex - High	Late - Institutional	0	1.2395
4DC21	Complex - High	Late - Institutional	1	1.2991
4DC31	Complex - High	Late - Institutional	2	1.4241
4EA11	MS Rehab - Low	Late - Institutional	0	1.1179
4EA21	MS Rehab - Low	Late - Institutional	1	1.1776
4EA31	MS Rehab - Low	Late - Institutional	2	1.3026
4EB11	MS Rehab - Medium	Late - Institutional	0	1.2453
4EB21	MS Rehab - Medium	Late - Institutional	1	1.3050
4EB31	MS Rehab - Medium	Late - Institutional	2	1.4300
4EC11	MS Rehab - High	Late - Institutional	0	1.3884
4EC21	MS Rehab - High	Late - Institutional	1	1.4481
4EC31	MS Rehab - High	Late - Institutional	2	1.5731
4FA11	Behavioral Health - Low	Late - Institutional	0	0.9484
4FA21	Behavioral Health - Low	Late - Institutional	1	1.0080
4FA31	Behavioral Health - Low	Late - Institutional	2	1.1330
4FB11	Behavioral Health - Medium	Late - Institutional	0	1.1260
4FB21	Behavioral Health - Medium	Late - Institutional	1	1.1856
4FB31	Behavioral Health - Medium	Late - Institutional	2	1.3106
4FC11	Behavioral Health - High	Late - Institutional	0	1.2143
4FC21	Behavioral Health - High	Late - Institutional	1	1.2739
4FC31	Behavioral Health - High	Late - Institutional	2	1.3990
4GA11	MMTA - Surgical Aftercare - Low	Late - Institutional	0	0.9254
4GA21	MMTA - Surgical Aftercare - Low	Late - Institutional	1	0.9850
4GA31	MMTA - Surgical Aftercare - Low	Late - Institutional	2	1.1100
4GB11	MMTA - Surgical Aftercare - Medium	Late - Institutional	0	1.0898
4GB21	MMTA - Surgical Aftercare - Medium	Late - Institutional	1	1.1494
4GB31	MMTA - Surgical Aftercare - Medium	Late - Institutional	2	1.2744
4GC11	MMTA - Surgical Aftercare - High	Late - Institutional	0	1.2457
4GC21	MMTA - Surgical Aftercare - High	Late - Institutional	1	1.3053
4GC31	MMTA - Surgical Aftercare - High	Late - Institutional	2	1.4303

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	CY 2019 Weight
4HA11	MMTA - Cardiac - Low	Late - Institutional	0	1.0150
4HA21	MMTA - Cardiac - Low	Late - Institutional	1	1.0747
4HA31	MMTA - Cardiac - Low	Late - Institutional	2	1.1997
4HB11	MMTA - Cardiac - Medium	Late - Institutional	0	1.1684
4HB21	MMTA - Cardiac - Medium	Late - Institutional	1	1.2281
4HB31	MMTA - Cardiac - Medium	Late - Institutional	2	1.3531
4HC11	MMTA - Cardiac - High	Late - Institutional	0	1.2831
4HC21	MMTA - Cardiac - High	Late - Institutional	1	1.3427
4HC31	MMTA - Cardiac - High	Late - Institutional	2	1.4677
4IA11	MMTA - Endocrine - Low	Late - Institutional	0	1.1341
4IA21	MMTA - Endocrine - Low	Late - Institutional	1	1.1937
4IA31	MMTA - Endocrine - Low	Late - Institutional	2	1.3187
4IB11	MMTA - Endocrine - Medium	Late - Institutional	0	1.2989
4IB21	MMTA - Endocrine - Medium	Late - Institutional	1	1.3586
4IB31	MMTA - Endocrine - Medium	Late - Institutional	2	1.4836
4IC11	MMTA - Endocrine - High	Late - Institutional	0	1.4211
4IC21	MMTA - Endocrine - High	Late - Institutional	1	1.4807
4IC31	MMTA - Endocrine - High	Late - Institutional	2	1.6058
4JA11	MMTA - GI/GU - Low	Late - Institutional	0	0.9746
4JA21	MMTA - GI/GU - Low	Late - Institutional	1	1.0342
4JA31	MMTA - GI/GU - Low	Late - Institutional	2	1.1593
4JB11	MMTA - GI/GU - Medium	Late - Institutional	0	1.1382
4JB21	MMTA - GI/GU - Medium	Late - Institutional	1	1.1978
4JB31	MMTA - GI/GU - Medium	Late - Institutional	2	1.3228
4JC11	MMTA - GI/GU - High	Late - Institutional	0	1.2319
4JC21	MMTA - GI/GU - High	Late - Institutional	1	1.2916
4JC31	MMTA - GI/GU - High	Late - Institutional	2	1.4166
4KA11	MMTA - Infectious - Low	Late - Institutional	0	1.0070
4KA21	MMTA - Infectious - Low	Late - Institutional	1	1.0667
4KA31	MMTA - Infectious - Low	Late - Institutional	2	1.1917
4KB11	MMTA - Infectious - Medium	Late - Institutional	0	1.1422
4KB21	MMTA - Infectious - Medium	Late - Institutional	1	1.2018
4KB31	MMTA - Infectious - Medium	Late - Institutional	2	1.3269
4KC11	MMTA - Infectious - High	Late - Institutional	0	1.2535
4KC21	MMTA - Infectious - High	Late - Institutional	1	1.3131
4KC31	MMTA - Infectious - High	Late - Institutional	2	1.4382
4LA11	MMTA - Respiratory - Low	Late - Institutional	0	0.9919
4LA21	MMTA - Respiratory - Low	Late - Institutional	1	1.0515
4LA31	MMTA - Respiratory - Low	Late - Institutional	2	1.1766
4LB11	MMTA - Respiratory - Medium	Late - Institutional	0	1.1358
4LB21	MMTA - Respiratory - Medium	Late - Institutional	1	1.1954
4LB31	MMTA - Respiratory - Medium	Late - Institutional	2	1.3205
4LC11	MMTA - Respiratory - High	Late - Institutional	0	1.2449
4LC21	MMTA - Respiratory - High	Late - Institutional	1	1.3045
4LC31	MMTA - Respiratory - High	Late - Institutional	2	1.4295

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of June 30, 2018) for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded.

In conjunction with the implementation of the PDGM, in the CY 2019 HH PPS proposed rule (83 FR 32420) we proposed to revise the

frequency with which we update the HH PPS Grouper software used to assign the appropriate HIPPS code used for case-mix adjustment onto the claim.

Since CY 2004 when the HH PPS moved from a fiscal year to a calendar year basis, we have updated the Grouper software twice a year. We provide an

updated version of the Grouper software effective every October 1 in order to address ICD coding revisions, which are effective on October 1. We also provide an updated version of the HH PPS Grouper software effective on January 1 in order to capture the new or revised HH PPS policies that become effective on January 1. In an effort to reduce provider burden associated with testing and installing two software releases, we proposed to discontinue the October release of the HH PPS Grouper software and provide a single HH PPS Grouper software release effective January 1 of each calendar year. We proposed that the January release of the HH PPS Grouper software would include the most recent revisions to the ICD coding system as well as the payment policy updates contained in the HH PPS final rule.

We solicited public comments on the proposed PDGM case-mix weights, case-mix weight methodology and proposed annual recalibration of the case-mix weights, updates to the HH PPS Grouper software, and the associated regulations text changes in section III.F.13 of this proposed rule. The following is a summary of the public comments on the case mix weight methodology under PDGM and the updates to the HH PPS Grouper Software and our responses:

Comment: A few commenters urged CMS to formalize a transparent process and timeline to refine the case-mix weights soon after implementation of the PDGM, to assess whether various factors will influence the ability of the model to better predict resource use, such as additional secondary diagnoses or interactions between such diagnoses. The commenters noted that it is imperative that the case-mix weights reflect current care protocols and resource needs. A few commenters suggested that CMS provide further explanation of how the new model addresses the concerns for those patients with complex, chronic care needs (for example, an ALS patient is referenced). Another commenter questioned how the PDGM could address issues of access, since beneficiaries without access to home health are by definition not included in the analysis (which was done based on prior utilization records).

Response: As noted in the CY 2019 HH PPS proposed rule (83 FR 32416), we proposed to annually recalibrate the PDGM case-mix weights to reflect the most recent utilization data available at the time of rulemaking. Once the PDGM is finalized, we will also continue to analyze all of the components of the case-mix adjustment, and make refinements as necessary to ensure that

payment for home health periods are in alignment with costs. We note that we provide a clinical example in section III.F.12 of this final rule with comment period, specifically relating to ALS, that shows how high cost periods of care could receive outlier payments under the PDGM.

Comment: Numerous commenters agreed that the October release of the Grouper should be discontinued (and only the January release be retained) as long as HHAs would not be at risk for violating HIPAA rules, if the agency were to potentially use an incorrect diagnosis code in the last quarter of the year (incorrect in the sense that the coding was made obsolete by ICD-10 refinements that were not reflected in the Grouper until the following January). A commenter expressed approval at this effort to reduce burdens on HHAs (although also expressed concern over the issue with HIPAA rules). Another commenter questioned how this would impact other Medicare claims and coding, noting that many agencies also operate hospice businesses, and the situation can be confusing if hospice still operates under the Fiscal Year guidance whereas Home Health operates under the Calendar Year guidance.

Response: We thank commenters for their support in findings ways to reduce regulatory burden and potentially streamlining the HH PPS Grouper into one annual release. However, upon further examination of this proposal, we recognize that this could lead to potential Health Insurance Portability and Accountability Act (HIPAA) violations for HHAs. HIPAA requires that covered entities use the current adopted code set (45 CFR 162.1000). If the ICD-10-CM code set is implemented in October then that would be the current code set and using outdated codes from October through the following January would be non-compliant with HIPAA requirements. However, in an effort to reduce provider burden associated with the release of two Groupers, we will continue to examine ways to minimize this burden. For example, if we do not update the functional impairment level points and thresholds on an annual basis, we could eliminate the need for a second Grouper release in January and instead update the Grouper for October 1 when ICD-10-CM code changes become effective. While we would continue to annually recalibrate the PDGM case-mix weights, we may not need to update the points and thresholds annually. Any changes to the Grouper releases or the updates to the functional points and thresholds

would be proposed in future rulemaking.

Final Decision: We are finalizing the PDGM, with the modifications previously discussed, effective for 30-day periods of care that start on or after January 1, 2020. Additionally, we are finalizing our proposal to generate PDGM case-mix weights for each of the different PDGM payment groups by regressing resource use on a series of indicator variables for each of the five categories previously listed (timing, admission source, clinical grouping, functional level, and comorbidity) using a fixed effects model and annually recalibrating the PDGM case-mix weights to ensure that the case-mix weights reflect the most recent utilization data available at the time of annual rulemaking. We are not finalizing the discontinuation of the October release of the HH PPS Grouper software update given the potential for HIPAA violations. Therefore, we will continue to release Grouper software in both October and January of each year. Any proposals to discontinue any one of the Grouper software releases would be included in future rulemaking for public comment.

11. Low-Utilization Payment Adjustment (LUPA) Add-On Payments and Partial Payment Adjustments Under PDGM

Currently, LUPA episodes qualify for an add-on payment when the episode is the first or only episode in a sequence of adjacent episodes. As stated in the CY 2008 HH PPS final rule, LUPA add-on payments are made because the national per-visit payment rates do not adequately account for the front-loading of costs for the first LUPA episode of care as the average visit lengths in these initial LUPAs are 16 to 18 percent higher than the average visit lengths in initial non-LUPA episodes (72 FR 49848). LUPA episodes that occur as the only episode or as an initial episode in a sequence of adjacent episodes are adjusted by applying an additional amount to the LUPA payment before adjusting for area wage differences. Under the PDGM, we proposed that the LUPA add-on factors will remain the same as the current payment system, described in the CY 2019 HH PPS proposed rule (83 FR 32372). We proposed to multiply the per-visit payment amount for the first SN, PT, or SLP visit in LUPA 30-day periods that occur as the only 30-day period or an initial 30-day period in a sequence of adjacent periods of care by the appropriate factor (1.8451 for SN, 1.6700 for PT, and 1.6266 for SLP) to

determine the LUPA add-on payment amount.

The current partial episode payment (PEP) adjustment is a proportion of the episode payment and is based on the span of days including the start-of-care date (the date of the first billable service) through and including the last billable service date under the original plan of care before an intervening event in a home health beneficiary's care defined as:

- A beneficiary elected transfer, or
- A discharge and return to home health that would warrant, for purposes of payment, a new OASIS assessment, physician certification of eligibility, and a new plan of care.

For 30-day periods of care, we proposed that the process for partial payment adjustments would remain the same as the existing policies pertaining to partial episode payments. When a new 30-day period begins due to the intervening event of a beneficiary elected transfer or there was a discharge and return to home health during the 30-day period, we proposed that the original 30-day period would be proportionally adjusted to reflect the length of time the beneficiary remained under the agency's care prior to the intervening event. The proportional payment is the partial payment adjustment. The partial payment adjustment would be calculated by using the span of days (first billable service date through and including the last billable service date) under the original plan of care as a proportion of 30. The proportion would then be multiplied by the original case-mix and wage index to produce the 30-day payment.

We solicited public comments on the LUPA add-on payments and partial payment adjustments proposed for the PDGM and the associated changes in the regulations text. The following is a summary of the public comments and our responses:

Comment: Another commenter requested clarification on the use of the word "episode" in the CY 2019 HH PPS proposed rule (83 FR 32421) and whether the first two 30-day periods (the former 60-day episode timeframe) would both receive the LUPA add-on payment or only the initial 30-day period. The commenter's expectation was that the add-on payment would only be paid to the initial 30-day period.

Response: The commenter's assumption was correct; the LUPA add-on payment amount under the PDGM will only be paid to LUPA periods that occur as the only period of care or the initial 30-day period of care in a

sequence of additional periods of care by the appropriate add-on factor.

Final Decision: We are finalizing our proposal to continue to multiply the per-visit payment amount for the first skilled nursing, physical therapy, or speech-language pathology visit in LUPA periods that occur as the only period of care or the initial 30-day period of care in a sequence of adjacent 30-day periods of care by the appropriate add-on factor (1.8451 for SN, 1.6700 for PT, and 1.6266 for SLP) to determine the LUPA add-on payment amount for 30-day periods of care under the PDGM. We are also finalizing our proposal to retain the current PEP policy and apply such policy to 30-day periods of care under the PDGM.

12. Payments for High-Cost Outliers Under the PGDM

As described in section III.E. of the CY 2019 HH PPS proposed rule (83 FR 32375), section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the home health payment amount in the case of outliers because of unusual variations in the type or amount of medically necessary care. The history of and current methodology for payment of high-cost outliers under the HH PPS is described in detail in section III.E. of the CY 2019 HH PPS proposed rule (83 FR 32375). We proposed that we would maintain the current methodology for payment of high-cost outliers upon implementation of the PGDM and that we would calculate payment for high-cost outliers based upon 30-day periods of care.

As discussed in the CY 2019 HH PPS proposed rule (83 FR 32421), we updated our outlier estimates for this final rule with comment period. Simulating payments using preliminary CY 2017 claims data and the CY 2019 payment rates, we estimated that outlier payments under the PGDM with 30-day periods of care would comprise approximately 4.77 percent of total HH PPS payments in CY 2019. Given the statutory requirement that estimated total outlier payments do not exceed the 2.5 percent of total payments (as required by section 1895(b)(5)(A) of the Act), we estimated that the FDL ratio under the PGDM would need to change to 0.71 to maintain compliance with statute. However, given the implementation of the PGDM for 30-day periods of care beginning on or after January 1, 2020, we will update our estimate of outlier payments as a percent of total HH PPS payments using the most current and complete utilization data available at the time of CY 2020 rate setting and would propose

a change in the FDL ratio for CY 2020, if needed.

We solicited public comments on maintaining the current outlier payment methodology for the PGDM and the associated changes in the regulations text. The following is a summary of the public comments and our responses:

Comment: Several commenters indicated their support for the proposal to continue outlier payments under the PDGM.

Response: We thank the commenters for the support of this continued payment policy.

Comment: Several commenters suggested that we develop an outlier policy under the PGDM that is comparable to the existing system but modified to reflect the change to the 30-day payment period and also consider further refinement to ensure a smooth transition within the framework of the PGDM. Another commenter expressed concern regarding the potential for more providers to exceed the 10 percent outlier cap under a 30-day period of care and also suggested modification to the 8-hour cap on the amount of time per day that is permitted to be counted toward the estimation of a period's costs for outlier calculation purposes. A few commenters stated that they believed that the cap on outlier payments would prevent necessary care and cause providers to seek beneficiaries with profiles that could help maximize profits.

Response: We believe that our proposal to maintain the existing outlier policy under the PGDM, except that outlier payments would be determined on a 30-day basis to align with the 30-day unit of payment under the PGDM, is comparable to the existing system and would ensure a smooth transition within the framework on the PGDM. We plan to closely evaluate and model projected outlier payments within the framework of the PGDM and consider modifications to the outlier policy as appropriate. We note that the maximum of 2.5 percent of outlier payments to total payments and the 10 percent cap on outlier payments at the home health agency level are statutory requirements, as described in section 1895(b)(5) of the Act. Therefore, we do not have the authority to adjust or eliminate the 10-percent cap or increase the 2.5 percent maximum amount.

Regarding the 8-hour limit on the amount of time per day counted toward the estimation of a period's costs, as noted in the CY2017 HH PPS final rule (81 FR 76729), where a patient is eligible for coverage of home health services, Medicare statute limits the amount of part-time or intermittent

home health aide services and skilled nursing services covered during a home health episode. Section 1861(m)(7)(B) of the Act states that the term “part-time or intermittent services” means skilled nursing and home health aide services furnished any number of days per week as long as they are furnished (combined) less than 8 hours each day and 28 or fewer hours each week (or, subject to review on a case-by-case basis as to the need for care, less than 8 hours each day and 35 or fewer hours per week).” Therefore, the daily and weekly cap on the amount of skilled nursing and home health aide services combined is a limit defined within the statute. As we further noted in the CY2018 HH PPS final rule (81 FR 76729), because outlier payments are predominately driven by the provision of skilled nursing services, the 8-hour daily cap on services aligns with the statute, which requires that skilled nursing and home health aide services be furnished less than 8 hours each day. Therefore, we believe that maintaining the 8-hour per day cap is appropriate under the new PDGM. However, we plan to monitor for any unintended results of this policy as data become available.

Comment: Another commenter expressed concern regarding the change to 30-day payment periods and its impact to the outlier payment policy. The commenter believes that the 30-day periods and resultant adjustment to the fixed dollar loss ratio would then make it harder for beneficiaries to obtain outlier services.

Response: As described in detail in the CY 2019 HH PPS proposed rule (83 FR 32340), for a given level of outlier payments, there is a trade-off between the values selected for the FDL ratio and the loss-sharing ratio. A higher FDL ratio reduces the number of episodes that can receive outlier payments, but makes it possible to select a higher loss-sharing ratio, and therefore, increase outlier payments for qualifying outlier episodes. Alternatively, a lower FDL ratio means that more episodes can qualify for outlier payments, but outlier payments per episode must then be lower. As we evaluate the final features of the PDGM for implementation in CY 2020, we will evaluate and consider the potential for impacts of a modified FDL. While a higher FDL value would

potentially lessen the number of home health periods that qualify for an outlier payment, those periods that did qualify for an outlier payment could potentially receive a proportionally higher outlier payment amount. Additionally, we note that the 2.5 percent target of outlier payments to total payments and the 10 percent cap on outlier payments at the home health agency level are statutory requirements, as described in section 1895(b)(5) of the Act. Moreover, the forthcoming change to the 30-day payment period is also statutory in that it is required by the BBA of 2018. We plan to closely evaluate and model projected outlier payments within the framework of the PDGM and consider modifications to the outlier policy as appropriate.

Comment: Several commenters suggested that eligibility for an outlier payment be updated to include NRS costs incurred and not just imputed costs of service visits. Commenters asserted that the outlier policy under the PDGM may not adequately cover the costs of wound care products necessary to achieve excellent patient outcomes and recommended that we design a more specific model that accurately pays for NRS separately and establish an outlier payment model for very complex wound-care patients.

Response: We appreciate the commenters’ suggestion regarding the inclusion of supplies in the outlier calculation under the PDGM. In order to incorporate supply costs into the outlier calculation, significant claims payment system modifications would be required. However, we will consider whether to add supply costs to the outlier calculations and evaluate whether such a policy change is appropriate for future rulemaking, potentially in conjunction with the implementation of the PDGM for CY 2020.

Comments: Commenters requested that we develop clinical examples illustrating how outliers would be paid under the proposed PDGM, similar to the examples provided for an ALS patient under the current payment system in the CY 2019 HH PPS proposed rule.

Response: In section III.D. of the CY 2019 HH PPS proposed rule (83 FR 32340), we described a clinical example

of how care for a patient with amyotrophic lateral sclerosis (ALS), could qualify for an additional outlier payment, which would serve to offset unusually high costs associated with providing home health to a patient with unusual variations in the amount of medically necessary care. Using the same clinical scenario, in this final rule with comment period we provide an example of how the provision of services per the home health plan of care could emerge for a beneficiary with ALS who qualifies for the Medicare home health benefit for the first two 30-day periods of care under the PDGM. We note that this example is provided for illustrative purposes only and does not constitute a specific Medicare payment scenario.

Example One: First 30-day Period under the PDGM:

An ALS beneficiary may be assessed by a physician in the community and subsequently be deemed to require home health services for skilled nursing, physical therapy, occupational therapy, and a home health aide. The beneficiary could receive skilled nursing twice a week for 45 minutes to assess dyspnea when transferring to a bedside commode, stage two pressure ulcer of the sacrum, and pain status. In addition, a home health aide could provide services for three hours in the morning and three hours on Monday, Wednesday and Friday and two and a half hours in the morning and two and half hours in the afternoon on Tuesday and Thursdays to assist with bathing, dressing and transferring. Physical therapy services twice a week for 45 minutes could be provided for adaptive transfer techniques, and occupational therapy services could be supplied twice a week for 45 minutes for assessment and teaching of assistive devices for activities of daily living to prevent or slow deterioration of the beneficiary’s condition. Because of the patient’s condition, the first 30-day period of care would be placed into the community early, neuro rehabilitation, high functional impairment, and low comorbidity group (1BC21). For the purposes of this example, we assume that services are rendered per week for a total of 4 weeks per 30-day period of care.

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TABLE 35: CLINICAL SCENARIO CALCULATION TABLE: FIRST 30-DAY PERIOD

HH Outlier CY 2019 30-Day Illustrative Values	Value	Operation	Adjuster	Equals	Output
National, Standardized 30-day Period Payment Rate	\$1,753.68				
Case-Mix Adjustment for Payment Group	1.5158				
Case-Mix Adjusted Period Payment Amount	\$1,753.68	*	1.5158	=	\$2,658.23
Labor Portion of the Case-Mix Adjusted Period Payment Amount	\$2,658.23	*	0.761	=	\$2,022.91
Non-Labor Portion of the Case-Mix Adjusted Period Payment Amount	\$2,658.23	*	0.239	=	\$635.32
Wage Index Value (Beneficiary resides in 31084, Los Angeles-Long Beach-Glendale, CA)	1.3055				
Wage-Adjusted Labor Portion of the Case-Mix Adjusted Period Payment Amount	1.3055	*	\$2,022.91	=	\$2,640.91
Total Case-Mix and Wage-Adjusted Period Payment Amount (Wage-Adjusted Labor Portion plus Non-Labor Portion of the Case-Mix Adjusted Period Payment Amount plus the NRS Amount)					\$3,276.23
Total Wage-Adjusted Fixed Dollar Loss Amount					
Fixed Dollar Loss Amount (National, Standardized 30-day Period Payment Rate*FDL Ratio)	\$1,753.68	*	0.71	=	\$1,245.11
Labor Portion of the Fixed Dollar Loss Amount	\$1,245.11	*	0.761	=	\$947.53
Non-Labor Amount of the Fixed Dollar Loss Amount	\$1,245.11	*	0.239	=	\$297.58
Wage-Adjusted Amount of the Fixed Dollar Loss Amount	\$947.53	*	1.3055	=	\$1,237.00
Total Wage-Adjusted Fixed Dollar Loss Amount (Wage-Adjusted Labor Portion plus Non-Labor Portion of the Case-Mix Adjusted Fixed Dollar Loss Amount)	\$1,237.00	+	\$297.58	=	\$1,534.58
Total Wage-Adjusted Imputed Cost Amount					
National Per-Unit Payment Amount - Skilled Nursing	\$49.05				
Number of 15-minute units (45 minutes = 3 units twice per week for 4 weeks)	24				
Imputed Skilled Nursing Visit Costs (National Per-Unit Payment Amount * Number of Units)	\$49.05	*	24	=	\$1,177.20
National Per-Unit Payment Amount - Home Health Aide	\$15.80				
Number of 15-minute units (28 hours per week = 112 units per week for 4 weeks)	448				
Imputed Home Health Aide Costs (National Per-Unit Payment Amount * Number of Units)	\$15.80	*	448	=	\$7,078.40
National Per-Unit Payment Amount - Occupational Therapy (OT)	\$51.35				
Number of 15-minute units (45 minutes = 3 units twice per week for 4 weeks)	24				
Imputed OT Visit Costs (National Per-Unit Payment Amount * Number of Units)	\$51.35	*	24	=	\$1,232.40
National Per-Unit Payment Amount - PT	\$51.55				
Number of 15-minute units (45 minutes = 3 units twice per week for 4 weeks)	24				
Imputed PT Visit Costs (National Per-Unit Payment Amount * Number of Units)	\$51.55	*	24	=	\$1,237.20
Total Imputed Costs for all Disciplines					\$10,725.20
Labor Portion of the Imputed Costs for All Disciplines	\$10,725.20	*	0.761	=	\$8,161.88
Non-Labor Portion of Imputed Cost Amount for All Disciplines	\$10,725.20	*	0.239	=	\$2,563.32
CBSA Wage Index (Beneficiary resides in 31084, Los Angeles-Long Beach-Glendale, CA)	1.3055				
Wage-Adjusted Labor Portion of the Imputed Cost Amount for All Disciplines	\$8,161.88	*	1.3055	=	\$10,655.33
Total Wage-Adjusted Imputed Cost Amount (Wage-Adjusted Labor Portion of the Imputed Cost Amount plus Non-Labor Portion of the Imputed Cost Amount)	\$10,655.33	+	\$2,563.32	=	\$13,218.65
Total Payment for 30-Day Period					

HH Outlier CY 2019 30-Day Illustrative Values	Value	Operation	Adjuster	Equals	Output
Outlier Threshold Amount (Total Wage-Adjusted Fixed Dollar Loss Amount + Total Case-Mix and Wage-Adjusted Period Payment Amount)	\$1,534.58	+	\$3,276.23	=	\$4,810.81
Total Wage-Adjusted Imputed Cost Amount - Outlier Threshold Amount (Total Wage-Adjusted Fixed Dollar Loss Amount + Total Case-Mix and Wage-Adjusted Period Payment Amount)	\$13,218.65	-	\$4,810.81	=	\$8,407.84
Outlier Payment = Imputed Costs Greater Than the Outlier Threshold * Loss-Sharing Ratio	\$8,407.84	*	0.8	=	\$6,726.27
Total Payment for 30-Day Period = Total Case-Mix and Wage-Adjusted Period Payment Amount + Outlier Payment	\$3,276.23	+	\$6,726.27	=	\$10,002.50

For the first 30-day period of this clinical scenario under the PDGM, the preceding calculation illustrates how HHAs would be paid by Medicare for providing care to patients with higher resource use in their homes.

Example Two: Second 30-day Period under the PDGM:

For the second 30-day period under the PDGM, the ALS beneficiary continues to require the home health services of skilled nursing, physical therapy, occupational therapy and a nurse's aide. The beneficiary continues

to receive skilled nursing twice a week to assess dyspnea when transferring to a bedside commode, stage two pressure ulcer at the sacrum, and pain status. A home health aide could provide services for three hours in the morning and three hours on Monday, Wednesday, and Friday and two and a half hours in the morning and two and half hours in the afternoon on Tuesday and Thursdays to assist with bathing, dressing, and transferring. Physical therapy services twice a week for 45 minutes could be

provided for adaptive transfer techniques, and occupational therapy services could be supplied twice a week for 45 minutes for assessment and teaching of assistive devices for activities of daily living to prevent or slow deterioration of the beneficiary's condition. Given the beneficiary's condition the second 30-day period of care would fall into the community late, neuro rehabilitation, high functional impairment, and low comorbidity group (3BC21).

TABLE 36: CLINICAL SCENARIO CALCULATION TABLE: SECOND 30-DAY PERIOD

HH Outlier CY 2019 30-Day Illustrative Values	Value	Operation	Adjuster	Equals	Output
National, Standardized 30-day Period Payment Rate	\$1,753.68				
Case-Mix Adjustment for Payment Group	1.1117				
Case-Mix Adjusted Period Payment Amount	\$1,753.68	*	1.1117	=	\$1,949.57
Labor Portion of the Case-Mix Adjusted Period Payment Amount	\$1,949.57	*	0.761	=	\$1,483.62
Non-Labor Portion of the Case-Mix Adjusted Period Payment Amount	\$1,949.57	*	0.239	=	\$465.95
Wage Index Value (Beneficiary resides in 31084, Los Angeles-Long Beach-Glendale, CA)	1.3055				
Wage-Adjusted Labor Portion of the Case-Mix Adjusted Period Payment Amount	1.3055	*	\$1,483.62	=	\$1,936.87
Total Case-Mix and Wage-Adjusted Period Payment Amount (Wage-Adjusted Labor Portion plus Non-Labor Portion of the Case-Mix Adjusted Period Payment Amount plus the NRS Amount)					\$2,402.81
Total Wage-Adjusted Fixed Dollar Loss Amount					
Fixed Dollar Loss Amount (National, Standardized 30-day Period Payment Rate*FDL Ratio)	\$1,753.68	*	0.71	=	\$1,245.11
Labor Portion of the Fixed Dollar Loss Amount	\$1,245.11	*	0.761	=	\$947.53
Non-Labor Amount of the Fixed Dollar Loss Amount	\$1,245.11	*	0.239	=	\$297.58
Wage-Adjusted Amount of the Fixed Dollar Loss Amount	\$947.53	*	1.3055	=	\$1,237.00
Total Wage-Adjusted Fixed Dollar Loss Amount (Wage-Adjusted Labor Portion plus Non-Labor Portion of the Case-Mix Adjusted Fixed Dollar Loss Amount)	\$1,237.00	+	\$297.58	=	\$1,534.58
Total Wage-Adjusted Imputed Cost Amount					
National Per-Unit Payment Amount - Skilled Nursing	\$49.05				
Number of 15-minute units (45 minutes = 3 units twice per week for 8 weeks)	24				
Imputed Skilled Nursing Visit Costs (National Per-Unit Payment Amount * Number of Units)	\$49.05	*	24	=	\$1,177.20
National Per-Unit Payment Amount - Home Health Aide	\$15.80				
Number of 15-minute units (28 hours per week = 112 units per week for 8 weeks)	448				
Imputed Home Health Aide Costs (National Per-Unit Payment Amount * Number of Units)	\$15.80	*	448	=	\$7,078.40
National Per-Unit Payment Amount – Occupational Therapy (OT)	\$51.35				
Number of 15-minute units (45 minutes = 3 units twice per week for 8 weeks)	24				
Imputed OT Visit Costs (National Per-Unit Payment Amount * Number of Units)	\$51.35	*	24	=	\$1,232.40
National Per-Unit Payment Amount - PT	\$51.55				
Number of 15-minute units (45 minutes = 3 units twice per week for 8 weeks)	24				
Imputed PT Visit Costs (National Per-Unit Payment Amount * Number of Units)	\$51.55	*	24	=	\$1,237.20
Total Imputed Costs for all Disciplines					\$10,725.20
Labor Portion of the Imputed Costs for All Disciplines	\$10,725.20	*	0.761	=	\$8,161.88
Non-Labor Portion of Imputed Cost Amount for All Disciplines	\$10,725.20	*	0.239	=	\$2,563.32
CBSA Wage Index (Beneficiary resides in 31084, Los Angeles-Long Beach-Glendale, CA)	1.3055				

Wage-Adjusted Labor Portion of the Imputed Cost Amount for All Disciplines	\$8,161.88	*	1.3055	=	\$10,655.33
Total Wage-Adjusted Imputed Cost Amount (Wage-Adjusted Labor Portion of the Imputed Cost Amount plus Non-Labor Portion of the Imputed Cost Amount)	\$10,655.33	+	\$2,563.32	=	\$13,218.65
Total Payment Per 30-Day Period					
Outlier Threshold Amount (Total Wage-Adjusted Fixed Dollar Loss Amount + Total Case-Mix and Wage-Adjusted Period Payment Amount)	\$1,534.58	+	\$2,402.81	=	\$3,937.39
Total Wage-Adjusted Imputed Cost Amount - Outlier Threshold Amount (Total Wage-Adjusted Fixed Dollar Loss Amount + Total Case-Mix and Wage-Adjusted Period Payment Amount)	\$13,218.65	-	\$3,937.39	=	\$9,281.26
Outlier Payment = Imputed Costs Greater Than the Outlier Threshold * Loss-Sharing Ratio	\$9,281.26	*	0.8	=	\$7,425.01
Total Payment Per 30-Day Period = Total Case-Mix and Wage-Adjusted Period Payment Amount + Outlier Payment	\$2,402.81	+	\$7,425.81	=	\$9,827.82

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For the second 30-day period of this clinical scenario, the previous calculation demonstrates how outlier payments could be made for patients with chronic, complex conditions under the PDGM. We note that this example is presented for illustrative purposes only, and is not intended to suggest that all diagnoses of ALS should receive the grouping assignment or number of periods described here. The CMS Grouper would assign these groups based on information in the OASIS. In general, we expect that outlier payments for unusually high cost periods in PDGM will be comparable to those under the current system, but there may be a small increase or decrease in rates depending on each beneficiary's specific situation. We reiterate that outlier payments could provide payment to HHAs for those patients with higher resource use and that the patient's condition does not need to improve for home health services to be covered by Medicare. We appreciate the feedback we have received from the public on the outlier policy under the HH PPS and look forward to ongoing collaboration with stakeholders on any further refinements that may be warranted, including the proposed outlier methodology under the PDGM.

Final Decision: We are finalizing our proposal to maintain the current methodology for payment of high-cost outliers upon implementation of the PGDM and that we would calculate payment for high-cost outliers based upon 30-day periods of care.

13. Conforming Regulations Text Revisions for the Implementation of the PDGM in CY 2020

We are finalizing a number of revisions to the regulations to implement the PDGM for periods of care

beginning on or after January 1, 2020, as outlined in sections through III.F.1 through III.F.12 of this final rule with comment period. We are finalizing to make conforming changes in § 409.43 and part 484 Subpart E to revise the unit of service from a 60-day episode to a 30-day period. In addition, we are finalizing to restructure § 484.205. These revisions would be effective on January 1, 2020. Specifically, we are doing the following:

- Revising § 409.43, which outlines plan of care requirements. We are revising several paragraphs to phase out the unit of service from a 60-day episode for claims beginning on or before December 31, 2019, and to implement a 30-day period as the new unit of service for claims beginning on or after January 1, 2020 under the PDGM. We are moving and revising paragraph (c)(2) to § 484.205 as paragraph (c)(2) aligns more closely with the regulations addressing the basis of payment.

- Revising the definitions of rural area and urban area in § 484.202 to remove "with respect to home health episodes ending on or after January 1, 2006" from each definition as this verbiage is no longer necessary.

- Restructuring § 484.205 to provide more logical organization and revise to account for the change in the unit of payment under the HH PPS for CY 2020. The PDGM uses 30-day periods rather than the 60-day episode used in the current payment system. Therefore, we are to revising § 484.205 to remove references to "60-day episode" and to refer more generally to the "national, standardized prospective payment". We are also revising § 484.205 as follows:

- ++ Adding paragraphs to paragraph (b) to define the unit of payment.
- ++ Moving language which addresses the requirement for OASIS submission

from § 484.210 and inserting it into § 484.205 as new paragraph (c).

- ++ Moving paragraph (c)(2) from § 409.43 to § 484.205 as new paragraph (g) in order to better align with the regulations detailing the basis of payment.

- ++ Adding paragraph (h) to discuss split percentage payments under the current model and the PDGM.

We are not changing the requirements or policies relating to durable medical equipment or furnishing negative pressure wound therapy using a disposable device.

- Removing § 484.210 which discusses data used for the calculation of the national prospective 60-day episode payment as we believe that this information is duplicative and already incorporated in other sections of part 484, subpart E.

- Revising the section heading of § 484.215 from "Initial establishment of the calculation of the national 60-day episode payment" to "Initial establishment of the calculation of the national, standardized prospective 60-day episode payment and 30-day payment rates." Also, we are adding paragraph (f) to this section to describe when the national, standardized prospective 30-day payment rate applies.

- Revising the section heading of § 484.220 from "Calculation of the adjusted national prospective 60-day episode payment rate for case-mix and area wage levels" to "Calculation of the case-mix and wage area adjusted prospective payment rates." We are removing the reference to "national 60-day episode payment rate" and replacing it with "national, standardized prospective payment".

- Revising the section heading in § 484.225 from "Annual update of the unadjusted national prospective 60-day

episode payment rate” to “Annual update of the unadjusted national, standardized prospective 60-day episode and 30-day payment rates”. Also, we are revising § 484.225 to remove references to “60-day episode” and to refer more generally to the “national, standardized prospective payment”. In addition, we are adding paragraph (d) to describe the annual update for CY 2020 and subsequent calendar years.

- Revising the section heading of § 484.230 from “Methodology used for the calculation of low-utilization payment adjustment” to “Low utilization payment adjustment”. Also, we are designating the current text to paragraph (a) and inserting language such that paragraph (a) applies to claims beginning on or before December 31, 2019, using the current payment system. We are adding paragraph (b) to describe how low utilization payment adjustments are determined for claims beginning on or after January 1, 2020, using the PDGM.

- Revising the section heading of § 484.235 from “Methodology used for the calculation of partial episode payment adjustments” to “Partial payment adjustments”. We are removing paragraphs (a), (b), and (c). We are removing paragraphs (1), (2), and (3) which describe partial payment adjustments from paragraph (d) in § 484.205 and incorporating them into § 484.235. We are adding paragraph (a) to describe partial payment adjustments under the current system, that is, for claims beginning on or before December 31, 2019, and paragraph (b) to describe partial payment adjustments under the PDGM, that is, for claims beginning on or after January 1, 2020.

- Revising the section heading for § 484.240 from “Methodology used for the calculation of the outlier payment” to “Outlier payments.” In addition, we are removing language at paragraph (b) and appending it to paragraph (a). We are adding language to revised paragraph (a) such that paragraph (a) will apply to payments under the current system, that is, for claims beginning on or before December 31, 2019. We are revising paragraph (b) to describe payments under the PDGM, that is, for claims beginning on or after January 1, 2020. In paragraph (c), we are replacing the “estimated” cost with “imputed” cost. Lastly, we are revising paragraph (d) to reflect the per-15 minute unit approach to imputing the cost for each claim.

We did not receive any comments on the corresponding regulations text changes regarding the PDGM; therefore, we are finalizing regulations text

changes as proposed without modification.

G. Changes Regarding Certifying and Recertifying Patient Eligibility for Medicare Home Health Services

1. Regulations Text Changes Regarding Information Used To Satisfy Documentation of Medicare Eligibility for Home Health Services

Section 51002 of the BBA of 2018 amended sections 1814(a) and 1835(a) of the Act to provide that, effective for physician certifications and recertifications made on or after January 1, 2019, in addition to using the documentation in the medical record of the certifying physician or of the acute or post-acute care facility (where home health services were furnished to an individual who was directly admitted to the HHA from such facility), the Secretary may use documentation in the medical record of the HHA as supporting material, as appropriate to the case involved. We believe the BBA of 2018 provisions are consistent with our existing policy in this area, which is currently reflected in sub-regulatory guidance in the Medicare Benefit Policy Manual (Pub. 100–02, chapter 7, section 30.5.1.2),³¹ and the Medicare Program Integrity Manual (Pub. 100–08, chapter 6 section 6.2.3).³² The subregulatory guidance describes the circumstances in which HHA documentation can be used along with the certifying physician and/or acute/post-acute care facility medical record to support the patient’s homebound status and skilled need. Specifically, we state that information from the HHA, such as the plan of care required in accordance with § 409.43, and/or the initial and/or comprehensive assessment of the patient required in accordance with § 484.55, can be incorporated into the certifying physician’s medical record for the patient and used to support the patient’s homebound status and need for skilled care.

In the CY 2019 HH PPS proposed rule, we proposed to amend the regulations text at § 424.22(c) to align the regulations text with current sub-regulatory guidance that allows medical record documentation from the HHA to be used to support the basis for certification and/or recertification of home health eligibility, if the following requirements are met:

- The documentation from the HHA can be corroborated by other medical record entries in the certifying physician’s and/or the acute/post-acute care facility’s medical record for the patient, thereby creating a clinically consistent picture that the patient is eligible for Medicare home health services as specified in § 424.22(a)(1) and (b).

- The certifying physician signs and dates the HHA documentation demonstrating that the documentation from the HHA was considered when certifying patient eligibility for Medicare home health services. HHA documentation can include, but is not limited to, the patient’s plan of care required in accordance with § 409.43 and/or the initial and/or comprehensive assessment of the patient required in accordance with § 484.55.

HHAs have the discretion to determine the type and format of any documentation used to support home health eligibility. Anecdotally, we have received reports from HHAs that they typically include this supporting information on the plan of care. In accordance with § 409.43(c)(3), the plan of care must be signed by the physician before the HHA submits its final claim for payment. In the CY 2019 HH PPS proposed rule, we stated that because existing sub-regulatory guidance allows HHA-generated documentation to be used as supporting material for the physician’s determination of eligibility for home health services, we expect that most HHAs already have a process in place to provide this information to the certifying physician or the acute/post-acute care facility. We solicited comments on the proposal to amend the regulations at § 424.22(c) to align the regulations text with current sub-regulatory guidance to allow medical record documentation from the HHA to be used to support the basis for certification and/or recertification of home health eligibility under certain conditions and the comments received are summarized in this final rule with comment period.

Comment: Overall, commenters were supportive of incorporating existing sub-regulatory guidance into regulations text as it provides them with reassurance that HHA-generated documentation can play an important role in confirming eligibility for Medicare home health services.

Response: We appreciate commenter support about aligning regulations text with existing regulatory guidance. The goal of this proposal is to be flexible to allow HHA-generated documentation to support eligibility for home health services given that the home health

³¹ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c07.pdf>.

³² <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c06.pdf>.

CoPs at § 484.55 require that the HHA must verify the patient's eligibility for the Medicare home health benefit, including homebound status, both at the time of the initial assessment visit and at the time of the comprehensive assessment. We agree that this proposal incorporates existing subregulatory flexibilities into the regulations text that allow HHA medical record documentation to support the basis of home health eligibility. By incorporating the existing subregulatory guidance into regulation, HHAs are assured that HHA-generated documentation can be used as supporting material for the basis of home health eligibility, as long as all conditions are met. However, we remind commenters that the certifying physician's and/or the acute/post-acute care facility's medical record (if the patient was directly admitted to home health from such setting) for the patient must contain sufficient documentation of the patient's medical condition(s) to substantiate eligibility for home health services. The information may include, but is not limited to, such factors as the patient's diagnosis, duration of the patient's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, etc. The certifying physician's and/or the acute/post-acute care facility's medical records can always stand alone in substantiating eligibility for home health services. Similarly, the certifying physician's/acute/post-acute care facility's medical record, in conjunction with appropriately incorporated HHA documentation (for example, plan of care, OASIS, etc.), may also substantiate the patient's eligibility for home health services. However, HHA-generated medical record documentation for the patient, by itself, is not sufficient in demonstrating the patient's eligibility for Medicare home health services. As noted earlier, in accordance with § 424.22(a) and (c), it is the patient's medical record held by the certifying physician and/or the acute/post-acute care facility that must support the patient's eligibility for home health services. Therefore, any documentation used to support certification that was generated by the HHA must be signed off by the certifying physician and incorporated into his/her medical record. The information provided to the certifying physician by the HHA and incorporated into the patient's medical record must be corroborated by the rest of the patient's medical record. This means that the HHA information, along

with the certifying physician's and/or the acute/post-acute care facility's medical record, creates a clinically consistent picture that the patient is eligible for Medicare home health services. This could include, but is not limited to, the plan of care required in accordance with § 409.43, the initial and/or the comprehensive assessment of the patient required in accordance with § 484.55, the inpatient discharge summary, or multi-disciplinary clinical notes, etc., which must correspond to the dates of service being billed and not contradict the certifying physician's and/or the acute/post-acute care facility's own documentation or medical record entries. Once incorporated into the certifying physician's medical record for the patient, the HHA information can be used to support the patient's homebound status and need for skilled care.

Comment: A commenter expressed concern that this proposal would allow HHAs to have too much control over Medicare coverage decisions and provides an opportunity for the HHA to override the physician's opinion. This commenter went on to state that there may be a physician's order for care that subsequently has been reduced or discontinued by the HHA and that beneficiaries are forced to settle for less care for fear that the HHA will not provide any services at all. This same commenter stated that certifying physicians are busy and do not have the time to read hundreds of detailed home health agency records. This commenter recommended that the HHA-generated documentation should be used only to confirm eligibility and not to deny coverage for patients that home health agencies no longer want to serve.

Response: We note that coverage of Medicare home health services is dependent upon beneficiary eligibility for Medicare home health services as set forth at § 409.42. We remind commenters that the HHA-generated documentation may only be used to support the certifying physician and/or the acute/post-acute care facility's medical record documentation for eligibility for Medicare home health services. As such, the HHA-generated documentation is not meant to supersede, override or negate the physician's opinion or any physician orders in the established home health plan of care. The HHA-generated documentation is only meant to augment, as necessary, the certifying physician's and/or acute/post-acute care facility's medical documentation to create a clinically consistent picture that the patient is eligible for home health services. Any HHA-generated

information provided to the certifying physician by the HHA and incorporated into the patient's medical record held by the certifying physician and/or the acute/post-acute care facility's medical record (if the patient was directly admitted to home health for such setting) must be corroborated by the rest of the patient's medical record. As such, we do not expect that HHAs would need to send voluminous clinical records to a certifying physician for his/her review when certifying a patient for home health eligibility as the certifying physician's and/or the acute/post-acute care facility's medical records are required to have sufficient information to serve as the basis for home health eligibility. Additionally, the certifying physician is responsible for establishing and periodically reviewing the home health plan of care in accordance with the home health CoPs at 42 CFR 484.60(a)(1). While the HHA is responsible for coordinating with the certifying physician regarding any revisions to the home health plan of care, drugs, services, and treatments are administered only as ordered by a physician. Therefore, it would be a violation of the home health CoPs for a HHA to revise the plan of care, including reducing or discontinuing any items or services identified on the plan of care, without specific orders from the certifying physician. Finally, the purpose of the supporting documentation is to confirm eligibility for Medicare home health services. However, if the certifying physician's and/or acute/post-acute care facility's documentation and the HHA-generated incorporated supporting documentation do not create a clinically consistent picture that the individual is eligible for Medicare home health services (for example, the individual is homebound and requires skilled services), this would not meet the requirements for coverage.

Comment: Another commenter asked if the certifying physician is required to sign every page of HHA-generated supporting documentation to demonstrate that the documentation from the HHA was considered when certifying patient eligibility for Medicare home health services.

Response: There are no specific regulations regarding physician signature on a document with multiple pages. In accordance with § 484.110(b) of our regulations, all patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided. Only when it is clear that an individual document

extends to multiple pages (for example, a notation on a multi-page document that identifies pagination—“page 2 of 4”), and that the entire document is then authenticated, would a signature on a single page suffice for other pages as well.³³ However, we recognize that there may be multiple variations in the way HHA documentation is incorporated into the certifying physician’s and/or acute/post-acute care facility’s medical records. As such, we will provide future sub-regulatory guidance to address any identified variations. We believe this will provide additional clarity for HHAs and decrease the likelihood that inconsistent decisions would be made by appeals adjudicators regarding certification of patient eligibility for home health services.

Comment: A commenter suggested that CMS should clarify that the patient’s plan of care, with sufficient information to support eligibility and signed by the certifying physician, may be used as documentation from the physician’s medical record to support eligibility for home health services. This commenter stated that CMS might consider revising the regulatory text at 42 CFR 424.22(c) to read:

“ . . . documentation can include, but is not limited to, the patient’s plan of care and/or the initial or the comprehensive assessment”.

Response: We agree with this commenter’s suggestion given we stated in the preamble of the CY 2019 HH PPS proposed rule that information from the HHA, such as the plan of care required in accordance with § 409.43 and/or the initial and/or comprehensive assessment of the patient required in accordance with § 484.55, can be incorporated into the certifying physician’s medical record for the patient and used to support the patient’s homebound status and need for skilled care. We also agree the patient’s plan of care could be the sole HHA documentation that is incorporated into the certifying physician’s and/or the acute/post-acute care facility’s medical record for the patient and used to support the basis for certification of home health eligibility if the plan of care provides sufficient information to support eligibility. We remind commenters that the CoPs at § 484.60 provide the content requirements for the plan of care including all pertinent diagnoses and functional limitations. Likewise, we remind commenters that the certifying physician’s and/or the acute/post-acute care facility’s medical

documentation shall be used as the basis for home health eligibility. The documentation from the HHA serves only as supporting documentation for the purposes of certification if incorporated into the certifying physician’s and/or the acute/post-acute care facility’s medical record for the patient. We will revise the regulatory text at § 424.22(c) accordingly to reflect commenters’ concerns.

Final Decision: We are finalizing the proposal to amend the regulations text at § 424.22(c) to align with current subregulatory guidance to allow medical record documentation from the HHA to be used to support the basis for certification and/or recertification of home health eligibility, if the certain requirements are met as previously described.

2. Elimination of Recertification Requirement To Estimate How Much Longer Home Health Services Will Be Required

In the CY 2018 HH PPS proposed rule (82 FR 35378), we invited public comments about improvements that can be made to the health care delivery system that reduce unnecessary burdens for clinicians, other providers, and patients and their families. Specifically, we asked the public to submit their ideas for regulatory, sub-regulatory, policy, practice, and procedural changes to reduce burdens for hospitals, physicians, and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible.

Several commenters requested that CMS consider eliminating the requirement that the certifying physician include an estimate of how much longer skilled services will be required at each home health recertification, as set forth at § 424.22(b)(2) and in sub-regulatory guidance in the Medicare Benefit Policy Manual (Chapter 7, Section 30.5.2). Commenters stated that this estimate is duplicative of the Home Health CoP requirements for the content of the home health plan of care, set out at § 484.60(a)(2).

We determined that the estimate of how much longer skilled care will be required at each recertification is not currently used for quality, payment, or program integrity purposes. Given this consideration and the existing home health CoP requirements for the content of the home health plan of care, in the CY 2019 HH PPS proposed rule we proposed to eliminate the regulatory requirement, as set forth at § 424.22(b)(2), that the certifying

physician, as part of the recertification statement, provide an estimate of how much longer skilled services will be required (83 FR 32424). All other recertification content requirements under § 424.22(b)(2) would remain unchanged. We noted that the elimination of this recertification requirement would result in a reduction of burden for certifying physicians by reducing the amount of time physicians spend on the recertification process, resulting in an overall cost savings of \$14.2 million. We provide a description of this burden reduction in section X.C.1.c. of this final rule with comment period.

We solicited comments regarding the proposed elimination of the requirement that the certifying physician include an estimate of how much longer skilled services will be required at each home health recertification, as well as the corresponding regulations text changes at § 424.22(b)(2).

Comment: Commenters overwhelmingly supported this proposal. Commenters stated that the elimination of this requirement would help to streamline documentation and make it easier for agencies to obtain necessary information from supervising physicians in a timely manner. Commenters also remarked that removing this requirement will also be consistent with the “Patients over Paperwork” initiative. Other commenters remarked that this would allow certifying physicians to focus more time on patient care.

Response: We appreciate commenter support on this proposal and we agree that elimination of this recertification requirement would reduce the amount of time certifying physicians would spend reviewing medical documentation. This change would reduce the time spent by physicians for recertification without diminishing existing documentation requirements and will allow greater emphasis to be placed on patient care.

Final Decision: Effective for recertifications made on and after January 1, 2019, we are finalizing our proposal to eliminate the regulatory requirement set forth at § 424.22(b)(2) that requires the certifying physician, as part of the recertification process, to provide an estimate of how much longer skilled services will be required. All other recertification content requirements under § 424.22(b)(2) would remain unchanged.

³³ See, <https://med.noridianmedicare.com/web/jfb/cert-reviews/signature-requirement-q-a>.

H. Change Regarding Remote Patient Monitoring Under the Medicare Home Health Benefit

In the CY 2019 HH PPS proposed rule (83 FR 32425), we acknowledged the potential benefit of the use of remote patient monitoring to augment the home health plan of care. We discussed how remote patient monitoring could enable the HHA to more quickly identify any changes in the patient's clinical condition, prompting physician review of, and potential changes to, the plan of care. For example, in cases where the home health patient is admitted for skilled observation and assessment of the patient's condition due to a reasonable potential for complications or an acute episode, remote patient monitoring could augment home health visits until the patient's clinical condition stabilized. Fluctuating or abnormal vital signs could be monitored between visits, potentially leading to quicker interventions and updates to the treatment plan. Additionally, we discussed findings of our literature review that revealed that remote patient monitoring may improve patients' ability to maintain independence, improving their quality of life. Particularly for patients with chronic obstructive pulmonary disease (COPD) and congestive heart failure (CHF), research indicates that remote patient monitoring has been successful in reducing readmissions and long-term acute care utilization.³⁴ Other benefits included fewer complications and decreased costs.

We explained that although section 1895(e)(1)(A) of the Act prohibits payment for services furnished via a telecommunications system if such services substitute for in-person home health services ordered as part of a plan of care, the statute does not define the term "telecommunications system" as it relates to the provision of home health care. While a service using a form of telecommunications, remote patient monitoring is not considered a Medicare telehealth service as defined under section 1834(m) of the Act. Additionally, there is no direct interaction between the patient and the practitioner. Remote monitoring, rather uses digital technology to relay information captured by the patient to the practitioner for review, and to potentially prompt changes to the plan of care. We explained that for these

reasons it would not be subject to the telehealth restrictions on originating site and interactive telecommunications systems technology under section 1834(m) of the Act.

Therefore, because the statute does not define the term "telecommunications system" as it relates to the provision of home health care, we proposed to define remote patient monitoring in regulation under the Medicare home health benefit as "the collection of physiologic data (for example, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the HHA." This definition aligns with the description for CPT code 99091, which allows physicians and other healthcare professionals to bill for the collection and interpretation of physiologic data digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional (82 CFR 53013). We recognized that HHAs cannot bill for this code (CPT code 99091); however, we believe the code's description accurately describes remote monitoring services. We also noted that CPT code 99091 includes the interpretation of the physiologic data, whereas the HHA would only be responsible for the collection of the data.

Currently home health costs associated with remote patient monitoring are reported on line 23.20 on Worksheet A as direct costs associated with telemedicine. For 2016, approximately 3 percent of HHAs reported telemedicine costs that accounted for roughly 1 percent of their total agency costs on the HHA cost report. However, these costs are not allocated to the costs per visit. Allowing HHAs to report the costs of remote patient monitoring on the HHA cost report as part of their operating expenses, which are factored into the costs per visit, would have important implications for assessing home health costs relevant to payment, including HHA Medicare margin calculations. Therefore, we proposed to amend the regulations at 42 CFR 409.46 to include the costs of remote patient monitoring as an allowable administrative cost (that is, operating expense), if remote patient monitoring is used by the HHA to augment the care planning process.

We solicited comments on the proposed regulatory definition of remote patient monitoring under the HH PPS to describe telecommunication services used to augment the plan of care during a home health episode. Additionally, we welcomed comments regarding additional utilization of

telecommunications technologies for consideration in future rulemaking. We also solicited comments on the proposed changes to the regulations at 42 CFR 409.46, to include the costs of remote patient monitoring as allowable administrative costs (that is, operating expenses) on the HHA cost report. The following is a summary of the public comments received and our responses.

Comment: Comments regarding the proposal to define remote patient monitoring in regulation for the Medicare home health benefit and to include the costs of remote patient monitoring as an allowable expense on the HHA cost report were overwhelmingly positive. Commenters stated that there are multiple benefits to integrating the costs of remote patient monitoring into home health, including providing clinicians with real-time updates on patient condition and providing patients with timely feedback, thereby encouraging patient engagement. Additionally, commenters stated that it allows for greater involvement with nurses and physicians, while decreasing travel, which may be advantageous not only in rural areas, but urban areas as well.

Response: We thank commenters for their positive feedback regarding these proposals. We agree that there are many benefits to remote patient monitoring and anticipate that defining it in regulation and allowing for more clear analysis of the associated costs through the cost report will encourage its use in home health and have a positive effect on patient outcomes.

Comment: Several commenters encouraged CMS to monitor utilization patterns to ensure that remote patient monitoring is not being used as a substitute for face-to-face visits. A commenter suggested that CMS require information about the frequency and duration of the use of remote patient monitoring services; specifically, that the HHA be required to report on the Medicare claim whether an episode included the use of remote patient monitoring.

Response: We agree with the recommendation to monitor utilization patterns to ensure appropriate use of the service under the home health benefit. We also agree that data concerning whether individuals received remote patient monitoring during the 30-day period of care could be informative. We will consider ways to obtain this information in the future.

Comment: Another commenter suggested that CMS clarify that if the remote monitoring service is a nursing service, it can help satisfy the skilled nursing requirement to trigger Medicare

³⁴ Broad, J., Davis, C., Bender, M., Smith, T. (2014) Feasibility and Acute Care Utilization Outcomes of a Post-Acute Transitional Telemonitoring Program for Underserved Chronic Disease Patients. *Journal of Cardiac Failure*. Vol 20 (8S) S116. <http://dx.doi.org/10.1016/j.cardfail.2014.06.328>.

coverage for other covered home health services such as home health aides and occupational therapy.

Response: In accordance with section 1861(m) of the Act, home health services must be furnished in the beneficiary's home. Additionally, § 409.48 defines a visit as an episode of personal contact with the beneficiary by staff of the HHA or others under arrangements with the HHA, for the purpose of providing a covered service. Finally, section 1895(e)(1)(B) of the Act states that services furnished via a telecommunications system are not considered home health visits for purposes of eligibility or payment. Therefore, we do not consider the use of remote patient monitoring alone and/or a visit solely for the purpose of setting up and/or training the patient on remote monitoring equipment to meet the criteria for prompting coverage of home health services under the Medicare home health benefit.

Comment: Several commenters suggested adding the descriptions of two new proposed Physician Fee Schedule CPT codes: CPT codes 990X0, set-up and patient education on use of equipment and 990X1, device supply with daily recordings or programmed alerts transmission, to the proposed home health definition in order to allow for a more appropriate and complete description of allowable costs for remote patient monitoring services in the home health setting. Commenters suggested this would also help to establish consistency regarding remote patient monitoring across Medicare sites of service.

Response: We recognize that the descriptors for these two codes allows for greater specificity of the process of remote patient monitoring, which in turn would lead to more accurate analysis of the associated costs. While the proposed home health regulations text at § 409.46(e) would permit the cost and service of the equipment to be allowable administrative costs, we agree that set-up and patient education should be allowable expenses reported on the cost report. However, we wish to clarify that a visit to set up and/or train the patient on the equipment would not be allowed on the HHA claim when no other skilled service is provided. In other words, a visit cannot be reported when the sole reason is to set up and/or train the patient on the use of the remote monitoring equipment. Therefore, we are adding language to the regulations text to ensure a more complete description of remote patient monitoring services, with the qualification that such set-up and patient education services cannot be

reported as a visit without the provision of another skilled service.

Comment: A commenter recommended that CMS describe how it plans to account for the adoption of new remote patient monitoring services as the agency monitors and evaluates the impact of previous or future rebasing adjustments made to the home health prospective payment rates since 2014. Another commenter stated that in order to implement in an effective and consistent manner, CMS needs to develop an appropriate corresponding payment methodology. Other commenters suggested CMS set up a demonstration project where HHAs have an incentive to make an investment in technologies, or incorporate telehealth waivers into all demonstration projects. Other commenters stated that CMS should have a more broad approach to telehealth and telemedicine to include virtual visits as a potential strategy to address workforce challenges. Others stated CMS should directly reimburse for remote patient monitoring, perhaps as a non-routine supply for agencies who are actually providing the service, as the proposal will indirectly provide increased reimbursement for all agencies, not specifically for those providing the service.

Response: We appreciate the commenters' suggestions. While we understand that these comments indicate that some commenters would like to see additional activities in incentivizing the use of remote patient monitoring in home health, we believe that allowing the costs associated with remote patient monitoring to be reported on the cost report is a necessary first step in determining the cost and frequency in which HHAs are currently utilizing this technology and whether the use of such technology improves health outcomes for home health patients. Additionally, we reiterate that section 1895(e)(1)(A) of the Act prohibits payment for services furnished via a telecommunications system if such services substitute for in-person home health services ordered as part of a plan of care certified by a physician. Thus virtual home health visits would not qualify for payment under the home health benefit. We plan to closely monitor remote patient monitoring costs and the impact that such technology may have on patient outcomes under the traditional Medicare home health benefit and we will consider ways to more broadly support such technology as part of home health.

Comment: A commenter suggested that rather than allowing the costs of

remote patient monitoring to be included on the home health cost report, remote patient monitoring should be excluded from the home health episode and provided as a distinct and separately reimbursed service. The commenter stated that this would recognize the value of remote patient monitoring services while also recognizing home health agencies as providers of these services. Home health agencies would then be able to provide these services to patients within home health but also to those who do not qualify for home health but would benefit from RPM services, despite not having a mechanism for reimbursement. Similarly, another commenter suggested that a telehealth chronic care management program conceptualized as a "step down" program from an episode of care would benefit many patients greatly and may serve as an alternative to successive full episodes of care.

Response: We thank the commenters for these suggestions; however, we believe that these comments suggest the implementation of a separate remote patient monitoring benefit under Medicare and are therefore outside of the scope of this rule. Additionally, we note that beginning in CY 2018, separate payment is made under the Physician Fee Schedule for CPT code 99091 (Collection and interpretation of physiologic data (for example., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional). This code, billed directly by a practitioner, allow remote patient monitoring to be provided outside of the home health benefit for non-homebound patients.

Comment: Several commenters requested that CMS clarify whether the agency intends that all qualified health professionals, specifically physical therapists, speech language pathologists, and occupational therapists, acting within their scope of practice, may use remote patient monitoring to augment the plan of care during a home health episode.

Response: Our definition does not specify which skilled professionals may utilize remote patient monitoring under home health. As therapy goals must be established by a qualified therapist in conjunction with the physician when determining the plan of care, we believe therapists involved in care planning, as well as other skilled professionals acting within their scope of practice, may utilize remote patient monitoring to augment this process.

Final decision: We are finalizing our proposal to define remote patient

monitoring under the Medicare home health benefit as “the collection of physiologic data (for example, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient or caregiver or both to the home health agency.” We are adding the following language to the regulations text to ensure a more complete description of remote patient monitoring services, while also ensuring that such services cannot be reported as a visit without the provision of another skilled service: Visits to a beneficiary’s home for the sole purpose of supplying, connecting, and/or training the patient on the remote patient monitoring equipment, without the provision of another skilled service are not separately billable. These services do constitute services included in the expense of providing remote patient monitoring allowed as administrative costs.

Additionally, we are finalizing our proposal to amend the regulations at 42 CFR 409.46 to include the costs of remote patient monitoring as an allowable administrative cost (that is, operating expense), if remote patient monitoring is used by the HHA to augment the care planning process.

IV. Home Health Value-Based Purchasing (HHVBP) Model

A. Background

As authorized by section 1115A of the Act and finalized in the CY 2016 HH PPS final rule (80 FR 68624), we began testing the HHVBP Model on January 1, 2016. The HHVBP Model has an overall purpose of improving the quality and delivery of home health care services to Medicare beneficiaries. The specific goals of the Model are to: (1) Provide incentives for better quality care with greater efficiency; (2) study new potential quality and efficiency measures for appropriateness in the home health setting; and (3) enhance the current public reporting process.

Using the randomized selection methodology finalized in the CY 2016 HH PPS final rule, we selected nine states for inclusion in the HHVBP Model, representing each geographic area across the nation. All Medicare-certified Home Health Agencies (HHAs) providing services in Arizona, Florida, Iowa, Maryland, Massachusetts, Nebraska, North Carolina, Tennessee, and Washington (competing HHAs) are required to compete in the Model. Requiring all Medicare-certified HHAs providing services in the selected states to participate in the Model ensures that: (1) There is no selection bias; (2) participating HHAs are representative of

HHAs nationally; and (3) there is sufficient participation to generate meaningful results.

As finalized in the CY 2016 HH PPS final rule, the HHVBP Model uses the waiver authority under section 1115A(d)(1) of the Act to adjust Medicare payment rates under section 1895(b) of the Act beginning in CY 2018 based on the competing HHAs’ performance on applicable measures. Payment adjustments will be increased incrementally over the course of the HHVBP Model in the following manner: (1) A maximum payment adjustment of 3 percent (upward or downward) in CY 2018; (2) a maximum payment adjustment of 5 percent (upward or downward) in CY 2019; (3) a maximum payment adjustment of 6 percent (upward or downward) in CY 2020; (4) a maximum payment adjustment of 7 percent (upward or downward) in CY 2021; and (5) a maximum payment adjustment of 8 percent (upward or downward) in CY 2022. Payment adjustments are based on each HHA’s Total Performance Score (TPS) in a given performance year (PY) comprised of: (1) A set of measures already reported via the Outcome and Assessment Information Set (OASIS) and completed Home Health Consumer Assessment of Healthcare Providers and Systems (HCAHPS) surveys for all patients serviced by the HHA and select claims data elements; and (2) three New Measures for which points are achieved for reporting data.

For CY 2019 (83 FR 32426), we proposed to remove five measures and add two new proposed composite measures to the applicable measure set for the HHVBP model, revise our weighting methodology for the measures, and rescure the maximum number of improvement points.

B. Quality Measures

1. Removal of Two OASIS-Based Measures Beginning With Performance Year 4 (CY 2019)

In the CY 2016 HH PPS final rule, we finalized a set of quality measures in Figure 4a: Final PY1 Measures and Figure 4b: Final PY1 New Measures (80 FR 68671 through 68673) for the HHVBP Model to be used in PY1, referred to as the starter set. We also stated that this set of measures will be subject to change or retirement during subsequent model years and revised through the rulemaking process (80 FR 68669).

The measures were selected for the Model using the following guiding principles: (1) Use a broad measure set that captures the complexity of the

services HHAs provide; (2) incorporate flexibility for future inclusion of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT) measures that cut across post-acute care settings; (3) develop ‘second generation’ (of the HHVBP Model) measures of patient outcomes, health and functional status, shared decision making, and patient activation; (4) include a balance of process, outcome and patient experience measures; (5) advance the ability to measure cost and value; (6) add measures for appropriateness or overuse; and (7) promote infrastructure investments. This set of quality measures encompasses the multiple National Quality Strategy (NQS) domains³⁵ (80 FR 68668). The NQS domains include six priority areas identified in the CY 2016 HH PPS final rule (80 FR 68668) as the CMS Framework for Quality Measurement Mapping. These areas are: (1) Clinical quality of care; (2) Care coordination; (3) Population & community health; (4) Person- and Caregiver-centered experience and outcomes; (5) Safety; and (6) Efficiency and cost reduction. Figures 4a and 4b of the CY 2016 HH PPS final rule identified 15 outcome measures (five from the HCAHPS, eight from OASIS, and two claims-based measures), and nine process measures (six from OASIS, and three New Measures, which were not previously reported in the home health setting) for use in the Model.

In the CY 2017 HH PPS final rule, we removed four measures from the measure set for PY1 and subsequent performance years: (1) Care Management: Types and Sources of Assistance; (2) Prior Functioning ADL/IADL; (3) Influenza Vaccine Data Collection Period: Does this episode of care include any dates on or between October 1 and March 31?; and (4) Reason Pneumococcal Vaccine Not Received, for the reasons discussed in that final rule (81 FR 76743 through 76747).

In the CY 2018 HH PPS final rule, we removed the OASIS-based measure, Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care, from the set of applicable measures beginning with PY3 for the reasons discussed in that final rule (82 FR 51703 through 51704).

For PY4 and subsequent performance years, we proposed (83 FR 32426 through 32427) to remove two OASIS-based process measures, Influenza Immunization Received for Current Flu

³⁵ 2015 Annual Report to Congress, <http://www.ahrq.gov/workingforquality/reports/annual-reports/nqs2015annlrpt.htm>.

Season and Pneumococcal Polysaccharide Vaccine Ever Received, from the set of applicable measures. We adopted the Influenza Immunization Received for Current Flu Season measure beginning PY1 of the model. Since that time, we have received input from both stakeholders and a Technical Expert Panel (TEP) convened by our contractor in 2017 that because the measure does not exclude HHA patients who were offered the vaccine but declined it and patients who were ineligible to receive it due to contraindications, the measure may not fully capture HHA performance in the administration of the influenza vaccine. In response to these concerns, we proposed to remove the measure from the applicable measure set beginning PY4.

We also adopted the Pneumococcal Polysaccharide Vaccine Ever Received measure beginning PY1 of the model. This process measure reports the percentage of HH episodes during which patients were determined to have ever received the Pneumococcal Polysaccharide Vaccine. The measure is based on guidelines previously issued by the Advisory Committee on Immunization Practices (ACIP),³⁶ which recommended use of a single dose of the 23-valent pneumococcal polysaccharide vaccine (PPSV23) among all adults aged 65 years and older and those adults aged 19–64 years with underlying medical conditions that put them at greater risk for serious pneumococcal infection.³⁷ In 2014, the ACIP updated its guidelines to recommend that both vaccines, the PCV13 and the PPSV23, be given to all immunocompetent adults aged ≥65 years.³⁸ The recommended intervals for sequential administration of PCV13 and PPSV23 depend on several patient factors including: The current age of the

adult, whether the adult had previously received PPSV23, and the age of the adult at the time of prior PPSV23 vaccination (if applicable). Because the Pneumococcal Polysaccharide Vaccine Ever Received measure does not fully reflect the current ACIP guidelines, we proposed to remove this measure from the model beginning PY4.

We invited public comment on our proposal to remove these two OASIS-based measures, Influenza Immunization Received for Current Flu Season and Pneumococcal Polysaccharide Vaccine Ever Received, from the set of applicable measures for PY4 and subsequent performance years.

The following is a summary of the public comments received on these proposals and our responses:

Comment: The majority of commenters supported removing both OASIS-based process measures, Influenza Immunization Received for Current Flu Season and Pneumococcal Polysaccharide Vaccine Ever Received, citing concerns that process measures may be burdensome on providers to report while yielding limited information to support clinical improvement. Commenters also noted that removal of the measures aligns with the Meaningful Measure Initiative. Several commenters opposed any changes to the HHVBP model's applicable measure set and recommended that CMS complete testing of the HHVBP model prior to making any changes. A commenter opposed removal of the Pneumococcal Polysaccharide Vaccine Ever Received measure, stating that removal may lead to reductions in pneumococcal immunization rates. The commenter believes that CMS should retain this measure until it is updated to reflect the most current ACIP guidelines. The commenter noted that the measure aligned with Meaningful Measures criteria on high-impact conditions and patient-centered care, adding that retaining the measure would not be burdensome to HHAs, given their ability to establish standing orders to support immunization processes. Another commenter opposed removal of the Influenza Immunization Received for Current Flu Season measure as the commenter believes that it is an important safety measure that may be overlooked if it is no longer required to be reported.

Response: With regard to those comments that opposed changes to the HHVBP Model's applicable measure set until testing of the Model has concluded, we reiterate that one of the goals of the Model is to study new potential quality and efficiency

measures for appropriateness in the home health setting. We indicated in the CY 2016 HH PPS final rule that the initial set of measures adopted for use in the Model would be subject to change during subsequent model years and, as summarized previously and in the proposed rule, we have finalized the removal of other measures included in the initial measure set in prior rulemaking. We continue to believe it is important to evaluate and consider changes to the measure set during the course of testing the Model because the relevance of certain quality measures may change over time (for example, a measure may become "topped out"). We also note that we attempt to align with other CMS reporting programs, such as the Home Health Quality Reporting Program (HH QRP), to the extent possible, in order to minimize HHAs' reporting burden, as well as to focus on outcome-based measures where possible and align to clinical or best practice.

With respect to the commenter's concern that removal of the "Influenza" measure from the HHVBP model's applicable measure set would result in the vaccine not being given, we note that while the purpose of including these measures may be to drive certain outcomes or processes, such as administering a vaccine, removing the measure from the HHVBP Model's applicable measure set does not mean that HHAs will avoid providing appropriate care when needed. Moreover, although the "Influenza" measure was removed from the Quality of Patient Care Star Rating effective April 2018, HHAs will continue to report the measure in the HH QRP and it will continue to be displayed on Home Health Compare (HHC). As discussed in the proposed rule, we proposed to remove this measure from the HHVBP model's applicable measure set in response to concerns that it may not fully capture HHA performance in the administration of the influenza vaccine. However, we believe that HHAs will continue to have an incentive to provide the vaccine where appropriate.

With respect to the removal of the Pneumococcal Polysaccharide Vaccine Ever Received measure, we note that CMS is finalizing in this final rule with comment period the removal of this measure for purposes of the HH QRP beginning with the CY 2021 HH QRP and will publicly report the measure on HHC until January 2021. As we discuss in response to comments in section V. of this final rule with comment period, while we understand that assessing and appropriately vaccinating patients are important components of the care

³⁶ The Advisory Committee on Immunization Practices was established under Section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended, to assist states and their political subdivisions in the prevention and control of communicable diseases; to advise the states on matters relating to the preservation and improvement of the public's health; and to make grants to states and, in consultation with the state health authorities, to agencies and political subdivisions of states to assist in meeting the costs of communicable disease control programs. (Charter of the Advisory Committee on Immunization Practices, filed April 1, 2018. <https://www.cdc.gov/vaccines/acip/committee/ACIP-Charter-2018.pdf>).

³⁷ Prevention of Pneumococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR 1997;46:1–24.

³⁸ Tomczyk S, Bennett NM, Stoecker C, et al. Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine among adults aged ≥65 years: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2014; 63: 822–5.

process, we also prioritize ensuring that quality measures can be used by practitioners to inform their clinical decision and care planning activities. The updated ACIP pneumococcal vaccination recommendations require information that is often not available to HHAs, including whether the patient has previously been vaccinated, the type of pneumococcal vaccine received by the patient, as well as the sequencing of vaccine administration. In addition, the physician issuing orders and responsible for the home health plan of care may not be the patient's primary care practitioner or other health care professional responsible for providing care and services to the patient before and after discharge from the agency, and therefore may not be best able to provide the HHA with such information. Finally, even if the pneumococcal vaccination status of the patient is available, OASIS Items M1051, Pneumococcal Vaccine and M1056, Reason Pneumococcal Vaccine not received that are used in the calculation of this measure do not correspond to the updated ACIP pneumococcal vaccination recommendations and therefore may not accurately measure HHA performance in this area. However, we understand and value the role pneumococcal vaccines play in preventing pneumococcal disease³⁹ and we encourage that, whenever possible and as appropriate, HHAs provide pneumococcal vaccinations for their patients. As with the influenza vaccination measure, we do not believe that our removal of this measure from the HHVBP model will result in HHAs failing to provide appropriate care for beneficiaries.

Final Decision: After considering public comments, we are finalizing as proposed the removal of the Influenza Immunization Received for Current Flu Season and Pneumococcal Polysaccharide Vaccine Ever Received measures from the set of applicable measures beginning with PY4 and subsequent years of the model.

2. Replacement of Three OASIS-Based Measures With Two Composite Measures Beginning With Performance Year 4

As previously noted, one of the goals of the HHVBP Model is to study new potential quality and efficiency measures for appropriateness in the home health setting. In the CY 2018 HH PPS Final Rule, we solicited comment

³⁹ CDC: Pneumococcal Disease. Retrieved from: <http://www.cdc.gov/pneumococcal/about/prevention.html>.

on additional quality measures for future consideration in the HHVBP model, specifically a Total Change in ADL/IADL Performance by HHA Patients Measure, a Composite Functional Decline Measure, and behavioral health measures (82 FR 51706 through 51711). For the reasons discussed in the proposed rule (83 FR 32427 through 32429), we proposed to replace three individual OASIS measures (Improvement in Bathing, Improvement in Bed Transferring, and Improvement in Ambulation-Locomotion) with two composite measures: Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility. As we discussed in the CY 2019 HH PPS proposed rule, these proposed measures use several of the same ADLs as the composite measures discussed in the CY 2018 HH PPS final rule (82 FR 51707). Our contractor convened a TEP in November 2017, which supported the use of two composite measures in place of the three individual measures because HHA performance on the three individual measures would be combined with HHA performance on six additional ADL measures to create a more comprehensive assessment of HHA performance across a broader range of patient ADL outcomes. The TEP also noted that HHA performance is currently measured based on any change in improvement in patient status, while the composite measures would report the magnitude of patient change (either improvement or decline) across six self-care and three mobility patient outcomes.

We indicated in the proposed rule that there are currently three ADL improvement measures in the HHVBP Model (Improvement in Bathing, Improvement in Bed Transferring, and Improvement in Ambulation-Locomotion). The maximum cumulative score across all three measures is 30. Because we proposed to replace these three measures with the two composite measures, we also proposed that each of the two composite measures would have a maximum score of 15 points, to ensure that the relative weighting of ADL-based measures would stay the same. That is, there would still be a maximum of 30 points available for ADL-related measures.

We stated that the proposed Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility measures would represent a new direction in how quality of patient care is measured in home health. We stated that both of these proposed composite measures combine several existing and endorsed

HH QRP outcome measures into focused composite measures to enhance quality reporting. These proposed composite measures fit within the *Patient and Family Engagement*⁴⁰ domain as functional status and functional decline are important to assess for residents in home health settings. Patients who receive care from an HHA may have functional limitations and may be at risk for further decline in function because of limited mobility and ambulation.

The proposed Total Normalized Composite Change in Self-Care measure computes the magnitude of change, either positive or negative, based on a normalized amount of possible change on each of six OASIS-based quality outcomes. These six outcomes are as follows:

- Improvement in Grooming (M1800)
- Improvement in Upper Body Dressing (M1810)
- Improvement in Lower Body Dressing (M1820)
- Improvement in Bathing (M1830)
- Improvement in Toileting Hygiene (M1845)
- Improvement in Eating (M1870)

The proposed Total Normalized Composite Change in Mobility measure computes the magnitude of change, either positive or negative, based on the normalized amount of possible change on each of three OASIS-based quality outcomes. These three outcomes are as follows:

- Improvement in Toilet Transferring (M1840)
- Improvement in Bed Transferring (M1850)
- Improvement in Ambulation/ Locomotion (M1860)

The magnitude of possible change for these OASIS items varies based on the number of response options. For example, M1800 (grooming) has four behaviorally-benchmarked response options (0 = most independent; 3 = least independent) while M1830 (bathing) has seven behaviorally-benchmarked response options (0 = most independent; 6 = least independent). The maximum possible change for a patient on item M1800 is 3, while the maximum possible change for a patient on item M1830 is 6. We indicated that both proposed composite measures would be computed and normalized at the episode level, then aggregated to the HHA level using the following steps:

- *Step 1:* Calculate absolute change score for each OASIS item (based on

⁴⁰ 2017 Measures under Consideration List. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/2017-CMS-Measurement-Priorities-and-Needs.pdf>.

change between Start of Care (SOC)/ Resumption of Care (ROC) and discharge) used to compute the Total Normalized Composite Change in Self-Care (6 items) or Total Normalized Composite Change in Mobility (3 items) measures.

- *Step 2:* Normalize scores based on maximum change possible for each OASIS item (which varies across different items). The normalized scores result in a maximum possible change for any single item equal to “1”; this score is provided when a patient achieves the maximum possible change for the OASIS item.

- *Step 3:* Total score for Total Normalized Composite Change in Self-Care or Total Normalized Composite Change in Mobility is calculated by summing the normalized scores for the items in the measure. Hence, the maximum possible range of normalized scores at the patient level for Total Normalized Composite Change in Self-

Care is – 6 to +6, and for Total Normalized Composite Change in Mobility is – 3 to +3.

We created two prediction models for the proposed Total Normalized Composite Change in Self-Care (TNC_SC) and Total Normalized Composite Change in Mobility (TNC_MOB) measures using information from OASIS items and patient clinical condition categories (see Table 37 for details on the number of OASIS items and OASIS clinical categories used in the prediction models). We computed multiple ordinary least squares (OLS) analyses beginning with risk factors that were available from OASIS D items and patient condition groupings. Any single OASIS D item might have more than one risk factor because we create dichotomous risk factors for each response option on scaled (from dependence to independence) OASIS items. Those risk factors that were statistically significant at p<0.0001 level

were kept in the prediction model. These two versions (CY 2014 and CY 2015) of the prediction models were done as “proof of concept.” We proposed that the actual prediction models for the composite measures, if finalized, would use episodes of care that ended in CY 2017, which we proposed would be the baseline year for the quality outcome measures used to compute the two proposed composite measures, as listed previously. The baseline year for these two composite measures would be CY 2017.

The following table (Table 37) provides an overview of results from the CY 2014 and CY 2015 prediction models for each proposed measure with estimated R-squared values comparing observed vs. predicted episode-level performance. This same information was included in Table 50 of the CY 2019 HH PPS proposed rule (83 FR 32428 through 32429).

TABLE 37: OBSERVED VERSUS PREDICTED EPISODE-LEVEL PERFORMANCE FOR THE PROPOSED TOTAL NORMALIZED COMPOSITE CHANGE MEASURES

Prediction Model for	Number of OASIS Items Used	Number of Clinical Categories	R-squared Value
2014 TNC_SC	42	14	0.299
2015 TNC_SC	41	13	0.311
2014 TNC_MOB	42	16	0.289
2015 TNC_MOB	41	18	0.288

Table 37 presents the following summary information for the prediction models for the two proposed composite measures.

- *Prediction Model for:* This column identifies the measure and year of data used for the two “proof of concept” prediction models created for each of the two proposed composite measures, Total Normalized Composite Change in Self-Care (TNC_SC) and Total Normalized Composite Change in Mobility (TNC_MOB). The development of the prediction models was identical in terms of the list of potential risk factors and clinical categories. The only difference was one set of prediction models used episodes of care that ended in CY 2014, while the other set of prediction models used episodes of care that ended in CY 2015.

- *Number of OASIS Items Used:* This column indicates the number of OASIS items used as risk factors in the prediction model. For each prediction model, the number of OASIS items used

is based on the number of risk factors that were statistically significant at p<0.0001 level in the prediction model.

- *Number of Clinical Categories:* This column indicates the number of patient clinical categories (for example, diagnoses related to infections or neoplasms or endocrine disorders) that are used as risk factors in the prediction model.

- *R-squared Value:* The R-squared values are a measure of the proportion of the variation in outcomes that is accounted for by the prediction model. The results show that the methodology that was used to create the prediction models produced very consistent models that predict at least 29 percent of the variability in the proposed composite measures.

The prediction models are applied at the episode level to create a specific predicted value for the composite measure for each episode of care. These episode level predicted values are averaged to compute a national

predicted value and an HHA predicted value. The episode level observed values are averaged to compute the HHA observed value. The HHA TNC_SC and TNC_MOB observed scores are risk adjusted based on the following formula:

$$\text{HHA Risk Adjusted} = \text{HHA Observed} + \text{National Predicted} - \text{HHA Predicted}$$

We explained in the proposed rule that HHAs are not allowed to skip any of the OASIS items that are used to compute these proposed composite measures or the risk factors that comprise the prediction models for the two proposed composite measures. The OASIS items typically do not include “not available (NA)” or “unknown (UK)” response options, and per HHQRP requirements,⁴¹ HHAs must provide responses to all OASIS items for

⁴¹ Data Specifications—<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/DataSpecifications.html>.

the OASIS assessment to be accepted into the CMS data repository. Therefore, while we believed the likelihood that a value for one of these items would be missing is extremely small, we proposed to impute a value of “0” if a value is “missing.” Specifically, if for some reason the information on one or more OASIS items that are used to compute TNC_SC or TNC_MOB is missing, we impute the value of “0” (no change) for the missing value. Similarly, if for some reason the information on one or more OASIS items that are used as a risk factor is missing, we impute the value of “0” (no effect) for missing values that comprise the prediction models for the two proposed composite measures. We presented summary information for these two proposed composite measures in Table 51 of the proposed rule (83 FR 32429 through 32431). We explained that because the proposed TNC_SC and TNC_MOB are composite measures rather than simple outcome measures, the terms “Numerator” and “Denominator” do not apply to how these measures are calculated.

Therefore, for these proposed composite measures, the “Numerator” and “Denominator” columns in Table 51 of the proposed rule were replaced with columns describing “Measure Computation” and “Risk Adjustment.”

We invited public comment on our proposals to replace three OASIS-based measures, Improvement in Ambulation-Locomotion, Improvement in Bed Transferring, and Improvement in Bathing, with two proposed composite measures, Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility, for PY4 and subsequent performance years.

Comment: Many commenters supported replacing the three OASIS-based measures, Improvement in Ambulation-Locomotion, Improvement in Bed Transferring, and Improvement in Bathing, with the two composite measures, Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility. Some commenters, including MedPAC, expressed concerns with the composite measures, stating that such measures represent reporting elements completely within the control of HHAs and may incentivize them to change their coding practices in order to improve performance on such measures (and thus, positively affect risk-adjustment or payment adjustments in their favor). Another commenter questioned the methodology for the maximum possible change calculation, as each patient’s maximum score for a specific question would be based upon

the total number of responses possible for that OASIS question. The commenter was concerned that this methodology does not create an equal ability for HHAs to improve outcomes for certain populations of patients, such as those who benefit from home health physical therapy but have limited ability to improve upon scores on certain OASIS items such as transferring due to chronic musculoskeletal or neurological conditions. This same commenter questioned the use of a CY 2017 baseline year for these new composite measures, rather than the CY 2015 baseline year used for the other measures in the measure set, which it believed added complexity to the model. Another commenter expressed concern about the proposed Total Normalized Composite Change in Self Care measure, citing that the proposed composite measure uses outcome measures that are not currently included in the HHVBP Model and have not been a priority focus for quality improvement for agencies participating in the HHVBP Model.

Response: With regard to the concerns raised by MedPAC and others regarding the data elements that comprise the composite measures, we note that we are also finalizing our proposal (as discussed elsewhere in this final rule with comment period) to reduce the weight of the OASIS-based measures relative to the other measure areas (claims-based and HHCAHPS). Although we continue to believe that the OASIS-based measures yield reliable information for assessing HHAs’ quality performance and capture important information about beneficiaries’ function and improvement, our weighting methodology will increase the collective weight of the claims-based and HHCAHPS measures, which utilize data from claims and patient surveys and not self-reported data, relative to the OASIS-based measures. Regarding the commenter’s concerns with the composite measure methodology, as discussed previously, our methodology uses normalized scores that take into account the difference in measure response scales, and result in a maximum possible change for any single OASIS item that is equal to “1” regardless of the possible range of response options for that particular OASIS item. This methodology accounts for changes to the scores on individual OASIS items while also taking into account that not all patients are able to significantly improve on all aspects of each composite measure. In the case of patients with certain chronic conditions where there is limited ability to improve

on some areas of mobility, as the commenter noted, such beneficiaries may still benefit from home health care services such as physical therapy. We believe that including the composite measure (versus including one or more individual OASIS items related to transfers, which would place more weight on those individual items) will encourage HHAs to focus on improving overall mobility without penalizing HHAs that are unable to improve on OASIS scores for certain patients on a particular item. Regarding the comment that CMS is adding complexity to the model by using CY 2017 as the baseline year for the composite measures rather than the CY 2015 baseline year used for the remainder of the measures in the measure set, we note that, as we indicated in the CY 2016 HH PPS final rule, for the starter set of quality measures used in the model, 2015 would consistently be used as the baseline period in order to evaluate the degree of change that may occur over the multiple years of the model (80 FR 68681). These new composite measures were not part of the model’s starter set. We believe that using more currently available calendar year data to assess HHA performance on these new composite measures will result in a more accurate performance score.

Finally, while not all of the OASIS items that comprise the Total Normalized Composite Change in Self Care composite measure are currently included in the measure set for the HHVBP Model, the composite measure would use data on these OASIS items that are already collected from the participating HHAs. All HHAs must report such data in order to meet the requirements for certification as an HHA, per the Medicare Conditions of Participation (CoP) requirements at § 484.55(c)(2). The individual OASIS items included in the Self-Care and Mobility composite measures focus on areas that target broad clinical goals related to therapy provided in the home setting: Improvement in ability to conduct activities of daily living for oneself (that is, dressing and bathing) and improvement in mobility (that is, ability to transfer). While not all of the individual OASIS items that comprise the composite measures are currently included in the HHVBP Model measure set, they reflect activities and goals that are consistent with the goals of the HHVBP Model: To encourage HHAs to improve the quality of care for beneficiaries. We expect that HHAs already focus on improvement in such areas not just because such items are included in the OASIS or are required

to be reported in order to become a Medicare-certified HHA, but also because self-care and mobility are areas of great importance to patients and families and improvement in such areas may allow beneficiaries to remain in the home setting (versus an institution) and contribute to beneficiaries' quality of life. Furthermore, we note that the Conditions of Participation require OASIS accuracy and that monitoring and reviewing is done by CMS surveyors. CMS also conducts activities to validate the same self-reported OASIS data that is used for payment.

Comment: Many commenters suggested that stabilization measures should be recognized in HHVBP as opposed to just focusing on improvement measures, given that stabilization is sometimes a more realistic goal than improvement for certain patients.

Response: We previously discussed our analyses of existing measures relating to stabilization in the CY 2016 HH PPS final rule. Specifically, we stated that while we considered using some of the stabilization measures for this model, we found that in contrast to the average HHA improvement measure

scores which ranged from 56 to 65 percent, the average HHA stabilization measure scores ranged from 94 to 96 percent. Using measures where the average rates are nearly 100 percent would not allow for meaningful comparisons between competing HHAs on the quality of care delivered (80 FR 68669 through 68670). While the commenters did not suggest specific stabilization measures for our consideration, we note that in the years since the CY 2016 HH PPS final rule was published, we have continued to explore whether the inclusion of stabilization measures may be appropriate for the HHVBP Model, however we have not identified any such measures that we believe would allow for meaningful comparison of HHA performance. Although we appreciate commenters' concerns that some beneficiaries may have limited opportunity to improve and that stabilization may be a more realistic goal for such patients, based on these analyses, we do not believe these measures are appropriate for inclusion in the Model at this time.

Final Decision: After consideration of the public comments we received and

for the reasons we discussed previously, we are finalizing our proposal to replace three OASIS-based measures, Improvement in Ambulation- Locomotion, Improvement in Bed Transferring, and Improvement in Bathing, with two composite measures, Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility, for PY4 and subsequent performance years.

Table 38 reflects our finalized polices to remove the Influenza Immunization Received for Current Flu Season and Pneumococcal Polysaccharide Vaccine Ever Received measures and to replace the Improvement in Ambulation- Locomotion, Improvement in Bed Transferring, and Improvement in Bathing measures with the new Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility measures. Table 38 identifies the applicable measures set for PY4 and each subsequent performance year until such time that another set of applicable measures, or changes to this measure set, are proposed and finalized in future rulemaking.

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TABLE 38: MEASURE SET FOR THE HHVBP MODEL BEGINNING PY 4*

NQS Domains	Measure Title	Measure Type	Identifier	Data Source	Numerator	Denominator
Clinical Quality of Care	Improvement in Dyspnea	Outcome	NA	OASIS (M1400)	Number of home health episodes of care where the discharge assessment indicates less dyspnea at discharge than at start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Communication & Care Coordination	Discharged to Community	Outcome	NA	OASIS (M2420)	Number of home health episodes where the assessment completed at the discharge indicates the patient remained in the community after discharge.	Number of home health episodes of care ending with discharge or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.
Efficiency & Cost Reduction	Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health	Outcome	NQF0171	CCW (Claims)	Number of home health stays for patients who have a Medicare claim for an unplanned admission to an acute care hospital in the 60 days following the start of the home health stay.	Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days.
Efficiency & Cost Reduction	Emergency Department Use without Hospitalization	Outcome	NQF0173	CCW (Claims)	Number of home health stays for patients who have a Medicare claim for outpatient emergency department use and no claims for acute care hospitalization in the 60 days following the start of the home health stay.	Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days.
Patient Safety	Improvement in Pain Interfering with Activity	Outcome	NQF0177	OASIS (M1242)	Number of home health episodes of care where the value recorded on the discharge assessment indicates less frequent pain at discharge than at the start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Patient Safety	Improvement in Management of Oral Medications	Outcome	NQF0176	OASIS (M2020)	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in taking oral medications correctly at discharge than at start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Patient & Caregiver-Centered Experience	Care of Patients	Outcome		CAHPS	NA	NA

NQS Domains	Measure Title	Measure Type	Identifier	Data Source	Numerator	Denominator
Patient & Caregiver-Centered Experience	Communications between Providers and Patients	Outcome		CAHPS	NA	NA
Patient & Caregiver-Centered Experience	Specific Care Issues	Outcome		CAHPS	NA	NA
Patient & Caregiver-Centered Experience	Overall rating of home health care	Outcome		CAHPS	NA	NA
Patient & Caregiver-Centered Experience	Willingness to recommend the agency	Outcome		CAHPS	NA	NA
Population/Community Health	Influenza Vaccination Coverage for Home Health Care Personnel	Process	NQF0431 (Used in other care settings, not Home Health)	Reported by HHAs through Web Portal	Healthcare personnel in the denominator population who during the time from October 1 (or when the vaccine became available) through March 31 of the following year: (a) received an influenza vaccination administered at the healthcare facility, or reported in writing or provided documentation that influenza vaccination was received elsewhere; or b) were determined to have a medical contraindication/condition of severe allergic reaction to eggs or to other components of the vaccine or history of Guillain-Barre Syndrome within 6 weeks after a previous influenza vaccination; or (c) declined influenza vaccination; or (d) persons with unknown vaccination status or who do not otherwise meet any of the definitions of the previously mentioned numerator categories.	Number of healthcare personnel who are working in the healthcare facility for at least 1 working day between October 1 and March 31 of the following year, regardless of clinical responsibility or patient contact.
Population/Community Health	Herpes zoster (Shingles) vaccination: Has the patient ever received the shingles vaccination?	Process	NA	Reported by HHAs through Web Portal	Total number of Medicare beneficiaries aged 60 years and over who report having ever received zoster vaccine (shingles vaccine).	Total number of Medicare beneficiaries aged 60 years and over receiving services from the HHA.
Communication & Care Coordination	Advance Care Plan	Process	NQF0326	Reported by HHAs through Web Portal	Patients who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advanced care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	All patients aged 65 years and older.

NQS Domains	Measure Title	Measure Type	Identifier	Data Source	Numerator	Denominator
Patient and Family Engagement	Total Normalized Composite Change in Self-Care**	Composite Outcome	NA	OASIS (M1800) (M1820) (M1830) (M1845) (M1870)	The total normalized change in self-care functioning across six OASIS items (grooming, bathing, upper & lower body dressing, toilet hygiene, and eating)	A prediction model is computed at the episode level. The predicted value for the HHA and the national value of the predicted values are calculated and are used to calculate the risk-adjusted rate for the HHA, which is calculated using this formula: HHA Risk Adjusted = HHA Observed + National Predicted – HHA Predicted.
Patient and Family Engagement	Total Normalized Composite Change in Mobility**	Composite Outcome	NA	OASIS (M1840) (M1850) (M1860)	The total normalized change in mobility functioning across three OASIS items (toilet transferring, bed transferring, and ambulation/locomotion)	A prediction model is computed at the episode level. The predicted value for the HHA and the national value of the predicted values are calculated and are used to calculate the risk-adjusted rate for the HHA, which is calculated using this formula: HHA Risk Adjusted = HHA Observed + National Predicted – HHA Predicted.

*Notes: For more detailed information on the measures using OASIS refer to the OASIS-C2 Guidance Manual effective January 1, 2017 available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/OASIS-C2-Guidance-Manual-6-29-16.pdf>

For NQF endorsed measures see The NQF Quality Positioning System available at <http://www.qualityforum.org/QPS>. For non-NQF measures using OASIS see links for data tables related to OASIS measures at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/index.html>. For information on HHCAHPS measures see <https://homehealthcahps.org/SurveyandProtocols/SurveyMaterials.aspx>.

** Because the Total Normalized Composite Change in Self-Care and Mobility measures are composite measures rather than simply outcome measures, the terms “Numerator” and “Denominator” do not apply.

3. Reweighting the OASIS-Based, Claims-Based, and HHCAHPS Measures

In the CY 2016 HH PPS final rule, we finalized weighting measures within each of the HHVBP Model's four classifications (Clinical Quality of Care, Care Coordination and Efficiency, Person and Caregiver-Centered Experience, and New Measures) the same for the purposes of payment adjustment. We finalized weighting each individual measure equally because we did not want any one measure within a classification to be more important than another measure, to encourage HHAs to approach quality improvement initiatives more broadly, and to address concerns where HHAs may be providing services to beneficiaries with different needs. Under this approach, a measure's weight remains the same even if some of the measures within a classification group have no available data. We stated that in subsequent years of the Model, we would monitor the impact of equally weighting the individual measures and may consider changes to the weighting methodology after analysis and in rulemaking (80 FR 68679).

For PY4 and subsequent performance years, we proposed to revise how we weight the individual measures and amend § 484.320(c) accordingly (83 FR 32431). Specifically, we proposed to change our methodology for calculating the Total Performance Score (TPS) by weighting the measure categories so that the OASIS-based measure category and the claims-based measure category would each count for 35 percent and the HHCAHPS measure category would count for 30 percent of the 90 percent of the TPS that is based on performance of the Clinical Quality of Care, Care Coordination and Efficiency, and Person and Caregiver-Centered Experience measures. We noted that these measures and their proposed revised weights

would continue to account for the 90 percent of the TPS that is based on the Clinical Quality of Care, Care Coordination and Efficiency, and Person and Caregiver-Centered Experience measures. Data reporting for each New Measure would continue to have equal weight and account for the 10 percent of the TPS that is based on the New Measures collected as part of the Model. As discussed further in the proposed rule and in this final rule with comment period, we stated that we believe that this proposed reweighting, to allow more weight for the claims-based measures, would better support improvement in those measures.

We explained in the proposed rule that weights would also be adjusted under our proposal for HHAs that are missing entire measure categories. For example, if an HHA is missing all HHCAHPS measures, the OASIS and claims-based measure categories would both have the same weight (50 percent each). We stated that we believe that this approach would also increase the weight given to the claims-based measures, and as a result give HHAs more incentive to focus on improving them. Additionally, if measures within a category are missing, the weights of the remaining measures within that measure category would be adjusted proportionally, while the weight of the category as a whole would remain consistent. We also proposed that the weight of the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health claims-based measure would be increased so that it has three times the weight of the Emergency Department Use without Hospitalization claims-based measure, based on our understanding that HHAs may have more control over the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of

Home Health claims-based measure. In addition, because inpatient hospitalizations generally cost more than ED visits, we stated that we believe improvement in the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health claims-based measure may have a greater impact on Medicare expenditures.

We proposed to reweight the measures based on our ongoing monitoring and analysis of claims and OASIS-based measures, which shows that there has been a steady improvement in OASIS-based measures, while improvement in claims-based measures has been relatively flat. For example, Figures 1 and 2 (which were included as Figures 5 and 6 in the proposed rule) show the change in average performance for the claims-based and OASIS-based performance measures used in the Model. For both figures, we report the trends observed in Model and non-Model states. In both Model and non-Model states, there has been a slight increase (indicating worse performance) in the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health measure. For all OASIS-based measures, except the Improvement in Management of Oral Medications measure and the Discharge to Community measure, there has been substantial improvement in both Model and non-Model states. Given these results, we stated that we believe that increasing the weight given to the claims-based measures, and the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health measure in particular, may give HHAs greater incentive to focus on quality improvement in the claims-based measures. Increasing the weight of the claims-based measures was also supported by our contractor's TEP.

FIGURE 1:

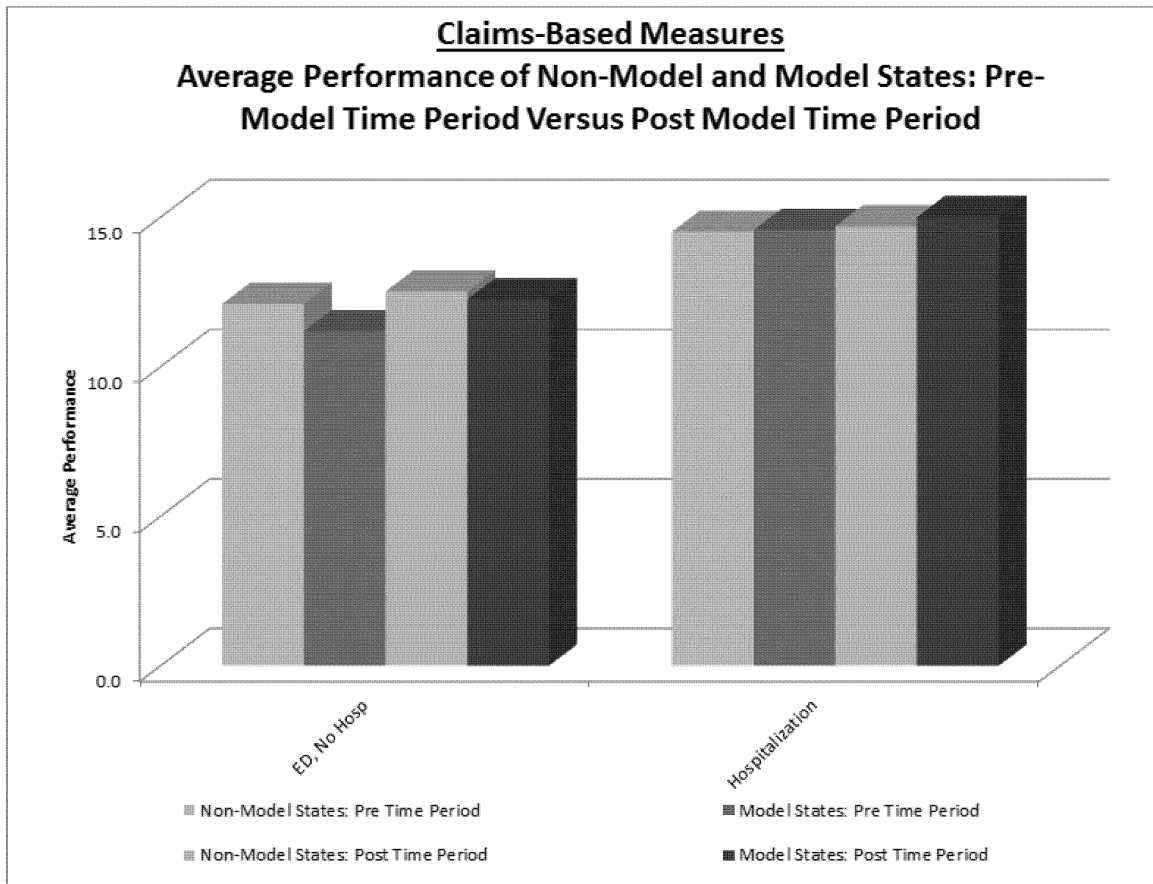


FIGURE 2:

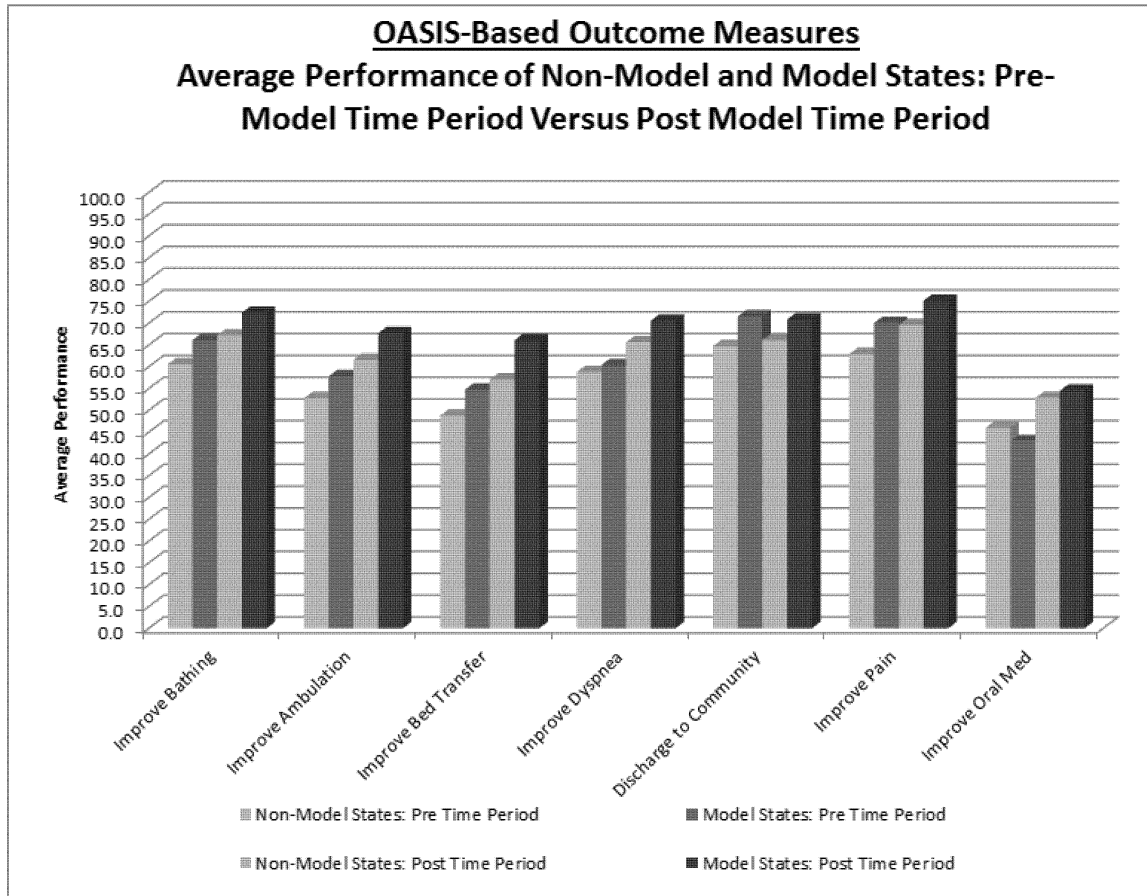


Table 52 of the proposed rule (83 FR 32434) showed the current weighting and the proposed revised weighting for each measure based on our proposal to change the weighting methodology from weighting each individual measure equally to weighting the OASIS, claims-based, and HHCAHPS measure categories at 35-percent, 35-percent and 30-percent, respectively. Table 52 of the proposed rule also showed the proposed weighting methodology based on various scoring scenarios. This same information is presented in Table 39 of this final rule with comment period. For example, for HHAs that are exempt from their beneficiaries completing HHCAHPS surveys, the total weight given to OASIS-based measures scores would be 50 percent, with all OASIS-based measures (other than the two composite measures) accounting for an equal proportion of that 50 percent, and the total weight given to the claims-based measures scores would be 50 percent, with the Acute Care Hospitalization: Unplanned Hospitalizations measure accounting for 37.50 percent and the ED Use without

Hospitalization measure accounting for 12.50 percent. The OASIS- and claims-based measure categories would have equal weights in this scenario because the weight for each remaining category when one category is missing is based on the relative weight of the category when all three are present. Because both the OASIS- and claims-based categories would have a weight of 35% when HHCAHPS data is reported, each would have a 50% weight if HHCAHPS data is not available. However, if no claims-based measure data is available, the OASIS-based measures would have a higher weight than the HHCAHPS category, because their weights when all three categories are available are 35% and 30%, respectively. Finally, both Table 52 of the proposed rule and Table 39 of this final rule with comment period show the change in the number of HHAs, by size, that would qualify for a TPS and payment adjustment under the current and proposed reweighting methodologies, using CY 2016 data. We noted in the proposed rule that Table 52 only reflects the proposed changes to the weighting methodology, and not the

other proposed changes to the HHVBP model for CY 2019 which, if finalized, would change the proposed weights as set forth in Table 52 (and Table 39 of this final rule with comment period). We referred readers to Table 65 of the proposed rule (83 FR 32506) which reflected the weighting that would apply if all of our proposed changes, including the proposed changes to the applicable measure set, were adopted for CY 2019. We indicated that as reflected in that table, the two proposed composite measures, if finalized, would have weights of 7.5 percent when all three measure categories are reported. For purposes of this final rule with comment period, we refer readers to Table 50 of this final rule with comment period, which reflects the weighting that will apply beginning in CY 2019 based on all of our finalized proposals, including the finalized reweighting and our finalized changes to the applicable measure set. As reflected in Table 50 of this final rule with comment period, the two finalized composite measures will have weights of 7.5 percent when all three measure categories are reported.

TABLE 39: CURRENT AND PROPOSED WEIGHTS FOR INDIVIDUAL PERFORMANCE MEASURES

	Current Weights (Equal Weighting)				Proposed Weights (OASIS 35%; Claims 35%; HHCAPHS 30%)			
	All Measures (n=1,026)	No HHCAPHS (n=465)	No Claims (n=20)	No Claims or HHCAPHS (n=99)	All Measures (n=1,026)	No HHCAPHS (n=460)	No Claims (n=20)	No Claims or HHCAPHS (n=73)
<i>Large HHAs</i>	1023	382	20	49	1023	380	20	39
<i>Small HHAs</i>	3	83	0	50	3	80	0	34
OASIS								
Flu vaccine ever received*	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Pneumococcal vaccine*	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Improve Bathing**	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Improve Bed Transfer**	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Improve Ambulation**	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Improve Oral Meds	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Improve Dyspnea	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Improve Pain	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Discharge to Community	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
<i>Total weight for OASIS measures</i>	<i>56.25%</i>	<i>81.82%</i>	<i>64.26%</i>	<i>100.00%</i>	<i>35.00%</i>	<i>50.00%</i>	<i>53.85%</i>	<i>100.00%</i>
Claims								
Hospitalizations	6.25%	9.09%	0.00%	0.00%	26.25%	37.50%	0.00%	0.00%
Outpatient ED	6.25%	9.09%	0.00%	0.00%	8.75%	12.50%	0.00%	0.00%
<i>Total weight for claims measures</i>	<i>12.50%</i>	<i>18.18%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>35.00%</i>	<i>50.00%</i>	<i>0.00%</i>	<i>0.00%</i>
HHCAPHS								
Care of patients	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
Communication between provider and patient	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
Discussion of specific care issues	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
Overall rating of care	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
Willingness to recommend HHA to family or friends	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
<i>Total weight for HHCAPHS measures</i>	<i>31.25%</i>	<i>0.00%</i>	<i>35.70%</i>	<i>0.00%</i>	<i>30.00%</i>	<i>0.00%</i>	<i>46.15%</i>	<i>0.00%</i>

Notes: *Measures proposed (and finalized) to be removed from the applicable measure set beginning CY 2019/PY 4.

**Measures proposed (and finalized) to be removed from the applicable measure set and replaced with two new composite measures beginning CY 2019/PY 4.

***The weights of the measure categories, when one category is removed, are based on the relative weight of each category when all measures are used. For example, if the two measure categories, Claims and OASIS, are expressed then each category represents 50% because each of these categories has the same weight (35%) when all 3 categories are represented. However, if only OASIS and HHCAPHS are expressed, OASIS represents 53.85% while HHCAPHS represents 46.15%, which represents the same relative proportion as 35% and 30%, the OASIS and HHCAPHS weights, respectively, when all three categories are present.

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We invited public comments on the proposal to reweight the measures within the Clinical Quality of Care, Care Coordination and Efficiency, and Person

and Caregiver-Centered Experience classifications so that the OASIS-based measures account for 35-percent, the claims-based measures account for 35-percent, and the HHCAPHS account for 30-percent of the 90 percent of the TPS that is based on performance on these measures, for PY4 and subsequent performance years. We also proposed to amend § 484.320 to reflect these proposed changes. Specifically, we proposed to amend § 484.320 to state that for performance years 4 and 5, CMS will sum all points awarded for each applicable measure within each category of measures (OASIS-based, claims-based, and HHCAPHS) excluding the New Measures, weighted at 35-percent for the OASIS-based measure category, 35-percent for the claims-based measure category, and 30-percent for the HHCAPHS measure category, to calculate a value worth 90-percent of the Total Performance Score. We also included a sample calculation in Table 53 of the proposed rule (83 FR 32435) to show how this proposal, in connection with the proposed changes to the measure set, would affect scoring under the model as set forth in prior rulemaking (80 FR 68679 through 68686) when all three measure categories are reported.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Many commenters generally supported the reweighting of the measure categories for the purpose of encouraging additional focus on the claims-based measures, and also supported the proposed revised weights. Some commenters were concerned that reweighting the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health claims-based measure to be three times the weight of the Emergency Department Use without Hospitalization claims-based measure would make one measure too impactful for the overall TPS, and that significant weight on a single measure would encourage HHAs to focus on that one measure at the expense of other measures. A commenter suggested that the claims-based measure category should be reweighted higher, such as 60 percent, because the commenter believed that claims-based measures were less likely to be subject to data manipulation than measures based on self-reported data. Another commenter recommended an increase in weighting for claims-based measures when HHCAPHS data are not available. MedPAC supported weighting claims measures more and recommended the OASIS measures be weighted less than

the HHCAPHS measures because they believe that patient experience can be an important way to assess quality of care.

Response: We appreciate the comments supporting reweighting in general as well as our proposed reweighting percentages. We proposed to weight the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health claims-based measure three times the weight of the Emergency Department Use without Hospitalization claims-based measure because of our belief that HHAs have greater ability to improve upon the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health claims-based measure than the ED measure, given that beneficiaries can self-refer to the ED but a hospitalization requires more direct clinician involvement (from either HHA staff or a community clinician with whom the HHA should be coordinating care) for an admission. As noted in the proposed rule, because inpatient hospitalizations generally cost more than ED visits, we also believe quality improvement in the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health claims-based measure may have a greater impact on reducing Medicare expenditures. We plan to monitor and evaluate the impact of weighting the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health claims-based measure three times the weight of the Emergency Department Use without Hospitalization claims-based measure.

With regard to the commenter's suggestion to reweight the claims-based measures to 60 percent, we are concerned that such an approach would encourage HHAs to focus on the claims-based measures (and particularly the Unplanned Hospitalization measure) at the expense of other quality improvement efforts, such as patient experience and mobility improvement, which are assessed through HHCAPHS and the OASIS measures. We are attempting to balance encouraging HHAs to focus on measures that may more heavily impact Medicare expenditures (such as the claims-based measures) with ensuring that HHAs focus on quality improvement across various focus areas, including those which are not directly measured through the claims-based measures, such as patient experience and mobility. As such, we do not believe we should increase the weight for claims-based measures above what we have proposed

when HHCAPHS data are not available; rather, we believe a more gradual approach is appropriate for increasing HHAs' focus on claims-based measures. In addition, we continue to believe that OASIS-based measures provide important information about quality of care and want to continue to encourage HHAs to further improve on such measures. Finally, with regard to MedPAC's suggestion to weight the HHCAPHS higher than the OASIS-based measures, we agree with MedPAC that measuring patient experience during home health episodes is important. As discussed in this section, while we proposed to weight the HHCAPHS category less than the other two categories, the overall change in the weight for the HHCAPHS is not significant. As Table 50 reflects, HHCAPHS were reduced from 31.25 percent to 30.00 percent for the category and from 6.25 percent to 6.00 percent for each individual HHCAPHS measure under our proposal. A greater reduction actually occurs for the OASIS-based measures (as shown in Table 50, total weight for OASIS measures goes from 56.25 percent to 35.00 percent for the category and 6.25 percent to 5.00 percent for individual OASIS measures, other than the two new composite measures). This is because under current policy each HHCAPHS, OASIS-based, and claims-based measure is weighted equally and because the number of measures in each category differs. We believe the proposed reweighting balances our interest in encouraging focus on claims-based measures as well as on the patient experience and OASIS-based measures.

Comment: Several commenters suggested the weight of the HHCAPHS measures category should not be reduced because they are concerned that HHAs may focus less on improving upon HHCAPHS. Another commenter suggested that the HHCAPHS measure category should not have a lower weight than the OASIS measures category because the commenter believes that a lower weight would suggest that patient experience is less important than the other measures.

Response: We acknowledge the importance of the HHCAPHS measures and gave them serious consideration when proposing measure category reweighting. In considering revisions to the weights for HHCAPHS versus the other measures, we attempted to balance placing more emphasis on claims-based measures (which may have a greater impact on Medicare expenditures) with continuing to encourage HHAs to focus on patient experience. We note that while the OASIS measures category will

be reweighted from 56.25 percent to 35.0 percent (a reduction of 21.25 percent), the HHCAHPS measures category will be reweighted from 31.25 percent to 30 percent (a reduction of only 1.25 percent). We believe this moderate reweighting of the HHCAHPS measures category is appropriate because smaller HHAs are not required to submit their HHCAHPS measure scores due to their limited episodes of care, and therefore we believe that more weight should be allotted to measure categories with broader HHVBP Model reporting across HHAs of all types. However, as noted, our proposal only reduces the HHCAHPS weights very slightly, which is consistent with our belief and the view expressed by several commenters that patient experience is a crucial component of quality measurement during home health episodes. Based on our examination of performance data, we proposed to increase the weight of the claims-based measures, while still seeking to encourage HHAs to focus on other measure categories. CMS will also monitor and evaluate the impact of the reweighting of the overall measure categories and determine if additional adjustments are necessary in future years through rulemaking.

Comment: Some commenters suggested that CMS should delay measure category reweighting or maintain the current weighting methodology because they believe that HHAs need more time to adapt to the HHVBP Model, and that CMS should wait for information on behavioral impacts from the new PDGM prior to making additional changes to HHVBP. Other commenters suggested that making changes, such as reweighting, would make the HHVBP Model difficult to evaluate and create an unfair environment for HHAs.

Response: We carefully considered the impact on HHAs of our proposed changes to reweight the measure categories, as well as the effects on quality improvement for beneficiaries. We proposed to reweight the measure categories to allow for more weight to the claims-based measures to encourage further improvement on those measures, and place increased focus on accountability for areas of significant Medicare spending, such as hospitalizations. Because these measures have been a part of the HHVBP model's applicable measure set from the start of the model, we believe HHAs will have sufficient time to appropriately adjust business practices and care methods as needed in light of the proposed reweighting. The evaluation of the HHVBP model will

take into account changes in the model methodology and in the corresponding HHA environment, such as changes to the Home Health Prospective Payment System.

Comment: Some commenters believed that the proposed reweighting may disincentivize some HHAs from serving vulnerable populations that are at risk for hospitalizations. A commenter stated that the proposed reweighting may incentivize further hospital stays.

Response: We believe that the reweighting will encourage HHAs to further enhance their service structures to appropriately address the needs of Medicare beneficiaries of all types by using quality improvement processes that support the Model's quality measures, including processes intended to reduce hospitalizations. We do not believe that reweighting the measures would discourage HHAs from serving vulnerable populations or incentivize further hospital stays. Rather, we believe that reweighting the measures to increase the emphasis on the claims-based ED use and unplanned hospitalization measures would encourage HHAs to increase the coordination with other providers and suppliers such as physicians and inpatient facilities (hospitals and post-acute care (PAC) facilities) in order to reduce ED visits and hospital admissions. We note that the claims-based ED and hospitalization measures are included in the HH QRP and reflect goals consistent with other CMS initiatives that focus on reducing avoidable hospital admissions, such as the Hospital Readmissions Reduction Program. We expect the proposed increase in the weight of these ED and hospitalization measures to incentivize avoiding hospital stays, not additional hospitalizations. We also do not expect that the reweighting will cause HHAs to implement policies that do not serve vulnerable populations at risk of hospitalization, but will instead encourage care coordination between HHAs and other health care providers to avoid hospitalizations, which may result in improved care for all beneficiaries, including vulnerable populations. Moreover, in determining the reweighting percentages, we proposed a weight of 30 percent for HHCAHPS in order to ensure patient experience across all vulnerable populations is not negatively affected by the reweighting. Finally, we note that HHAs in the HHVBP Model have opportunities to share strategies for success under the model, including reducing hospitalizations, through specialized technical assistance and

learning events provided through the Model.

Comment: A commenter suggested that the proposed reweighting was arbitrary and that providers should be evaluated based on the most important aspects of care.

Response: We disagree that the proposed reweighting was arbitrary. The HHVBP model examines a broad array of quality measures that address critical quality areas. The selected measures are intended to have a high impact on care delivery and support the combined priorities of HHS and CMS to improve health outcomes, quality, safety, efficiency, and experience of care for patients. As discussed in response to other comments, the claims-based ED and hospitalization measures are included in the HH QRP and reflect goals consistent with other CMS initiatives that focus on reducing avoidable hospital admissions, and we believe our proposed reweighting will encourage increased focus on accountability for areas of significant Medicare spending, such as hospitalizations.

Final Decision: For the reasons stated and after consideration of the comments received, we are finalizing the measure category reweighting as proposed. Specifically, we are finalizing our proposal to change our methodology for calculating the Total Performance Score (TPS) by weighting the measure categories so that the OASIS-based measure category and the claims-based measure category will each count for 35 percent and the HHCAHPS measure category will count for 30 percent of the 90 percent of the TPS that is based on performance on the Clinical Quality of Care, Care Coordination and Efficiency, and Person and Caregiver-Centered Experience measures. We refer readers to Table 50 in section X. Regulatory Impact Analysis of this final rule with comment period, which reflects the weighting that will apply beginning in CY 2019 based on all of our finalized proposals, including the finalized reweighting and our finalized changes to the applicable measure set. We are also finalizing our proposed amendments to § 484.320 without change. Specifically, we are amending § 484.320 to state that for performance years 4 and 5, CMS will sum all points awarded for each applicable measure within each category of measures (OASIS-based, claims-based, and HHCAHPS) excluding the New Measures, weighted at 35-percent for the OASIS-based measure category, 35-percent for the claims-based measure category, and 30-percent for the HHCAHPS measure category, to

calculate a value worth 90-percent of the Total Performance Score. Table 40 (which is identical to Table 53 of the proposed rule) is a sample calculation to

show how this finalized policy, in connection with the finalized changes to the measure set, will affect the scoring under the model, as set forth in prior

rulemaking (80 FR 68679 through 68686), when all three measure categories are reported.

TABLE 40: SAMPLE HHVBP TOTAL PERFORMANCE SCORE CALCULATION UNDER CURRENT AND FINALIZED NEW WEIGHTS FOR INDIVIDUAL PERFORMANCE MEASURES

	Points for Current Measures	Current Weight	Points for Finalized Measures	Weight	Weighted Points
OASIS					
Composite self-care	N/A	0.00%	7.661	7.50%	9.19
Composite mobility	N/A	0.00%	5.299	7.50%	6.36
Flu vaccine ever received	7.662	6.25%	N/A	0.00%	N/A
Pneumococcal vaccine	8.162	6.25%	N/A	0.00%	N/A
Improvement in bathing	5.064	6.25%	N/A	0.00%	N/A
Improvement in bed transfer	4.171	6.25%	N/A	0.00%	N/A
Improvement in ambulation	3.725	6.25%	N/A	0.00%	N/A
Improve oral meds	3.302	6.25%	3.302	5.00%	2.64
Improve Dyspnea	4.633	6.25%	4.633	5.00%	3.71
Improve Pain	4.279	6.25%	4.279	5.00%	3.42
Discharge to community	0.618	6.25%	0.618	5.00%	0.49
Claims					
Outpatient ED	0	6.25%	0	8.75%	0.00
Hospitalizations	1.18	6.25%	1.18	26.25%	4.96
HHAHPS					
Care of patients	10	6.25%	10	6.00%	9.60
Communication between provider and patient	10	6.25%	10	6.00%	9.60
Discussion of special care issues	10	6.25%	10	6.00%	9.60
Overall rating of care	5.921	6.25%	5.921	6.00%	5.68
Willingness to recommend HHA to family and friends	8.406	6.25%	8.406	6.00%	8.07
Total	87.123	100.00%		100.00%	57.776
Total Performance Score Calculation					
		Current		Finalized	
Raw score		87.123		57.776	
Scaled score (adjusted for # of measures present)		58.082		57.776	
Weighted score (90% of scaled score)		52.274		51.998	
New measure score		100.000		100.000	
Weighted new measure score (10% of new measure score)		10		10	
TPS (sum of weighted score and weighted new measure score)		62.274		61.998	

C. Performance Scoring Methodology

1. Rescoring the Maximum Amount of Improvement Points

In the CY 2016 HH PPS final rule, we finalized that an HHA could earn 0 to 10 points based on how much its performance in the performance period improved from its performance on each measure in the Clinical Quality of Care, Care Coordination and Efficiency, and Person and Caregiver-Centered Experience classifications during the baseline period. We noted, in response to public comment about our scoring methodology for improvement points,

that we will monitor and evaluate the impact of awarding an equal amount of points for both achievement and improvement and may consider changes to the weight of the improvement score relative to the achievement score in future years through rulemaking (80 FR 68682).

We proposed to reduce the maximum amount of improvement points, from 10 points to 9 points, for PY4 and subsequent performance years for all measures except for the Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility measures, for which

we proposed the maximum improvement points would be 13.5 (83 FR 32435). The maximum score of 13.5 represents 90 percent of the maximum 15 points that could be earned for each of the two composite measures. The HHVBP Model focuses on having all HHAs provide high quality care and we stated in the proposed rule that we believe that awarding more points for achievement than for improvement beginning with PY4 of the model would support this goal. We stated that we expect that at this point several years into participation in the Model, participating HHAs have had enough

time to make the necessary investments in quality improvement efforts to support a higher level of care, warranting a slightly stronger focus on achievement over improvement on measure performance. Furthermore, we stated that we believe that reducing the maximum improvement points to 9 would encourage HHAs to focus on achieving higher performance levels, and incentivizing in this manner would encourage HHAs to rely less on their improvement and more on their achievement.

We also stated in the proposed rule that this proposal would be consistent with public comments from prior rulemaking, and suggestions provided by our contractor's TEP. As summarized in the CY 2016 HH PPS final rule, we received comments encouraging us to focus on rewarding the achievement of specified quality scores, and reduce the emphasis on improvement scores after the initial 3 years of the HHVBP Model. Some commenters suggested measuring performance primarily based on achievement of specified quality scores with a declining emphasis over time on improvement versus achievement (80 FR 68682).

The TEP also agreed with reducing the maximum number of improvement

points, which they believed would better encourage HHAs to pursue improved health outcomes for beneficiaries. We noted in the proposed rule that for the Hospital Value-Based Purchasing (HHVBP) Program, CMS finalized a scoring methodology where hospitals could earn a maximum of 9 improvement points if their improvement score falls between the improvement threshold and the benchmark (76 FR 26515). We proposed that HHVBP would employ a similar scoring methodology where HHAs could earn a maximum of 9 improvement points.

We proposed that an HHA would earn 0–9 points based on how much its performance during the performance period improved from its performance on each measure in the Clinical Quality of Care, Care Coordination and Efficiency, and Person and Caregiver-Centered Experience classifications during the baseline period. We stated that a unique improvement range for each measure would be established for each HHA that defines the difference between the HHA's baseline period score and the same state level benchmark for the measure used in the achievement scoring calculation,

according to the proposed improvement formula. If an HHA's performance on the measure during the performance period was—

- Equal to or higher than the benchmark score, the HHA could receive an improvement score of 9 points, or 13.5 points for the Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility measures (an HHA with performance equal to or higher than the benchmark score could still receive the maximum of 10 points for achievement (or 15 points, for the composite measures));
- Greater than its baseline period score but below the benchmark (within the improvement range), the HHA could receive an improvement score of 0–9 based on the formula and as illustrated in the examples (except for the Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility measures, for which the maximum improvement score would be 13.5, as noted previously);⁴² or,
- Equal to or lower than its baseline period score on the measure, the HHA could receive zero points for improvement.

$$9 \times \left(\frac{\text{HHA Performance Period Score} - \text{HHA Baseline Period Score}}{\text{Benchmark} - \text{HHA Baseline Period Score}} \right) - 0.5$$

We also presented examples of how the proposed changes to the performance scoring methodology would be applied in the context of the measures in the Clinical Quality of Care, Care Coordination and Efficiency, and Person and Caregiver Centered Experience classifications (83 FR 32426 through 32438). We invited public comment on the proposal to reduce the maximum amount of improvement points, from 10 points to 9 points for PY 4 and subsequent performance years. The following is a summary of the public comments received on this proposal and our responses:

Comment: Many commenters supported rescoring in general and the proposed rescoring. A commenter suggested that HHVBP should reward agencies based on achievement only, and another commenter stated that the

proposed rescoring did not go far enough and would still penalize high performing agencies.

Response: We appreciate the positive feedback on our proposed methodology. We believe that removing improvement scores from the Model could disadvantage smaller HHAs and those HHAs with limited resources. Although we proposed to reduce the maximum improvement points, we believe that the improvement points continue to play a necessary role in promoting the consistent improvement of HHAs within the Model states that are not performing equal to or above the state benchmark. We will monitor and evaluate the impact of reducing the maximum improvement points from 10 to 9 to determine if additional rescoring is necessary in future years through rulemaking.

Final Decision: For the reasons stated and after consideration of the comments received, we are finalizing the rescoring of the maximum amount of improvement points, as proposed. Specifically, we are finalizing the reduction of the maximum amount of improvement points, from 10 points to 9 points, for PY4 and subsequent performance years for all measures except for the Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility measures, for which the maximum improvement points will be 13.5.

2. Examples of Calculating Achievement and Improvement Scores

For illustrative purposes we present the following examples of how the changes to the performance scoring

⁴² We note that in the proposed rule (83 FR 32436), we inadvertently stated that the HHA could receive a maximum improvement score of 15 for

these composite measures. As explained elsewhere in the proposed rule (83 FR 32435), we proposed

that the maximum improvement points for these composite measures would be 13.5.

methodology will be applied in the context of the measures in the Clinical Quality of Care, Care Coordination and Efficiency, and Person and Caregiver Centered Experience classifications. These HHA examples are based on data from 2015 (for the baseline period) and 2016 (for the performance year). We note that the figures and examples presented in this final rule with comment period are the same figures and examples set forth in the proposed rule (83 FR 32436 through 32438). Figure 3 shows the scoring for HHA 'A' as an example. The benchmark calculated for the improvement in pain measure is 97.676 for HHA A (note that the benchmark is calculated as the mean of the top decile in the baseline period for the state). The achievement threshold was 75.358 (this is defined as the performance of the median or the 50th percentile among HHAs in the baseline period for the state). HHA A's Year 1 performance rate for the measure was 98.348, which exceeds the benchmark so the HHA earned the

maximum 10 points based on its achievement score. Its improvement score is irrelevant in the calculation because measure performance exceeded the benchmark.

Figure 3 also shows the scoring for HHA 'B.' HHA B's performance on this measure went from 52.168 (which was below the achievement threshold) in the baseline period to 76.765 (which is above the achievement threshold) in the performance period. Applying the achievement scale, HHA B will earn 1.067 points for achievement, calculated as follows: $9 * (76.765 - 75.358) / (97.676 - 75.358) + 0.5 = 1.067$.⁴³ Calculating HHA B's improvement score yields the following result: based on HHA B's period-to-period improvement, from 52.168 in the baseline year to 76.765 in the performance year, HHA B will earn 4.364 points, calculated as follows: $9 * (76.765 - 52.168) / (97.676$

⁴³ Achievement points are calculated as $9 * (\text{HHA Performance Year Score} - \text{Achievement Threshold}) / (\text{Benchmark} - \text{Achievement threshold}) + 0.5$.

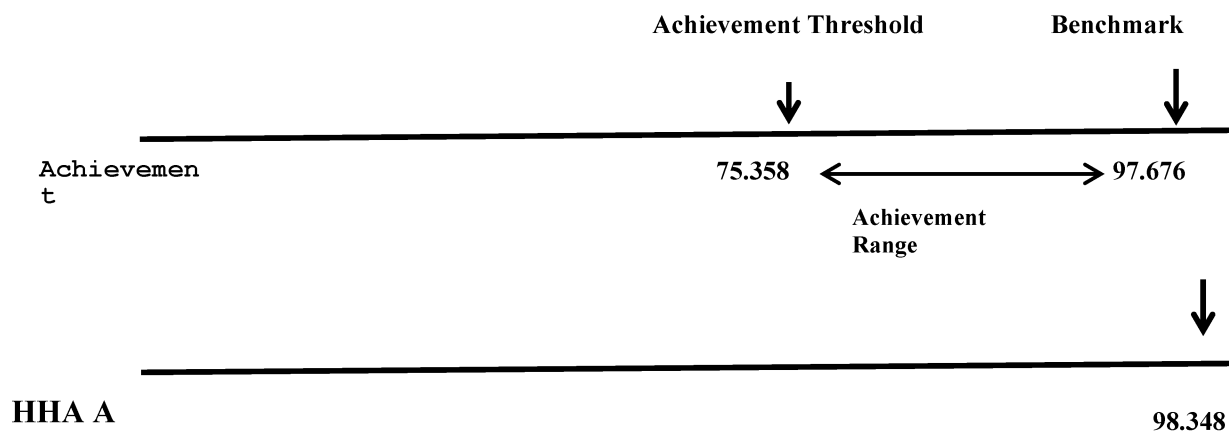
$- 52.168) - 0.5 = 4.364$.⁴⁴ Because the higher of the achievement and improvement scores is used, HHA B will receive 4.364 points for this measure.

In Figure 4, HHA 'C' yielded a decline in performance on the improvement in pain measure, falling from 70.266 to 58.487. HHA C's performance during the performance period was lower than the achievement threshold of 75.358 and, as a result, the HHA will receive zero points based on achievement. It will also receive zero points for improvement, because its performance during the performance period was lower than its performance during the baseline period.

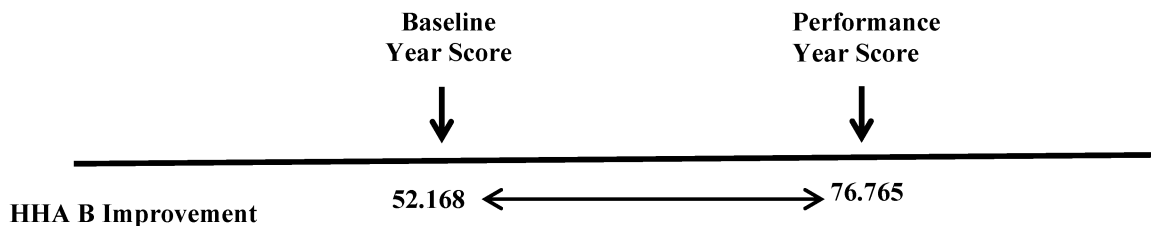
⁴⁴ As finalized, the revised formula for calculating improvement points is $9 * (\text{HHA Performance Year Score} - \text{HHA Baseline Period Score}) / (\text{HHA Benchmark} - \text{HHA Baseline Period Score}) - 0.5$. We note that in the proposed rule (83 FR 32436), we inadvertently included the achievement threshold of 75.358 in the denominator of this equation rather than HHA B's baseline period score of 52.168, however, the calculated figures were correct.

FIGURE 3: EXAMPLE OF AN HHA EARNING POINTS BY ACHIEVEMENT OR IMPROVEMENT SCORING

Measure: Improvement in Pain

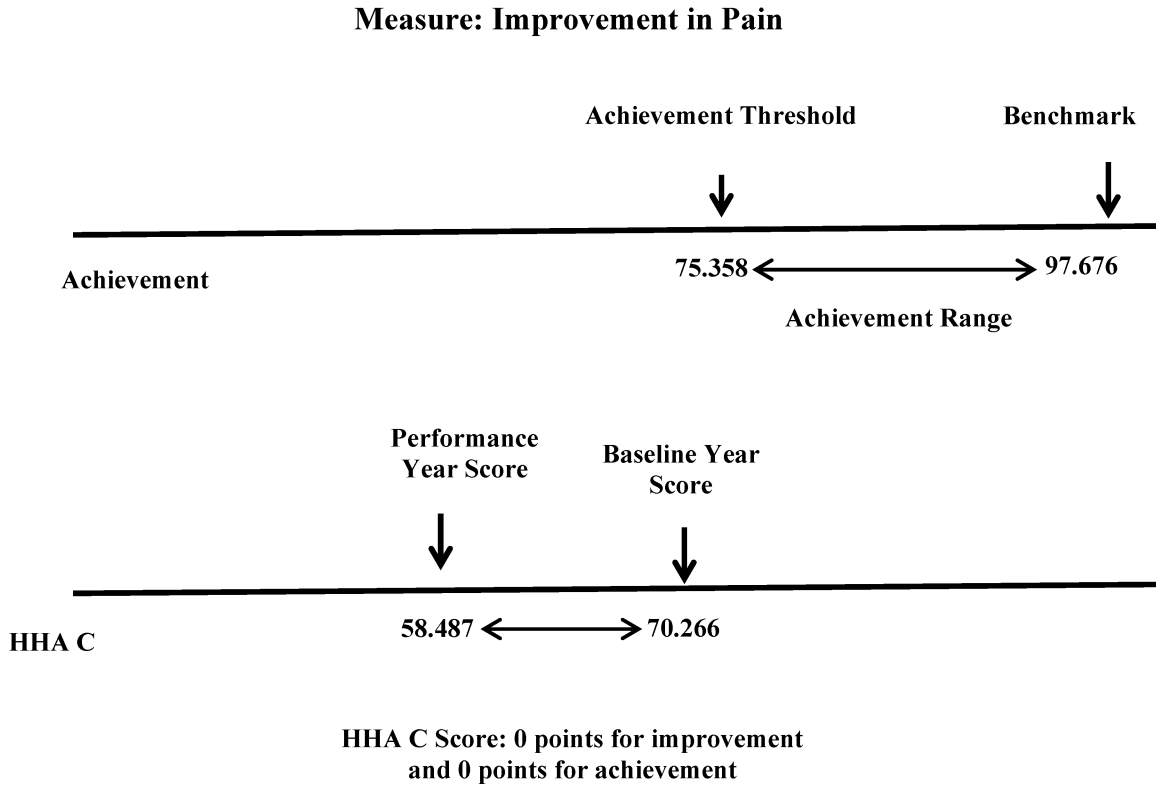


HHA A Score: 10 maximum points for achievement



HHA B Score: The greater of 1.067 points for achievement and 4.364 points for improvement.

FIGURE 4: EXAMPLE OF AN HHA NOT EARNING POINTS BY ACHIEVEMENT OR IMPROVEMENT SCORING



We will monitor and evaluate the impact of reducing the maximum improvement points to 9 and will consider whether to propose more changes to the weight of the improvement score relative to the achievement score in future years through rulemaking.

D. Update on the Public Display of Total Performance Scores

In the CY 2016 HH PPS final rule (80 FR 68658), we stated that one of the three goals of the HHVBP Model is to enhance the current public reporting processes. We reiterated this goal and continued discussing the public display of HHAs' Total Performance Scores (TPSs) in the CY 2017 HH PPS final rule (81 FR 76751 through 76752). We believe that publicly reporting a participating HHA's TPS will encourage providers and patients to use this information when selecting an HHA to provide quality care. We stated in the proposed rule that we were encouraged by the previous stakeholder comments and support for public reporting that could assist patients, physicians, discharge planners, and other referral sources to choose higher-performing HHAs.

In the CY 2017 HH PPS final rule, we noted that a commenter suggested that we not consider public display until after the Model was evaluated. Another commenter favored the public display of the TPS, but recommended that CMS use a transparent process and involve stakeholders in deciding what will be reported, and provide a review period with a process for review and appeal before reporting.

As discussed in the CY 2017 HH PPS final rule, we are considering public reporting for the HHVBP Model after allowing analysis of at least eight quarters of performance data for the Model and the opportunity to compare how these results align with other publicly reported quality data (81 FR 76751). While we did not make a specific proposal in the CY 2019 HH PPS proposed rule, we solicited further public comment on what information, specifically from the CY 2017 Annual Total Performance Score and Payment Adjustment Reports and subsequent annual reports, should be made publicly available. We noted that HHAs have the opportunity to review and appeal their Annual Total Performance Score and Payment Adjustment Reports as outlined in the appeals process finalized

in the CY 2017 HH PPS final rule (81 FR 76747 through 76750). Examples of the information included in the Annual Total Performance Score and Payment Adjustment Report include the agency: name, address, TPS, payment adjustment percentage, performance information for each measure used in the Model (for example, quality measure scores, achievement, and improvement points), state and cohort information, and percentile ranking. We stated that based on the public comments received, we will consider what information, specifically from the annual reports, we may consider proposing for public reporting in future rulemaking.

Comment: Several commenters expressed support for publicly reporting information from the Annual Total Performance Score and Payment Adjustment Reports as they believe it would better inform consumers and allow for more meaningful and objective comparisons among HHAs. A commenter suggested that CMS consider providing an actual percentile ranking for HHAs along with their TPS as this would provide more information to both HHAs and the public. Another commenter expressed interest in publicly reporting all information

relevant to the HHVBP Model such as the agency's performance on the individual measures, percentile rankings, and comparison by state and cohort. Several commenters expressed concern with publicly displaying HHAs' TPSs citing that the methodology is still evolving and this data would only represent a subset of home health providers participating in the Model. Commenters also pointed out that consumers already have access to the quality measures in the Model as the measures themselves are already publicly reported on Home Health Compare. A commenter recommended not publicly reporting the data until all states are participating in the Model because it believes publicly reporting data for one state but not the other can be confusing for consumers.

Response: We appreciate the comments on when and what to publicly report and will work to ensure any data that are publicly reported from the Annual Total Performance Score and Payment Adjustment Reports are thoroughly explained and gives patients, physicians, discharge planners, and other referral sources the knowledge they need to choose higher-performing HHAs. We intend, if appropriate, to propose what would be publicly reported and when in future rulemaking.

We received a number of out-of-scope comments on policy areas not addressed by our proposals, including requests for us to expand the HHVBP Model to a national program. We thank the commenters for their input and would address any future changes through rulemaking.

V. Home Health Quality Reporting Program (HH QRP)

A. Background and Statutory Authority

Section 1895(b)(3)(B)(v)(II) of the (the Act) requires that for 2007 and subsequent years, each HHA submit to the Secretary in a form and manner, and at a time, specified by the Secretary, such data that the Secretary determines are appropriate for the measurement of health care quality. To the extent that an HHA does not submit data with respect to a year in accordance with this clause, the Secretary is directed to reduce the HH market basket percentage increase applicable to the HHA for such year by 2 percentage points. As provided at section 1895(b)(3)(B)(vi) of the Act, depending on the market basket percentage increase applicable for a particular year, for 2015 and each subsequent year (except 2018), the reduction of that increase by 2 percentage points for failure to comply

with the requirements of the HH QRP and further reduction of the increase by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act may result in the home health market basket percentage increase being less than 0.0 percent for a year, and may result in payment rates under the Home Health PPS for a year being less than payment rates for the preceding year.

For more information on the policies we have adopted for the HH QRP, we refer readers to the CY 2007 HH PPS final rule (71 FR 65888 through 65891), the CY 2008 HH PPS final rule (72 FR 49861 through 49864), the CY 2009 HH PPS update notice (73 FR 65356), the CY 2010 HH PPS final rule (74 FR 58096 through 58098), the CY 2011 HH PPS final rule (75 FR 70400 through 70407), the CY 2012 HH PPS final rule (76 FR 68574), the CY 2013 HH PPS final rule (77 FR 67092), the CY 2014 HH PPS final rule (78 FR 72297), the CY 2015 HH PPS final rule (79 FR 66073 through 66074), the CY 2016 HH PPS final rule (80 FR 68690 through 68695), the CY 2017 HH PPS final rule (81 FR 76752), and the CY 2018 HH PPS final rule (82 FR 51711 through 51712).

Although we have historically used the preamble to the HH PPS proposed and final rules each year to remind stakeholders of all previously finalized program requirements, we have concluded that repeating the same discussion each year is not necessary for every requirement, especially if we have codified it in our regulations. Accordingly, the following discussion is limited as much as possible to a discussion of our proposals, the comments we received on those proposals and our responses to those comments, and policies we are finalizing for future years of the HH QRP after consideration of the comments. We intend to use this approach in our rulemakings for the HH QRP going forward.

B. General Considerations Used for the Selection of Quality Measures for the HH QRP

1. Background

For a detailed discussion of the considerations we historically use for measure selection for the HH QRP quality, resource use, and others measures, we refer readers to the CY 2016 HH PPS final rule (80 FR 68695 through 68696).

Comment: A few commenters provided input on several topics associated with measure adoption the HH QRP. Specifically, a commenter expressed that the pace of removing historical OASIS items has not matched

the addition of new measures that meet IMPACT Act requirements. The same commenter also requested that as IMPACT Act measures are added, along with the burden of data collection, the applicability of the measures to different settings be taken into consideration. Another commenter recommended that measures account for patients who do not have a goal of improvement and be tested to ensure their reliability and validity in the home setting.

Response: We appreciate the comments. The removal of historic OASIS items has been guided by our assessment regarding their continued need, as well as our goal to streamline reporting requirements for HHAs and minimize the reporting burden as much as possible. Adopting measures that meet IMPACT Act requirements at the same pace that we remove other OASIS items would not further our goal to reduce burden.

We interpret the comment regarding the applicability of quality measures across the post-acute care settings to mean that we should take into consideration the appropriateness of measures that would be used in both institutional and home-based settings. While we believe there can be overlap in patient populations across the four post-acute care (PAC) providers for which we are required to adopt measures that meet requirements under section 1899B of the Act, we recognize that each PAC provider setting also has unique attributes, and we take these differences into consideration during our measure development and maintenance work.

With regard to the comment that we should consider the adoption of measures that take into account patients who may not have goals for improvement, we agree that not all patients may have goals associated with improvement and we are interested in the utilization of such measures that address this population in the HH QRP and in post-acute care in general. Further, we agree that such measures should be tested to ensure their reliability and validity in the home setting.

2. Accounting for Social Risk Factors in the HH QRP Program

In the CY 2018 HH PPS final rule (82 FR 51713 through 51714) we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being

near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.⁴⁵ Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in our value-based purchasing programs.⁴⁶ As we noted in the CY 2018 HH PPS final rule (82 FR 51713 through 51714), ASPE's report to Congress, which was required by the IMPACT Act, found that, in the context of value based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. ASPE is continuing to examine this issue in its second report required by the IMPACT Act, which is due to Congress in the fall of 2019. In addition, as we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38428 through 38429), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures. The trial period ended in April 2017 and a final report is available at: http://www.qualityforum.org/SES_Trial_Period.aspx. The trial concluded that "measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship" between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on

social risk factors. NQF has extended the socioeconomic status (SES) trial,⁴⁷ allowing further examination of social risk factors in outcome measures.

In the CY 2018/FY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a provider that will also allow for a comparison of those differences, or disparities, across providers.

Feedback we received across our quality reporting programs included encouraging CMS to explore whether factors could be used to stratify or risk adjust the measures (beyond dual eligibility), to consider the full range of differences in patient backgrounds that might affect outcomes, to explore risk adjustment approaches, and to offer careful consideration of what type of information display will be most useful to the public.

We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned CMS to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discouraging the provision of care to more medically complex patients. Commenters also noted that value-based payment program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, we are considering options to improve health disparities among patient groups within and across hospitals by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for

more details, where we discuss the potential stratification of certain Hospital IQR Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

Comment: Several comments supported continued investigation of ways that social risk factors can be applied to quality measures. These commenters also provided recommendations for possible social risk factors, including family caregiver presence and degree of involvement, the Area Deprivation Index, patient preference, needs of specialty populations and disproportionate percentage of Medicaid patients. A commenter recommended collaboration with Accountable Health Communities to measure and eventually mitigate issues for those with advanced illness. Another commenter noted that there are statistical methods that can adjust for socioeconomic status (SES) factors that are independent of quality of care and will not adjust away actual quality disparities. The commenter also suggested that we explore the influence of neighborhood factors that could be available from other data sources and linked to a patient using address information. MedPAC noted that CMS should account for social risk factors in quality programs by adjusting payment through peer grouping and targeting technical assistance to low-performing providers. A few commenters expressed support for rewarding better outcomes for beneficiaries with social risk factors. Commenters also expressed support for the reporting of stratified outcomes measures to providers.

Response: We thank the commenters for their comments and will take them into account as we further consider how to appropriately account for social risk factors in the HH QRP. We also refer the reader to the CY 2018 HH PPS final rule (82 FR 51713 through 51714), where we discussed many of the issues raised by these commenters.

C. Removal Factors for Previously Adopted HH QRP Measures

As a part of our Meaningful Measures Initiative, discussed in section I.D.1 of this final rule with comment period and in the CY 2019 HH PPS proposed rule (83 FR 32440 through 32441), we strive to put patients first, ensuring that they,

⁴⁵ See United States Department of Health and Human Services. "Healthy People 2020: Disparities. 2014." Available at: <http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities>; or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

⁴⁶ Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), "Report to Congress: Social Risk Factors and Performance under Medicare's Value-Based Purchasing Programs." December 2016. Available at: <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicare-value-based-purchasing-programs>.

⁴⁷ Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357>.

along with their clinicians, are empowered to make decisions about their own healthcare using data-driven information that is increasingly aligned with a parsimonious set of meaningful quality measures. We stated that we began reviewing the HH QRP measure set in accordance with the Meaningful Measures Initiative discussed in section I.D.1 of this final rule with comment period and in the CY 2019 HH PPS proposed rule (83 FR 32440 through 32441), and that we are working to identify how to move the HH QRP forward in the least burdensome manner possible, while continuing to prioritize and incentivize improvement in the quality of care provided to patients.

Specifically, we stated our belief that the goals of the HH QRP and the measures used in the program overlap with the Meaningful Measures Initiative priorities, including making care safer, strengthening person and family engagement, promoting coordination of care, promoting effective prevention and treatment, and making care affordable.

We also stated that we had evaluated the appropriateness and completeness of the HH QRP's current measure removal factors. In the CY 2017 HH PPS final rule (81 FR 76754 through 76755), we noted that we had adopted a process for retaining, removing, and replacing previously adopted HH QRP measures. To be consistent with other established quality reporting programs, in the CY 2019 HH PPS proposed rule (83 FR 32440 through 32441), we proposed to replace the six criteria used when considering a quality measure for removal, finalized in the CY 2017 HH PPS final rule (81 FR 76754 through 76755), with the following seven measure removal factors, finalized for the LTCH QRP in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614 through 53615), for the SNF QRP in the FY 2016 SNF PPS final rule (80 FR 46431 through 46432), and for the IRF QRP in the CY 2013 OPSS/ASC final rule (77 FR 68502 through 68503), for use in the HH QRP:

- Factor 1. Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.
- Factor 2. Performance or improvement on a measure does not result in better patient outcomes.
- Factor 3. A measure does not align with current clinical guidelines or practice.
- Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.

- Factor 5. A measure that is more proximal in time to desired patient outcomes for the particular topic is available.

- Factor 6. A measure that is more strongly associated with desired patient outcomes for the particular topic is available.

- Factor 7. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

As we stated in the proposed rule, we believe these measure removal factors are substantively consistent with the criteria we previously adopted (but noted that we would be changing the terminology to call them “factors”) and appropriate for use in the HH QRP. However, we stated that even if one or more of the measure removal factors applies, we might nonetheless choose to retain the measure for certain specified reasons. We stated that examples of such instances could include when a particular measure addresses a gap in quality that is so significant that removing the measure could result in poor quality, or in the event that a given measure is statutorily required. Furthermore, we noted that consistent with other quality reporting programs, we would apply these factors on a case-by-case basis.

We finalized in the CY 2017 HH PPS final rule (81 FR 76755) that removal of a HH QRP measure would take place through notice and comment rulemaking, unless we determined that a measure is causing concern for patient safety. Specifically, in the case of a HH QRP measure for which there is a reason to believe that the continued collection raised possible safety concerns, we stated that we would promptly remove the measure and publish the justification for the removal in the **Federal Register** during the next rulemaking cycle. In addition, we stated that we would immediately notify HHAs and the public through the usual communication channels, including listening sessions, memos, email notification, and Web postings. We stated that if we removed a measure from the HH QRP under these circumstances but also collected data on that measure under different statutory authority for a different purpose, we would notify stakeholders that we would also cease collecting the data under that alternative statutory authority.

In the CY 2019 HH PPS proposed rule (83 FR 32440 through 32441), we also proposed to adopt an additional factor to consider when evaluating potential measures for removal from the HH QRP measure set:

- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

As we discussed in the CY 2019 HH PPS proposed rule (83 FR 32344 through 32345, 32440 through 32441), with respect to our new Meaningful Measures Initiative, we are engaging in efforts to ensure that the HH QRP measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. We stated our belief that these costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. We also stated that we had identified several different types of costs, including, but not limited to the following:

- Provider and clinician information collection burden and burden associated with the submitting/reporting of quality measures to CMS.
- The provider and clinician cost associated with complying with other HH programmatic requirements.
- The provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs.
- The cost to CMS associated with the program oversight of the measure, including measure maintenance and public display.
- The provider and clinician cost associated with compliance with other federal and state regulations (if applicable).

For example, we stated that it may be of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports program objectives (for example, informing beneficiary choice). It may also be costly for HHAs to track confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. We may also have to expend resources to maintain the specifications for the measure, including the tools needed to collect, validate, analyze, and publicly report the measure data.

When these costs outweigh the evidence supporting the continued use of a measure in the HH QRP, we stated our belief that it may be appropriate to remove the measure from the program. Although we recognize that one of the main goals of the HH QRP is to improve beneficiary outcomes by incentivizing health care providers to focus on specific care issues and making public data related to those issues, we also

recognize that those goals can have limited utility where, for example, the publicly reported data is of limited use because it cannot be easily interpreted by beneficiaries and used to influence their choice of providers. In these cases, removing the measure from the HH QRP may better accommodate the costs of program administration and compliance without sacrificing improved health outcomes and beneficiary choice.

We proposed that we would remove measures based on Factor 8 on a case-by-case basis. For example, we may decide to retain a measure that is burdensome for HHAs to report if we conclude that the benefit to beneficiaries is so high that it justifies the reporting burden. We stated that our goal is to move the HH QRP program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

We invited public comment on our proposals to replace the six criteria used when considering a quality measure for removal with the seven measure removal factors currently adopted in the LTCH QRP, IRF QRP, and SNF QRP. We also invited public comment on our proposal to adopt new measure removal Factor 8: The costs associated with a measure outweigh the benefit of its continued use in the program.

Comment: The majority of commenters supported the proposal to replace the current six criteria with the seven factors to create alignment with the other PAC settings. The majority of commenters also supported the addition of Factor 8. A few commenters strongly agreed that quality measure reporting is important, but noted that the costs of such reporting can at times exceed the value of the data.

Response: We thank these commenters for their support.

Comment: With respect to Factor 1, a commenter noted support but added that automatically removing topped out measures creates a risk of decreased adherence to those evidence-based measures. The commenter urged CMS to consider continuing to require data reporting on topped out measures for a certain period time to ensure that performance in certain areas of quality, such as depression and fall risk, does not decline. Another commenter recommended that CMS periodically reassess any measure removed under Factor 1 to determine if there has been a decline in performance since the time the measure was removed.

Response: We thank these commenter for their comments. We do not

automatically remove topped out measures, and wish to reiterate that a topped out measure may be retained for specified reasons. We may retain a particular measure with high performance rates if the measure addresses a topic related to quality that is so significant that we do not want to risk a decline in quality that could result if we removed the measure, or if the measure addresses a topic that is statutorily required. In response to the commenters' concern about a decline in performance that could result if a measure is removed based on Factor 1, we currently monitor for gaps in the quality of care related to the topic which a removed measure addressed, and we would consider whether to reintroduce a measure on that topic if we discovered such a gap.

Comment: A commenter raised concerns about the rationale of removing relatively precise measures in favor of more broadly applicable ones, noting that broader applicability and reportability do not necessarily equate to better measures. This commenter recommended choosing measures on the basis of their clinical significance.

Response: We agree that replacing a narrow measure with one that is more broadly applicable would be problematic if the more broadly applicable measure did not correlate with high quality outcomes. We intend to only consider measure replacement under Factor 4 if the more broadly applicable measure is at least comparable in terms of how well it addresses quality outcomes as the measure it is replacing.

Comment: A commenter recommended that CMS change the wording of Factor 2 from "Performance or improvement on a measure does not result in better patient outcomes" to "Performance or improvement on a measure is not associated with better patient outcomes" so that the factor does not suggest that causality.

Response: We thank the commenter for its suggestion. We believe that there is a direct correlation between performance improvement on a measure and better patient outcomes. We would apply Factor 2 when our data analysis indicates that, despite performance improvement on a measure, there is no improvement in patient outcomes.

Comment: A few commenters expressed specific support for the adoption of the new measure removal Factor 8: The costs associated with a measure outweigh the benefit of its continued use in the program for the HH QRP. Other commenters noted that Factor 8 was consistent with CMS' Patients over Paperwork initiative.

Response: We appreciate the support of the addition of this measure removal factor for the HH QRP.

Comment: Another commenter recommended that Factor 8 be applied on a case-by-case basis, and another commenter recommended that CMS consider a variety of costs in Factor 8's application, including costs to providers and clinicians participating in multiple quality programs. Another commenter opposed the adoption of Factor 8, citing the difficulty of measuring benefits to patients when comparing costs and benefits.

Response: We note that there are challenges in weighing the overall benefits for patients against the associated costs. We also recognize that various stakeholders may have different perspectives on such benefits and costs. In light of these challenges, we intend to evaluate each measure on a case-by-case basis, taking into account the input from a variety of stakeholders, including, but not limited to: Patients, caregivers, patient and family advocates, providers, provider associations, healthcare researchers, data vendors, and other stakeholders with insight into the benefits and costs (financial and otherwise) of maintaining the specific measure in the HH QRP. Because for each measure the relative benefit to each stakeholder may vary, we believe that the benefits to be evaluated for each measure are specific to the measure and the original rationale for including the measure in the program. Therefore, when evaluating whether a measure should be removed under Factor 8, we intend to assess and take into consideration issues including the holistic balance of the costs, benefits, data, input from stakeholders, and our policy objectives.

Final Decision: After consideration of the public comments, we are finalizing our proposal to replace the six criteria used when considering a quality measure for removal with the seven measure removal factors currently adopted in other CMS programs, including LTCH QRP, IRF QRP, and SNF QRP. We are also finalizing our proposal to add to the HH QRP measure removal Factor 8: The costs associated with a measure outweigh the benefit of its continued use in the program.

D. Quality Measures Currently Adopted for the HH QRP

The HH QRP currently has 30⁴⁸ measures for the CY 2020 program year, as outlined in Table 41.

⁴⁸In the CY 2019 HH PPS proposed rule (83 FR 32441) we incorrectly stated that there are 31 measures for the CY 2020 program year. The current

TABLE 41: MEASURES CURRENTLY ADOPTED FOR THE CY 2020 HH QRP

Short Name	Measure Name & Data Source
OASIS-based	
Ambulation	Improvement in Ambulation/Locomotion (NQF #0167).
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).
Application of Functional Assessment	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).
Bathing	Improvement in Bathing (NQF #0174).
Bed Transferring	Improvement in Bed Transferring (NQF # 0175).
Depression Assessment	Depression Assessment Conducted.
Diabetic Foot Care	Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care (#0519).
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues- Post Acute Care (PAC) HH QRP.
Drug Education	Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care.
Dyspnea	Improvement in Dyspnea.
Falls Risk	Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537).
Influenza	Influenza Immunization Received for Current Flu Season (NQF #0522).
Oral Medications	Improvement in Management of Oral Medications (NQF #0176).
Pain	Improvement in Pain Interfering with Activity (NQF #0177).
PPV	Pneumococcal Polysaccharide Vaccine Ever Received.
Pressure Ulcer/Injury	Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), removed as of January 1, 2019. Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure, effective January 1, 2019.
Surgical Wounds	Improvement in Status of Surgical Wounds (NQF #0178).
Timely Care	Timely Initiation Of Care (NQF #0526).
Claims-based	
ACH	Acute Care Hospitalization During the First 60 Days of HH (NQF #0171).
DTC	Discharge to Community-Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP).
ED Use	Emergency Department Use without Hospitalization During the First 60 Days of HH (NQF #0173).
ED Use without Readmission	Emergency Department Use without Hospital Readmission During the First 30 Days of HH (NQF #2505).
MSPB	Total Estimated Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) HH QRP.
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH Quality Reporting Program.
Rehospitalization	Rehospitalization During the First 30 Days of HH (NQF #2380).
HCAHPS-based	
Communication	How well did the home health team communicate with patients.
Overall Rating	How do patients rate the overall care from the home health agency.
Professional Care	How often the home health team gave care in a professional way.
Team Discussion	Did the home health team discuss medicines, pain, and home safety with patients.
Willing to Recommend	Will patients recommend the home health agency to friends and family.

E. Removal of HH QRP Measures Beginning With the CY 2021 HH QRP

To address the Meaningful Measures Initiative discussed in the CY 2019 HH

PPS proposed rule in the CY 2019 HH PPS proposed rule (83 FR 32442 through 32446) we proposed to remove seven measures from the HH QRP beginning with the CY 2021 HH QRP.

We received a few general comments on the proposed removal of these measures.

Comment: Most commenters, including MedPAC, supported CMS' proposal to remove all seven measures.

Pressure Ulcer/Injury measure, Percent of Residents or Patients with Pressure Ulcers That Are New or

Worsened (Short Stay) (NQF #0678), will be replaced by a modified version of that measure,

Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, effective January 1, 2019.

Response: We thank the commenters for their support of all of our measure removal proposals.

Comment: While supportive of the proposals to remove the seven measures, two commenters urged CMS to consider not waiting until the CY 2021 HH QRP program year to remove them from the HH QRP. These commenters also noted that if CMS continues to collect data through the OASIS on process measures that have been removed from the HH QRP but still represent best practices, HHAs can continue to monitor their performance on those measures without being concerned about having to report them for the HH QRP.

Response: We thank the commenters for their support of the measure removal proposals and note that we are finalizing all of them. We are unable to update the OASIS submission system before January 1, 2020, which is midway through the data collection period that we use for the HH QRP (see 81 FR 76783). As a result, with respect to the five HH QRP measures that are calculated using OASIS data (Depression Assessment Conducted, Diabetic Foot Care and Patient/Caregiver Education Implemented During All Episodes of Care, Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537), Pneumococcal Polysaccharide Vaccine Ever Received, and Improvement in the Status of Surgical Wounds), HHAs will be required to continue submitting data on those measures with respect to home health quality episodes that begin during the first two quarters of the CY 2021 program year (that is, for home health episodes that occur during the 3rd and 4th quarters of CY 2019). With respect to the two HH QRP measures we are removing that are calculated using claims data (Emergency Department Use without Hospital Readmission During the First 30 Days of HH (NQF #2505) and Rehospitalization During the First 30 Days of HH (NQF #2380)), we will stop collecting claims data for the calculation of these two measures beginning with home health quality episodes that begin on or after July 1, 2019.

We remind HHAs that the removal of a measure from the HH QRP does not prevent HHAs from continuing to incorporate the quality process addressed by that measure in their own quality monitoring activities, and we would encourage HHAs to do so.

1. Removal of the Depression Assessment Conducted Measure

In the CY 2019 HH PPS proposed rule (83 FR 32442), we proposed to remove

the Depression Assessment Conducted Measure from the HH QRP beginning with the CY 2021 HH QRP under Factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

In the CY 2010 HH PPS final rule (74 FR 58096 through 58098), we adopted the Depression Assessment Conducted Measure beginning with the CY 2010 HH QRP. Depression in the elderly is associated with disability, impaired well-being, service utilization,⁴⁹ and mortality.⁵⁰ This process measure reports the percentage of HH episodes in which patients were screened for depression (using a standardized depression screening tool) at start of care/resumption of care (SOC/ROC). The measure is calculated solely using the OASIS Item M1730, Depression Screening.⁵¹ Item M1730 is additionally used at SOC/ROC as a risk adjuster in the calculation of several other OASIS-based outcome measures currently adopted for the HH QRP.⁵²

We stated in the CY 2019 HH PPS proposed rule that in our evaluation of the Depression Assessment Conducted Measure, we found that HHA performance is very high and that meaningful distinctions in improvements in performance cannot be made. The mean and median agency performance scores for this measure in 2017 (96.8 percent and 99.2 percent, respectively) when compared to the mean and median agency performance scores for this measure in 2010 (88.0 percent and 96.6 percent, respectively) indicate that an overwhelming majority of patients are screened for depression in the HH setting. Further, these performance scores demonstrate the

⁴⁹ Beekman AT, Deeg DJ, Braam AW, et al.: Consequences of major and minor depression in later life: a study of disability, well-being and service utilization. *Psychological Medicine* 27:1397–1409, 1997.

⁵⁰ Schulz, R., Beach, S.R., Ives, D.G., Martire, L.M., Ariyo, A. A., & Kop, W.J. (2000). Association between depression and mortality in older adults—The Cardiovascular Health Study. *Archives of Internal Medicine*, 160(12), 1761–1768.

⁵¹ Measure specifications can be found in the Home Health Process Measures Table on the Home Health Quality Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Process-Measures-Table_OASIS-C2_4-11-18.pdf).

⁵² The OASIS-based HH QRP outcome measures that use OASIS Item M1730 as a risk adjuster in the calculation of the measure are: Improvement in Bathing (NQF #0174), Improvement in Bed Transferring (NQF #0175), Improvement in Ambulation/Locomotion (NQF #0167), Improvement in Dyspnea, Improvement in Pain Interfering with Activity (NQF #0177), Improvement in Management of Oral Medications (NQF #0176), and Improvement in Status of Surgical Wounds (NQF #0178).

improvement in measure performance since its adoption in the HH QRP. In addition, in 2017 the 75th percentile measure score (100 percent) and the 90th percentile measure score (100 percent) are statistically indistinguishable from each other, meaning that the measure scores do not meaningfully distinguish scores between HHAs. Further, the Truncated Coefficient of Variation (TCV)⁵³ for this measure is 0.03, suggesting that it is not useful to draw distinctions between individual agency performance scores for this measure.

For these reasons, we proposed to remove the Depression Assessment Conducted Measure from the HH QRP beginning with the CY 2021 HH QRP under our Factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

We stated in the proposed rule that if we finalized this proposal, HHAs would no longer be required to submit OASIS Item M1730, Depression Screening at SOC/ROC for the purposes of this measure beginning January 1, 2020. HHAs would, however, continue to submit data on M1730 at the time point of SOC/ROC as a risk adjuster for several other OASIS-based outcome measures currently adopted for the HH QRP.⁵⁴ We also stated that if we finalized this proposal, data for this measure would be publicly reported on HH Compare until January 2021.

We invited public comment on this proposal.

Comment: A commenter expressed general support for the removal of the Depression Assessment Conducted measure but encouraged CMS to consider how else mood could be assessed in the HH setting, noting that behavioral health is a key aspect of patient outcomes.

Response: We agree that behavioral health is a key aspect of patient outcomes and wish to clarify that the

⁵³ The truncated coefficient of variation (TCV) is the ratio of the standard deviation to the mean of the distribution of all scores, excluding the 5 percent most extreme scores. A small TCV (≤ 0.1) indicates that the distribution of individual scores is clustered tightly around the mean value, suggesting that it is not useful to draw distinctions between individual performance scores.

⁵⁴ The OASIS-based HH QRP outcome measures that use OASIS Item M1730 as a risk adjuster in the calculation of the measure are: Improvement in Bathing (NQF #0174), Improvement in Bed Transferring (NQF #0175), Improvement in Ambulation/Locomotion (NQF #0167), Improvement in Dyspnea, Improvement in Pain Interfering with Activity (NQF #0177), Improvement in Management of Oral Medications (NQF #0176), and Improvement in Status of Surgical Wounds (NQF #0178).

removal of this measure would not eliminate mood assessment in the HH setting. HHAs will continue to report OASIS Item M1730, Depression Screening at the time point of SOC/ROC as part of their reporting of data for other OASIS-based outcome measures currently used in the HH QRP. In addition, we continue to develop and test standardized patient assessment data elements that, if adopted, would assess the cognitive function and mental status of patients in PAC settings.⁵⁵

Final Decision: After considering public comment, we are finalizing our proposal to remove the Depression Assessment Conducted Measure from the HH QRP. HHAs will no longer be required to submit OASIS Item M1730, Depression Screening at SOC/ROC for the purposes of this measure beginning with Home Health quality episodes of care that begin on or after January 1, 2020. HHAs will, however, continue to submit data on M1730 at the time point of SOC/ROC as a risk adjuster for several other OASIS-based outcome measures currently adopted for the HH QRP. Data for this measure will be publicly reported until such data are no longer available for public reporting of this measure on HH Compare.

2. Removal of the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure

In the CY 2019 HH PPS proposed rule (83 FR 32442 through 32443), we proposed to remove the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

In the CY 2010 HH PPS final rule (74 FR 58096 through 58098), we adopted the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure beginning with the CY 2010 HH QRP. This process measure reports the percentage of HH quality episodes in which diabetic foot care and patient/caregiver education were included in the physician-ordered plan of care and implemented (at the time of or at any

time since the most recent SOC/ROC assessment). The measure numerator is calculated using OASIS Item M2401 row a, Intervention Synopsis: Diabetic foot care.⁵⁶

We stated in the CY 2019 HH PPS proposed rule (83 FR 32443) that in our evaluation of the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure, we found that HHA performance is very high and that meaningful distinctions in improvements in performance cannot be made. The mean and median agency performance scores for this measure in 2017 (97.0 percent and 99.2 percent, respectively) when compared to the mean and median agency performance score for this measure in 2010 (86.2 percent and 91.7 percent, respectively), indicate that an overwhelming majority of HH episodes for patients with diabetes included education on foot care. Further, these scores demonstrate the improvement in measure performance since the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure's adoption in the HH QRP. In addition, in 2017, the 75th percentile measure score (100 percent) and the 90th percentile score (100 percent) are statistically indistinguishable from each other, meaning that the measure scores do not meaningfully distinguish between HHAs. Further, the TCv for this measure is 0.03, suggesting that it is not useful to draw distinctions between individual agency performance scores for this measure.

For these reasons, we proposed to remove the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure from the HH QRP beginning with CY 2021 HH QRP under our proposed Factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

We stated in the proposed rule that if we finalized this proposal, HHAs would no longer be required to submit OASIS Item M2401 row a, Intervention Synopsis: Diabetic foot care at the time point of Transfer to an Inpatient Facility (TOC) and Discharge from Agency—Not to an Inpatient Facility (Discharge) for the purposes of the HH QRP beginning

January 1, 2020. HHAs may enter an equal sign (=) for M2401, row a, at the time point of TOC and Discharge on or after January 1, 2020. We also stated that if we finalized this proposal, data for this measure would be publicly reported on HH Compare until January 2021.

We invited public comment on this proposal.

Comment: Another commenter expressed general support for the removal of the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure, but encouraged CMS to provide clear updates to providers about how they should complete items until the next OASIS version is released.

Response: We thank the commenter for its support. We intend to provide further guidance and training on how to properly complete the OASIS.

Final Decision: After considering public comment, we are finalizing our proposal to remove the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure from the HH QRP. HHAs will no longer be required to submit OASIS Item M2401 row a, Intervention Synopsis: Diabetic foot care at the time point of Transfer to an Inpatient Facility (TOC) and Discharge from Agency—Not to an Inpatient Facility (Discharge) for the purposes of the HH QRP beginning January 1, 2020. HHAs may enter an equal sign (=) for M2401, row a, at the time point of TOC and Discharge on or after January 1, 2020. Data for this measure will be publicly reported until such data are no longer available for public reporting of this measure on HH Compare.

3. Removal of the Multifactor Fall Risk Assessment Conducted for All Patients Who Can Ambulate (NQF #0537) Measure

In the CY 2019 HH PPS proposed rule (83 FR 32443), we proposed to remove the Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537) Measure from the HH QRP beginning with the CY 2021 HH QRP, under our proposed Factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

In CY 2010 HH PPS final rule (74 FR 58096 through 58098), we adopted the Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537) Measure.⁵⁷

⁵⁷ At the time, this measure was adopted as "Falls risk assessment for patients 65 and older." The

⁵⁵ Development and Maintenance of Standardized Cross Setting Patient Assessment Data for Post-Acute Care: Summary Report of Findings from Alpha 2 Pilot Testing. Retrieved from <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Alpha-2-SPADE-Pilot-Summary-Documents.pdf>.

⁵⁶ Measure specifications can be found in the Home Health Quality Measures Table on the Home Health Quality Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Process-Measures-Table_OASIS-C2_4-11-18.pdf).

beginning with the CY 2010 HH QRP. This process measure reports the percentage of HH quality episodes in which patients had a multifactor fall risk assessment at SOC/ROC. The measure is calculated using OASIS Item M1910, Falls Risk Assessment.⁵⁸

We stated in the proposed rule (83 FR 32443) that in our evaluation of the Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537) Measure, we found that HHA performance is very high and that meaningful distinctions in improvements in performance cannot be made. The mean and median agency performance scores for this measure in 2017 (99.3 percent and 100.0 percent, respectively) when compared to the mean and median agency performance score for this measure in 2010 (94.8 percent and 98.9 percent, respectively), indicate that an overwhelming majority of patients in an HHA have had a multifactor fall risk assessment at SOC/ROC and demonstrates the improvement in measure performance since its adoption. In addition, in 2017, the 75th percentile measure score (100 percent) and the 90th percentile measure score (100 percent) are statistically indistinguishable from each other, meaning that the measure scores do not meaningfully distinguish between HHAs. Further, the TCV for this measure is 0.01, suggesting that it is not useful to draw distinctions between individual agency performance scores for this measure.

For these reasons, we proposed to remove the Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537) Measure from the HH QRP beginning with the CY 2021 HH QRP, under our proposed Factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

We stated in the proposed rule that if we finalized this proposal, HHAs would no longer be required to submit OASIS Item M1910, Falls Risk Assessment at SOC/ROC beginning January 1, 2020. HHAs may enter an equal sign (=) for M1910 at the time point of SOC and ROC beginning January 1, 2020. We also stated that if we finalized this proposal, data for this measure would be publicly

name of this measure was updated in the CY 2018 HH PPS final rule (82 FR 51717).

⁵⁸ Measure specifications can be found in the Home Health Process Measures Table on the Home Health Quality Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Process-Measures-Table_OASIS-C2_4-11-18.pdf).

reported on HH Compare until January 2021.

We invited public comment on this proposal.

Comment: Another commenter expressed general support for the removal of the Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537) Measure, but encouraged CMS to consider whether it is appropriate to adopt measures when performance is high initially.

Response: We thank the commenter for its support. We agree that it is important to evaluate whether the measure rates on a measure being considered for adoption are already high because that analysis bears on the question of whether the measure is needed to address a gap in quality. However, we wish to note that there may be quality measures that address an important Meaningful Measure Area in which most providers will likely perform well. Examples of such measures include those that take into account “never events,” such as falls with major injury, or topics such as potentially preventable readmissions. In these instances, such performance information remains useful to consumers and providers even if the measure performance is high initially.

Final Decision: After considering public comment, we are finalizing our proposal to remove the Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537) Measure from the HH QRP. HHAs will no longer be required to submit OASIS Item M1910, Falls Risk Assessment at SOC/ROC beginning January 1, 2020. HHAs may enter an equal sign (=) for M1910 at the time point of SOC and ROC beginning January 1, 2020. Data for this measure will be publicly reported until such data are no longer available for public reporting of this measure on HH Compare.

4. Removal of the Pneumococcal Polysaccharide Vaccine Ever Received Measure

In the CY 2019 HH PPS proposed rule (83 FR 32443 through 32444), we proposed to remove the Pneumococcal Polysaccharide Vaccine (PPV) Ever Received Measure from the HH QRP beginning with the CY 2021 HH QRP, under our proposed Factor 3: A measure does not align with current clinical guidelines or practice.

In the CY 2010 HH PPS final rule (74 FR 58096 through 58098), we adopted the Pneumococcal Polysaccharide Vaccine Ever Received Measure beginning with CY 2010 HH QRP. This

process measure reports the percentage of HH quality episodes during which patients were determined to have ever received the Pneumococcal Polysaccharide Vaccine. The measure is calculated using OASIS Items M1051, Pneumococcal Vaccine and M1056, Reason Pneumococcal Vaccine not received.⁵⁹

At the time that this measure was adopted in the HH QRP, the Advisory Committee on Immunization Practices (ACIP),⁶⁰ which sets current clinical guidelines, recommended use of a single dose of the 23-valent pneumococcal polysaccharide vaccine (PPSV23) among all adults aged 65 years and older and those adults aged 19 to 64 years with underlying medical conditions that put them at greater risk for serious pneumococcal infection.⁶¹

Since this measure was added to the HH QRP, the ACIP has updated its pneumococcal vaccination recommendations.⁶² Two pneumococcal vaccines are currently licensed for use in the United States: The 13-valent pneumococcal conjugate vaccine (PCV13) and the 23-valent pneumococcal vaccine (PPSV23). The ACIP currently recommends that both PCV13 and PPSV23 be given to all immunocompetent adults aged ≥65 years. The recommended intervals for sequential administration of PCV13 and PPSV23 depend on several patient factors including: The current age of the adult, whether the adult had previously received PPSV23, and the age of the adult at the time of prior PPSV23 vaccination (if applicable).

⁵⁹ Measure specifications can be found in the Home Health Process Measures Table on the Home Health Quality Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Process-Measures-Table_OASIS-C2_4-11-18.pdf).

⁶⁰ The Advisory Committee on Immunization Practices was established under section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended, to assist states and their political subdivisions in the prevention and control of communicable diseases; to advise the states on matters relating to the preservation and improvement of the public's health; and to make grants to states and, in consultation with the state health authorities, to agencies and political subdivisions of states to assist in meeting the costs of communicable disease control programs. (Charter of the Advisory Committee on Immunization Practices, filed April 1, 2018 (<https://www.cdc.gov/vaccines/acip/committee/ACIP-Charter-2018.pdf>)).

⁶¹ Prevention of Pneumococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR 1997;46:1–24.

⁶² Tomczyk S, Bennett NM, Stoecker C, et al. Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine among adults aged ≥65 years: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2014;63: 822–5.

We stated in the proposed rule that the specifications for the Pneumococcal Polysaccharide Vaccine Ever Received Measure do not fully reflect the current ACIP guidelines. Therefore, we believe that the Pneumococcal Polysaccharide Vaccine Ever Received Measure no longer aligns with the current clinical guidelines or practice. For this reason, we proposed to remove the Pneumococcal Polysaccharide Vaccine Ever Received Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 3: A measure does not align with current clinical guidelines or practice.

We stated in the proposed rule (83 FR 32444) that if we finalized this proposal, HHAs would no longer be required to submit OASIS Items M1051, Pneumococcal Vaccine and M1056, Reason Pneumococcal Vaccine not received at the time point of TOC and Discharge for the purposes of the HH QRP beginning January 1, 2020. HHAs may enter an equal sign (=) for Items M1051 and M1056 at the time point of TOC and Discharge on or after January 1, 2020. We also stated that if we finalized this proposal, data for this measure would be publicly reported on HH Compare until January 2021.

We invited public comment on this proposal.

Comment: A few commenters supported the measure removal because it does not reflect current Advisory Committee on Immunization Practices (ACIP) guidelines.

Response: We thank the commenters for their support.

Comment: A few commenters did not support the removal of the PPV measure from the HH QRP, citing concerns with patient care consequences that could occur as a result of its removal. Some of these commenters noted that HHAs play a valuable role in providing immunizations to home-bound patients who experience barriers to vaccination access. Another commenter recommended retaining the current PPV measure until it is updated to reflect the most recent ACIP guidelines for both pneumococcal vaccinations, adding that its removal may be confusing to HHAs and may also lead to reductions in pneumococcal immunization rates. This commenter stated that the measure is aligned with Meaningful Measures objectives on addressing high-impact and patient-centered measure areas, and that retaining the measure would not be burdensome to HHAs, given their ability to establish standing orders to support immunization processes.

Response: While we understand that assessing and appropriately vaccinating patients are important components of

the care process, we also prioritize ensuring that quality measures can be used by practitioners to inform their clinical decision and care planning activities. The updated ACIP pneumococcal vaccination recommendations require information that is often not available to HHAs, including whether the patient has previously been vaccinated, the type of pneumococcal vaccine received by the patient, and the sequencing of vaccine administration. In addition, the physician who is responsible for the home health plan of care may not be the patient's primary care practitioner or other health care professional responsible for providing care and services to the patient before and after discharge from the HHA, and therefore may not be best able to provide the HHA with such information. Also, even if the pneumococcal vaccination status of the patient is available, OASIS Items M1051, Pneumococcal Vaccine and M1056, Reason Pneumococcal Vaccine not received, both of which are used in the calculation of this measure, do not correspond to the updated ACIP pneumococcal vaccination recommendations and therefore may not accurately measure HHA performance in this area. However, we understand and value the role pneumococcal vaccines play in preventing pneumococcal disease⁶³ and we encourage that, whenever possible and as appropriate, HHAs provide pneumococcal vaccinations to their patients.

Comment: A few commenters recommended that CMS consider using an alternative pneumococcal measure, Pneumonia Vaccination Status for Older Adults (NQF #0043).

Response: The specifications for the Pneumococcal Vaccination Status for Older Adults measure also do not fully reflect the current ACIP guidelines. Therefore, this measure would not be an appropriate measure to consider for adoption into the HH QRP.

Final Decision: After considering public comment, we are finalizing our proposal to remove the Pneumococcal Polysaccharide Vaccine Ever Received Measure from the HH QRP. HHAs will no longer be required to submit OASIS Items M1051, Pneumococcal Vaccine and M1056, Reason Pneumococcal Vaccine not received at the time point of TOC and Discharge for the purposes of the HH QRP beginning January 1, 2020. HHAs may enter an equal sign (=) for Items M1051 and M1056 at the time point of TOC and Discharge on or after

January 1, 2020. Data for this measure will be publicly reported until such data are no longer available for public reporting of this measure on HH Compare.

5. Removal of the Improvement in the Status of Surgical Wounds Measure

In the CY 2019 HH PPS proposed rule (83 FR 32444 through 32445), we proposed to remove the Improvement in the Status of Surgical Wounds Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 4: A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.

In the CY 2008 HH PPS final rule (72 FR 49861 through 49863), we adopted the Improvement in the Status of Surgical Wounds Measure for the HH QRP beginning with the CY 2008 program year. This risk-adjusted outcome measure reports the percentage of HH episodes of care during which the patient demonstrates an improvement in the condition of skin integrity related to the surgical wounds. This measure is solely calculated using OASIS Items M1340, Does this patient have a Surgical Wound? and M1342, Status of Most Problematic Surgical Wound that is Observable.⁶⁴ Items M1340 and M1342 are also used at the time points of SOC/ROC as risk adjusters in the calculation of several other OASIS-based outcome measures currently adopted for the HH QRP.⁶⁵ Additionally, Items M1340 and M1342 are used at the time point of Discharge for the Potentially Avoidable Events measure Discharged to the Community Needing Wound Care or Medication Assistance that is used by HH surveyors during the survey process.⁶⁶

We stated in the proposed rule (83 FR 32444) that the Improvement in the

⁶⁴ Measure specifications can be found in the Home Health Outcomes Measures Table on the Home Health Quality Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Outcome-Measures-Table-OASIS-C2_4-11-18.pdf).

⁶⁵ The OASIS-based HH QRP outcome measures that use OASIS Items M1340 and M1342 as a risk adjuster in the calculation of the measure are: Improvement in Bathing (NQF #0174), Improvement in Bed Transferring (NQF #0175), Improvement in Ambulation/Locomotion (NQF #0167), Improvement in Dyspnea, Improvement in Pain Interfering with Activity (NQF #0177), and Improvement in Management of Oral Medications (NQF #0176).

⁶⁶ Measure specifications can be found in the Home Health Potentially Avoidable Events Measures Table on the Home Health Quality Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-PAE-Measures-Table-OASIS-C2_4-11-18.pdf).

⁶³ CDC: Pneumococcal Disease. Retrieved from: <http://www.cdc.gov/pneumococcal/about/prevention.html>.

Status of Surgical Wounds Measure is limited in scope to surgical wounds incurred by surgical patients and excludes HH episodes of care where the patient, at SOC/ROC, did not have any surgical wounds or had only a surgical wound that was unobservable or fully epithelialized. As a result, the majority of HHAs are not able to report data on the measure and the measure is limited in its ability to compare how well HHAs address skin integrity. For example, in 2016, only 13 percent of HH patients had a surgical wound at the beginning of their HH episode and only 36.6 percent of HHAs were able to report data on the measure with respect to that year.

In contrast, the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) Measure (NQF #0678)⁶⁷ and its replacement measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury Measure, more broadly assess the quality of care furnished by HHAs with respect to skin integrity. These measures encourage clinicians to assess skin integrity in the prevention of pressure ulcers, as well as to monitor and promote healing in all HH patients, not just those with surgical wounds.

Therefore, we proposed to remove the Improvement in the Status of Surgical Wounds Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 4: A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.

We stated in the proposed rule that if we finalized this proposal, HHAs would no longer be required to submit OASIS Items M1340, Does this patient have a Surgical Wound and M1342, Status of Most Problematic Surgical Wound that is Observable, at the time points of SOC/ROC and Discharge for the purposes of this measure beginning with January 1, 2020 episodes of care. However, HHAs would still be required to submit data on Items M1340 and M1342 at the time point of SOC/ROC as risk adjusters for several other OASIS-based outcome measures currently adopted for the HH QRP,⁶⁸ and also at the time point of

Discharge for the Potentially Avoidable Events measure Discharged to the Community Needing Wound Care or Medication Assistance⁶⁹ that is used by HH surveyors during the survey process. We also stated that if we finalized this proposal, data on this measure would be publicly reported on HH Compare until January 2021.

We invited public comment on this proposal.

Comment: A commenter supported removal of the Improvement in the Status of Surgical Wounds Measure, while encouraging CMS to monitor other skin integrity measures to ensure that the full range of patient skin integrity issues is captured. Another commenter opposed the removal of this measure, but did not clarify the reason.

Response: We thank the commenters for their feedback. We will continue to closely monitor the performance data of other skin integrity measures.

Final Decision: After considering public comment, we are finalizing our proposal to remove the Improvement in the Status of Surgical Wounds Measure from the HH QRP. HHAs will no longer be required to submit OASIS Items M1340, Does this patient have a Surgical Wound? and M1342, Status of Most Problematic Surgical Wound that is Observable, at the time points of SOC/ROC and Discharge for the purposes of this measure beginning January 1, 2020. However, HHAs will still be required to submit data on Items M1340 and M1342 at the time point of SOC/ROC as risk adjusters for several other OASIS-based outcome measures currently adopted for the HH QRP and also at the time point of Discharge for the Potentially Avoidable Events measure Discharged to the Community Needing Wound Care or Medication Assistance that is used by HH surveyors during the survey process. Data for this measure will be publicly reported until such data are no longer available for public reporting of this measure on HH Compare.

6. Removal of the Emergency Department Use Without Hospital Readmission During the First 30 Days of HH (NQF #2505) Measure

In the CY 2019 HH PPS proposed rule (83 FR 32445), we proposed to remove the Emergency Department (ED) Use without Hospital Readmission during the First 30 Days of HH (NQF #2505) Measure from the HH QRP beginning

with the CY 2021 HH QRP, under our proposed Factor 4: A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.

In the CY 2014 HH PPS final rule (78 FR 72297 through 72301), we adopted the claims-based ED Use without Hospital Readmission during the first 30 days of HH (NQF #2505) Measure beginning with CY 2014 HH QRP. The particular topic for this measure is ED utilization, as it estimates the risk-standardized rate of ED use without acute care hospital admission during the 30 days following the start of the HH stay for patients with an acute inpatient hospitalization in the 5 days before the start of their HH stay. The ED Use without Hospital Readmission during the First 30 Days of HH (NQF #2505) Measure is limited to Medicare FFS patients with a prior, proximal inpatient stay. Recent analyses from 2016 and 2017 show that this measure annually captured approximately 2.5 million (25.1 percent in 2016 and 25.1 percent in 2017) of Medicare FFS HH stays and was reportable for less than two-thirds of the HHAs (62.1 percent in 2016 and 62.6 percent in 2017).

We stated in the proposed rule (83 FR 32444) that the ED Use without Hospitalization During the First 60 Days of HH (NQF #0173) Measure also addresses the topic of ED utilization during a HH stay. This measure reports the percentage of Medicare FFS HH stays in which patients used the ED but were not admitted to the hospital during the 60 days following the start of the HH stay. The ED Use without Hospitalization during the First 60 days of HH (NQF #0173) Measure includes Medicare FFS patients irrespective of whether or not they had an acute inpatient hospitalization in the 5 days prior to the start of the HH stay and spans the first 60 days of a HH episode. Recent analyses using 2016 and 2017 data show this measure annually captures approximately 8.3 million stays (81.9 percent in 2016 and 81.8 percent in 2017) and is reportable by a greater number of HHAs (88.8 percent in 2016 and 88.1 percent in 2017) than the ED Use without Hospital Readmission During the First 30 Days of HH (NQF #2505) Measure.

We stated in the proposed rule (83 FR 32445) that the ED Use without Hospital Readmission During the First 30 Days of HH (NQF #2505) Measure addresses outcomes of Medicare FFS patients for a 30-day interval after the start of their HH care, regardless of the length of their HH stay. The more broadly applicable ED Use without Hospitalization during the First 60 days of HH (NQF #0173)

⁶⁷ To be replaced with a modified version of that measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, beginning with the CY 2020 HH QRP.

⁶⁸ The OASIS-based HH QRP outcome measures that use OASIS Items M1340 and M1342 as a risk adjuster in the calculation of the measure are: Improvement in Bathing (NQF #0174), Improvement in Bed Transferring (NQF #0175), Improvement in Ambulation/Locomotion (NQF #0167), Improvement in Dyspnea, Improvement in Pain Interfering with Activity (NQF #0177), and Improvement in Management of Oral Medications (NQF #0176).

⁶⁹ Measure specifications can be found in the Home Health Potentially Avoidable Events Measures Table on the Home Health Quality Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-PAE-Measures-Table-OASIS-C2_4-11-18.pdf).

Measure addresses these same outcomes for a greater number of Medicare FFS patients during the first 60 days of a HH stay and includes the 30-day interval of the ED Use without Hospital Readmission During the First 30 Days of HH (NQF #2505) Measure. The measure specifications for both measures are otherwise harmonized along several measure dimensions, including data source, population, denominator exclusions, numerator, and risk adjustment methodology. As a result, removing the ED Use without Hospital Readmission During the First 30 Days of HH (NQF #2505) Measure in favor of the ED Use without Hospitalization during the First 60 days of HH (NQF #0173) Measure will not result in a loss of the ability to measure the topic of ED utilization for HH patients.

For these reasons, we proposed to remove the ED Use without Hospital Readmission During the First 30 Days of HH (NQF #2505) Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 4: A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available. We stated in the proposed rule that if we finalized this proposal, data for this measure would be reported on HH Compare until January 2020.

We invited public comment on this proposal.

Comment: A commenter supported the removal of this measure and expressed appreciation that CMS identified measures for removal in favor of more widely applicable ones.

Response: We thank the commenter for its support.

Final Decision: After considering public comment, we are finalizing our proposal as proposed to remove the Emergency Department (ED) Use without Hospital Readmission during the First 30 Days of HH (NQF #2505) Measure from the HH QRP beginning with the CY 2021 HH QRP. Data for this measure will be publicly reported until such data are no longer available for public reporting of this measure on HH Compare.

7. Removal of the Rehospitalization During the First 30 Days of HH (NQF #2380) Measure

In the CY 2019 HH PPS proposed rule (83 FR 32445 through 32446), we proposed to remove the Rehospitalization during the First 30 Days of HH (NQF #2380) Measure from the HH QRP beginning with the CY 2021 HH QRP, under our proposed Factor 4: A more broadly applicable measure (across settings, populations, or

conditions) for the particular topic is available.

In the CY 2014 HH PPS final rule (78 FR 72297 through 72301), we adopted the claims-based Rehospitalization during the first 30 Days of HH Measure beginning with the CY 2014 HH QRP. The measure was NQF-endorsed (NQF #2380) in December 2014. The Rehospitalization during the first 30 Days of HH (NQF #2380) Measure addresses the particular topic of acute care hospital utilization during a HH stay. This measure estimates the risk-standardized rate of unplanned, all-cause hospital readmissions for patients who had an acute inpatient hospitalization in the 5 days before the start of their HH stay and were admitted to an acute care hospital during the 30 days following the start of the HH stay (78 FR 72297 through 72301). The Rehospitalization During the First 30 Days of HH (NQF #2380) Measure only includes Medicare FFS patients. Recent analyses from 2016 and 2017 show that this measure annually captured approximately 2.5 million (25.1 percent in 2016 and 25.1 percent in 2017) of Medicare FFS HH stays and was reportable for less than two-thirds of the HHAs (62.1 percent in 2016 and 62.6 percent in 2017).

In the CY 2013 HH PPS final rule (77 FR 67093 through 67094), we finalized the claims-based Acute Care Hospitalization Measure. The measure's title was later updated to Acute Care Hospitalization During the First 60 Days of HH (NQF #0171) to improve clarity.⁷⁰ The Acute Care Hospitalization During the First 60 Days of HH (NQF #0171) Measure also addresses the topic of acute care hospital utilization during a HH stay. This measure reports the percentage of HH stays in which Medicare FFS patients were admitted to an acute care hospital during the 60 days following the start of the HH stay. The Acute Care Hospitalization during the First 60 Days of HH (NQF #0171) Measure includes Medicare FFS patients irrespective of whether or not they had an acute inpatient hospitalization in the 5 days prior to the start of the HH stay and spans the first 60 days of a HH episode. Recent analyses using 2016 and 2017 data show this measure annually captures approximately 8.3 million stays (81.9 percent in 2016 and 81.8 percent in 2017) and is reportable by a greater number of HHAs (88.8 percent in 2016 and 88.1 percent in 2017) than the

Rehospitalization during the First 30 Days of HH (NQF #2380) Measure.

We stated in the proposed rule (83 FR 32446) that the Rehospitalization during the First 30 Days of HH (NQF #2380) Measure addresses outcomes of Medicare FFS patients for a 30-day interval after the start of their HH care, regardless of the length of their HH stay. In contrast, the Acute Care Hospitalization During the First 60 Days of HH (NQF #0171) Measure is broader because it addresses these same outcomes for a greater number of Medicare FFS patients during the first 60 Days of a HH stay, which includes the 30-day interval of the Rehospitalization during the First 30 Days of HH (NQF #2380) Measure. The measure specifications for both measures are otherwise harmonized along several measure dimensions, including data source, population, denominator exclusions, numerator, and risk adjustment methodology. As a result, removing the Rehospitalization during the First 30 Days of HH (NQF #2380) Measure in favor of the Acute Care Hospitalization during the First 60 Days of HH (NQF #0171) Measure will not result in a loss of the ability to measure the topic of acute care hospital utilization across the HH setting.

For these reasons, we proposed to remove the Rehospitalization during the First 30 Days of HH (NQF #2380) Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 4: A more broadly applicable measure (across settings, populations, or conditions) for particular topic is available. We stated in the proposed rule that if we finalized this proposal, data for this measure would be publicly reported on HH Compare until January 2020.

We invited public comment on this proposal.

Comment: A commenter supported the removal of this measure and expressed appreciation that CMS identified measures for removal in favor of more widely applicable ones.

Response: We thank the commenter for its support.

Final Decision: After considering public comment, we are finalizing our proposal as proposed to remove the Rehospitalization during the First 30 Days of HH (NQF #2380) Measure from the HH QRP beginning with the CY 2021 HH QRP. Data for this measure will be publicly reported on HH Compare until January 2020.

F. IMPACT Act Implementation Update

In the CY 2018 HH PPS final rule (82 FR 51731), we stated that we intended to specify two measures that will satisfy

⁷⁰ All-Cause Admissions and Readmissions 2015–2017 Technical Report, National Quality Forum, Washington DC, 2017. (<http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=85033>) page 20.

the domain of accurately communicating the existence and provision of the transfer of health information and care preferences under section 1899B(c)(1)(E) of the Act no later than January 1, 2019 and intended to propose to adopt them for the CY 2021 HH QRP, with data collection beginning on or about January 1, 2020.

We stated in the proposed rule that as a result of the input provided during a public comment period between November 10, 2016 and December 11, 2016, input provided by a technical expert panel (TEP) convened by our contractor, and pilot measure testing conducted in 2017, we are engaging in continued development work on these two measures, including supplementary measure testing and providing the public with an opportunity for comment in 2018. Further, we reconvened a TEP for these measures in April 2018. We now intend to specify the measures under section 1899B(c)(1)(E) of the Act no later than January 1, 2020, and intend to proposed to adopt the measures beginning with the CY 2022 HH QRP, with data collection at the time point of SOC, ROC and Discharge beginning with January 1, 2021. For more information on the pilot testing, we refer readers to: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Comment: A commenter supported the continued development of measures to satisfy the IMPACT Act domain of transfer of health information and care preferences, noting its belief that these measures will improve continuity of care and care transitions. Another commenter did not express support or opposition, but encouraged CMS to consider data collection burden across settings prior to adopting cross-setting measures that satisfy the requirements of the IMPACT Act.

Response: We thank the commenters for their feedback.

G. Form, Manner, and Timing of OASIS Data Submission

Our home health regulations, codified at § 484.250(a), require HHAs to submit OASIS assessments and Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey® (HCAHPS) data to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act. In the CY 2019 HH PPS proposed rule (83 FR 32446), we proposed to revise § 484.250(a) to clarify that not all OASIS data described in § 484.55(b) and (d) are

needed for purposes of complying with the requirements of the HH QRP. OASIS data items may be submitted for other established purposes unrelated to the HH QRP, including payment, survey, the HH VBP Model, or care planning. Any OASIS data that are not submitted for the purposes of the HH QRP are not used for purposes of HH QRP compliance.

We invited public comment on our proposal to revise our regulations at § 484.250(a) to clarify that not all OASIS data described in § 484.55(b) and (d) are needed for purposes of complying with the requirements of the HH QRP.

Comment: A commenter supported all proposed changes to the HH QRP, including updated regulations clarifying OASIS data collection requirements. Another commenter noted that the clarification confirms its understanding of the regulations.

Response: We thank the commenters for their support.

Final Decision: After considering public comment, we are finalizing our proposal as proposed to revise our regulations at § 484.250(a) to clarify that not all OASIS data described in § 484.55(b) and (d) are needed for purposes of complying with the requirements of the HH QRP.

H. Policies Regarding Public Display for the HH QRP

Section 1899B(g) of the Act requires that data and information regarding PAC provider performance on quality measures and resource use and other measures be made publicly available beginning not later than 2 years after the applicable specified 'application date'. In the CY 2018 HH PPS final rule (82 FR 51740 through 51741), we finalized that we will publicly display the Medicare Spending Per Beneficiary (MSPB)-PAC HH QRP beginning in CY 2019 based on 1 year of claims data on discharges from CY 2017.

In the CY 2019 HH PPS proposed rule (83 FR 32446), we proposed to increase the number of years of data used to calculate the MSPB-PAC HH QRP for purposes of display from 1 year to 2 years. Under this proposal, data on this measure would be publicly reported in CY 2019, or as soon thereafter as operationally feasible, based on discharges from CY 2016 and CY 2017. We also stated that increasing the measure calculation and public display periods from 1 to 2 years of data would increase the number of HHAs with enough data adequate for public reporting for the MSPB-PAC HH QRP measure from 90.7 percent (based on August 1, 2014–July 31, 2015 Medicare FFS claims data) to 94.9 percent (based

on August 1, 2014–July 31, 2016 Medicare FFS claims data). We further stated that increasing the measure public display periods to 2 years would align with the public display periods of these measures in the IRF QRP, LTCH QRP, and SNF QRP.

We invited public comment on our proposal to increase the number of years of data used to calculate the MSPB-PAC HH QRP for purposes of display from 1 year to 2 years.

Comment: Most commenters supported changing the reporting period for the MSPB-PAC HH QRP measure from 1 year to 2 years.

Response: We thank the commenters for their support.

Comment: Several commenters opposed changing the reporting period for the MSPB measure from 1 to 2 years. A commenter opposed the 2-year reporting period for the MSPB measure, noting that measurement may be "smoothed" and current performance diluted by relying on 2 years of data instead of 1 year. This commenter recommended using two years of historical data only for low-volume home health agencies that would otherwise report insufficient data, and retaining the one-year reporting period for larger home health agencies. Two other commenters opposed the change to a 2-year reporting period, noting that measures should reflect recent data and performance. Another commenter questioned the rationale for using a 2-year measure period, noting that while this may increase the denominator, measure accuracy might be compromised by any changes that occurred during the measurement period.

Response: We appreciate the commenters' concern about the impact of aggregating data across 2 years on the ability to demonstrate improvement in a 1-year period. However, we believe that the benefit of increasing the number of HHAs in public reporting outweighs the expressed concern associated with increasing the measurement period to 2 years because it enables us to provide more information to consumers who may have a limited number of HHAs in their area. Further, improvements in performance in a measure over a 1-year period will also be included in the 2 years of data, so providers' improvement efforts can still be reflected in their 2-year measure scores.

We disagree with the recommendation to use 2 years of data for low-volume HHAs but 1 year of data for larger HHAs because HHA performance may no longer be comparable using different time periods for data collection. Finally, there is no

evidence to support that increasing the number of years of data used for the calculation of measure scores of all HHAs from 1 year to 2 years might compromise the accuracy of a measure.

Final Decision: After consideration of public comments we received, we are finalizing our proposal as proposed to increase the number of years of data used to calculate the MSPB–PAC HH QRP measure for purposes of display from 1 year to 2 years.

I. Home Health Care Consumer Assessment of Healthcare Providers and Systems® (HHCAPHS)

In the CY 2019 HH PPS proposed rule (83 FR 32446), we did not propose changes to the Home Health Care Consumer Assessment of Healthcare Providers and Systems® (HHCAPHS) Survey requirements for CY 2019. Therefore, HHCAPHS Survey requirements are as codified in § 484.250 and the HHCAPHS survey vendors' data submission deadlines are as posted on HHCAPHS website at <https://homehealthcahps.org>.

VI. Medicare Coverage of Home Infusion Therapy Services

In this section of the rule, we discuss the new home infusion therapy benefit that was established in section 5012 of the 21st Century Cures Act. This benefit covers the professional services, including nursing services, patient training and education, and monitoring services associated with administering infusion drugs by an item of durable medical equipment (DME) in a patient's home. This final rule with comment period will establish health and safety standards for home infusion therapy and provide consistency in coverage for home infusion therapy services. In addition, this final rule with comment period establishes regulations for the approval and oversight of accrediting organizations that provide accreditation to home infusion therapy suppliers. This rule also provides information on the implementation of the home infusion therapy services temporary transitional payments for CYs 2019 and 2020, as mandated by section 50401 of the BBA of 2018, and finalizes a regulatory definition of "Infusion Drug Administration Calendar Day."

A. General Background

1. Overview

Infusion drugs and administration services can be furnished in multiple health care settings, including inpatient hospitals, skilled nursing facilities (SNFs), hospital outpatient departments (HOPDs), physicians' offices, and in the

home. Traditional Fee-for-Service (FFS) Medicare provides coverage for infusion drugs, equipment, supplies, and administration services. However, Medicare coverage requirements and payment vary for each of these settings. Infusion drugs, equipment, supplies, and administration are all covered by Medicare in the inpatient hospital, SNFs, HOPDs, and physicians' offices.

Generally, Medicare payment under Part A for the drugs, equipment, supplies, and services are bundled, meaning a single payment is made on the basis of expected costs for clinically defined episodes of care. For example, if a beneficiary is receiving an infusion drug during an inpatient hospital stay, the Part A payment for the drug, supplies, equipment, and drug administration is included in the diagnosis-related group (DRG) payment to the hospital under the Medicare inpatient prospective payment system. Beneficiaries are liable for the Medicare inpatient hospital deductible.

Similarly, if a beneficiary is receiving an infusion drug while in a SNF under a Part A stay, the payment for the drug, supplies, equipment, and drug administration are included in the SNF prospective payment system payment. After 20 days of SNF care, there is a daily beneficiary cost-sharing amount through day 100 when the beneficiary becomes responsible for all costs for each day after day 100 of the benefit period.

Under Medicare Part B, certain items and services are paid separately while other items and services may be packaged into a single payment together. For example, in an HOPD and in a physician's office, the drug is paid separately, generally at the average sales price (ASP) plus 6 percent. There is also a separate payment for drug administration in which the payment for infusion supplies and equipment is packaged in the payment for administration. The separate payment for infusion drug administration in an HOPD and in a physician's office generally includes a base payment amount for the first hour and a payment add-on that is a different amount for each additional hour of administration. The beneficiary is responsible for the 20 percent coinsurance under Medicare Part B.

Medicare FFS covers outpatient infusion drugs under Part B, "incident to" a physician's services, provided the drugs are not usually self-administered by the patient. Drugs that are "not usually self-administered," are defined in our manual according to how the Medicare population as a whole uses the drug, not how an individual patient

or physician may choose to use a particular drug. For the purpose of this exclusion, the term "usually" means more than 50 percent of the time for all Medicare beneficiaries who use the drug. The term "by the patient" means Medicare beneficiaries as a collective whole. Therefore, if a drug is self-administered by more than 50 percent of Medicare beneficiaries, the drug is excluded from Part B coverage. This determination is made on a drug-by-drug basis, not on a beneficiary-by-beneficiary basis.⁷¹ The MACs update Self-Administered Drug (SAD) exclusion lists on a quarterly basis.⁷²

Home infusion therapy involves the intravenous or subcutaneous administration of drugs or biologicals to an individual at home. Certain drugs can be infused in the home, but the nature of the home setting presents different challenges than the settings previously described. The components needed to perform home infusion include the drug (for example, antibiotics, immune globulin), equipment (for example, a pump), and supplies (for example, tubing and catheters). Likewise, nursing services are necessary to train and educate the patient and caregivers on the safe administration of infusion drugs in the home. Visiting nurses often play a large role in home infusion. Nurses typically train the patient or caregiver to self-administer the drug, educate on side effects and goals of therapy, and visit periodically to assess the infusion site and provide dressing changes. Depending on patient acuity or the complexity of the drug administration, certain infusions may require more nursing time, especially those that require special handling or pre- or post-infusion protocols. The home infusion process typically requires coordination among multiple entities, including patients, physicians, hospital discharge planners, health plans, home infusion pharmacies, and, if applicable, home health agencies. With regard to payment for home infusion therapy under traditional Medicare, drugs are generally covered under Part B or Part D. Certain infusion pumps, supplies (including home infusion drugs), and nursing are covered in some circumstances through the Part B durable medical equipment (DME) benefit, the Medicare home health benefit, or some combination of these benefits.

⁷¹ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>.

⁷² www.cms.gov/medicare-coverage-database/reports/sad-exclusion-list-report.aspx?bc=AQAAAAAAAAAAAA%3D%3D.

Medicare Part B covers a limited number of home infusion drugs through the DME benefit if: (1) The drug is necessary for the effective use of an external or implantable infusion pump classified as DME and determined to be reasonable and necessary for administration of the drug; and (2) the drug being used with the pump is itself reasonable and necessary for the treatment of an illness or injury. Only certain types of infusion pumps are covered under the DME benefit. The Medicare *National Coverage Determinations Manual*, chapter 1, part 4, § 280.1 describes the types of infusion pumps that are covered under the DME benefit.⁷³ For DME infusion pumps, Medicare Part B covers the infusion drugs and other supplies and services necessary for the effective use of the pump, but does not explicitly require or pay separately for any associated home infusion nursing services beyond what is necessary for teaching the patient and/or caregiver how to operate the equipment in order to administer the infusion safely and effectively.⁷⁴ Through local coverage policies, the DME Medicare administrative contractors (MACs) specify the details of which infusion drugs are covered with these pumps. Examples of covered Part B DME infusion drugs include, among others, certain IV drugs for heart failure and pulmonary arterial hypertension, immune globulin for primary immune deficiency (PID), insulin, antifungals, antivirals, and chemotherapy, in limited circumstances.

2. Home Infusion Therapy Legislation

Section 5012 of the 21st Century Cures Act (Pub. L. 114–255) (Cures Act) creates a separate Medicare Part B benefit category under section 1861(s)(2)(GG) of the Act for coverage of home infusion therapy-associated professional services for certain drugs and biologicals administered intravenously, or subcutaneously through a pump that is an item of DME, effective January 1, 2021. The infusion pump and supplies (including home infusion drugs) will continue to be covered under the DME benefit. Section 1861(iii)(2) of the Act defines home infusion therapy to include the following items and services: The professional services (including nursing

services), furnished in accordance with the plan, training and education (not otherwise included in the payment for the DME), remote monitoring, and other monitoring services for the provision of home infusion therapy furnished by a qualified home infusion therapy supplier in the patient's home. Section 1861(iii)(3)(B) of the Act defines the patient's home to mean a place of residence used as the home of an individual as defined for purposes of section 1861(n) of the Act. As outlined in section 1861(iii)(1) of the Act, to be eligible to receive home infusion therapy services under the home infusion therapy benefit, the patient must be under the care of an applicable provider (defined in section 1861(iii)(3)(A) of the Act as a physician, nurse practitioner, or physician's assistant), and the patient must be under a physician-established plan of care that prescribes the type, amount, and duration of infusion therapy services that are to be furnished. The plan of care must be periodically reviewed by the physician in coordination with the furnishing of home infusion drugs (as defined in section 1861(iii)(3)(C) of the Act). Section 1861(iii)(3)(C) of the Act defines a "home infusion drug" under the home infusion therapy benefit as a drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the patient's home, through a pump that is an item of DME as defined under section 1861(n) of the Act. This definition does not include insulin pump systems or any self-administered drug or biological on a self-administered drug exclusion list.

Section 1861(iii)(3)(D)(i) of the Act defines a qualified home infusion therapy supplier as a pharmacy, physician, or other provider of services or supplier licensed by the state in which supplies or services are furnished. The provision specifies qualified home infusion therapy suppliers must furnish infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; ensure the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis; be accredited by the organization designated by the Secretary; and meet other such requirements as the Secretary deems appropriate, taking into account the standards of care for home infusion therapy established by Medicare Advantage (MA) plans under part C and in the private sector. The supplier may subcontract with a pharmacy, physician, other qualified supplier or provider of

medical services, in order to meet these requirements.

Section 1834(u)(1) of the Act requires the Secretary to implement a payment system under which, beginning January 1, 2021, a single payment is made to a home infusion therapy supplier for the items and services (professional services, including nursing services; training and education; remote monitoring, and other monitoring services). The single payment must take into account, as appropriate, types of infusion therapy, including variations in utilization of services by therapy type. In addition, the single payment amount is required to be adjusted to reflect geographic wage index and other costs that may vary by region, patient acuity, and complexity of drug administration. The single payment may be adjusted to reflect outlier situations, and other factors as deemed appropriate by the Secretary, which are required to be done in a budget neutral manner. Section 1834(u)(3) of the Act specifies that annual updates to the single payment are required to be made beginning January 1, 2022, by increasing the single payment amount by the percent increase in the CPI for all urban consumers for the 12-month period ending with June of the preceding year, reduced by the multi-factor productivity adjustment. The unit of single payment for each infusion drug administration calendar day, including the required adjustments and the annual update, cannot exceed the amount determined under the fee schedule under section 1848 of the Act for infusion therapy services if furnished in a physician's office, and the single payment amount cannot reflect more than 5 hours of infusion for a particular therapy per calendar day. Section 1834(u)(4) of the Act also allows the Secretary discretion, as appropriate, to consider prior authorization requirements for home infusion therapy services. Finally, section 5012(c)(3) of the 21st Century Cures Act amended section 1861(m) of the Act to exclude home infusion therapy from the HH PPS beginning on January 1, 2021.

B. Health and Safety Standards for Home Infusion Therapy

1. Introduction

Section 5012 of the Cures Act requires that, to receive payment under the Medicare home infusion therapy benefit, home infusion therapy suppliers must select a CMS-approved accreditation organization (AO) and undergo an accreditation review process to demonstrate that the home infusion therapy supplier meets the AO's standards. Section 1861(iii) of the Act,

⁷³ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS014961.html>.

⁷⁴ See 42 CFR 424.57(c)(12), which states that the DME "supplier must document that it or another qualified party has at an appropriate time, provided beneficiaries with necessary information and instructions on how to use Medicare-covered items safely and effectively."

as added by section 5012 of the Cures Act, sets forth four elements for home infusion therapy in the following areas: (1) Requiring that the patient be under the care of a physician, nurse practitioner, or physician assistant; (2) requiring that all patients have a plan of care established and updated by a physician that sets out the care and prescribed infusion therapy necessary to meet the patient specific needs; (3) providing patients with education and training on the effective use of medications and equipment in the home (not otherwise paid for as durable medical equipment); and (4) providing monitoring and remote monitoring services associated with administering infusion drugs in a patient's home.

The Journal of Infusion Nursing standards of practice specifically address patient education, and state that it is the clinician's role to educate the patient, caregiver, and/or surrogate about the prescribed infusion therapy and plan of care including, but not limited to, purpose and expected outcome(s) and/or goals of treatment, infusion therapy administration; infusion device-related care; potential complications; or adverse effects associated with treatment. (Infusion Therapy Standards of Practice, 2015).⁷⁵

Currently, standards for home infusion therapy have been established by the current AOs; however, they are not necessarily consistent. In order to assure consistency in the areas identified in the Act, we are establishing basic standards that all AOs will be required to meet or exceed. We proposed universal standards for Medicare-participating qualified home infusion therapy suppliers to ensure the quality and safety of home infusion therapy services for all beneficiaries that these suppliers serve.

In preparation for developing these standards and to gain a clear understanding of the current home infusion therapy supplier private sector climate, we reviewed the requirements established by section 5012 of the 21st Cures Act, performed an extensive review of the standards from all six AOs that accredit home infusion suppliers (The Joint Commission, Accreditation Commission for Health Care, Compliance Team, Community Health Accreditation Partner, Healthcare Quality Association on Accreditation, and National Association of Boards of Pharmacy), and reviewed various other government and industry publications listed in this final rule with comment

⁷⁵ Infusion Therapy: Standards of Practice, Journal of Infusion Nursing, Wolters Kluwer: Jan/Feb 2016 pp S25–S26.

period. In addition to the standards, we reviewed the following documents related to coverage:

- Government Accountability Office-10–426 report, which describes the state of coverage of home infusion therapy components under Medicare fee-for-service prior to the enactment of the Cures Act (GAO, 2010).⁷⁶

- Medicare and Home Infusion white paper written by the National Home Infusion Association (NHIA), which provided an overview of Medicare coverage provided for Home Infusion Therapy services prior to the enactment of the Cures Act, as well as results of a study conducted by Avalere Health on the potential savings that could result from Medicare coverage of infusion therapy provided in the home (National Home Infusion Therapy Association, NDS).⁷⁷

- American Society of Health System Pharmacists Guidelines on Home Infusion Pharmacy Services, which provided an in-depth overview of specialized, complex pharmaceuticals, best practices on providing home infusion therapy in the home or alternative site settings, and the plans to execute and manage the therapy (American Society of Health-System Pharmacists. ASHP guidelines on Home Infusion Pharmacy Service, 2014).⁷⁸

- The requirements of numerous Medicare Advantage plans, Medicare FFS, and private insurance plans.

Upon review of these materials, we believe that there is a sufficient private-sector framework already in place to address many of the areas that will typically be included in the establishment of basic health and safety standards for home infusion therapy. For example, existing AO standards include requirements related to plan of care, monitoring, patient assessment, quality improvement, and infection control. While the exact content of the AO standards vary, we believe that the standards are adequate to ensure patient health and safety. The AO representing the largest number of home infusion therapy suppliers requires that home infusion pharmacies provide certain

⁷⁶ Government Accountability Office. (2010). Home Infusion Therapy. Differences between Medicare and Private Insurers' coverage. (GAO Publication No. 10–426). Washington, DC, U.S. Government Printing Office.

⁷⁷ National Home Infusion therapy Association. Medicare and Home Infusion White Paper. Retrieved from <https://www.nhia.org/resource/legislative/documents/NHLAWhitePaper-Web.pdf>.

⁷⁸ American Society of Health-System Pharmacists. ASHP guidelines on Home Infusion Pharmacy Service, 2014. Retrieved from: <https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/home-infusion-pharmacy-services.ashx?la=en&hash=255092A51D0AE4746C151C51A7BF82217AC2F76>.

services to ensure safe and appropriate therapy, in compliance with nationally recognized standards of practice. Patient training and education activities, as part of their required admission procedures, include the use of medical and disposable equipment, medication storage, emergency procedures, vascular access device management, recognition of a drug reaction, and when to report any adverse drug event. As such, we concluded that it was appropriate to propose requirements for only those elements specifically identified in section 1861(iii) of the Act. Through the CMS accreditation organization process, we would monitor home infusion therapy suppliers to assure that services are provided in a safe and effective manner, and would consider future rulemaking to address any areas that may need improvement in the future. We solicited public comment on this approach and invited comments related to the home infusion therapy standards.

2. Home Infusion Therapy Supplier Requirements (Part 486, Subpart I)

We propose to add a new 42 CFR part 486, subpart I, to incorporate the home infusion therapy supplier requirements. The proposed regulations would provide a framework for CMS to approve home infusion therapy accreditation organizations and give them the authority to approve Medicare certification for home infusion therapy suppliers. Final subpart I would include General Provisions (Basis and Scope, and Definitions) and Standards for Home Infusion Therapy (Plan of Care and Required Services).

a. Basis and Scope (§ 486.500)

We proposed to set forth the basis and scope of part 486 at § 486.500. Part 486 is based on sections 1861(iii)(2)(D) of the Act, which establishes the requirements that a home infusion therapy supplier must meet in order to participate in the Medicare program. These proposed provisions serve as the basis for survey activities for the purposes of determining whether a home infusion therapy supplier meets the requirements for participation in Medicare. Section 1834(u) of the Act serves as the basis for the establishment of a prospective payment system for home infusion therapy covered under Medicare. In addition, section 1834(u)(5) of the Act establishes the factors for the Secretary to designate organizations to accredit suppliers furnishing home infusion therapy and requires that organizations be designated not later than January 1, 2021.

b. Definitions (§ 486.505)

At proposed § 486.505, we define certain terms that would be used in the home infusion therapy requirements. We define the terms “applicable provider”, “home”, “home infusion drug”, and “qualified home infusion therapy supplier” in accordance with the definitions set forth in section 1861(iii) of the Act. Furthermore, section 1861(iii) of the Act includes a definition of the term “home infusion therapy” that is the basis of the health and safety requirements set forth in this final rule with comment period. In accordance with the Act, we proposed the following definitions:

- “Applicable provider” would mean a physician, a nurse practitioner, and a physician assistant.

- “Home” would mean a place of residence used as the home of an individual, including an institution that is used as a home. However, an institution that is used as a home may not be a hospital, CAH, or SNF as defined in sections 1861(e), 1861(mm)(1), and 1819 of the Act, respectively.

- “Home infusion drug” would mean a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment. The term does not include insulin pump systems or a self-administered drug or biological on a self-administered drug exclusion list.

- “Qualified home infusion therapy supplier” would mean a supplier of home infusion therapy that meets all of the following criteria which are set forth at section 1861(iii)(3)(D)(i) of the Act: (1) Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; (2) ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis; (3) is accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act; and (4) meets such other requirements as the Secretary determines appropriate.

c. Standards for Home Infusion Therapy

Proposed subpart I, as required by section 5012 of the Cures Act, would specify that the qualified home infusion therapy supplier ensure that all patients have a plan of care established by a physician.

(1) Plan of Care (§ 486.520)

Proposed § 486.520(a), requires that all patients must be under the care of an “applicable provider” as defined at § 486.505. Proposed § 486.520(b) requires that the qualified home infusion therapy supplier ensure that all patients must have a plan of care established by a physician that prescribes the type, amount, and duration of home infusion therapy services that are furnished. The plan of care would also include the specific medication, the prescribed dosage and frequency as well as the professional services to be utilized for treatment. In addition, the plan of care would specify the care and services necessary to meet the patient-specific needs.

We also proposed, at § 486.520(c), that the qualified home infusion therapy supplier must ensure that the plan of care for each patient is periodically reviewed by the physician. We did not propose to establish a specific timeframe for review requirements, but the expectation is that the physician is active in the patient’s care and can make appropriate decisions related to the course of therapy if changes are necessary in regards to the progress of the patient and goal achievement with the infusion therapy.

(2) Required Services (§ 486.525)

Section 1861(iii)(2)(D)(II) of the Act specifically mandates that qualified home infusion therapy suppliers ensure the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis. Infusion drugs are administered directly into a vein or under the skin, eliciting a more rapid clinical response than with oral medications. Consequently, an adverse effect or a medication error could result in a quicker and/or more severe complication. Therefore, at § 486.525(a), we proposed to require the provision of professional services, including nursing services, furnished in accordance with the plan of care. We proposed to require that home infusion therapy suppliers ensure that professional services are available on a 7-day-a-week, 24-hour-a-day basis in order to ensure that patients have access to expert clinical knowledge and advice in the event of an urgent or emergent infusion-related situation. This requirement is imperative, as the success of home infusion therapy is often dependent upon the professional services being available during all hours and days of the week that allows for the patient to safely and effectively manage all aspects of treatment.

At § 486.525(b), we proposed to require patient training and education, not otherwise paid for as durable medical equipment, and as described in 42 CFR 424.57(c)(12). This requirement is consistent with section 1861(iii)(2)(B) of the Act. In addition, the patient training and education requirements are consistent with standards that are already in place, as established by the current AOs of home infusion therapy suppliers. This is a best practice, as home infusion therapy may entail the use of equipment and supplies with which patients’ may not be comfortable or familiar.

At § 486.525(c), we proposed to require qualified home infusion therapy suppliers to provide remote monitoring and monitoring services for the provision of home infusion therapy services and home infusion drugs furnished by a qualified home infusion therapy supplier. This proposed requirement is also consistent with section 1861(iii)(2)(B) of the Act. Monitoring the patient receiving infusion therapy in their home is an important standard of practice that is an integral part of providing medical care to patients in their home.⁷⁹ The expectation is that home infusion therapy suppliers would provide ongoing patient monitoring and continual reassessment of the patient to evaluate response to treatment, drug complications, adverse reactions, and patient compliance. Remote monitoring may be completed through follow-up telephone or other electronic communication, based on patient preference of communication. However, we do not propose to limit remote monitoring to these methods. Suppliers would be permitted to use all available remote monitoring methods that are safe and appropriate for their patients and clinicians and as specified in the plan of care as long as adequate security and privacy protections are utilized. Monitoring may also be performed directly during in-home patient visits. Additional discussion on remote monitoring and monitoring services can be found in section II.C.2.d. of this final rule with comment period.

Comment: We received a few comments related to whether we should include specific timeframes for review of the plan of care. Most comments suggested that CMS should align the physician review of the plan of care with State laws where they exist, while another commenter suggested that we require the plan of care be reviewed

⁷⁹ Infusion Therapy: Standards of Practice, Journal of Infusion Nursing, Wolters Kluwer: Jan/ Feb 2016 pp S25–S26.

every 30 days. Most commenters also stated that they believed adding additional reviews could conflict with the State laws and would create undue burden on home infusion therapy suppliers.

Response: We agree with the commenters that establishing timeframe requirements for the physician review of the patient plan of care could create duplicative requirements and add burden to home infusion therapy suppliers. Therefore, we are not including specific timeframes for the review of the plan of care, and will defer to existing State laws and regulations.

Comment: We received several comments requesting that the proposed home infusion therapy health and safety standards include various requirements for pharmaceutical standards, such as drug preparation and dispensing procedures. Specifically, commenters recommended compliance with sterile compounding standards and those requirements enforced by the United States Pharmacopeia and Food and Drug Administration.

Response: We agree it is important that all health care providers and suppliers, including home infusion therapy suppliers, provide services to patients in a safe and professional manner, and in accordance with professional standards of practice. To address these concerns, we have amended the regulation text at § 486.525 Required services, by adding § 486.525(b) which requires that all home infusion therapy suppliers must provide home infusion therapy services in accordance with nationally recognized standards of practice, and in accordance with all applicable state and federal laws and regulations. This could include the applicable provisions in the Federal Food, Drug, and Cosmetic Act.

Comment: Several commenters suggested we expand the standard under proposed § 486.525, Required services, (a) Professional services. Specifically the comments requested that CMS define the term “Professional services,” and to specify the specific services that would be applicable. Commenters suggested that the term “professional services” could be defined to include things such as clinical care planning, care coordination, pharmacy services, and nursing services to name a few.

Response: We agree various professional services may be necessary in the care of beneficiaries utilizing the Medicare home infusion therapy benefit. As stated in the proposed rule preamble, we have mirrored the language in section 1861(iii)(2)(A) that requires the provision of professional

services, including nursing services, furnished in accordance with the plan of care by the home infusion therapy supplier. By specifically enumerating a specific list of services we would risk inadvertently excluding services that may be necessary for the care of a specific patient as part of the required services under the home infusion therapy benefit. We acknowledge that pharmacy services are closely related to the home infusion therapy benefit; however, at this time pharmacy services associated with the preparation and dispensing of home infusion therapy drugs are covered under the Medicare Part B DME benefit and are not part of this specific home infusion therapy benefit.

Comment: We received several comments that did not appear to support the proposed regulation. However, the comments were non-specific in nature, and did not provide any detailed information to which we could provide an appropriate response.

Response: We believe the proposed home infusion therapy health and safety standards are important and essential because they provide the essential basis for establishing a robust accreditation program that will protect the health and safety of Medicare beneficiaries. Therefore, we are finalizing, with modifications, the home infusion therapy health and safety regulations. As previously described, we received several public comments regarding the home infusion therapy supplier health and safety regulations proposed at § 486.520, Plan of care and § 486.525, Required services. We are finalizing these regulations, and are adding the following requirement to § 486.525(b): All home infusion therapy suppliers must provide home infusion therapy services in accordance with nationally recognized standards of practice, and in accordance with all applicable state and federal laws and regulations.

C. Approval and Oversight of Accrediting Organizations for Home Infusion Therapy Suppliers

1. Background

Section 1861(iii)(3)(D)(III) of the Act, as added by section 5012(b) of the Cures Act, requires that a home infusion therapy supplier be accredited by an AO designated by the Secretary in accordance with section 1834(u)(5) of the Act. Section 1834(u)(5)(A) of the Act identifies factors for designating AOs and modifying the list of designated AOs. These statutory factors are: (1) The ability of the organization to conduct timely reviews of accreditation applications; (2) the ability of the

organization take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D) of the Act); (3) whether the organization has established reasonable fees to be charged to suppliers applying for accreditation; and, (4) such other factors as the Secretary determines appropriate.

Section 1834(u)(5)(B) of the Act requires the Secretary to designate AOs to accredit home infusion therapy suppliers furnishing home infusion therapy not later than January 1, 2021. In the proposed rule we stated that, there are six AOs that are currently providing accreditation to home infusion therapy suppliers, which are: (1) The Joint Commission (TJC); (2) Accreditation Commission for Health Care (ACHC); (3) Compliance Team (TCT); (4) Community Health Accreditation Partner (CHAP); (5) Healthcare Quality Association on Accreditation; and (6) National Association of Boards of Pharmacy. However, since the publication of the proposed rule, we have learned that there are two additional organizations that provide accreditation to home infusion therapy suppliers. These organizations are: (1) The Centers for Pharmacy Practice Accreditation (CPPA) and (2) URAC.

Five of these AOs are providing accreditation to home infusion therapy suppliers as part of the overall accreditation of home health agencies. The remaining AOs are pharmacy associations that have home infusion therapy accreditation programs that have not been approved by Medicare.

We proposed to publish a solicitation notice in the **Federal Register**, in which we would invite national AOs to submit an application to CMS for approval of their home infusion therapy accreditation program. We proposed that this solicitation notice would be published after the final rule is published, so that we can designate AOs to accredit home infusion therapy suppliers by no later than January 1, 2021 as required by 1834(u)(5)(B) of the Act. We further proposed that the application submitted by any AOs that respond to the solicitation notice would be required to meet all requirements set forth in proposed § 488.1010 and demonstrate that their substantive accreditation requirements are equal to or more stringent than our proposed regulations at part 485, subpart I.

Section 1861(iii)(3)(D) of the Act requires “qualified home infusion therapy suppliers” to be accredited by a CMS-approved AO. We proposed that, in order for the home infusion therapy suppliers accredited by the eight AOs that currently provide non-Medicare

approved home infusion therapy accreditation to continue receiving payment for the home infusion therapy services they provide, the eight existing home infusion therapy AOs must submit applications to CMS for Medicare approval of their home infusion therapy accreditation programs. We made this proposal because the accreditation currently being provided by these AOs has not been approved by CMS as required by section 1861(iii)(3)(D) of the Act. More specifically, five of these existing home infusion AOs are home health agency (HHA) AOs that have been approved by CMS to provide HHA accreditation to home health agencies (HHAs). These HHA AOs started offering home infusion therapy accreditation as part of their HHA accreditation program, but none of these HHA AOs have received separate CMS approval for their home infusion therapy accreditation programs. The remaining 3 of the existing home infusion AOs are pharmacy association that offer a non-CMS approved home infusion therapy accreditation programs. As noted, all these existing home infusion AOs would have to submit an application to CMS for Medicare approval of their home infusion therapy accreditation program.

We proposed that the home infusion therapy accreditation program be a separate and distinct accreditation program from the HHA AO's home health accreditation program. This would mean that AOs currently surveying HHAs would have a separate accreditation program with separate survey processes and standards for the accreditation of home infusion therapy suppliers. In addition, we proposed to require that the applications submitted by all HHA and pharmacy AOs that currently provide accreditation to home infusion therapy suppliers meet the application requirements set forth in the proposed home infusion therapy AO approval and oversight regulations at § 488.1010 and meet or exceed the substantive home infusion therapy health and safety standards proposed to be set out at 42 CFR part 485, subpart I.

Section 1834(u)(5)(C)(ii) of the Act states that in the case where the Secretary removes a home infusion therapy AO from the list of designated home infusion therapy AOs, any home infusion therapy supplier that is accredited by the home infusion therapy AO during the period beginning on the date on which the home infusion therapy AO is designated as an CMS-approved home infusion therapy AO and ending on the date on which the

home infusion therapy AO is removed from such list, shall be considered to have been accredited by an home infusion therapy AO designated by the Secretary for the remaining period such accreditation is in effect. Under section 1834(u)(5)(D) of the Act, in the case of a home infusion therapy supplier that is accredited before January 1, 2021 by a home infusion therapy AO designated by the Secretary as of January 1, 2019, such home infusion therapy supplier shall be considered to be accredited by a home infusion therapy AO designated by the Secretary as of January 1, 2023, for the remaining period such accreditation is in effect. Home infusion therapy suppliers are required to receive accreditation before receiving Medicare payment for services provided to Medicare beneficiaries.

Section 1861(iii)(3)(D) of the Act defines "qualified home infusion therapy suppliers" as being accredited by a CMS-approved AO. In the proposed rule, we proposed to establish regulations for the approval and oversight of AOs that accredit home infusion therapy suppliers to address the following: (1) The required components to be included in a home infusion therapy AO's initial or renewal application for CMS approval of the AO's home infusion therapy accreditation program; (2) the procedure for CMS' review and approval of a home infusion therapy AOs application for CMS approval of its home infusion therapy accreditation program; and (3) the process for ongoing monitoring and oversight of the CMS-approved home infusion therapy AOs.

Comment: Another commenter stated that they were slightly confused by the use of this proposed rule as the appropriate forum for these significant changes.

Response: The issues presented in the proposed rule involve the payment for home infusion therapy services, the accreditation of suppliers that provide home infusion therapy services to patients in their homes and the approval and oversight of AOs that accredit home infusion therapy suppliers. Most of the AOs that currently provide accreditation for home infusion therapy suppliers are AOs that also accredit Home Health Agencies (HHAs). Further, the home infusion therapy accreditation offered by these HHA AOs is currently provided as part of these HHA AO's home health accreditation program. Therefore, we believe that the Home Health Prospective Payment System (HH PPS) rule is an appropriate venue in which to present these issues.

Comment: Several commenters stated general support for the establishment of

an accreditation program for home infusion therapy suppliers. One of these commenters stated that home infusion therapy is a service that can be safely and effectively provided in the home setting, when provided by an accredited home infusion therapy supplier under a physician ordered plan of care. Several commenters stated general agreement with the AO approval and oversight provisions for home infusion therapy AOs but suggested that the health and safety standard regulations need to include additional provisions including pharmacy safety standards such the requirements for sterile compounding.

Response: We thank these commenters for their support of these proposals. We refer those commenter that suggested changes or additions to the home infusion therapy health and safety standards to section VI.B. of this for further discussion of these comments.

Comment: Several commenters stated that the accreditation section of the rule is silent as to when CMS plans on making accreditation a requirement of participation for reimbursement. These commenters requested that CMS provide clarity on the effective date of this requirement.

Response: Section 1834(u)(5)(B) of the Act requires that "not later than January 1, 2021, the Secretary shall designate organizations to accredit suppliers furnishing home infusion therapy". The permanent home infusion therapy benefit provided under the 21st Century Cures Act is to begin on January 1, 2021. Therefore, all home infusion therapy suppliers must be accredited by no later than January 1, 2021 in order to receive Medicare payment for furnishing home infusion therapy services under the permanent home infusion therapy benefit. CMS plans to publish a solicitation notice in the **Federal Register** which will announce that we are seeking national AOs to accredit home infusion therapy suppliers and invite interested AOs to submit their applications to CMS. We plan to publish this solicitation notice very soon after publication of the final rule. We will be prepared to begin accepting applications from prospective AOs seeking CMS approval of a home infusion therapy accreditation program immediately after publication of the solicitation notice.

Comment: A commenter stated the opinion that "the accreditation section of the rule is a statutory construct of the 21st Century Cures Act as a requirement to become a qualified home infusion provider for the permanent home infusion services reimbursement." This commenter further stated the belief that "the BBA does not require accreditation

to become a “qualified” home infusion therapy supplier and relies on a qualified home infusion provider to be a qualified home infusion provider and a pharmacy enrolled in the DME program and a pharmacy licensed in the state where applicable home infusion drugs are administered.”

Response: Section 50401 of the Bipartisan Budget Act (BBA) of 2018 does not specifically state accreditation is required to become a “qualified” home infusion therapy for payment of the temporary transitional home infusion therapy services. However for the permanent home infusion therapy services benefit, section 5012 of the 21st Century Cures Act added section 1861(iii)(3)(D)(i) to the Act that defines the term qualified home infusion therapy supplier as a “pharmacy, physician, or other provider of services or supplier licensed by the State in which the pharmacy, physician, or provider or services or supplier furnishes items or services and that”(III) is accredited by an organization designated by the Secretary pursuant to section 1834(u)(5)”. Further, this statutory provision does not restrict “qualified” home infusion therapy suppliers to only pharmacies, but includes physicians, other providers of services and suppliers as possible types of home infusion therapy suppliers. However, section 50401(a) of the BBA of 2018, adding new section 1834(u)(7)(F) to the Act, requires that “eligible home infusion suppliers” for the temporary transitional payment be a pharmacy that provides external infusion pumps and external infusion pump supplies and that maintains all pharmacy licensure requirements in the State in which the applicable infusion drugs are administered. Accreditation for home infusion therapy services is not required for these pharmacies.

Comment: Another commenter requested that CMS clarify that all eligible accrediting organizations may submit an application to CMS for approval of a home infusion therapy accreditation program and not just the eight AOs listed in the proposed rule.

Response: Regarding comments on the eight AOs listed in the proposed rule, since publication of the proposed rule, we are made aware of two additional AOs for home infusion therapy suppliers. The eight existing AOs that provide home infusion therapy accreditation are: (1) The Joint Commission; (2) Accreditation Commission for Healthcare (ACHC); (3) Community Health Accreditation Partner (CHAP); (4) The Compliance Team (TCT); (5) National Association of Pharmacy Boards (NAPB); (6)

Healthcare Quality Association on Accreditation (HQAA); (7) The Centers for Pharmacy Practice Accreditation (CPPA) and (8) URAC. In accordance with this final rule with comment period, any national AO that provides accreditation for home infusion therapy suppliers that meets the following requirements may submit an application to CMS requesting approval of their home infusion therapy accreditation program: (1) The AO must be national in scope; (2) the AO must have a home infusion therapy accreditation program that is separate and distinct from other accreditation programs they have; (3) the AO must have home infusion therapy accreditation standards that meets or exceeds the Medicare home infusion therapy health and safety standards to be codified at 42 CFR 486.500 to 486.525; and (4) the home infusion therapy AO must accredit only those home infusion therapy suppliers that provide all services required by the Medicare home infusion therapy health and safety and payment regulations.

Upon receipt of an application from a home infusion therapy AO seeking CMS approval of its home infusion therapy accreditation program, CMS will determine its completeness in accordance with the requirements set forth at § 488.1010(a). Once CMS has determined that an application is complete, CMS will then review it to determine whether the application meets the requirements set forth at § 488.1000 to § 488.1050 and whether the AOs accreditation standards meet or exceed the Medicare home infusion therapy health and safety accreditation requirements set forth at proposed § 486.500 to § 486.525. CMS will also assess whether the AO accredits only those home infusion therapy suppliers that provide all services required by the Medicare home infusion therapy health and safety and payment regulations. Pursuant to § 488.1010(d), CMS must complete the application review process and issue a decision within 210 days from the date that CMS determines that the application is complete. In accordance with § 488.1020(b), CMS will publish a final notice in the **Federal Register** announcing our decision to approve or deny a national accrediting organization application. The notice will specify the basis for the CMS decision.

Comment: Several commenters raised the question of whether the National Association of Boards of Pharmacy (NABP), which is one of the existing AOs that provide accreditation to home infusion therapy suppliers, would qualify as a CMS-approved home infusion therapy AO. These commenters

stated that the NABP’s survey process focuses only on pharmacy personnel education, practice of pharmacy including sterile compounding, patient counseling. These commenters further stated that the NABP addresses sterile compounding in their standards but does not address the plan of care process, the complexities of patient care monitoring or any professional staff components. These commenters further stated that they do not consider NABP a full-service home infusion accreditation organization and few third party payers in the private sector accept or recognize NABP alone as sufficient accreditation for home infusion. These commenters expressed the opinion that they want the industry to be held to a higher standard than what NABP accreditation provides.

Response: Any national AO that provides accreditation for home infusion therapy suppliers that meets the requirements set forth previously may submit an application to CMS requesting approval of a home infusion therapy accreditation program. In addition, we cannot predetermine whether the NABP would qualify as a CMS-approved home infusion therapy AO nor can we prohibit any organization from applying to be an AO.

Upon receipt of an application, CMS will determine its completeness in accordance with the requirements set forth at § 488.1010(a). Once CMS has determined that the application is complete, CMS will review it to determine whether the application meets the requirements set forth at § 488.1000 to § 488.1050 and whether the AOs accreditation standards meet or exceed the Medicare home infusion therapy health and safety accreditation requirements set forth at proposed § 486.500 to § 486.525. CMS will also assess whether the AO accredits only those home infusion therapy suppliers that provide all services required by the Medicare home infusion therapy health and safety and payment regulations. Pursuant to § 488.1010(d), CMS must complete the application review process and issue a decision within 210 days from the date CMS determines that the application is complete. In accordance with § 488.1020(b), CMS will publish a final notice in the **Federal Register** announcing our decision to approve or deny a national accrediting organization’s application. The final notice will specify the basis for CMS’ decision.

If the NABP were to submit an application to CMS for approval of a home infusion therapy accreditation program, we would be required to give the same consideration to that

application as we would give to any other application we receive. We would be required to review the application to determine whether the NABP's home infusion therapy accreditation program meets the previously stated requirements. We would also be required to review the application to determine whether the NABP's application meets the requirements set forth in § 488.1010.

It is interesting to point out that these same commenters strongly advocated for CMS to "grandfather" in the existing eight home infusion therapy AOs which were recognized in the proposed rule. These commenters argued that for CMS to do otherwise would be to defeat Congress's clear direction and understanding that the accreditation program be functional by January 1, 2019, and would severely disrupt care for patients. As the NABP is one of eight existing home infusion therapy accrediting organizations, it would seem that these commenters have on one hand, advocated that the NABP should "grandfathered" in as one of the eight existing home infusion therapy AOs, while also advocating for their exclusion as a home infusion therapy AO. These arguments conflict with one another.

Comment: Several commenters expressed the belief that the HHA AOs with an existing home infusion therapy accreditation program should not be required to have a Home Infusion therapy accreditation program that is separate and distinct from their HHA accreditation programs because this would place unnecessary burden on these HHA AOs. These commenters stated their disagreement with CMS' proposal that the home infusion therapy benefit should fall under an entirely separate accreditation process from an existing home care program. These commenters strongly recommended that CMS allow HHA AOs to satisfy the specified home infusion therapy accreditation requirement within their home care programs. In support of this request, a commenter stated the belief that including home infusion therapy services as part of the larger home health accreditation would promote a higher quality of care as well as a more coordinated and comprehensive approach to care delivery.

Several commenters suggested that the accreditation of home infusion therapy suppliers should be allowed as part of an HHA AO's overall accreditation and not require a totally separate accreditation as long as the accreditation organization meets all the CMS mandated home infusion therapy accreditation health and safety

standards. Some of these commenters stated the belief that requiring AOs with existing home infusion therapy accreditation programs to submit a home infusion therapy accreditation program that is separate and distinct from their HHA accreditation program could affect the quality of care provided by these AOs and that such a policy would further fragment care delivery.

Another commenter suggested that CMS should permit a separate home infusion therapy accreditation module, approved by CMS, under an existing accreditation program because CMS has already done considerable review of the existing HHA accreditation programs and could benefit from working with the AOs to build on already existing standards to establish a standard set of standards that could be included for all accreditation organizations rather than developing a totally separate, free-standing home infusion therapy accreditation program.

Several commenters stated the belief that the requirement for a distinct, freestanding accreditation program for home infusion therapy suppliers would place additional burden on home care programs that currently provide home infusion therapy services as well as on accrediting organizations (AOs). One of these commenters expressed the concern that a totally separate accreditation program for HIT only would involve excessive cost and personnel time for agencies and CMS.

Response: We believe that it would not be permissible for CMS to allow the Home Health accrediting organizations to maintain the home infusion therapy accreditation program as part of their overall HHA accreditation program for several reasons. First, sections 1861(iii)(3)(D)(i) and 1834(u)(5) of the Act are clear that an accreditation is required for qualified home infusion therapy suppliers and that CMS must approve AOs accrediting these suppliers. Pursuant to section 1834(u)(5)(B) of the Act, CMS is mandated to designate AOs to accredit home infusion therapy suppliers by no later than January 1, 2021. This statutory mandate does not include language that would allow CMS to approve existing home infusion therapy accreditation programs that are co-mingled with other accreditation programs.

Second, given that our review of the commenter's HHA accreditation program standards occurred prior to the passage of the statutory mandate for CMS to designate AOs to accredit home infusion therapy suppliers our review of AOs' HHA programs focus on and assess the AO's HHA accreditation program

standards and adherence to the CMS Home Health Conditions of Participation. Therefore, the reliance on our previous review of the HHA accreditation program standards and survey processes would not be sufficient to ensure that a HHA AO's home infusion therapy accreditation program would meet or exceed Medicare home infusion therapy health and safety standards that we are finalizing in this rule.

In addition, in this rule, we have proposed to establish new home infusion therapy health and safety accreditation standards that each home infusion therapy AO must incorporate into their home infusion therapy accreditation standards. When we reviewed the HHA AOs previous application, this review would have occurred prior to the publication of the CY 2019 Home Health proposed rule. Therefore, the HHA AOs could not yet have incorporated the new home infusion therapy health and safety standards into the accreditation standards they submitted with their applications. The establishment of the Medicare home infusion therapy health and safety accreditation standards will require that the existing home HHA/home infusion therapy AOs revise their home infusion therapy accreditation standards to ensure that they meet or exceed these new home infusion therapy health and safety standards. Therefore, we must require that each of the existing HHA/home infusion therapy AOs submit for our review, a new application seeking approval for a separate and distinct accreditation program for home infusion therapy suppliers, to ensure that the accreditation standards used meet or exceed the Medicare home infusion therapy health and safety standards.

Comment: Several commenters have stated that CMS should allow home health agency AOs to continue to provide home infusion accreditation services as part of their larger home health accreditation program. These commenters believe that providing home infusion therapy accreditation services as part of the AO home health program would both promote higher quality care for beneficiaries and reduce administrative burden.

Response: We respectfully disagree with these commenters, because the commenters have provided no specific facts or circumstances which would explain how having a separate and distinct home infusion therapy accreditation program would promote a higher quality of care.

Moreover, the statutory requirement of section 1834(u)(5) of the Act

contemplates an independent accreditation process for home infusion therapy suppliers.

Comment: Several commenters stated concern that it would be too burdensome to require HHA AOs with existing home infusion therapy accreditation programs to develop a new home infusion therapy accreditation program that is distinct from their existing HHA accreditation program.

Response: We respectfully disagree with these commenters. We believe the additional burden will be minimal.

Moreover, the statute mandates an AO program and application process that is structurally separate from accreditation for HHAs. While these commenters may incur some initial burden to create a home infusion therapy accreditation program that is separate and distinct from their home health accreditation program, we believe that this burden would be limited for several reasons. First, these commenters have stated in their comments that they do have established home infusion therapy standards and survey processes but that they are co-mingled with the AOs home health accreditation standards and survey processes. As these home health AOs already have established home infusion therapy accreditation standards and survey processes, we believe that it would be an uncomplicated matter for these AOs to separate their home infusion therapy standards and survey processes from their home health accreditation standards and survey processes. What we mean by this is that the AO could simply take the documents which contains the combined home health/home infusion therapy accreditation standards and survey processes and cut and paste the home infusion therapy accreditation language into a separate document. This task would only need to be performed once. Further, we believe the benefits of having a home infusion therapy accreditation program that is separate and distinct from the home health AOs home health accreditation program far outweighs the burden associated with the initial separation of the home infusion therapy accreditation program and home health accreditation program standards and survey processes.

Comment: Another commenter pointed out that “HHAs have historically provided professional services associated with home infusion to individuals under their care, and further stated that they applauded both Congress and CMS for moving forward in implementing this important benefit and the additional support and resources it represents.” However, several other commenters stated that

home health agencies do not own or operate pharmacies, prepare home infusion drugs, provide the care coordination necessary to manage drug infusion, or provide a home infusion benefit. These commenters further stated that home infusion providers are neither certified nor authorized to offer the myriad of care services required of a home health agency. Thus, there is no relationship, overlap or intersection between the two benefits. Home health agencies will continue to provide the home health benefit for Medicare patients, and home infusion pharmacies will provide the new separate home infusion benefit for their Medicare patients.

Response: We agree with this commenter and we believe that HHAs are in a unique position to provide both home infusion therapy services and home health services to patients in their homes. Under the Medicare home infusion therapy benefit in section 1861(iii) of the Act, as added by section 5012 of the Cures Act, home infusion therapy services are available for those individuals receiving eligible home infusion drugs. Eligible home infusion therapy drugs are defined under section 1861(iii)(3)(C) of the Act, as a drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of DME. The services that are to be provided and paid for by Medicare do not include the provision of the home infusion drug, DME infusion pump, or supplies therefore, it is not necessary for a home infusion therapy supplier to be a licensed pharmacy.

Comment: Several commenters expressed the opinion that CMS has delayed in proposing the home infusion therapy AO regulations, and that this has caused the likelihood that the home infusion therapy AOs will be unable to apply for CMS approval, much less that CMS will have completed the accreditation process for home infusion AOs, prior to January 1, 2019. These commenters urged CMS to “grandfather” in existing accreditations to entities such as the eight AOs recognized in the proposed rule. The commenters suggest that for CMS to do otherwise would be to defeat Congress’s clear direction and understanding that the accreditation program be functional by such date, and would severely disrupt care for patients. These commenters stated the belief that such action would be consistent with section 1834(u)(7)(F) of the Act, as added by section 50401 of the BBA of 2018, where Congress expressed its acceptance of

such accreditation as sufficient on January 1, 2019 when the Transition benefit will begin.

Response: We respectfully disagree with these commenters’ contention that CMS delayed in proposing the home infusion therapy AO regulations. The 21st Century Cures Act, which is the legislation that established the requirement for accreditation of home infusion therapy suppliers, was signed into law December 13, 2016. Thereafter, time was required to develop our plan for implementation, which occurred through mid to late 2017. By the time that the implementation planning phase was completed, the CY 2018 Home Health Prospective Payment proposed and final rules had already been published. Therefore, the CY 2019 Home Health Prospective Payment System Proposed Rule was the first appropriate venue in which CMS could make these proposals. Moreover, section 1834(u)(5)(B) of the Act, as added by the 21st Century Cures Act, requires that “[n]to later than January 1, 2021, the Secretary shall designate organizations to accredit suppliers furnishing home infusion therapy.” This means that it was intended that CMS would have until January 1, 2021 to solicit and approve AOs to accredit home infusion therapy suppliers for the permanent Medicare home infusion therapy services benefit for which payment to qualified home infusion therapy supplier will begin on January 1, 2021.

As stated in the proposed rule, we plan to publish a solicitation notice seeking national AOs to accredit home infusion therapy suppliers shortly after publication of the final rule. In addition, § 488.1010(d) requires CMS to complete its review of an application submitted by a home infusion therapy AO within 210 calendar days from the date that CMS determines that an application is complete. If we publish the solicitation notice by December 31, 2018 and receive applications from prospective home infusion therapy AOs during the first 5 months of 2019, we would be required to complete our review of these applications and issue our decisions by December 31, 2019, which is 1 full year before the January 1, 2021 deadline. Assuming we publish the solicitation notice by December 31, 2018, and considering that we must complete review of the application within 210 days, there would be a 16-month period in which prospective home infusion therapy AOs could submit their application for CMS review and obtain approval by the January 1, 2021 deadline specified in section 1834(u)(5)(B) of the Act.

The existing AOs that have been providing accreditation of home infusion therapy suppliers already have established home infusion therapy accreditation programs and accreditation standards. A number of commenters have stated that their respective home infusion therapy standards already meet or exceed the CMS proposed home infusion therapy accreditation health and safety standards and therefore believe that they should not be required to submit an application to CMS for approval. However, if this is the case, we believe that it should not take these AOs long to prepare the information and documentation required to apply for CMS approval of their home infusion therapy accreditation programs.

Likewise, we do not believe that it would take a long period of time for the HHA AOs that accredit home infusion therapy suppliers to prepare and submit their applications for CMS approval of a separate and distinct home infusion therapy accreditation program. It is our understanding from the comments received that these AOs have home infusion therapy accreditation standards that already meet or exceed the CMS proposed home infusion therapy accreditation health and safety standards; however, these home infusion therapy accreditation standards are integrated into the AO's HHA accreditation program. We believe that it would be an uncomplicated matter for these HHA AOs to segregate their home infusion therapy accreditation program into an individual accreditation program. As these AOs have previously established one or more accreditation programs and survey processes in the past, and have prepared and submitted one or more applications to CMS for approval of these accreditation programs, we believe that it would take these AOs less time and effort to do so for a separate and distinct home infusion therapy accreditation program.

Comment: Several commenters expressed the opinion that the Congressional intent was for CMS to accept the accreditation provided by the existing home infusion therapy AOs as being sufficient as of January 1, 2019 when the transitional benefits begin. Several commenters suggested that section 1834(u)(5)(D) requires CMS to deem any home infusion supplier accredited by a home infusion therapy AO designated or otherwise recognized and accepted by CMS prior to January 1, 2019, to be deemed accredited through January 1, 2023.

Response: We do agree that the existing home infusion therapy accreditation provided by the 8 existing

home infusion therapy accreditation organizations prior to or on January 1, 2019 and still in effect on January 1, 2021, would be deemed to meet our accreditation requirements through at least January 1, 2023, once the permanent program goes into effect on January 1, 2021. Accreditation is not required for the transitional program set out at 1834(u)(7) of the Act. CMS cannot designate AOs until after January 1, 2019 (when our standards and designation procedures become effective).

Section 1834(u)(5)(D) titled "*Rule for Accreditations Made Prior to Designation*" refers to accreditations of home infusion suppliers that occurred "prior to the Secretary's designation" of AOs. This provision applies only to those AOs that are ultimately approved by CMS; the eight AOs currently providing accreditation receive no special consideration. Should any of the eight apply and be approved, any supplier with an active accreditation as of January 1, 2019 that is still active on January 1, 2021, when the accreditation requirement goes into effect, will be deemed to have a recognized accreditation until at least January 1, 2023, and longer if their accreditation lasts for a longer period.

2. Process and Standards for Home Infusion Therapy Accreditation and the Approval and Oversight of Accrediting Organizations With CMS-Approved Accreditation Programs for Home Infusion Therapy Services

a. Establishment of Regulatory Requirements

We proposed to establish new regulations in a new subpart L in 42 CFR part 488 that would govern CMS' approval and oversight of AOs that accredit home infusion therapy suppliers. We believe these new regulations would provide CMS with reasonable assurance that the home infusion therapy AO's accreditation program requirements are consistent with the appropriate Medicare accreditation program requirements. Further, we believe that these proposed regulations would provide CMS with a way to provide oversight for AOs that accredit home infusion therapy suppliers, and provide CMS with authority over the home infusion therapy suppliers.

We proposed to implement a comprehensive, consistent and standardized set of AO oversight regulations for accreditors of home infusion therapy suppliers. It is our intention to provide home infusion therapy AOs with the flexibility to

innovate within the framework of these regulations while assuring that their accreditation standards meet or exceed the appropriate Medicare requirements, and their survey processes are comparable to those of Medicare.

"Flexibility to innovate" means that AOs retain the freedom to develop their own accreditation standards and survey processes, so long as the AO ensures that they meet the health and safety standards (contained in 42 CFR part 486, subpart B) and the AO meets the requirements of the AO approval and oversight regulations.

The proposed regulations would reflect requirements similar to those in place for the oversight of national AOs for Medicare-certified providers and suppliers which are codified at 42 CFR 488.1 through 488.13 and 42 CFR part 489, but would be modified, as appropriate, to be applicable for accreditors of home infusion therapy suppliers. We believe that it is important to have AO approval and oversight regulations that are as consistent as possible across all AOs and to treat all AOs in a similar manner.

b. Consideration of Existing Regulations

In formulating our approach to implementing the statutory requirements related to accreditation organizations, we had considered using the regulations at 42 CFR 488.1 to 488.13 for the approval and oversight of AOs that accredit home infusion therapy suppliers. However, we decided not to do so because we believe that Congress, by setting out separate accreditation organization approval standards for home infusion therapy suppliers at 1834(u)(5)(A) of the Act, intended approval for this accreditation program to be a discrete process. We believe that having a separate set of approval regulations applicable only to home infusion therapy suppliers will best reflect Congress's intent.

Only limited portions of the regulations at §§ 488.1 through 488.13 will apply to AOs that accredit home infusion therapy suppliers. For example, § 488.6, regarding accredited provider entities' participation in Medicaid, will not apply to home infusion therapy because home infusion therapy suppliers is not a benefit specified in our Medicaid regulations.

Section 488.7, titled "Release and use of accreditation surveys" and § 488.8 titled "Ongoing review of accrediting organizations" will have parallel provisions applicable to AOs that accredit home infusion therapy suppliers (§ 488.1025). However, § 488.9 titled "Validation surveys" will not have a parallel provision applicable to

AOs for home infusion therapy suppliers because the State Survey Agency (SA) only performs validation surveys for AOs that operate under the statutory authority of section 1865 of the Act. In addition, section 1864(a) of the Act provides, that by agreement with the Secretary, the SA shall provide services to the following Medicare certified healthcare providers: hospitals, skilled nursing facilities, home health agencies, hospice programs, rural health clinics, critical access hospitals, comprehensive outpatient rehabilitation facilities, laboratories, clinics, rehabilitation agencies, public health agencies, or ambulatory surgical centers. Home infusion therapy suppliers are not included in this list.

Section 488.10, titled "State survey agency review: Statutory provisions", § 488.11 titled "State survey agency functions" and § 488.12 titled "Effect of survey agency certification" will also not have parallel provisions applicable to home infusion therapy AOs. This is because, as stated previously, the SA does not perform validation surveys for AOs that accredit home infusion therapy providers. Section 488.13, titled "Loss of accreditation" provides that "if an accrediting organization notifies CMS that it is terminating a provider or supplier due to non-compliance with its CMS-approved accreditation requirements, the SA will conduct a full review in a timely manner." This section will also not have parallel provisions applicable to AOs that accredit home infusion therapy suppliers because this regulation section requires use of the SA.

Section 488.14 titled, "Effect of QIO review" provides that "when a QIO is conducting review activities under section 1154 of the Act and part 466 of this chapter, its activities are in lieu of the utilization review and evaluation activities required of health care institutions under sections 1861(e)(6), and 1861(k) of the Act." This section will not have parallel provisions applicable to AOs for home infusion therapy suppliers because it is only applicable only to hospitals.

Finally, § 488.18, titled "Documentation of findings" states that "the findings of the State agency with respect to each of the conditions of participation, requirements (for SNFs and NFs), or conditions for coverage must be adequately documented." As noted previously, we will not be including a parallel provision applicable to AOs that accredit home infusion therapy suppliers because it involves the activities of the SAs, which will not be involved in the home

infusion therapy supplier accreditation process.

In conclusion, a majority of sections contained in §§ 488.1 through 488.13 do not apply to home infusion therapy AOs and home infusion therapy suppliers. Therefore, we have created a separate set of regulations that are specifically applicable to home infusion therapy AOs.

We sought comment on our decision not to use the existing regulation at §§ 488.1 through 488.13. We did not receive any comments on this topic.

c. Consideration of a Validation Process for Accrediting Organizations That Accredit Home Infusion Therapy Suppliers

Our conventional validation process involves the participation of the CMS Regional Offices (ROs) to request the State Survey Agency to conduct an onsite validation (follow-up) survey within 60 days of an AO's onsite survey. The purpose of a validation survey is to evaluate the ability of that AO's survey process to identify serious, condition level deficiencies.

We did not propose to establish a validation program requirement for home infusion therapy AOs and suppliers due to a number of resource constraints. Several factors limit our ability to establish and implement a validation program for home infusion therapy AOs. First, as mentioned previously, the SAs are not available to perform validation surveys for home infusion therapy AOs. This is because, pursuant to section 1864(a) of the Act, the SA, enters into an agreement with the Secretary to provides services to only a limited number of healthcare provider types (that is, hospitals, skilled nursing facilities, home health agencies, hospice programs, rural health clinics, critical access hospitals, comprehensive outpatient rehabilitation facilities, laboratories, clinics, rehabilitation agencies, public health agencies, or ambulatory surgical centers.

We sought public comment on the decision not to propose a validation process at this time.

Even though we would not have a formal validation process in place, we would be able to monitor the performance of the home infusion therapy AOs as part of the ongoing AO oversight process provided for in the home infusion therapy AO approval and oversight regulations at §§ 488.1010 through 488.1050. For example, under proposed § 488.1030 we would have the ability to carry out performance reviews to evaluate the performance of each CMS-approved home infusion therapy accreditation program on an ongoing

basis; comparability reviews to assess the equivalency of a home infusion therapy AO's CMS-approved program requirements with the comparable Medicare home infusion therapy accreditation requirements after CMS imposes new or revised Medicare accreditation requirements; and standards reviews when a home infusion therapy accrediting organization proposes to adopt new or revised accreditation standards. We may also perform CMS-approved home infusion therapy accreditation program review if a comparability, performance, or standards review reveals evidence of substantial non-compliance of a home infusion therapy AO's CMS-approved home infusion therapy accreditation program with the requirements of this subpart. (See § 488.1005 for a definition of "substantial non-compliance").

In addition, proposed § 488.1035 would require the home infusion therapy AOs to submit information to CMS which would help us monitor the AO's performance. This information would also help to ensure that the home infusion therapy suppliers accredited by the AO provide care that meets the health and safety standards contained in 42 CFR part 486, subpart B. This information includes the following:

- Copies of all home infusion therapy supplier accreditation surveys, together with any survey-related information.
- Notice of all accreditation decisions.
- Notice of all complaints related to the AO's accredited suppliers.
- Information about all home infusion therapy accredited suppliers against which the home infusion therapy accreditation organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the providers or suppliers accreditation.
- Annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.
- Notice of any changes in the home infusion therapy accrediting organization's accreditation standards or requirements or survey process.

Comment: Several commenters agreed with CMS that validation surveys should not be required for home infusion therapy AOs. One of these commenters agreed with CMS' position that the performance reviews performed under proposed § 488.1030 would provide more objective and effective data about the AOs performance.

Response: We thank these commenters for their input.

Final Decision: In consideration of the comments received, we are finalizing this proposal without modification and

will perform ongoing monitoring as part of the approval and ongoing oversight process for home infusion therapy AOs.

d. Application Requirement for AOs That Currently Provide Accreditation for Home Infusion Therapy Suppliers

We proposed to establish regulations for the approval and oversight of AOs for home infusion therapy suppliers. We also proposed the health and safety standards which home infusion therapy suppliers must meet, and which the home infusion AOs must meet or exceed in their accreditation standards. These health and safety standards are being set forth in this final rule with comment period at 42 CFR part 486, subpart I. The AOs that currently accredit home infusion therapy suppliers have not heretofore been governed by any CMS regulations related to home infusion therapy accreditation or health and safety standards. These AOs have each created their own set of accreditations standards. These accreditation standards vary from AO to AO.

Section 1834(u)(5)(C) of the Act requires home infusion therapy suppliers to be accredited in order to receive payment for the services they provide. We proposed to require that the home infusion therapy accreditation program submitted to CMS for approval by each of the AOs that currently accredit home infusion therapy suppliers be separate and distinct accreditation programs that are not part of the AOs home health accreditation program. We proposed to further require that the AOs home infusion therapy accreditation standards meet or exceed the health and safety standards for home infusion therapy suppliers. Finally, we would require that the application meet the requirements of proposed 42 CFR 488.1010.

e. Oversight of Home Infusion Therapy Accrediting Organizations

As noted previously, we proposed to create a new set of regulations titled, "Approval and Oversight of Home Infusion Therapy Supplier Accrediting Organizations" at 42 CFR part 488, subpart L. These proposed regulations would set forth the application and reapplication procedures for national AOs seeking approval or re-approval of authority to accredit home infusion therapy suppliers; ongoing CMS oversight processes for approved AOs that accredit home infusion therapy suppliers; and, appeal procedures for AOs that accredit home infusion therapy suppliers. In this section of the final rule, we describe our regulatory provisions.

The following sections discuss the regulations, in their order.

(1) Basis and Scope (§ 488.1000)

We proposed at § 488.1000 to set forth the statutory authority related to this set of regulations. Sections 1834(u)(5) and 1861(iii) of the Act would be the statutory basis for these regulations. These sections of the Act provide the Secretary with the authority necessary to carry out the administration of the Medicare program. Section 1861 of the Act defines services, supplier types and benefits, and over whom Medicare may have authority. Section 1861(d) defines the term "supplier." Section 1834(u)(5) of the Act governs accreditation of home infusion therapy suppliers.

Section 1861(iii)(3)(D)(i)(III) of the Act requires that home infusion therapy suppliers be accredited by an organization designated under section 1834(u)(5) of the Act. Section 1834(u)(5) of the Act requires that the Secretary establish factors in designating accrediting organizations and designate accrediting organizations to accredit suppliers furnishing home infusion therapy by January 1, 2021.

Proposed § 488.1000(a) would set forth the statutory authority for the accreditation of home infusion therapy suppliers by the home infusion therapy AOs. Title 42 CFR 488.1000(b) would set forth the scope of the regulation, which is the application and reapplication procedures for national AOs seeking approval or re-approval of authority to accredit home infusion therapy suppliers; ongoing CMS oversight processes for approved of home infusion therapy AOs; and, appeal procedures for AOs of home infusion therapy suppliers.

(2) Definitions (§ 488.1005)

We proposed the following definitions:

- "*Accredited home infusion therapy supplier*" means a supplier that has demonstrated substantial compliance with a CMS-approved national home infusion therapy AO's applicable CMS-approved home infusion therapy accreditation program standards, which meet or exceed those of Medicare, and has been awarded accreditation by that AO.

- "*Qualified home infusion therapy supplier*" means an entity that meets the following criteria which are set forth at 1861(iii)(3)(D)(i): (1) Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; (2) ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-

hour-a-day basis; (3) is accredited by an organization designated by the Secretary pursuant to section 1834(u)(5); and (4) meets such other requirements as the Secretary determines appropriate.

- "*Immediate jeopardy*" means a situation in which the provider's or supplier's non-compliance with one or more Medicare accreditation requirements has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient, as codified at § 488.1.

- "*National accrediting organization*" means an organization that accredits supplier entities under a specific program and whose accredited supplier entities under each program are widely dispersed geographically across the United States. In addition, the specific program is active, fully implemented, and operational. This definition is codified at § 488.1.

- "*Reasonable assurance*" means an AO has demonstrated to CMS' satisfaction that its accreditation program requirements meet or exceed the Medicare program requirements. This definition is codified at § 488.1.

- "*Rural*" area means an area as defined at section 1886(d)(2)(D) of the Act.

- "*Substantial allegation of non-compliance*" means a complaint from any of a variety of sources (such as patient, relative, or third party), including complaints submitted in person, by telephone, through written correspondence, or in the newspaper, magazine articles or other media, that will, if found to be present, adversely affect the health and safety of patients and raises doubts as to a supplier's compliance with any of the Medicare home infusion therapy accreditation requirements. This definition is codified at § 488.1.

(3) Application and Reapplication Procedures for National Accrediting Organizations (§ 488.1010)

Proposed § 488.1010 would contain application and re-application procedures for all national AOs seeking CMS-approval of an accreditation program for home infusion therapy suppliers. Proposed § 488.1010(a) would provide a comprehensive listing of the information, supporting documentation, certifications, written statements and other data that prospective AOs for home infusion therapy suppliers would be required to include in their application for approval to accredit home infusion therapy suppliers. The proposed requirements under this section would apply to both initial applications for CMS-approval as well as applications for re-approval of an

existing CMS-approved home infusion therapy accreditation program. This proposed provision would also require the AOs for home infusion therapy supplies to furnish CMS with information that demonstrates that their accreditation program requirements meet or exceed the applicable Medicare requirements.

Proposed § 488.1010(a)(1) requires AOs for home infusion therapy suppliers seeking initial or renewed CMS-approval of their home infusion therapy accreditation program to demonstrate that they meet the definition of a “national accrediting organization.” Section 1865 of the Act requires that accrediting organizations be national in scope.

Proposed § 488.1010(a)(2) requires AOs to specifically identify the Medicare supplier type for which they are requesting CMS-approval or reapproval.

Proposed § 488.1010(a)(3) requires AOs to demonstrate their ability to take into account the capacities of home infusion therapy suppliers in rural areas (as defined in section 1834(u)(5)(A)(ii) of the Act.

Proposed § 488.1010(a)(4) requires the home infusion therapy AO to provide information that documents their knowledge, expertise, and experience in the healthcare field for which they offer accreditation and for which they are requesting approval.

Proposed § 488.1010(a)(5) requires the AO to submit a detailed crosswalk (in table format) that identifies, for each of the applicable Medicare health and safety requirements, the exact language of the accrediting organization’s comparable accreditation requirements and standards. This proposed requirement would allow CMS to evaluate whether the accreditation program standards meet or exceed the applicable Medicare requirements.

Proposed § 488.1010(a)(6) requires each AO for home infusion therapy suppliers to provide a detailed description of its survey process. This requirement is intended to allow CMS to gain a better understanding of an AO’s survey process and ensure that its survey and enforcement processes are comparable to Medicare’s health and safety standards (contained in 42 CFR part 486, subpart I).

Proposed § 488.1010(a)(7)(ii) requires home infusion therapy AOs that use offsite audits, or other evaluation strategies to evaluate the quality of services provided by a home infusion therapy supplier, to follow up these offsite audits with periodic onsite visits. We believe that it is very important for the AOs that accredit home infusion

therapy suppliers to follow-up off-site survey reviews with periodic on-site visits to ensure that the home infusion therapy supplier is complying with all accreditation standards and meeting all health and safety regulations.

We proposed at § 488.1010(a)(8), to require an AO for home infusion therapy suppliers to provide a description of the criteria for determining the size and composition of the onsite survey or offsite audit teams or teams used for other accreditation evaluation strategies.

We proposed at § 488.1010(a)(9) to require that an AO for home infusion therapy suppliers provide CMS with information regarding the overall adequacy of the number of surveyors, auditors, and other staff available to perform all survey related activities. Under this section, the home infusion therapy AO would also be required to provide an explanation as to how it will maintain an adequate number of trained surveyors on staff. The home infusion therapy AO must also describe its ability to increase the size of survey, audit, and other survey program staff to match growth in the number of accredited home infusion therapy suppliers while maintaining re-accreditation intervals for existing accredited home infusion therapy suppliers.

We proposed at § 488.1010(a)(10) to require that an AO for home infusion therapy suppliers provide CMS with detailed information about the individuals who perform survey activities, including onsite surveys, offsite audits and other review processes, for the purpose of ensuring accredited home infusion therapy suppliers maintain adherence to the accreditation program requirements.

Proposed § 488.1010(a)(11) requires each AO for home infusion therapy suppliers to describe the content, frequency and types of in-service training provided to survey and audit personnel.

We proposed at § 488.1010(a)(12) to require AOs for home infusion therapy suppliers to provide documentation which describes the evaluation systems used to monitor the performance of individual surveyors, survey teams, and staff that perform audit activities. This requirement will provide CMS with insight into how each home infusion therapy AO measures the performance of their surveyors, survey teams and staff that perform audit activities.

We proposed at § 488.1010(a)(13) to require the AO for home infusion therapy suppliers to provide the organization’s policies and procedures for avoiding and handling conflicts of

interest, including the appearance of conflicts of interest, involving individuals who conduct surveys, audits or participate in accreditation decisions.

Proposed § 488.1010(a)(14) requires the AO for home infusion therapy suppliers to provide CMS with documentation of its policies and procedures for handling disputes filed by a home infusion therapy supplier regarding survey or audit findings, or an adverse decision.

We proposed at § 488.1010(a)(15) requires that home infusion therapy AOs provide CMS with copies of the policies and procedures to be used when an accredited home infusion therapy supplier either—(1) removes or ceases furnishing services for which they are accredited; or (2) adds home infusion therapy services for which they are not accredited.

We proposed at § 488.1010(a)(16) to require the home infusion therapy AOs to provide CMS with the organization’s policies and procedures for responding to and investigating complaints and grievances against accredited suppliers.

We proposed at § 488.1010(a)(17) to require that the home infusion therapy AOs furnish a description of the AO’s accreditation status decision-making process.

We proposed at § 488.1010(a)(18) to require a home infusion therapy AOs to provide CMS with a list of all home infusion therapy suppliers currently accredited by that home infusion therapy AO.

We proposed at § 488.1010(a)(19) to require that the home infusion therapy AOs provide CMS with a schedule of all survey activity (including but not limited to onsite surveys, offsite audits and other types if survey strategies), expected to be conducted by the home infusion therapy AO during the 6-month period following submission of the application.

We proposed at § 488.1010(a)(20) to require that the home infusion therapy AO submit a written statement or document that demonstrates the organization’s ability to furnish CMS with the electronic data the home infusion therapy AO must report to CMS as required by proposed § 488.1035.

We proposed at § 488.1010(a)(21) to require that the home infusion therapy AO provide a description of the organization’s data management and analysis system with respect to its surveys and accreditation decisions.

We proposed at § 488.1010(a)(22) to require the home infusion therapy AO to furnish the three most recent annual

audited financial statements from their organization.

We proposed at § 488.1010(a)(23) to require the home infusion therapy AOs to provide a written statement, in which the home infusion therapy AO acknowledges, as a condition for approval, that the organization agrees to the items set forth in § 488.1010(a)(23)(i) through (vi).

Proposed § 488.1010(a)(23)(i) requires the home infusion therapy AO to provide a written statement acknowledging that, as a condition for approval, that if the home infusion therapy AO decides to voluntarily terminate its accreditation program, the home infusion therapy AO must provide written notification to CMS and all home infusion therapy suppliers accredited by that AO. This written notice must be provided at least 180 calendar days in advance of the effective date of the home infusion therapy AOs decision to voluntarily terminate its CMS-approved accreditation program.

Proposed § 488.1010(a)(24) requires the home infusion therapy AOs to provide CMS with a listing of the organization's fees for home infusion therapy accreditation. The home infusion therapy AO must notify CMS of any plans for reducing the burden and cost of accreditation to small or rural home infusion therapy suppliers. While CMS does not undertake to set or regulate the fees charges by a home infusion therapy AO, we do review fees charged by AOs to determine whether they are reasonable as directed by sections 1834(u)(5)(A)(iii) of the Act.

Proposed § 488.1010(b) requires home infusion therapy AOs to agree to submit any additional information, documentation, or attestations, including items not previously listed that CMS may deem necessary to make a determination for approval or denial of the home infusion therapy AO's application. Should we require this additional information, we would notify the home infusion therapy AO of the request and provide the home infusion therapy AO with a reasonable timeframe to submit the requested information.

We proposed at § 488.1010(c) to allow a home infusion therapy AO to withdraw its initial application for CMS's approval of its home infusion therapy accreditation program at any time before we publish the final **Federal Register** notice described at proposed § 488.1020(b). Proposed § 488.1020(b) requires that the final notice, published by CMS, specify the basis for our decision.

Proposed § 488.1010(d) requires CMS to complete its review of an application submitted by a home infusion therapy

AO within 210 calendar days from the date that CMS determines that the application is complete. We proposed that to determine completeness, each application would be assigned to a technical review team upon receipt by CMS.

We sought public comment on the application requirements set forth in § 488.1010. We further sought comments on the burden related to the requirements of the application procedure. We received the following public comments:

Comment: Several commenters expressed general concern about the time and cost burden that would be incurred by a home infusion therapy AO related to obtaining CMS approval for their accreditation program. Another commenter questioned what the additional time and cost burden to home infusion therapy AOs for the ongoing administration of their home infusion therapy accreditation program, after CMS approval is obtained.

Response: While we understand that there would be some time and cost burden associated with the accreditation process for home infusion therapy AOs, this burden is necessary because the CMS approval process is required by section 1834(u)(5)(B) of the Act which requires the Secretary to designate AOs to accredit home infusion therapy suppliers furnishing home infusion therapy not later than January 1, 2021.

Comment: Several home infusion therapy suppliers expressed concern that the additional or increased operational costs incurred by new of existing home infusion therapy AOs (such as training, staff wages, revision of accreditation standards to meet the new Medicare home infusion therapy health and safety standards, preparation of the application for CMS seeking CMS approval of the AOs home infusion therapy accreditation program meet new and/or different accreditation standards, etc.) are likely that these standards and associated costs will vary among AOs.

Response: While we understand that there would be some time and cost burden associated with the accreditation process for home infusion therapy AOs, this burden is necessary because the CMS approval process is required by section 1834(u)(5)(B) of the Act which requires the Secretary to designate AOs to accredit home infusion therapy suppliers furnishing home infusion therapy not later than January 1, 2021.

Comment: Several commenters urged CMS to amend proposed § 488.1010(a)(23)(i) to require an AO to provide home infusion therapy suppliers with a 180 day notice, rather than a 90 day notice of the AO's

voluntary withdrawal from the CMS accreditation program. These commenters stated the belief that the 90 day notice requirement would be too short a period of time for an otherwise compliant home infusion therapy supplier to secure new accreditation from a different CMS-approved home infusion therapy AO.

Response: We believe that, in most cases, an home infusion therapy AO that has decided to voluntarily terminate their CMS-approved home infusion therapy accreditation program is likely make this decision at least 6 months prior to the date that they would completely cease operations, in order to give them time to wrap up their business affairs and wind down operations. For example, the AO would need to complete any surveys that had been scheduled or refer these clients to other AOs. They would also need to provide notice to their accredited home infusion therapy suppliers of their decision to voluntarily terminate their CMS-approved home infusion therapy accreditation program.

We agree with these commenters that the 90 day notice period may not be a sufficient period of time in which an otherwise compliant home infusion therapy provider could seek out another CMS-approved home infusion therapy AO, file the required application, and complete the accreditation process. Therefore, we have decided to increase the notice requirement specified in § 488.1010(a)(23)(i) from 90 days to 180 days as requested.

It is important to note that § 488.1010(a)(23) requires the home infusion therapy AOs to provide a written statement in their application to CMS, in which the home infusion therapy AO acknowledges, as a condition for approval, that the organization agrees to the items set forth in § 488.1010(a)(23)(i) through (vi). However, the actual requirement that the home infusion therapy AO provide notice is set forth at § 488.1045(a). Since we will be increasing the notice requirement that is to be included in the statement that is to be provided in the application submitted by the home infusion therapy AO as a condition for approval as required by § 488.1010(a)(23)(i), we must also make a corresponding change to the notice requirement in § 488.1045(a).

Final Decision: Section 488.1010(23)(a)(i) will be amended by changing the notice requirement for home infusion therapy AOs that voluntarily terminate their CMS-approved accreditation program from 90 days to 180 days. This change requires that we also make a corresponding

change to the notice requirement of § 488.1045(a). (See the discussion of § 488.1045(a) in this final rule with comment period) for this corresponding change.

(4) Resubmitting a Request (§ 488.1015)

Proposed § 488.1015(a) requires that except as provided in paragraph (b), a home infusion therapy AO whose request for CMS' approval or re-approval of a home infusion therapy accreditation program was denied, or an organization that has voluntarily withdrawn an initial application, could resubmit its application if the organization had: (1) Revised its accreditation program to address the issues related to the denial of its previous request or its voluntary withdrawal; and (2) resubmitted the application in its entirety.

Proposed § 488.1015(b) provides that a home infusion therapy AO that has requested reconsideration of an application denial by CMS could not submit a new application until the pending reconsideration was administratively final. This proposed provision would ensure that review of accreditation matters on reconsideration are pending before only one administrative agency and one administrative level at a time.

We sought public comments on the requirements of § 488.1015. We did not receive any comments regarding § 488.1015.

Final Decision: Having received no comments in regards to § 488.1015, this section will be finalized as drafted, without modification.

(5) Public Notice and Comment (§ 488.1020)

Proposed § 488.1020(a) requires CMS to publish a notice in the **Federal Register** upon receipt of a complete application package. The notice would identify the organization, the type of home infusion therapy suppliers covered by the accreditation program, and provides for at least a 30-day public comment period (which begins on the date of publication of the **Federal Register** notice). The purpose of the **Federal Register** notice is to notify the public that a national AO has filed an application for approval of a home infusion therapy accreditation program and to seek public comment in response to this application. The requirement for the publication of a notice in the **Federal Register** when an application is received is an existing regulatory procedural requirement for all other AO types. We have added this requirement to the home infusion therapy AO approval and oversight regulations for

consistency, and because we believe that it is important for the public to have notice of accreditation organization activities.

Section 488.1020(b) requires that when CMS approves or re-approves an application for approval of a home infusion therapy AO's accreditation program, a final notice will be published in the **Federal Register**. This notice would have to specify the basis for CMS' decision. Section 488.1020(b)(1), requires that our final notice include at a minimum, the following information: (1) How the accreditation program met or exceeded Medicare accreditation program requirements; (2) the effective date of the CMS approval, which is not later than the publication date of the notice; and (3) the term of the approval (6 years or less).

If CMS makes a decision to disapprove a home infusion therapy AOs application, our final notice would state the deficiencies found in the application and the reason why the AOs accreditation program did not meet or exceeded Medicare accreditation program requirements. However, an AO has the option of voluntarily withdrawing its application at any time up until the publication of the final notice.

We proposed at § 488.1020(b)(2) that if CMS did not approve a home infusion therapy AO's application for approval of its home infusion therapy accreditation program, the final notice would explain how the home infusion therapy AO failed to meet Medicare home infusion therapy accreditation program requirements. This notice would indicate the effective date of the decision.

We sought comment on the requirements of § 488.1020, including on the appropriate term for approval of an AO. We did not receive any comments regarding § 488.1020.

Final Decision: Having received no comments in regards to § 488.1020, this section will be finalized as drafted, without modification.

(6) Release and Use of Accreditation Surveys (§ 488.1025)

Proposed § 488.1025 requires a home infusion therapy AO to include, in its accreditation agreement with each home infusion therapy supplier, an acknowledgement that the home infusion therapy supplier agrees to release to CMS a copy of its most current accreditation survey and any information related to the survey that CMS may require, including the home infusion therapy supplier's corrective action plans. Proposed § 488.1025(a)

provides that CMS may determine that a home infusion therapy supplier does not meet the applicable Medicare conditions or requirements on the basis of its own investigation of the accreditation survey or any other information related to the survey.

Proposed § 488.1025(b) prohibits CMS from disclosing home infusion therapy survey reports or survey related information according to section 1865(b) of the Act. However, CMS would be permitted to publicly disclose an accreditation survey and information related to the survey, upon written request, to the extent that the accreditation survey and survey information is related to an enforcement action taken by CMS.

CMS would use the home infusion therapy supplier accreditation survey information for purposes such as: (1) Confirmation of the home infusion therapy supplier's eligibility for Medicare participation; (2) to review and approve the home infusion therapy AO's recommendations regarding accreditation; (3) to review the home infusion therapy AO's investigations of complaints; and (4) to review the corrective action taken by the AO when deficiencies are found on survey.

We sought public comments on the requirements of § 488.1025. We did not receive any comments regarding § 488.1025.

Final Decision: Having received no comments in regards to § 488.1025, this section will be finalized as drafted, without modification.

(7) Ongoing Review of Accrediting Organizations (§ 488.1030)

Proposed § 488.1030 clarifies that a formal accreditation program review could be opened on an ongoing basis. Specifically, this proposed section would describe standardized requirements related to the ongoing federal review of home infusion therapy AOs and their approved accreditation programs. This proposed section would clarify that CMS oversight of accreditation programs is consistent across home infusion therapy AOs. We are committed to treating all home infusion therapy AOs subject to our oversight in the same manner. Under proposed § 488.1030, we could conduct the following three types of reviews of an AO's home infusion therapy accreditation programs: (1) Performance review; (2) comparability review; and (3) CMS-approved accreditation program review.

Proposed § 488.1030(a) allows CMS to perform a performance review, in which we would evaluate the performance of each CMS-approved home infusion

therapy accreditation program on an ongoing basis. Specifically, we would review the following aspects of a home infusion therapy AO's for home infusion therapy program performance: The organization's survey activity, and the organization's continued fulfillment of the requirements stated in § 488.1010.

Proposed § 488.1030(b) allows CMS to perform a comparability review to assess the equivalency of a home infusion therapy AO's CMS-approved home infusion therapy accreditation program requirements with comparable Medicare home infusion therapy accreditation requirements. Proposed § 488.1030(b)(1) allows CMS to perform a comparability review when CMS imposes new or revised Medicare accreditation requirements. When this occurs, proposed § 488.1030(b)(1) requires CMS to provide written notice to the home infusion therapy AOs when changes have been made to the Medicare home infusion therapy accreditation requirements. Proposed § 488.1030(b)(2) requires the home infusion therapy accrediting organization to make revision to its home infusion therapy accreditation standards or survey process so as to incorporate the new or revised Medicare accreditation requirements.

Proposed § 488.1030(b)(3) would further require that the written notice sent by CMS to the home infusion therapy AO specify a deadline (not less than 30 days) by which the home infusion therapy AO must prepare and submit their home infusion therapy accreditation program requirement revisions and the timeframe for implementation. Proposed § 488.1030(b)(4) would allow a home infusion therapy AO to submit a written request for an extension of the submission deadline as long as this request was submitted prior to the original deadline.

Proposed at § 488.1030(b)(5) requires that, after completing the comparability review, CMS would provide written notification to the home infusion therapy AO, specifying whether or not their revised home infusion therapy accreditation program standards continued to meet or exceed all applicable Medicare requirements. We propose at § 488.1030(b)(6) that if, no later than 60 days after receipt of the home infusion therapy AO's accreditation standard changes, CMS did not provide the written notice to the home infusion therapy AO, then the revised home infusion therapy program accreditation standards would be deemed to meet or exceed all applicable Medicare requirement and the accreditation program will have

continued CMS-approval without further review or consideration.

Proposed § 488.1030(b)(7) provide that if a home infusion therapy AO was required to submit a new application because CMS imposed new regulations or made significant substantive revisions to the existing regulations, CMS would provide notice of the decision to approve or disapprove the application within the time period specified in proposed § 488.1010(d).

We proposed at § 488.1030(b)(8) that if a home infusion therapy AO failed to submit its changes within the required timeframe, or failed to implement the changes that had been determined by CMS to be comparable, CMS could open an accreditation program review in accordance with § 488.1030(d).

When a home infusion therapy AO proposes to adopt new home infusion therapy accreditation standards or changes, in its survey process, we proposed at § 488.1030(c)(1) to require the home infusion therapy AO to provide notice to CMS no less than 60 days prior to the planned implementation date of the changes. Proposed § 488.1030(c)(2) prohibits the home infusion therapy AO from implementing these changes before receiving CMS' approval except as provided in proposed § 488.1030(c)(4). Proposed § 488.1030(c)(3) requires that this written notice contain a detailed description of the changes to be made to the organization's home infusion therapy accreditation standards, including a detailed crosswalk (in table format) that states the exact language of the revised accreditation requirements and the corresponding Medicare requirements for each. The requirements of proposed §§ 488.1030(c)(2) and 488.10(c)(3) ensures that the home infusion therapy AO provides CMS with advance notice of any changes to their home infusion therapy accreditation requirements and survey processes. This notice would allow CMS time to review these changes to ensure that the revised home infusion therapy accreditation standards and survey processes continue to meet or exceed all applicable Medicare home infusion therapy requirements and continue to be comparable to all applicable Medicare home infusion therapy survey processes, and provide a response to the home infusion therapy AO. This proposed section would also prohibit home infusion therapy AOs from implementing any of the changes in their home infusion therapy accreditation requirements and survey processes, until CMS approval has been received.

Proposed § 488.1030(c)(4) requires CMS to provide written notice to the home infusion therapy accrediting organization indicating whether the home infusion therapy accreditation program, including the revisions, continued or does not continue to meet or exceed all applicable Medicare home infusion therapy requirements. If CMS found that the accrediting organization's home infusion therapy accreditation program, including the revisions did not continue to meet or exceed all applicable Medicare home infusion therapy requirements, CMS would have to state the reasons for these findings.

Section 488.1030(c)(5) requires CMS to provide this written notice to the home infusion therapy AO by the 60th calendar day following receipt of the home infusion therapy AO's written changes as to whether the home infusion therapy AO's revised home infusion therapy accreditation program standards and survey processes have been deemed to meet or exceed all applicable Medicare home infusion therapy requirements and have continued CMS approval without further review or consideration. This proposed section would further specify that if CMS failed to provide the required written notice to the home infusion therapy AO by the 60-day deadline, the home infusion therapy AO's revised accreditation program standards would be deemed to meet or exceed all applicable Medicare requirements and have continued CMS approval without further review or consideration.

Proposed § 488.1030(c)(5) permits CMS to open an accreditation program review, in accordance with § 488.1030(d), if a home infusion therapy AO implemented changes to their home infusion therapy accreditation requirements or survey process that were not determined nor deemed by CMS to be comparable to the applicable Medicare requirements.

We proposed at § 488.1030(d) to permit CMS to initiate an accreditation program review when a comparability or performance review reveals evidence that a home infusion therapy AO's CMS-approved home infusion therapy accreditation program is in substantial non-compliance with the requirements of the home infusion therapy health and safety regulations contained in 42 CFR part 486, subpart B. Proposed § 488.1030(d)(1) requires CMS to provide written notice to the home infusion therapy AO when a home infusion therapy accreditation program review is initiated. Proposed § 488.1030(d)(1)(i) through (iv) set forth the requirements for this written notice,

which should contain the following information: (i) A statement of the instances, rates or patterns of non-compliance identified, as well as other related information, if applicable; (ii) a description of the process to be followed during the review, including a description of the opportunities for the home infusion therapy AO to offer factual information related to CMS' findings; (iii) a description of the possible actions that may be imposed by CMS based on the findings of the accreditation program review; and (iv) the actions the home infusion therapy AO will have to take to address the identified deficiencies, and the length of the accreditation program review probation period, which would include monitoring of the home infusion therapy AO's performance and implementation of the corrective action plan. The probation period is not to exceed 180 calendar days from the date that CMS has approved the home infusion therapy AOs plan of correction (which is the AO written plan for correcting any deficiencies in its home infusion therapy accreditation program that were found by CMS on a program review).

At § 488.1030(d)(2), we proposed that CMS reviews and approves the home infusion therapy AO's plan of correction for acceptability within 30 days after receipt. Proposed § 488.1030(d)(3) provides that CMS monitors the implementation of the home infusion therapy accrediting organization's plan of correction for a period not to exceed 180 days from the date of approval. During the 180-day review period, CMS monitors implementation of the accepted plan of correction as well as progress towards correction of identified issues and areas of non-compliance that triggered the accreditation program review.

We proposed at § 488.1030(d)(4) to authorize CMS to place the home infusion therapy AO's CMS-approved accreditation program on probation for a subsequent period of up to 180 calendar days, if necessary. The additional period of time may be necessary if CMS determines, as a result of the home infusion therapy accreditation program review or a review of an application for renewal of an existing CMS-approved accreditation program, that the home infusion therapy AO has failed to meet any of the requirements of proposed § 488.1010, or has made significant progress correcting identified issues or areas of non-compliance, but requires additional time to complete full implementation of corrective actions or demonstrate sustained compliance. If a home

infusion therapy AO's term of approval expires before the 180-day period is completed, the probationary period would be deemed to end upon the day of expiration of the home infusion therapy AO's term of approval. In the case of a renewal application where we have placed the home infusion therapy accreditation program on probation, we proposed that any approval of the applications must be conditional while the program remains on probation.

If we place a home infusion therapy AO's accreditation program on probation, proposed § 488.1030(d)(4)(i) requires CMS to issue a written determination to the home infusion therapy AO, within 60 calendar days after the end of any probationary period. The written determination must state whether or not the CMS-approved home infusion therapy accreditation program continued to meet the requirements of this section and the reasons for the determination.

If we determined that withdrawal of approval from a CMS-approved accreditation program was necessary, proposed § 488.1030(d)(4)(ii) requires CMS to send written notice to the home infusion therapy AO which contained the following information: (1) Notice of CMS' removal of approval of the home infusion therapy AOs accreditation program; (2) the reason(s) for the removal; and (3) the effective date of the removal determined in accordance with § 488.1030(d)(4)(ii).

If CMS withdrew the approval of a home infusion therapy AO accreditation program, § 488.1030(d)(4)(iii) requires CMS to publish a notice of its decision to withdraw approval of the accreditation program in the **Federal Register**. This notice will have to include the reasons for the withdrawal, and a notification that the withdrawal will become effective 60 calendar days after the date of publication in the **Federal Register**. The publication of this **Federal Register** notice is notice will be necessary to put interested stakeholders, such as the home infusion therapy suppliers that are accredited by the affected AO on notice about the withdrawal of CMS-approval of their AO, because this will have an effect on the status of their accreditation.

Proposed § 488.1030(e) allows CMS to immediately withdraw the CMS approval of an home infusion therapy AO's home infusion therapy accreditation program, if at any time CMS makes a determination that the continued approval of that home infusion therapy accreditation program poses an immediate jeopardy to the patients of the entities accredited under the program; or the continued approval

otherwise constitutes a significant hazard to the public health.

We proposed at § 488.1030(f) to mandate that any home infusion therapy AO whose CMS approval of its home infusion therapy accreditation program has been withdrawn must notify, in writing, each of its accredited home infusion therapy suppliers of the withdrawal of CMS approval and the implications for the home infusion therapy suppliers' payment status no later than 30 calendar days after the notice is published in the **Federal Register**. This proposed requirement would protect the home infusion therapy suppliers that have received their accreditation from a home infusion therapy AO that has had its CMS approval of their home infusion therapy accreditation program removed.

We sought public comments on the requirements and the burden associated with the requirements of § 488.1030.

We did not receive any comments related to the burden associated with requirements § 488.1030. However, we did receive the following comment related to the requirements of § 488.1030:

Comment: Several commenters have requested that CMS clarify that the non-compliance that triggers a review under § 488.1030 must not only be "substantial" but also be "material."

Response: The term "substantial" means "of considerable importance, size or worth." The term "material" means "important, relevant or essential."⁸⁰ We believe that these terms are similar enough in nature that adding the word "material" would be duplicative. Our goal, as stated in the proposed rule, is to make the AO approval and oversight regulations as consistent, as possible, with the AO approval and oversight regulations for Medicare-certified providers and suppliers at 42 CFR 488.5 to 488.13. The term "substantial and material" is not used in regulation § 488.8 titled "Ongoing review of accrediting organizations," which is the comparable regulation to § 488.1030 regulations for Medicare-certified providers and suppliers. Therefore, we believe that to add a different standard for home infusion therapy AOs would be inconsistent and would result in different standards across the AO types.

Also, many AOs have accreditation programs for numerous types of providers and suppliers. If CMS were to use varying standards for different types of providers and suppliers, it would make it difficult for these AOs with multiple accreditation programs to administer these programs in a smooth

⁸⁰ Merriam Webster Online Dictionary.

and consistent manner. Therefore, we believe that it is important that CMS keep the language of § 488.1030 consistent with that of § 488.8. We would also note that we have broad discretion to monitor the performance of AOs and to take action when necessary.

Final Decision: After consideration on the comments received, we have decided to finalize § 488.1030 without modification.

(8) Ongoing Responsibilities of a CMS-Approved Accreditation Organization (§ 488.1035)

Proposed § 488.1035 requires a home infusion therapy AO to provide certain information to CMS and carry out certain activities on an ongoing basis. More specifically § 488.1035(a) requires the home infusion therapy AO to provide CMS with all of the following in written format (either electronic or hard copy):

- Copies of all home infusion therapy accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of findings with respect to unmet CMS requirements);
- Notice of all home infusion therapy accreditation decisions.
- Notice of all complaints related to home infusion therapy suppliers.
- Information about all home infusion therapy accredited suppliers against which the home infusion therapy AO has taken remedial or adverse action, including revocation, withdrawal, or revision of the home infusion therapy supplier's accreditation.
- Summary data specified by CMS that relate to the past year's home infusion therapy accreditation activities and trends which is to be provided on an annual basis.
- Notice of any changes in its home infusion therapy accreditation standards or requirements or survey process.

Proposed § 488.1035(b) requires a home infusion therapy AO to submit an acknowledgment of receipt of CMS' notification of a change in CMS requirements within 30 days from the date of the notice. Section 488.1035(c) requires that a home infusion therapy AO permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

Proposed § 488.1035(d) requires that within 2 business days of identifying a deficiency of an accredited home infusion therapy supplier that poses immediate jeopardy to a beneficiary or to the general public, the home infusion therapy AO must provide CMS with written notice of the deficiency and any adverse action implemented by the home infusion therapy AO. Section

488.1035(e) requires that within 10 calendar days after our notice to a CMS-approved home infusion therapy AO that CMS intends to withdraw approval of the home infusion therapy AO, the home infusion therapy AO must provide written notice of the withdrawal to all of the organization's accredited home infusion therapy suppliers.

We sought public comment on the requirements and the burden associated with § 488.1035. We received no comments in regards to requirements and the burden associated with § 488.1035.

Final Decision: As no comments related to § 488.1035 were received, this section to the proposed regulations will be finalized as drafted and without modifications.

(9) Onsite Observations of Accrediting Organization Operations (§ 488.1040)

We proposed at § 488.1040(a) and (b) to permit CMS to conduct an onsite inspection of the home infusion therapy AOs operations and offices at any time to verify the organization's representations and to assess the organization's compliance with its own policies and procedures. Activities to be performed by CMS staff during the onsite inspections may include, but are not limited to: (1) Interviews with various home infusion therapy AO staff; (2) review of documents, and survey files, audit tools and related records; (3) observation of meetings concerning the accreditation process; (4) auditing meetings concerning the accreditation process; (5) observation of in-progress surveys and audits; (6) evaluation of the home infusion therapy AO's survey results and accreditation decision-making process.

CMS would perform onsite visits to a home infusion therapy AOs offices only for specific reasons. For example, when an AO had filed an initial or renewal application for approval of its home infusion therapy accreditation program, CMS would perform an onsite visit to the AOs offices as part of the application review process. If CMS has opened a program review and put the home infusion therapy AO on probation for a 180 day period, we would perform an onsite visit to the AOs offices to check of the AOs progress in implementing the plan of correction.

If CMS decides to perform an onsite visit to the home infusion therapy AOs offices, we would notify the AO. We would coordinate with the AO staff to schedule the onsite visit at mutually agreed upon date and time.

The intended purpose of this proposed section is to provide CMS with an opportunity to observe, first

hand, the daily operations of home infusion therapy AOs and to ensure that the home infusion therapy accreditation program is fully implemented and operational as presented in the written application. Onsite inspections would strengthen our continuing oversight of the home infusion therapy AO performance because they provide an opportunity for us to corroborate the verbal and written information submitted to CMS by the home infusion therapy AO in their initial and renewal applications. In addition, onsite inspections would allow CMS to assess the home infusion therapy AO's compliance with its own policies and procedures.

We sought public comments on the requirements of and the burden related to § 488.1040. However, we received no comments in regards to requirements and the burden associated with § 488.1040.

Final Decision: As no comments related to § 488.1040 were received, this section to the proposed regulations will be finalized as drafted and without modifications.

(10) Voluntary and Involuntary Termination (§ 488.1045)

The proposed provisions related to the voluntary and involuntary termination of CMS approval of a home infusion therapy AO's accreditation program are set out at § 488.1045. Proposed § 488.1045(a) addresses voluntary termination of a home infusion therapy AO's accreditation program by the home infusion therapy AO. A home infusion therapy AO that decides to voluntarily terminate its CMS-approved accreditation program must provide written notice to CMS and each of its accredited home infusion therapy suppliers at least 180 days in advance of the effective date of the termination. This written notice must state the implications for the home infusion therapy supplier's payment should there be a lapse in their accreditation status.

Proposed § 488.1045(b) addresses CMS' involuntary termination of a home infusion therapy AO's CMS-approved accreditation program. Once CMS publishes the notice in the **Federal Register** announcing its decision to terminate the accrediting organization's home infusion therapy accreditation program, the home infusion therapy AO would have to provide written notification to all home infusion therapy suppliers accredited under its CMS-approved home infusion therapy accreditation program no later than 30 calendar days after the notice was published in the **Federal Register**. This

notice would state that CMS is withdrawing its approval of the home infusion therapy AO's accreditation program and the implications for their payment, should there be a lapse in their accreditation status.

Proposed § 488.1045(c) addresses the requirements that would apply to both voluntary and involuntary terminations of CMS approval of the home infusion therapy AO. Proposed § 488.1045(c)(1) provides that the accreditation status of affected home infusion therapy suppliers will be considered to remain in effect until their current term of accreditation expired. In the case where a home infusion therapy AO has been removed as a CMS-approved AO, any home infusion therapy supplier that is accredited by the organization during the period beginning on the date the organization was approved by CMS until the date the organization was removed, shall be considered accredited for its remaining accreditation period.

Proposed § 488.1045(c)(2) provides that for any home infusion therapy supplier, whose home infusion therapy AO's CMS approval has been voluntarily or involuntarily terminated by CMS, and who wishes to continue to receive reimbursement from Medicare, must provide written notice to CMS at least 60-calendar days prior to its accreditation expiration date which states that the home infusion therapy supplier has submitted an application for accreditation under another CMS-approved home infusion therapy accreditation program. This proposed section further states that failure to comply with this 60-calendar day requirement prior to expiration of their current accreditation status could result in a suspension of payment.

Proposed § 488.1045(c)(3) requires that the terminated home infusion therapy AO must provide a second written notification to all accredited suppliers 10 calendar days prior to the organization's accreditation program effective date of termination.

The proposed notice provisions at § 488.1045(c)(2) and (3) could help prevent home infusion therapy suppliers from suffering financial hardship that could result from a denial of payment of Medicare claims if their home infusion therapy accreditation lapses as a result of the voluntary or involuntary termination of a CMS-approved home infusion therapy AO program.

We proposed at § 488.1045(d), that if a home infusion therapy supplier requests a voluntary withdrawal from accreditation, it will not be possible for the withdrawal to become effective until the home infusion therapy AO

completes three required steps. First, the AO would have to contact the home infusion therapy supplier to seek written confirmation that the home infusion therapy supplier intended to voluntarily withdraw from the accreditation program. Second, the home infusion therapy AO would have to advise home infusion therapy supplier, in writing, of the statutory requirement at section 1861(iii)(3)(D)(i)(III) of the Act for requiring accreditation for all home infusion therapy suppliers. Third, the home infusion therapy AO would have to advise the home infusion therapy supplier of the possible payment consequence for a lapse in accreditation status. Section 488.1045(d)(3) requires the home infusion therapy AO to submit their final notice of the voluntary withdrawal of accreditation by the home infusion therapy supplier 5 business days after the request for voluntary withdrawal was ultimately processed and effective.

We believe that it is important that the home infusion therapy seek confirmation that the home infusion therapy supplier has indeed requested a voluntary termination of their accreditation. This confirmation would prevent the erroneous termination of the accreditation of a home infusion therapy supplier that did not request it or had subsequently withdrawn their request for voluntary termination.

We believe that it is also important for the home infusion therapy AO to provide the required written notice to the home infusion therapy supplier that requests a voluntary withdrawal from accreditation, so that the home infusion therapy supplier has been fully informed of the requirements for accreditation according to section 1861(iii)(3)(D)(i)(III) of the Act and the payment consequences of being unaccredited. If there is a lapse in the accreditation status of the home infusion therapy supplier, they would not be eligible to receive payment from Medicare for services furnished to Medicare beneficiaries. A home infusion therapy supplier that is unaware of this payment consequence could suffer financial hardship due to furnishing services to Medicare beneficiaries for which they cannot be reimbursed after a lapse in accreditation.

We solicited public comments on the requirements of and the burden related to § 488.1045.

Comment: A commenter expressed concern that the requirements of proposed § 488.1045(d) would be extremely burdensome for the home infusion therapy AO to implement. This

section provides that if a home infusion therapy supplier requested a voluntary withdrawal from accreditation, it would not be possible for the withdrawal to become effective until the home infusion therapy AO completed the following three required steps: (1) The AO must contact the home infusion therapy supplier to seek written confirmation that the home infusion therapy supplier intended to voluntarily withdraw from the accreditation program; (2) the home infusion therapy AO must advise home infusion therapy supplier, in writing, of the statutory requirement at 1861(iii)(3)(D)(i)(III) of the Act for requiring accreditation for all home infusion therapy suppliers; and (3) the home infusion therapy AO must advise the home infusion therapy supplier of the possible payment consequence for a lapse in accreditation status. Proposed § 488.1045(d)(3) would require the home infusion therapy AO to submit their final notice of the voluntary withdrawal of accreditation by the home infusion therapy supplier 5 business days after the request for voluntary withdrawal was ultimately processed and effective.

In support of this contention that the previous requirements would be too burdensome, the commenter stated the belief that the home infusion therapy supplier would be responsible for knowing the CMS rules of coverage. AO's should provide this information to the supplier in the form of the AO's accreditation process and/or procedures. The AO should not have the burden of producing documentation that they informed the supplier at 3 separate times of what could happen if they withdrew their accreditation.

Response: We disagree with this commenter's contention that the requirements of proposed § 488.1045(d) are burdensome for the home infusion therapy AO to implement with the business technology that is readily available to each AO. It is important to point out that all 3 of these previously discussed steps can be accomplished quickly and effectively and would take a relatively short period of time. We say this because this section merely requires that each of the 3 categories of information is obtained and disseminated to the home infusion therapy supplier. This section does not require them to be accomplished separately at different times or on different dates.

Similarly, we believe that this task can be accomplished by the AO sending one single correspondence to the home infusion therapy supplier and simple follow-up monitoring to ensure that the

home infusion therapy supplier returns the required written confirmation to the AO acknowledging that they do intend to voluntarily withdraw from the accreditation program. To simplify matters further and save even more time, we believe that the AO could create a pre-prepared home infusion therapy supplier notification letter and an acknowledgment of withdrawal from accreditation form in a fillable .pdf template format. Thereafter, when a home infusion therapy supplier notifies an AO that they are withdrawing from that AO, all the AO would need to do is open up the AO notification and home infusion therapy supplier acknowledgement templates on their computer, fill in the blanks on the fillable .pdf template forms, print the forms and send them HIT supplier via hand deliver, text, email, fax or U.S.P., federal Express, etc. Then AO would only have to await for the HIT supplier to return the signed acknowledgement form.

Comment: § 488.1045(c)(2) provides that if a home infusion therapy supplier, whose home infusion therapy AO's CMS approval has been voluntarily or involuntarily terminated by CMS wishes to continue to receive reimbursement from Medicare, that home infusion therapy supplier must provide written notice to CMS at least 60-calendar days prior to its accreditation expiration date which states that the home infusion therapy supplier has submitted an application for accreditation under another CMS-approved home infusion therapy accreditation program. This proposed section further states that failure to comply with this 60-calendar day requirement prior to expiration of their current accreditation status could result in a suspension of payment.

Several commenters have urged CMS to amend the notice requirement of proposed § 488.1045(c)(2). These commenters have requested that CMS decrease the minimum time period by which affected home infusion therapy suppliers must provide their written notice to CMS informing us that they have filed an application with another home infusion therapy AO from 60 days to 5 days prior to the effective date of the termination of the home infusion therapy suppliers current term of accreditation. These commenters stated the belief that the change to a 5 day notice requirement will ensure that the second AO termination notice to providers can be acted upon if, for any reason, the original termination notice was missed.

Response: We understand the concern on the part of home infusion therapy suppliers about possibly missing the

first notice sent by their home infusion therapy AO when that AOs CMS-approval has been voluntarily or involuntarily withdrawn. We believe that in the event a home infusion therapy AO voluntarily or voluntarily has its CMS-approval terminated, there will be ample notice provided.

In the case of an involuntary termination of an AOs CMS approval, § 488.1045(b) as finalized requires that CMS publish a notice in the **Federal Register** announcing its decision to terminate the accrediting organization's home infusion therapy accreditation program, therefore, the home infusion therapy AO will have to provide written notification to all home infusion therapy suppliers accredited under its CMS-approved home infusion therapy accreditation program no later than 30 calendar days after the notice is published in the **Federal Register**. This notice must state that CMS is withdrawing its approval of the home infusion therapy AO's accreditation program, and also discuss the implications for the supplier's payment, should there be a lapse in their accreditation status. In the case of a voluntary termination of an AO's CMS approval, proposed § 488.1045(d) provides that it will not be possible for the withdrawal to become effective until the home infusion therapy AO completes three required steps: (1) The AO must contact the home infusion therapy supplier to seek written confirmation that the home infusion therapy supplier intends to voluntarily withdraw from the accreditation program; (2) the home infusion therapy AO must advise home infusion therapy supplier, in writing, of the statutory requirement at section 1861(iii)(3)(D)(i)(III) of the Act for requiring accreditation for all home infusion therapy suppliers; and (3) the home infusion therapy AO must advise the home infusion therapy supplier of the possible payment consequence for a lapse in accreditation status. Furthermore, § 488.1045(d)(3) requires the home infusion therapy AO to submit a final notice of the voluntary withdrawal of accreditation by the home infusion therapy supplier 5 business days after the request for voluntary withdrawal is ultimately processed and effective.

In addition to the notices required by the regulatory provisions previously referenced, CMS will take all appropriate steps to ensure that the affected home infusion therapy suppliers are given timely notice about the termination of their home infusion therapy AO's CMS-approved home infusion therapy accreditation program.

Some possible methods CMS would use to make this information available to these affected home infusion therapy suppliers include, but are not limited to posting of information on the Quality, Safety and Oversight Group (QSOG) web page, notification sent via email and email blasts, information published in the Medicare Learning Network newsletter, Medicare payment manual bulletin, newsletter and in Medicare Learning Network publications, and discussion during Open Door Forums.

We believe that the requirement that affected home infusion therapy suppliers provide CMS with written notice that they have filed an application for accreditation with another CMS-approved home infusion therapy AO at least 60 days prior to the expiration of their current term of accreditation is an essential requirement for several reasons. First, it ensures CMS that all home infusion therapy suppliers affected by a voluntary or involuntary termination of a particular AO's CMS-approved accreditation program have indeed filed applications with other CMS-approved home infusion therapy AOs in a timely manner.

Second, the required 60 day written notice to be provided by these affected home infusion therapy suppliers informs CMS that they have already filed an application and initiated the accreditation process with another CMS-approved home infusion therapy AO. This in turn, will trigger the CMS payment system not to continue paying these home infusion therapy suppliers until their new accreditation information is received.

The requirement that written notice be submitted by all affected home infusion therapy suppliers at least 60 days prior to the expiration of their current terms of accreditation provides CMS with assurances that the accreditation process for each these affected home infusion therapy suppliers has already been initiated, is either substantially completed or will be completed prior to the expiration of the affected home infusion therapy suppliers current term of accreditation and that CMS can be assured that they are not going to be paying claims submitted by non-accredited home infusion therapy supplier.

The accreditation process takes several months, at a minimum. If CMS were to allow these home infusion therapy suppliers to wait until 5 days prior to the expiration date of their current term of accreditation to notify CMS that they have initiated the accreditation process (filed an application) with another AO, CMS would have no assurance that the

accreditation process will be completed or substantially completed by the time their current term of accreditation lapses. If this were the case, CMS would not be able to prevent a lapse in payment to these home infusion therapy suppliers that find themselves in the situation in which the CMS-approval of their AO has been withdrawn. Therefore, this requirement is intended to protect those otherwise compliant home infusion therapy suppliers, who find themselves, through no fault of their own, in the situation in which their current AO is no longer CMS-approved.

Final Decision: After consideration of the comments received, we have decided not to change the notification requirement set forth in § 488.1045(c)(2). Therefore, we are finalizing the provisions of section § 488.1045 without modification.

(11) Reconsideration (§ 488.1050)

We proposed at § 488.1050 to set forth the appeal process through which a home infusion therapy AO may request reconsideration of an unfavorable decision made by CMS. Proposed at § 488.1050(b)(1), the home infusion therapy AO will have to submit a written request for reconsideration within 30 calendar days of the receipt of the CMS notification of an adverse determination or non-renewal. Proposed § 488.1050(b)(2) requires the home infusion therapy AOs to submit a written request for reconsideration which specifies the findings or issues with which the home infusion therapy AO disagreed and the reasons for the disagreement. Proposed § 488.1050(b)(3) allows a home infusion therapy AO to withdraw their request for reconsideration at any time before the administrative law judge issues a decision.

We proposed at § 488.1050(c)(1) to establish requirements for CMS when a request for reconsideration has been received from a home infusion therapy AO. Specifically, CMS would be required to provide the home infusion therapy AO with: The opportunity for an administrative hearing with a hearing officer appointed by the Administrator of CMS; the opportunity to present, in writing and in person, evidence or documentation to refute CMS' notice of denial, termination of approval, or non-renewal of CMS approval and designation. Proposed § 488.1050(c)(2) requires CMS to send the home infusion therapy AO written notice of the time and place of the informal hearing at least 10 business days before the scheduled hearing date.

We proposed at § 488.1050(d)(1) to establish rules for the administrative hearing such as who may attend the hearing on behalf of each party, including but not limited to legal counsel, technical advisors, and non-technical witnesses that have personal knowledge of the facts of the case. This proposed section would also specify the type of evidence that may be introduced at the hearing. Specifically, we would specify and clarify, at proposed § 488.1050(d)(4), that the hearing officer would not have the authority to compel by subpoena the production of witnesses, papers, or other evidence. Proposed § 488.1050(d)(5) provides that the legal conclusions of the hearing officer within 45 calendar days after the close of the hearing. Proposed § 488.1050(d)(6) requires the hearing officer to present his or her findings and recommendations in a written report that includes separately numbered findings of fact. According to proposed § 488.1050(d)(7), the decision of the hearing officer would be final.

We sought public comments on the requirements of § 488.1050. We received no comments on the requirements of § 488.1050.

Final Decision: Having received no comments in regards to § 488.1050, we are finalizing this provision without modification.

D. Payment for Home Infusion Therapy Services

1. Temporary Transitional Payment for Home Infusion Therapy Services for CYs 2019 and 2020

In the CY 2019 HH PPS proposed rule (83 FR 32340) we discussed the implementation of the home infusion therapy services temporary transitional payment under paragraph (7) of section 1834(u) of the Act, as added by section 50401 of the BBA of 2018 (Pub. L. 115-123). This section provided for a temporary transitional payment for administration of home infusion drugs for 2019 and 2020. These services must be furnished by an eligible home infusion supplier in the individual's home to an individual who is under the care of an applicable provider and where there is a plan of care established and periodically reviewed by a physician prescribing the type, amount, and duration of infusion therapy services. Section 1834(u)(7)(F) of the Act defines eligible home infusion suppliers as suppliers that are enrolled in Medicare as pharmacies that furnish external infusion pumps and external infusion pump supplies, and that maintain all pharmacy licensure requirements in the State in which the

applicable infusion drugs are administered. This means that existing DME suppliers that are enrolled in Medicare as pharmacies that provide external infusion pumps and supplies are considered eligible home infusion suppliers. Section 1834(u)(7)(A)(iii) of the Act defines the term "transitional home infusion drug" using the same definition as "home infusion drug" under section 1861(iii)(3)(C) of the Act, which is a drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of DME. Additionally, section 1834(u)(7)(C) of the Act specifies the HCPCS codes for the drugs and biologicals covered under the Local Coverage Determinations (LCDs) for External Infusion Pumps, and identifies three payment categories for which a single payment amount will be established for home infusion therapy services furnished on each infusion drug administration calendar day. Payment category 1 includes antifungals and antivirals, uninterrupted long-term infusions, pain management, inotropic, and chelation drugs. Payment category 2 includes subcutaneous immunotherapy infusions. Payment category 3 includes certain chemotherapy drugs. The payment category for subsequent transitional home infusion drug additions to the LCDs and compounded infusion drugs not otherwise classified, as identified by HCPCS codes J7799 and J7999, will be determined by the Medicare administrative contractors.

As set out at new section 1834(u)(7)(D) of the Act, each payment category will be paid amounts equal to amounts for statutorily specified codes for which payment is made under the Physician Fee Schedule for each infusion drug administration calendar day in the individual's home for drugs assigned to such category. No geographic adjustment applies to the payments. In accordance with section 1834(u)(7)(E)(ii) of the Act, in the case that two (or more) home infusion drugs or biologicals from two different payment categories are administered to an individual concurrently on a single infusion drug administration calendar day, one payment for the highest payment category would be made.

In the CY 2019 HH PPS proposed rule, we outlined the billing procedure for the temporary transitional payment. We created a new HCPCS G-code for each of the three payment categories. We stated that the eligible home infusion supplier will submit, in line-item detail on the claim, a G-code for each infusion drug administration

calendar day, which would include the length of time for which professional services were furnished (in 15 minute increments). These G-codes can be billed separately from or on the same claim as the DME, supplies, and infusion drug. However, under the temporary transitional payment period, the eligible home infusion supplier is required to be enrolled as a pharmacy that provides external infusion pumps and external infusion pump supplies and maintains all pharmacy licensure requirements. Therefore, during this period, it is likely that the G-codes will be billed on the same claim as the equipment, supplies, and drug. However, for the full implementation of the benefit in 2021, there may be two different suppliers: One furnishing the home infusion therapy services in the home and one furnishing the DME, supplies, and drug. The claims for the temporary transitional payment will be processed through the DME MACs. In order to implement the requirements of section 1834(u)(7) of the Act for this temporary transitional payment, we will issue a Change Request (CR) prior to implementation of this temporary transitional payment, including the G-codes needed for billing, outlining the requirements for the claims processing changes needed to implement this payment.

In general, section 1834(u)(7) specifies, in detail, the requirements of the temporary transitional payment for home infusion therapy services, and in most instances, we generally do not have the discretion to apply different policies. However, we proposed a regulatory definition of “infusion drug administration calendar day” to specify in more detail, the policy in the statute as to when Medicare should make a single payment for home infusion therapy services. As required by section 1834(u)(1)(A)(ii) of the Act, a unit of single payment under the home infusion therapy benefit payment system is for each infusion drug administration calendar day in the individual’s home. Section 1834(u)(7)(E)(i) clarifies that an infusion drug administration calendar day in the individual’s home refers to payment only for the date on which professional services (as described in section 1861(iii)(2)(A)) were furnished to administer such drugs to such individual. Therefore, we proposed to define in regulation that “infusion drug administration calendar day” refers to payment for the day on which home infusion therapy services are furnished by skilled professional(s) in the individual’s home on the day of infusion drug administration. As we

stated in the proposed rule, we believe this to mean skilled services as set out at 42 CFR. 409.32. This regulation states that the skilled services furnished on such day must be so inherently complex that they can only be safely and effectively furnished by, or under the supervision of, professional or technical personnel.

The following is a summary of the public comments received on the “Proposed Temporary Transitional Payment for Home Infusion Therapy Services for CYs 2019 and 2020” and our responses.

Comment: Several commenters supported the proposed definition of “infusion drug administration calendar day” and noted that the home infusion payment rates for 2019 and 2020 specified in the statute are generally comparable and, in some cases, higher than the payment rates for an in-home visit under the home health prospective payment system. MedPAC agreed with CMS’ requirement that home infusion therapy providers report the length of home visits on their claims submissions, as it would allow the agency to consider this data as it establishes the payment rates for 2021, and could help to inform the agency’s consideration of potential payment adjustments based on patient acuity or drug administration complexity.

Response: We thank the commenters for their review and support of both the temporary and permanent payment structures for home infusion therapy services. We agree that the data obtained by requiring the length of the visit on the claim will be helpful in establishing payment adjustments for the full implementation of the benefit in 2021.

Comment: In general, other commenters stated that the definition of “infusion drug administration calendar day”, and the resulting payment limitation based on physical presence would be contrary to law and Congressional intent, and would inappropriately limit the number of days of payment for home infusion therapy professional services. Commenters expressed concern that tying payment to days for which a nurse provides in-person professional services, would limit payment only to a small subset of the many professional services furnished in connection with home infusion. Commenters stated that CMS should define infusion drug administration calendar day to include a broader set of professional services such as drug preparation, including sterile compounding; clinical care planning; care coordination; and other professional services that most often occur outside of the patient’s home and

remove the physical requirement that a nurse be in the home for payment to occur. Commenters also disagreed with the reference to the definition of “skilled services” as set out at § 409.32. Commenters stated that it seems inappropriate to define home infusion therapy professional services as skilled services in a skilled nursing facility (SNF).

Response: We agree that there are a variety of providers and professional services involved in home infusion therapy and recognize their significance in ensuring that therapy is safe and effective in the home.

However, in accordance with section 1861(iii)(1) of the Act, the term “home infusion therapy” means the items and services furnished by a qualified home infusion therapy supplier, which are furnished in the individual’s home. Likewise, section 1834(u)(7)(B)(iv) establishes a single payment amount for each infusion drug administration calendar day in the individual’s home. Additionally, section 1834(u)(7)(E)(i) of the Act states that payment to an eligible home infusion supplier or qualified home infusion therapy supplier for an infusion drug administration calendar day in the individual’s home refers to payment only for the date on which professional services, as described in section 1861(iii)(2) of the Act, were furnished to administer such drugs to such individual. This includes all such drugs administered to such individual on such day. We believe the BBA of 2018 includes this clarification of “infusion drug administration calendar day” in order to establish clear parameters so as to explicitly pay for services that occur in the patient’s home when the drug is being administered. Our interpretation of the phrase “only for the date on which professional services, as described in section 1861(iii)(2) of the Act, were furnished” is that mere infusion without any professional services furnished cannot trigger a home infusion therapy services payment for any day the drug is infused by the DME pump. Thus, we believe that the language in the statute clearly delineates a subset of days on which professional services are provided in the patient’s home in order for payment to occur.

Additionally, section 1834(u)(7)(A)(i) of the Act states that payment to an eligible home infusion supplier is for items and services furnished in coordination with the furnishing of transitional home infusion drugs. The language does not indicate that payment is for the furnishing of the home infusion drug, but for the services provided together and in cooperation

with the furnishing of the drug. The Medicare payment for the drug is made separately from home infusion therapy services. The statute also states that payment is for the professional services furnished “to administer” such drugs to such individual. As the term “administered” refers only to the physical process by which the drug enters the patient’s body,⁸¹ then the professional must be in the patient’s home furnishing services specifically related to this process. We noted in the CY 2019 HH PPS proposed rule that we understand that there may be professional services furnished in the patient’s home that do not occur on a day the drug is being administered (83 FR 32464). However, we note that the home infusion therapy services temporary transitional payment is a unit of single payment, meaning all home infusion therapy services furnished, which include professional services, training and education, remote monitoring and monitoring, are built into the payment for the day the professional services are furnished in the home and the drug is being administered. With the addition of the home infusion therapy services temporary transitional payment, suppliers will still receive payments for furnishing the equipment, the supplies, and the drug (technically considered a supply) under the DME benefit; but will also receive a separate payment when professional services are furnished in the patient’s home under the home infusion therapy benefit.

Furthermore, we note that the payment for an infusion drug administration calendar day is a single payment amount covering: professional services, including nursing services, furnished in accordance with a plan of care; training and education (not otherwise paid for as durable medical equipment); remote monitoring; and monitoring services furnished by a qualified home infusion therapy supplier. Therefore, at § 486.525, we have mirrored the language in section 1861(iii)(2)(A) of the Act that requires the provision of professional services, including nursing services, furnished by the home infusion therapy supplier in accordance with the plan of care. Since the Medicare payment is a single payment amount, we do not believe it is necessary to define “professional services” in regulation. By specifically enumerating a specific list of services we would risk inadvertently excluding services that may be necessary for the

care of a specific patient as part of the required services under the home infusion therapy benefit.

Section 1861(iii)(1)(B) requires the individual to be under a plan of care, established by a physician, prescribing the type, amount, and duration of home infusion therapy services that are to be furnished. Thus, it is the individual’s physician who is responsible for establishing the type and scope of professional services needed in the home in order to ensure home infusion therapy is successful. In the proposed rule, we did state that the services on this day must meet the criteria for skilled services as set out at § 409.32. This criteria states that to be considered a skilled service, the service must be so inherently complex that it can be safely and effectively performed only by, or under the supervision of, professional or technical personnel. Although this is a requirement for coverage of post-hospital SNF care, the definition of skilled services is not specific to skilled nursing services in a SNF. Section 409.42(c)(1) under the home health benefit also references § 409.32 as the criteria for intermittent skilled nursing services. Additionally, although both benefits require “skilled services” in reference to nursing, the definition is not exclusive to nursing services.

Finally, section 1834(u)(7)(D) of the Act sets the temporary transitional payment equal to 4 units at the amounts determined under the physician fee schedule (that is, equivalent to 4 hours of infusion in a physician’s office). Payment for an infusion drug administered in a physician’s office or outpatient center is made based on the occurrence of the professional services furnished during the visit. The professional services necessary for the infusion drug administration at these sites of care are factored into the payment for the visit, not separately payable. As such, it is not necessary to define the professional services required for infusion drug administration in a physician’s office or outpatient center because payment is not dependent upon the individual services furnished, but rather the occurrence of the visit and the professional services furnished at the time. Likewise, the home infusion therapy services temporary transitional payment includes payment for any professional services furnished in the patient’s home to administer the infusion drug.

Comment: A commenter recommended CMS add additional payment for visits exceeding a median visit time period such as 2 or 3 hours, as initial visits in particular can vary from 1 to 6 hours. The commenter stated

that in the absence of these additional payments, home infusion suppliers may limit the types of patients they accept during the transitional period.

Response: Section 1834(u)(7)(D) of the Act sets the temporary transitional payment equal to 4 units at the amounts determined under the physician fee schedule (that is, equivalent to 4 hours of infusion in a physician’s office). Although we do recognize that there may be some visits that exceed the number of units allowed, some visits may also be shorter. The temporary transitional payment is statutorily limited to the payment methodology as put forth in section 1834(u)(7)(D) of the Act.

Comment: Another commenter stated that many chronically ill patients depend on home health agencies for home infusion therapy services and supplies, and stated that home health agencies should continue to be paid as they currently are for home infusion. Another commenter stated that many home infusion suppliers do not actually provide the necessary skilled nursing support and must contract with home health agencies, which in turn, requires the home infusion company to assume responsibility for visits which may be unrelated to the patient’s infusion therapy.

Response: It is important to emphasize that the home infusion therapy services temporary transitional payment is separate from the home health benefit. Home infusion therapy is excluded from the Medicare home health benefit, and separately payable, beginning January 1, 2019. Section 1842(u)(7)(F) of the Act requires eligible home infusion suppliers to be Medicare DME suppliers that are enrolled as pharmacies that supply external infusion pumps and supplies in order to receive the home infusion therapy services temporary transitional payment. Not until the full implementation of the benefit in 2021 will home health agencies have the option of becoming home infusion therapy suppliers.

It is unclear why the commenter states that the home infusion supplier would be required to assume responsibility for visits which may be unrelated to the patient’s infusion therapy. We recognize that currently home infusion suppliers may contract with HHAs to furnish the nursing services; however, it is incumbent upon the home infusion supplier to negotiate appropriate contract terms in order to only assume responsibility for services related to home infusion therapy.

We also note that section VI.C.2.f. of the proposed rule discusses the

⁸¹ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>.

potential relationship/interaction between the home infusion therapy benefit and home health benefit. We stated that although the patient is not required to be homebound in order to receive home infusion therapy services, we anticipate that there may be circumstances when a patient may utilize both the home health benefit and the home infusion therapy benefit concurrently. We will provide further discussion on this relationship, including how we anticipate HHAs that furnish both home health and home infusion therapy services would submit claims for each of these services, in future rulemaking.

Comment: A few commenters expressed support for the inclusion of requirements for remote monitoring in the home infusion benefit, and encouraged CMS to consider how to incorporate the use of telehealth into the final home infusion payment system. A commenter suggested that CMS include requirements that monitoring be performed using medical devices cleared by the FDA for remote monitoring purposes.

Response: As we do not have specific policies surrounding the technology used in remote monitoring, for now we choose not to be prescriptive regarding how remote monitoring, or which remote monitoring devices, are used in home infusion. Anecdotally, we have heard from many home infusion providers that monitoring in home infusion consists mainly of phone calls. Likewise, the consensus from TEP members was that physical assessment and in-person monitoring is more common in home infusion due to the importance of visualizing the access site.

Comment: Many commenters stated that the proposed definition of infusion drug administration calendar day assumes that a nurse would be present for each administration of the home infusion drug. Several comments stated that requiring a nurse to come for every infusion day was inefficient, unnecessary, and would put a tremendous financial burden on patients who could not afford to have a nurse come every day to administer the drug. Several commenters stated concern regarding the potential inability to receive their infusion drugs on those days in which a skilled professional is not present in the home during the administration of the infusion drug. Some commenters stated that this requirement would also cause an access issue for home infusion patients, possibly resulting in an increase in deaths among those who receive home infusion drugs, though no specific

reason was provided as to why this would be the case. Another commenter stated that infusion suppliers would be forced to cut back on services, especially in rural areas, due to a limited supply of nurses. Additionally, this commenter stated that agencies will have to determine whether financially they are able to cover non-reimbursed costs associated with the benefit for Medicare patients, given that other payers do not require nurses to be present when drugs are infused in a patient's home.

Response: We wish to remind stakeholders that the provision of home infusion is not contingent upon a nurse being present each and every day a drug is being infused, nor that a nurse is present during the entire administration of the drug. An important goal of home infusion therapy services is to teach patients to safely, effectively, and independently self-administer the drug in the home. The home infusion therapy services paid under this benefit furnished in the patient's home help ensure that patients and/or their caregivers can reach this goal. The requirement that a skilled professional be in the home on a day an infusion drug is administered is only for purposes of determining the days for which the bundled payment for home infusion therapy services is made. We also note that there is no limit on the number of times that a home infusion therapy services payment would be made if a nurse needed to visit the beneficiary's home more than once a week.

The payment for professional services and training and education (not otherwise paid for under the Medicare Part B DME benefit), remote monitoring and monitoring services is only made when a skilled professional is physically present in a patient's home on a day of drug administration. This does not mean that the external infusion pump, drug, and related supplies are not covered on days when there is not a skilled professional in the home. The home infusion therapy services temporary transitional payment is a separately paid amount from the external infusion pump, drug, and related supplies.

Additionally, we state in the proposed rule that the professional services covered under this benefit are not intended to provide on-going nursing supervision throughout each infusion. We do not expect a nurse to be present for every infusion, or to stay for the duration of each infusion once the patient and/or caregiver has been taught to operate the pump. In section VI.C.2.d. of the proposed rule, we outline the

training and education services that we believe the home infusion therapy payment would cover. We state that these would include a limited amount of teaching and training on the provision of home infusion drugs that is not already covered under the DME benefit.

Furthermore, section 1861(iii)(2)(B) includes the provision of monitoring and remote monitoring as part of the home infusion therapy benefit. In the proposed rule, we indicated that we understand that some home infusion therapy patients may require daily monitoring, but generally do not need to be seen by a practitioner daily. In section VI.C.2.d. of the proposed rule, we state our belief that monitoring and remote monitoring can enable daily contact with, or assessment of certain patients without necessitating a visit.

Considering that we do not expect a visit to be made for each infusion drug administration, we also do not believe the supplier should be paid every day that the medication is infused regardless of whether or not direct care services are furnished. We should also emphasize that the patient is responsible for 20 percent coinsurance for every home infusion therapy services payment in addition to the 20 percent coinsurance charged for the DME infusion pump supplies and the drug. Therefore, we believe tying the payment to a visit in the beneficiary's home would ensure that the beneficiary is receiving direct care services for which he/she is paying 20 percent coinsurance. We state in the proposed rule that we generally anticipate that a home infusion therapy supplier would provide a visit approximately two times a week for the first week and then weekly thereafter over the course of infusion therapy depending on the drug and patient. Therefore, the proposed definition of infusion drug administration calendar day would result in payment only for these days when a visit occurs. Likewise, the beneficiary would be responsible for the 20 percent coinsurance amount only on these days. Section 1834(u)(7) requires that the temporary transitional home infusion therapy services payment be equal to 4 units at the amounts determined under the physician fee schedule (that is, the equivalent of 4 hours of infusion in a physician's office). This amount would range from \$141 to \$240 (using CY 2018 fee schedule amounts). If payment were to be made every day an infusion occurred, regardless of whether a visit was made, the beneficiary would be responsible for the home infusion therapy services coinsurance amount each and every day the infusion

occurred. For some patients on daily, continuous infusions, this would mean paying a 20 percent coinsurance amount every day (approximately \$900 per month in cost-sharing and more than \$10,000 annually). In accordance with CMS' proposed definition of infusion drug administration calendar day, the infusion therapy supplier would be paid every time a visit is made and a skilled service was furnished in the individual's home, which we anticipate would be at least weekly. Furthermore, we believe requiring that direct patient care services be made in order to receive payment promotes visits that provide direct care to the patient, which may help to mitigate any infusion related reactions or unplanned readmissions or ED visits. Similar to the physician office and the hospital outpatient setting, Medicare payment is made for direct care services furnished to a patient for infusion drug administration. We believe that, clinically, it is occasionally necessary for a nurse to visualize part of the administration of the infusion drug as this is part of his/her overall patient assessment while in the home. For instance, a nurse may observe dyspnea, tachycardia, or infiltration during an infusion and can appropriately intervene to ensure the safe and effective administration of the infusion.

We also do not anticipate that this requirement would lead to any additional home visits than are currently provided by home infusion suppliers. As many commenters pointed out, visits are often provided weekly, which aligns with what we stated in the proposed rule. Furthermore, we consider this benefit to be an additional payment for the direct care services associated in coordination with the furnishing of home infusion drugs.

Comment: Some commenters expressed concern regarding availability and categorization of specific infusions such as Total Parenteral Nutrition (TPN), intravenous hydration, or antiemetic drugs.

Response: While "home infusion drug" is defined under section 1861(iii)(3)(C) as a drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of DME, section 1834(u)(7)(A)(iii) of the Act includes an exception to the definition of home infusion drug if the drug is identified under section 1834(u)(7)(C) of the Act. This provision for the temporary transitional payment specifies the HCPCS codes for the drugs and biologicals covered under the Local Coverage Determinations (LCD) for

External Infusion Pumps. Therefore, only these drugs are covered under the home infusion therapy services temporary transitional payment. We intend to examine the criteria for home infusion drugs for coverage of home infusion therapy services, for implementation of the full home infusion therapy benefit in 2021.

Comment: A few commenters pointed out a technical edit regarding billing related to the creation of the G-codes and questioned whether our intent is to create three new G-codes for each of the three payment categories or one new G-code for each of the categories.

Response: We thank the commenters for bringing this to our attention. To clarify, we plan on creating one new G-code for each of the three payment categories.

Final Decision: We are finalizing the definition of infusion drug administration calendar day for the home infusion therapy services temporary transitional payment to mean payment is for the day on which home infusion therapy services are furnished by skilled professional(s) in the individual's home on the day of infusion drug administration. The skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel. *We recognize the concerns from stakeholders and members of Congress on our interpretation of "infusion drug administration calendar day", including with respect to professional services that may be provided outside of the home and, as applicable, payment amounts for such services. It is our intention to ensure access to home infusion therapy services in accordance with section 50401 of the BBA of 2018. Therefore, we believe the best course of action is to monitor the effects on access to care of finalizing this definition and, if warranted and within the limits of our statutory authority, engage in additional rulemaking or guidance regarding this definition for temporary transitional payments. We seek comments on this interpretation and on its potential effects on access to care."*

1. Solicitation of Public Comments Regarding Payment for Home Infusion Therapy Services for CY 2021 and Subsequent Years

Upon the expiration of the home infusion therapy services temporary transitional payment, we will be fully implementing the home infusion therapy services payment system under section 1834(u)(1) of the Act, as added by section 5012 of the 21st Century

Cures Act (Pub. L. 114–255). In the CY 2019 HH PPS proposed rule (83 FR 32340), we discussed the provisions of the law, and in anticipation of future rulemaking, solicited comments regarding the payment system for home infusion therapy services beginning in CY 2021. We discussed the relationship between the new home infusion therapy benefit and the existing Medicare DME and home health benefits; the definition of infusion drug administration day; payment basis, limitation on payment, required and discretionary adjustments, and billing procedures; the professional/nursing services and monitoring related to the administration of home infusion drugs; and the role of prior authorization. Specifically, we requested comments on retaining the definition of "infusion drug administration calendar day", as proposed in section IV.C.2. of the proposed rule for the full implementation of the home infusion therapy services benefit, and invited comments on any additional interpretations of professional, nursing, training and education, and monitoring services that may be considered under the scope of the home infusion therapy benefit. We solicited comments on ways to account for therapy type and complexity of administration, as well as ways to capture patient acuity, and requested feedback on situations that may incur an outlier payment and potential designs for an outlier payment calculation. And finally, we invited comments on the unit of single payment; limitations on payment; prior authorization; and required and discretionary adjustments, and solicited any additional suggestions as to how qualified home infusion therapy suppliers should bill and be paid for services under the home infusion therapy benefit, including whether it is reasonable to require two separate claims submissions to account for different components of home infusion therapy.

As there is overlap between the provisions of the home infusion therapy services temporary transitional payment and the full home infusion therapy benefit to be implemented in 2021, many of the proposed rule comments we received pertained to both. However, while we did not include proposals regarding payment for home infusion therapy services for CY 2021 and beyond, we did receive several comments related specifically to implementation of the full benefit. These comments included suggestions regarding billing, payment basis and adjustments, prior authorization, and

the relationship between the home infusion and home health benefits. We appreciate commenters' review of, and input regarding the discussion of the home infusion benefit, and will give careful consideration to all comments received when implementing the permanent Medicare payment structure for home infusion therapy services.

We did receive several technical comments regarding certain provisions that are addressed in the responses in this section of this final rule with comment period.

Comment: Several commenters expressed concern with retaining the proposed definition of "infusion drug administration calendar day" for the full implementation of the home infusion therapy benefit in 2021 as required by the 21st Century Cures Act.

Response: While we did not formally propose a definition of "infusion drug administration calendar day" in the discussion of the full implementation of the home infusion therapy benefit in 2021, we will note that the clarification in section 1834(u)(7)(E)(i) of the Act, as added by the BBA of 2018, regarding "infusion drug administration calendar day" provides that this definition is with respect to the furnishing of "transitional home infusion drugs" or "home infusion drugs" to an individual by an "eligible home infusion supplier" or a "qualified home infusion therapy supplier." As "home infusion drugs" and "qualified home infusion therapy supplier" are terms for the permanent benefit in the 21st Century Cures Act, this definition of "infusion drug administration calendar day" would pertain to both the temporary benefit and the full benefit.

Comment: A few commenters expressed concern with the potential exclusion of particular drugs from the full implementation of the home infusion therapy services benefit. Another commenter stated the understanding that Intravenous Immune Globulin (IVIG) is covered under the legislation enacted by the 21st Century Cures Act. Additionally, this commenter expressed concern with the conclusion of the Medicare IVIG demonstration as it relates to the full implementation of the home infusion therapy benefit and encouraged CMS to expedite the final report prior to the implementation of the benefit. Another commenter expressed concern that, because the legislation excludes drugs and biologicals on a self-administered drug (SAD) exclusion list, some subcutaneous immune globulins (SCIG) that are covered under the temporary transitional payment would be excluded from the benefit in 2021.

Response: We appreciate the commenter's concern regarding the conclusion of the IVIG demonstration; however, the timeline of the demonstration's final report is out of the scope of this rule. While section 50401 of the BBA of 2018 defines "transitional home infusion drug" by identifying the HCPCS codes for drugs under the LCD that are for coverage under the home infusion therapy services temporary transitional payment, the full implementation of the benefit in 2021 is less specific with regard to particular home infusion drugs. Section 1861(iii)(3)(C) of the Act defines a "home infusion drug" as a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment. Such term does not include insulin pump systems or self-administered drugs or biologicals on a self-administered drug exclusion list. We understand commenter concern regarding certain drugs and biologicals, specifically SCIG and IVIG, and will continue to examine the scope of drugs covered under Part B, along with the criteria for inclusion on the Self-Administered Drug Exclusion list for full implementation of the home infusion therapy benefit in 2021.

Comment: A commenter urged CMS to ensure that coverage guidelines for home infusion therapy make continued coverage available even if the beneficiary and/or family member is unwilling or unable to be trained to assume responsibility for the infusion themselves.

Response: We should reiterate that the home infusion therapy benefit is intended for drugs that are administered through an item of DME. As DME must be appropriate for use in the home, DMEPOS supplier standards require suppliers to document that they or another qualified party provided beneficiaries with instructions and education on safe and effective operation of the equipment (42 CFR 424.57(c)(12)). CMS convened a technical expert panel (TEP) in August of 2018, during which TEP members concurred that despite a physician's belief that home infusion may be medically acceptable and appropriate for a patient, success is very individualized and to a great extent, patient-dependent. We solicited comments regarding a reasonable number of visits needed to train the patient and caregiver on safe and effective use of the pump, and many commenters supported our assumption of two visits the first week and then

weekly thereafter. We also acknowledged that there may be patients that are unable or unwilling to self-administer, in which case the home would not be the appropriate site of care.

We appreciate commenter feedback and will take all comments under consideration while implementing the permanent home infusion therapy services benefit. We encourage commenters to submit additional comments regarding the full implementation of the benefit to the home infusion policy mailbox at HomeInfusionPolicy@cms.hhs.gov.

VII. Changes to the Accreditation Requirements for Certain Medicare-Certified Providers and Suppliers

A. Background

To participate in the Medicare program, Medicare-certified providers and suppliers of health care services, must be substantially in compliance with specified statutory requirements of the Act, as well as any additional regulatory requirements related to the health and safety of patients specified by the Secretary of the Department of Health and Human Services (HHS). Medicare certified providers and suppliers are enrolled in the Medicare program by entering into an agreement with Medicare. They include hospitals, skilled nursing facilities, home health agencies, hospice programs, rural health clinics, critical access hospitals, comprehensive outpatient rehabilitation facilities, laboratories, clinics, rehabilitation agencies, public health agencies, and ambulatory surgical centers. These health and safety requirements are generally called conditions of participation (CoPs) for most providers, requirements for skilled nursing facilities (SNFs), conditions for coverage (CfCs) for ambulatory surgical centers (ASCs) and other suppliers, and conditions for certification for rural health clinics (RHCs). A Medicare-certified provider or supplier that does not substantially comply with the applicable health and safety requirements risks having its participation in the Medicare program terminated.

In accordance with section 1864 of the Act, state health departments or similar agencies, under an agreement with CMS, survey health care providers and suppliers to ascertain compliance with the applicable CoPs, CfCs, conditions of certification, or requirements, and certify their findings to us. Based on these State Survey Agency (SA) certifications, we determine whether the provider or

supplier qualifies, or continues to qualify, for participation in the Medicare program.

Section 1865(a) of the Act allows most health care facilities to demonstrate compliance with Medicare CoPs, requirements, CfCs, or conditions for certification through accreditation by a CMS-approved program of a national accreditation body. If an AO is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider or supplier accredited by the AO's CMS-approved accreditation program may be deemed by us to meet the Medicare conditions or requirements.

We are responsible for the review, approval and subsequent oversight of national AOs' Medicare accreditation programs, and for ensuring providers or suppliers accredited by the AO meet the quality and patient safety standards required by the Medicare CoPs, requirements, CfCs, and conditions for certification. Any national AO seeking approval of an accreditation program in accordance with section 1865(a) of the Act must apply for and be approved by CMS for a period not to exceed 6 years.

The AO must reapply for renewed CMS approval of an accreditation program before the date its approval period expires. This allows providers or suppliers accredited under the program to continue to be deemed to be in compliance with the applicable Medicare CoPs, requirements, CfCs, and conditions for certification. Regulations implementing these provisions are found at 42 CFR 488.1 through 488.9.

We believe that it is necessary to revise the regulations for Medicare-certified providers and providers to add two new requirements for the AOs that accredit certified providers and providers. First, we proposed at § 488.5 to require AOs for Medicare-certified providers and suppliers to include a written statement in their application which states that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the AO's CMS-approved accreditation program, the AO must continue the facility's current accreditation until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first. We also proposed to modify the AO oversight regulations at § 488.5 by adding new requirements for training for AO surveyors.

B. Changes to Certain Requirements for Medicare-Certified Providers and Suppliers at Part 488

1. Continuation of Term of Accreditation When a Medicare-Certified Provider or Supplier Decides to Voluntarily Terminate the Services of an Accrediting Organization (§ 488.5)

We proposed adding a new provision to the approval and oversight regulations for AOs that accredit Medicare certified providers and suppliers at § 488.5(a)(17)(iii), which would require that, with an initial or renewal application for CMS-approval of a Medicare certified provider or supplier accreditation program, an AO must include a written statement agreeing that when a fully accredited, deemed provider or supplier in good standing notifies its AO that it wishes to voluntarily withdraw from the AO's accreditation program, the AO would honor the provider's or supplier's current term of accreditation until the effective date of withdrawal identified by the facility, or the expiration date of the term of accreditation, whichever comes first. We made this proposal because we have received numerous complaints from accredited and deemed facilities in good standing with their then-current AO stating that once they provide notification to the AO of their intent to voluntarily withdraw their accreditation business from that AO, the AO frequently terminated their accreditation immediately, without regard to their current accreditation status, up to date payment of fees, contract status, or the facility's requested effective date of withdrawal. We do not believe it is reasonable for AOs to penalize facilities because they choose to terminate the services of an AO.

Providers and suppliers may be left without an accreditation status that would allow them to continue to participate in Medicare.

Comment: Several commenters expressed general support for our proposal at § 488.5(a)(17)(iii), which would require that, with an initial or renewal application for CMS-approval of a Medicare certified provider or supplier accreditation program, AO must include a written statement agreeing that when a fully accredited, deemed provider or supplier in good standing notifies its AO that it wishes to voluntarily withdraw from the AO's accreditation program, the AO would honor the provider's or supplier's current term of accreditation until the effective date of withdrawal identified by the facility, or the expiration date of the term of accreditation, whichever

comes first. A commenter stated that "we agree with this proposed change because when a provider/supplier is accredited in good standing their accreditation should be good for the full term of their agreement with the accreditor." Another commenter stated the opinion that "we agree that it is unreasonable for AOs to penalize facilities who choose to terminate the services of that AO, and as such, support this proposal. Another commenter stated full agreement with this proposal and stated that this is the standard operating procedure for this commenter's AO.

Response: We thank these commenters for their input.

Comment: Another commenter expressed agreement with the proposal regarding § 488.5(a)(17)(iii) and in addition, expressed the opinion CMS should require all AOs for Medicare certified providers and suppliers to document the dates of accreditation as the dates of the actual survey and acceptance of the plan of correction. This commenter argued that the requirement was necessary because AOs that accredit large multiple site providers/suppliers use a corporate accreditation cycle where the dates of the accreditation cycle are the same for all sites.

Response: We thank this commenter for their support for our proposal. We further that this commenter for the suggestion that CMS should consider a policy applicable to AOs that accredit large multiple site providers/suppliers which utilize a corporate accreditation cycle where the dates of the accreditation cycle are the same for all sites. However, this is an issue that is outside the scope of the proposed rule. We will take this information under advisement. We thank this commenter for bringing this concern to our attention.

Comment: A commenter expressed disapproval of our proposal, stating the proposal, as written, undermines the autonomy of this and all other AOs to enforce their own policies. The commenter also stated that each AO develops its own policies and procedures related to accreditation termination effective dates, which CMS subsequently approves.

The commenter also stated that this proposal would allow facilities to circumvent the mechanisms AOs for Medicare certified providers and suppliers have had in place for ongoing review of accredited facilities. The commenter believes that the rule, as written, would require this AO to maintain a facility's accreditation status regardless of the commenter AO's

policies and procedures related to termination of a facility's accreditation status. The commenter noted that throughout the accreditation process, participating facilities are obligated to comply with an AO's standards, policies, and procedures until an awarded accreditation term expires or terminates; therefore, this proposal would conflict with an AO's operation of its accreditation program and its authority to make accreditation decisions. The commenter strongly urged CMS to withdraw this requirement.

Response: We respectfully disagree with the views expressed by this commenter. We do not agree that the requirement would undermine the autonomy of this AO to enforce its own policies or conflict with commenter's AOs operation of its accreditation program and its authority to make accreditation decisions. This commenter provided no examples or explanation for how the addition of the proposed policy would do so.

It is our position that if an accredited provider or supplier has paid the agreed upon accreditation fees, successfully gone through the survey process, and is in good standing with their AO, but has, for whatever reason, decided to switch accreditation to another AO or to submit to a survey by a state agency, there is no justifiable reason for the current AO to cancel that provider/suppliers accreditation prior to the expiration date.

CMS has seen cases in which shortly after an AOs has been informed by one of its accredited providers/suppliers in good standing that said provide/supplier wishes to withdraw their accreditation business from that AO and become accredited by another AO (or obtain state certification), the current AO terminates that provider/suppliers accreditation, regardless of how much time remains on that provider's or supplier's existing term of accreditation. We believe that these instances of early termination of the accreditation of a provider/suppliers in good standing, with no performance or complaint issues who has recently informed their AO that they were switching to another AO are either retaliatory in nature, or done because these providers were no longer considered a viable source of revenue. We agree that it is unreasonable for AOs to penalize facilities who choose to terminate the services of that AO, and as such, support this proposal.

Final Decision: In consideration of the comments received, this provision will be added to 42 CFR 488.5(a)(17)(iii) as drafted, without modification.

2. Training Requirements for Accrediting Organization Surveyors (§ 488.5(a)(7))

We proposed to add a new requirement at § 488.5(a)(7) which imposes a new training requirement for surveyors of AO that accredit Medicare-certified provider and supplier types by amending the provision at § 488.5(a)(7). We proposed that all AO surveyors be required to complete the relevant program-specific CMS online trainings initially, and thereafter, consistent with requirements established by CMS for state surveyors. CMS provides a wide variety of comprehensive trainings through an on-demand integrated surveyor training website. These online trainings are available and can be accessed by state and federal surveyors and the public, free of charge, 24 hours a day, 365 days a year. These online trainings are currently publically available for the SA surveyors.

As part of our oversight of the AOs performance, CMS has contracted with the SAs to perform validation surveys on a sample of providers and suppliers (such as hospitals, critical access hospital, ambulatory surgical centers, and home health agencies) accredited by the AOs that accredit Medicare certified providers and suppliers. Validation surveys must be performed by the SA within 60 days of the survey performed by the AO. As a validation survey is performed within 60 days of the AO survey, we believe that the conditions at the hospital or other facility being surveyed will be similar at the time of the validation survey.

The purpose of a validation survey is to compare the survey findings of the AO to the survey findings of the SA to see if there are any disparities. The amount of disparities found in the AO's survey is called the "disparity rate" and is tracked by CMS as an indication of the quality of the surveys performed by the AO.

CMS has determined that many of the AOs' disparity rates have been consistently high. This means that the AOs have consistently failed to find the same condition level deficiencies in the care provided by the hospital or other providers surveyed that were found by the SA during the validation survey.

At the time of the writing of the proposed rule, we believed that the disparity in findings made by the AO surveyors and those of the SA surveyors could largely be attributed the difference in the training and education provided to the AO surveyors. Each AO is responsible for providing training and education to their surveyors. In the proposed rule, we stated that because

each AO is an independent entity, the surveyor training and education provided by each AO to its surveyor's varies and is not consistent. We further stated that CMS provides comprehensive online training to the SA surveyor staff on the CMS Surveyor Training website⁸² which are specific to each type of provider of supplier type to be surveyed.

In the proposed rule, we stated that it was our belief that the AO's disparity rate would be decreased if all surveyors took the same training. We further stated the belief that completion of the same surveyor training by both SA and AO surveyors would increase the consistency between the results of the surveys performed by the SAs and AOs and have a positive impact on the historically high disparity rate. Therefore, we proposed that all AO surveyors be required to take the CMS online surveyor training offered on the CMS website. We further proposed to require each AO to provide CMS with documentation which provides proof that each surveyors had completed the CMS online surveyor training. Finally, we proposed that if the AO fails to provide this documentation, CMS could place the AO on an accreditation program review pursuant to § 488.8(c). We received a number of comments in response to this proposals.

Comment: Several commenters stated strong support CMS' proposal to require consistent, comprehensive training for AO surveyors.

Response: We thank these commenters for their support of our proposal.

Comment: Another commenter who supported CMS' proposal to require consistent, comprehensive training for AO surveyors stated that they did not believe the proposal went far enough. This commenter recommended that CMS undertake a rigorous review of the entire "deemed status" system. This commenter further stated concern that since these deemed-status health care providers are not subject to routine state certification surveys, they are not subject to the civil monetary penalties that could result from surveys conducted by state agencies. This commenter urged CMS to fix the flaws and loopholes in the deemed status program.

Response: We thank this commenter for their support of the proposal to require AO surveyors to take the CMS online surveyor training. We further thank this commenter for the remainder of their suggestions. As these suggestions are outside the scope of the

⁸² <https://surveyortraining.cms.hhs.gov/>.

topics discussed in the proposed rule they will not be discussed here. However, we will take this commenters suggestions under advisement.

Comment: Several commenters urged CMS to consider including a corresponding decrease in CMS validation surveys for those AOs whose surveyors have completed the training, since the CMS online surveyor training which is supposed to decrease the disparity rate. Another commenter suggested that CMS resources devoted to validation surveys could be reduced, saving taxpayer dollars and lessening HHA time and effort spend on largely redundant surveys.

In support of the request to decrease the number of validation surveys to be performed if this requirement for surveyor training is finalized, a commenter pointed out that there are other administrative reviews including the RAC, Pre Claim Review, Probe & Educate, and routine MAC ADR probes that could assess an AOs compliance and performance. Another commenter stated that while there are ample enforcement tools, CMS has not clearly targeted these efforts to bad actors and high-value HHAs have had to divert resources from direct care to administrative functions. This commenter suggestion that audit frequency should be determined using current data along with Program for Evaluating Payment Patterns Electronic Report (PEPPER) reports to identify underperforming and/or noncompliant agencies and that audits should be limited to topics within statutory and regulatory parameters.

Response: CMS is currently in the process of reviewing and redesigning the validation process in an effort to make it more accurate, effective and less burdensome for facilities. While outside the scope of the proposals made, we will take the suggestions made by these commenters under advisement.

Comment: In this section of this final rule with comment period is a summary of the remainder of the comments received in response to our response to our proposal to require surveyors for the AOs that accredit Medicare certified providers and suppliers to the take CMS online surveyor training:

- A commenter recommended that CMS make the online surveyor trainings available but not mandatory for all AO surveyor so that each AO could then evaluate its own training and education materials and make an independent decision regarding how best to use the CMS training tools.

- A commenter stated that they support the CMS aim of reducing disparity rates, but that they cannot

support the proposal as written due to its vagueness.

- Another commenter stated that the proposed rule offers little guidance on CMS implementation of this new requirement. Another commenter expressed concern regarding how this requirement would be fully operationalized.

- A commenter noted that the proposed rule does not specify the CMS online training courses for which it expects completion. Another commenter expressed the concern that it is unclear from the text of this rule, how often surveyors would be required to participate in the training.

- Several commenters stated the belief that there are ambiguities in the proposal that essentially create further opportunity for non-uniformity in surveyor training across the industry. Any non-uniformity in training could reduce the meaningfulness of any presumed links between surveyor training mandates and disparity rates that CMS hopes to identify and impact.

- Another commenter requested more clarity concerning training requirements including course enrollment expectations, frequency of course completion, and clarification regarding whether CMS intends to implement a reporting mechanism for AOs to validate surveyor course completion. This commenter expressed concern that, while the proposed rule proposed completion of “relevant program specific CMS online trainings established for state surveyor,” the variety of online training programs offered and the lack of specificity over the precise training modules required per program could create confusion over which precise training elements would be required for full rule compliance.

- Another commenter expressed doubt that a mandatory requirement for AO surveyors to take CMS online surveyor training would improve AO the disparity rates, and that reviewing online training does not guarantee surveyors will retain and then apply all the information from the trainings during their surveys.

- Several commenters strongly suggested that CMS needs to establish a measurable correlation between the proposal and the expected outcome before CMS proposes to require AOs to implement any costly program.

- Several commenters suggested that if CMS has questions and concerns with the current surveyor education provided by AOs, it seems like this would be an issue to be addressed when reevaluating that AO’s own accreditation from CMS.

- A commenter also made the suggestion that CMS should also

evaluate the length of surveys and determine whether it would make sense to have a minimum (or standard) length for all individuals surveying for a specific provider or supplier type. Or have a minimum (or standard) number of surveyors participating in each survey. This commenter stated the belief that there could be a number of factors involved in the disparity rate.

- Several commenters stated that they do not agree with CMS’ assumptions that inconsistent training between SA surveyors and AO surveyors is the reason for high disparity rates. One of these commenters stated that they fail to see the correlation between different AO surveyor training programs and disparity rates when the disparity rate is a comparison of an SA survey result against an AO survey result and not a comparison between AOs.

- Another commenter recognizes that disparity rates are a constant challenge for CMS and AOs, and that root-cause factors driving high disparity rates are complex and multi-faceted. Yet another of these commenters stated that while surveyor training may be a factor that influences disparity rates, it is unclear whether mandating that AOs to require that surveyors complete CMS training modules will actually reduce the disparity rate. The hypothesis that mandating additional AO surveyor training will lower disparity rates is untested and unproven, and the basis for the hypothesis is unclear.

- Several commenters expressed the belief that unknown or alternative factors may truly drive high disparity rates and that there are multiple explanations as to why the disparity rate could be elevated that are not related to surveyor training. For example, according to these commenters, it is possible that there could be variance or issues with the validation surveyors. Reviewing online training does not guarantee surveyors will retain and then apply all the information from the trainings during their surveys.

- A number of commenters raised the following points in objection to our proposal that AO surveys complete CMS-provided mandatory surveyor training:

- ++ CMS reviews and approves all AO training, verifying its adequacy.

- ++ State agency surveyors are not required to have actual experience in the health care field for which they survey. This commenter stated that at least one accreditor requires a minimum of 5 years’ experience in the same field that they will survey, thus making them a subject matter expert.

- ++ State agencies send multiple surveyors for multiple days, where AOs

usually send one surveyor for 2 to 5 days. The length of the survey depends on the number of unduplicated admissions the facility bills over a 12 month period.

++ State agencies cite the same deficiencies multiple times. AOs normally do not.

++ There is not an appeal process for the AO in regard to a validation survey. When a validation survey comes back with deficiencies that the AO did not cite and does not agree with, CMS only accepts the state validation surveyors' deficiencies as accurate.

- Several commenters expressed concern that this new requirement would place significant new burden on AOs.

A commenter recommended that CMS delay implementation of the current proposal, and instead bring together accreditation organizations and providers and suppliers to more fully explore how to improve disparity rates between AO and validation surveys. Several other commenters encouraged CMS to engage the AOs directly in both the initiative to reduce disparity rates and on any initiatives that may impact AO accreditation program operations.

General Response: We agree with these commenters that the text of this section of the proposed rule may have been unclear about how the requirement for online surveyor training was to be operationalized and that it was not clear about the number and types of training the AO surveyor would have to take. While we do believe that the disparity rate would be decreased somewhat by the requirement that AO surveyors take the CMS online surveyor training, at this time CMS is not able to demonstrate that such training will significantly reduce the validation disparity rate. After consideration of the comments received, we acknowledge that root-cause factors driving high disparity rates are complex and multi-faceted and that there are a number of other factors that could have an impact on the disparity. We also acknowledge that while

surveyor training may be a factor that influences disparity rates, it is unclear whether requiring that AOs require that surveyors complete CMS training modules will reduce the disparity rate. Therefore, after consideration of the comments received, we have decided not to finalize our proposal to require the surveyors for AOs that accredit Medicare certified providers and suppliers to take the CMS online surveyor training. However, it is important to note that many of the AOs' disparity rates have been consistently high. We are continuing to monitor these rates and look for ways to reduce them.

Final Decision: After consideration of the comments received, we have decided not to finalize our proposal to require the surveyors for AOs that accredit Medicare certified providers and suppliers to take the CMS online surveyor training.

VIII. Requests for Information

This section addressed two requests for information (RFI).

A. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

In the CY 2019 HH PPS proposed rule (83 FR 32471 through 32473), we included a Request for Information (RFI) related to promoting interoperability and electronic health care information exchange. We received approximately 28 timely pieces of correspondence on this RFI. We appreciate the input provided by commenters.

B. Request for Information on Price Transparency: Improving Beneficiary Access to Home Health Agency Charge Information

In the CY 2019 HH PPS proposed rule (83 FR 32473 and 32474), we included

a Request for Information (RFI) related to price transparency and improving beneficiary access to home health agency charge information. We received approximately 15 timely pieces of correspondence on this RFI. We appreciate the input provided by commenters.

IX. 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.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2017 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following Table 42 presents the mean hourly wage rate, fringe benefits costs and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 42: MAY 2017 NATIONAL INDUSTRY-SPECIFIC OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES--NAICS 621600 - HOME HEALTH CARE SERVICES

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Overhead (100%)/(\$/hr)	Adjusted Hourly Wage (\$/hr)
Registered Nurse (RN)	29-1141	\$33.77	\$33.77	\$67.54
Physical therapists HHAs	29-1123	\$46.19	\$46.19	\$92.38
Speech-Language Pathologists (SLP)	29-1127	\$43.93	\$43.93	\$87.86
Occupational Therapists (OT)	29-1122	\$43.70	\$43.70	\$87.40

This final rule with comment period makes reference to associated information collections that are not discussed in the regulation text contained in this document. These final changes are associated with the information collection request (ICR)—Outcome and Assessment Information Set (OASIS) OASIS-C2/ICD-10 (CMS-10545), approved under OMB control number 0938-1279. We note that on March 12, 2018 (83 FR 10730) we published a notice in the **Federal Register** seeking public comment on a revision to CMS-10545 (OMB control number 0938-1279), which will modify the OASIS and refer to the revised item set as the OASIS-D upon implementation of the revised data set on January 1, 2019. We solicited public comment on additional changes related to when certain OASIS items are required to be completed by HHA clinicians due to the implementation of the patient-driven groupings model (PDGM) for CY 2020, as outlined in section III.F of this final rule with comment period; and the changes to due to the removal of HH QRP measures beginning with the CY 2021 HH QRP, as outlined in section V.E. of this final rule with comment period.

B. ICRs Regarding the OASIS

We believe that the burden associated with the OASIS is the time and effort associated with data collection and reporting. As of April 1, 2018, there are approximately 11,623 HHAs reporting OASIS data to CMS.

In section V.E.1. of this final rule with comment period, we are removing the Depression Assessment Conducted Measure from the HH QRP under measure removal Factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made. Removing this measure will not impact our collection of information because OASIS Item M1730, which is used to

calculate this measure, is also used as a risk adjuster to calculate other OASIS-based outcome measures currently adopted for the HH QRP.⁸³

In section V.E.2. of this final rule with comment period, we are removing the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure from the HH QRP under measure removal Factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made. This measure is calculated using OASIS Item M2401, row a at the time point of Transfer to an Inpatient Facility (TOC) and Discharge from Agency—Not to an Inpatient Facility (Discharge). Specifically, we are removing this one data element at the TOC and Discharge time points.

In section V.E.3. of this final rule with comment period, we are removing the Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537) Measure from the HH QRP under measure removal Factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made. This measure is calculated using OASIS Item M1910 at the time point of SOC/ROC. Specifically, we are removing this one data element at the SOC/ROC time point.

In section V.E.4. of this final rule with comment period, we are removing the Pneumococcal Polysaccharide Vaccine Ever Received Measure from the HH

⁸³ The OASIS-based HH QRP outcome measures that use OASIS Item M1730 as a risk adjuster in the calculation of the measure are: Improvement in Bathing (NQF #0174), Improvement in Bed Transferring (NQF #0175), Improvement in Ambulation/Locomotion (NQF #0167), Improvement in Dyspnea, Improvement in Pain Interfering with Activity (NQF #0177), Improvement in Management of Oral Medications (NQF #0176), and Improvement in Status of Surgical Wounds (NQF #0178).

QRP, under measure removal Factor 3: A measure does not align with current clinical guidelines or practice. This measure is calculated using OASIS Items M1051 and M1056 at the time points of TOC and Discharge. Specifically, we are removing these two data elements at the TOC and Discharge time points.

In section V.E.5. of this final rule with comment period, we are removing the Improvement in the Status of Surgical Wounds Measure from the HH QRP under measure removal Factor 4: A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available. Removing this measure will not impact our collection of information because OASIS Items M1340 and M1342 are used as risk adjusters to calculate other OASIS-based outcome measures currently adopted for the HH QRP and OASIS Items M1340 and M1342 are also used for the Potentially Avoidable Events measure Discharged to the Community Needing Wound Care or Medication Assistance that is used by HH surveyors during the survey process.^{84 85}

In sections V.E.6. and V.E.7. of this final rule with comment period, we are removing the Emergency Department Use without Hospital Readmission during the First 30 Days of HH (NQF #2505) Measure and the Rehospitalization during the First 30

⁸⁴ The OASIS-based HH QRP outcome measures that use OASIS Items M1340 and M1342 as a risk adjuster in the calculation of the measure are: Improvement in Bathing (NQF #0174), Improvement in Bed Transferring (NQF #0175), Improvement in Ambulation/Locomotion (NQF #0167), Improvement in Dyspnea, Improvement in Pain Interfering with Activity (NQF #0177), and Improvement in Management of Oral Medications (NQF #0176).

⁸⁵ Measure specifications can be found in the Home Health Potentially Avoidable Events Measures Table on the Home Health Quality Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-PAE-Measures-Table-OASIS-C2_4-11-18.pdf).

Days of HH (NQF #2380) Measure from the HH QRP beginning with the CY 2021 HH QRP under measure removal Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available. Because these are both claims-based measures, removing them will not impact our collection of information.

In summary, we are finalizing the net reduction of 1 data element at SOC, 1 data element at ROC, 3 data elements at TOC and 3 data elements at Discharge associated with OASIS item collection as a result of the measure removals from the HH QRP.

The OASIS instrument is used for meeting the home health Conditions of Participation, requirements under the HH QRP, and for payment purposes under the HH PPS. As outlined in section III.F. of this final rule with comment period, to calculate the case-mix adjusted payment amount for the PDGM, we are finalizing our proposal to add collection of two current OASIS items (10 data elements) at the follow-up (FU) time point:

- M1033: Risk for Hospitalization (9 data elements)
- M1800: Grooming (1 data element).

As outlined in section III.F of this final rule with comment period, several OASIS items will not be needed in case-mix adjusting the period payment for the PDGM; therefore, 19 current OASIS items (48 data elements) are optional at the FU time point:

- M1021: Primary Diagnosis (3 data elements)

- M1023: Other Diagnosis (15 data elements)
- M1030: Therapies (3 data elements)
- M1200: Vision (1 data element)
- M1242: Frequency of Pain Interfering (1 data element)
- M1311: Current Number of Unhealed Pressure Ulcers at Each Stage (12 data elements)
- M1322: Current Number of Stage 1 Pressure Ulcers (1 data element)
- M1324: Stage of Most Problematic Unhealed Pressure Ulcer that is Stageable (1 data element)
- M1330: Does this patient have a Stasis Ulcer? (1 data element)
- M1332: Current Number of Stasis Ulcer(s) that are Observable (1 data element)
- M1334: Status of Most Problematic Stasis Ulcer that is Observable (1 data element)
- M1340: Does this patient have a Surgical Wound (1 data element)
- M1342: Status of Most Problematic Surgical Wound that is Observable (1 data element)
- M1400: Short of Breath (1 data element)
- M1610: Urinary Incontinence or Urinary Catheter Presence (1 data element)
- M1620: Bowel Incontinence Frequency (1 data element)
- M1630: Ostomy for Bowel Elimination (1 data element)
- M2030: Management of Injectable Medications (1 data element)
- M2200: Therapy Need (1 data element)

Therefore, we are finalizing the net reduction of 38 data elements at FU

associated with OASIS item collection as a result of the implementation of the PDGM for CY 2020.

In summary, as a net result of the policies we are finalizing in this final rule with comment period, we will be removing 1 data element at SOC, 1 data element at ROC, 38 data elements at FU, 3 data elements at TOC and 3 data elements at Discharge associated with OASIS item collection as a result of the measure removals from the HH QRP and the implementation of the PDGM starting January 1, 2020.

We assume that each data element requires 0.3 minutes of clinician time to complete. Therefore, we estimate that there is a reduction in clinician burden per OASIS assessment of 0.3 minutes at SOC, 0.3 minutes at ROC, 11.4 minutes at FU, 0.9 minutes at TOC and 0.9 minutes at Discharge.

The OASIS is completed by RNs or physical therapists (PTs), or very occasionally by occupational therapists (OT) or speech language pathologists (SLP/ST). Data from 2016 show that the SOC/ROC OASIS is completed by RNs (approximately 87 percent of the time), PTs (approximately 12.7 percent of the time), and other therapists, including OTs and SLP/STs (approximately 0.3 percent of the time). We estimated a weighted clinician average hourly wage of \$70.75, inclusive of fringe benefits, using the hourly wage data in Table 41. Individual providers determine the staffing resources necessary.

Table 43 shows the total number of assessments submitted in CY 2017 and estimated burden at each time point.

TABLE 43: CY 2017 OASIS SUBMISSIONS AND ESTIMATED BURDEN, BY TIME POINT

Time Point	CY 2017 Assessments Completed	Estimated Burden (\$)
Start of Care	6,420,299	-\$2,271,180.77
Resumption of Care	1,062,962	-\$376,022.81
Follow-up	3,688,651	-\$49,584,691.07
Transfer to an inpatient facility	1,925,270	-\$2,043,192.79
Death at Home	41,183	0
Discharge from agency	5,249,483	-\$5,571,013.83
TOTAL	18,387,848	-\$59,846,101.27

* Estimated Burden (\$) at each Time-Point = (# CY 2017 Assessments Completed) x (clinician burden [min]/60) x (\$70.75 [weighted clinician average hourly wage]).

Based on the data in Table 43 for the 11,623 active Medicare-certified HHAs in April 2018, we estimate the total average decrease in cost associated with

changes with OASIS item collection at \$5,148.94 per HHA annually, or \$59,846,101.27 for all HHAs annually. This corresponds to an estimated

reduction in clinician burden associated with changes to collection of information associated with the OASIS of 72.8 hours per HHA annually, or

845,881.3 hours for all HHAs annually. This burden decrease will be accounted for in the information collection under OMB control number 0938–1279. We did not receive comments on collection of information requirements associated with the OASIS.

C. ICRs Regarding Home Infusion Therapy

At § 486.520, Plan of Care, we propose that all patients must have a plan of care established by a physician that prescribes the type, amount, and duration of infusion therapy services that are to be furnished. This requirement directly implements section 5012 of the 21st Century Cures Act. Accredited home infusion therapy suppliers are already required by their accrediting bodies to provide all care in accordance with a plan of care that specifies the type, amount, and duration of infusion therapy services to be furnished to each patient; therefore this requirement will not impose a burden upon accredited agencies. Furthermore, all existing home infusion therapy suppliers are already accredited due to existing payment requirements established by private insurers and Medicare Advantage plans. In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(3), this requirement exists even in the absence of a federal requirement; therefore, the associated burden is not subject to the PRA. We did not receive any comments from the public, either in agreement or opposition, regarding our estimation of burden for information collection requirements in relation to the implementation of the home infusion therapy standards as delineated by section 5012 of the 21st Century Cures Act; therefore, we are finalizing this estimate without modification.

We did not receive any comments from the public, either in agreement or opposition, regarding our estimation of burden for information collection requirements in relation to the implementation of the home infusion therapy standards as delineated by section 5012 of the 21st Century Cures Act; therefore, we are finalizing this estimate without modification.

D. ICRs Regarding the Approval and Oversight of Accrediting Organizations for Home Infusion Therapy

1. Background

We are finalizing establish a new set of regulations related to the approval and oversight of accrediting organizations that accredit home infusion therapy suppliers. If finalized,

these new regulatory requirements will impose burden on those new AOs that seek approval of their Home Infusion Therapy accreditation program. This burden will include, but is not limited to the time and costs associated with the following activities: (1) Preparation and filing of an initial application seeking CMS approval of the AOs home infusion therapy accreditation program; (2) participation in the application review process (that is, meetings, provide additional information and materials that may be required, participate in a site visit, etc.); (3) seeking new accreditation clients; (4) performing on-site surveys, off-site survey audits or the performance of other types of survey activities; (5) participation in CMS ongoing accreditation program review activities; (6) performance of periodic re-accreditation activities; (7) investigation of complaints and performing complaint surveys; (8) administration of the appeals process for providers that have been denied accreditation; (9) staff training, in-services and continuing education; and (10) ensuring that surveyor staff have the proper education, training, and credentials.

The following is a discussion of the potential ICR burdens associated with the home infusion therapy supplier accreditation oversight regulations and well as any PRA exceptions that may apply.

2. Applicable PRA Exception

We believe that the information collection burden associated with the preparation and submission of an initial or renewal application for approval and designation as a home infusion therapy AO and the participation in other accreditation related activities does not meet the definition of “collection of information” as defined in 5 CFR 1320.3(c) because it is “not imposed on 10 or more persons.” This information collection burden will be imposed only on those national AOs that accredit home infusion therapy suppliers.

At this time, there are five CMS-approved HHA AOs that provide home infusion therapy accreditation as part of the deeming accreditation of home health agencies. These HHA AOs are The Joint Commission (TJC), the Accreditation Commission for Health Care (ACHC), The Compliance Team (TCT), the Community Health Accreditation Partner (CHAP), and the Healthcare Quality Association on Accreditation.

There are three pharmacy association AOs that provide non-CMS approved home infusion therapy accreditation. These non-CMS approved Home

infusion AOs are the National Association of Boards of Pharmacy, the Centers for Pharmacy Practice Accreditation (CPPA) and URAC.

In this final rule with comment period, we have to require that these AO must apply for CMS approval of a home infusion therapy accreditation that is separate and distinct from its home health accreditation program. When we do solicit AOs to accredit home infusion therapy suppliers, we do not anticipate receiving more than the six applications which will be submitted by the existing AOs seeking approval of a home infusion therapy accreditation program, because this is a specialized area of accreditation.

It is possible that the number of AOs that we designate to accredit home infusion therapy suppliers may increase to 10 or more in the future, when we begin accepting applications for home infusion therapy AOs. However, we do not anticipate that the number of AOs that will accredit home infusion therapy suppliers will increase to 10 or more in the foreseeable future.

Should the number of AOs that accredit home infusion therapy suppliers rise to 10 or more, we will prepare and submit an information collection request (ICR) for the burden associated with the accreditation process, as well as obtain OMB approval, prior to accepting additional applications.

We did not receive comments on these information collection requirements.

E. ICR Regarding Modifications to 42 CFR 488.5

We are modifying the AO approval and oversight regulations for Medicare certified providers and suppliers by adding a new requirement. Section 488.5(a)(17)(iii) will require that the AOs for Medicare certified providers and suppliers include a written statement in their application for CMS approval agreeing that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the accrediting organization’s CMS-approved accreditation program, the accrediting organization must continue the facility’s current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

An AO would prepare this written statement as part of the preparation of the initial or renewal applications they submit to CMS seeking initial and renewal approval of the CMS approval

of their accreditation program. This statement would be included in a written document with other required written statements. As the AO would already be in the process of preparing the documentation for their application, we believe that there would be little, if any burden associated with the preparation of this statements.

We believe that it would take no more than 15 minutes for the AO to add this statement to the written document containing all the statements and affirmations that AO must submit as a condition of approval. We believe that this task would be performed by an administrative assistant. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for an executive administrative assistant is \$28.56 (<https://www.bls.gov/oes/current/oes436011.htm>). We estimate that the AO would incur a cost burden for wages related to the preparation of the required statement in the amount of \$14.28 ($\$28.56 \times 15 \text{ minutes} = \7.14) + (\$7.14 for fringe benefits and overhead).

We had also proposed to add a new requirement at § 488.5(a)(7) to require surveyors for AOs that accredit non-certified providers and suppliers to take the CMS online surveyor training. However, after consideration of the public comments received regarding this proposal, we have decided not to finalize the proposal.

F. Submission of PRA-Related Comments

We have submitted a copy of this final rule with comment period 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.

We invite public comments on these information collection requirements. If you wish to comment, please identify the rule (CMS-1689-F) and, where applicable, the ICR's CFR citation, CMS ID number, and OMB control number.

To obtain copies of a supporting statement and any related forms for the collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

See this rule's **DATES** and **ADDRESSES** sections for the comment due date and for additional instructions.

X. Regulatory Impact Analysis

A. Statement of Need

1. Home Health Prospective Payment System (HH PPS)

Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of home health services paid under Medicare. In addition, section 1895(b) of the Act requires: (1) The computation of a standard prospective payment amount include all costs for home health services covered and paid for on a reasonable cost basis and that such amounts be initially based on the most recent audited cost report data available to the Secretary; (2) the prospective payment amount under the HH PPS to be an appropriate unit of service based on the number, type, and duration of visits provided within that unit; and (3) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs. Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the HH applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of appropriate case-mix adjustment factors for significant variation in costs among different units of services. Lastly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage related costs applicable to home health services furnished in a geographic area compared to the applicable national average level.

Section 1895(b)(3)(B)(iv) of the Act provides the Secretary with the authority to implement adjustments to the standard prospective payment amount (or amounts) for health services paid under Medicare. In addition, section 1895(b) of the Act requires: (1) The computation of a standard prospective payment amount include all costs for home health services covered and paid for on a reasonable cost basis and that such amounts be initially based on the most recent audited cost report data available to the Secretary; (2) the prospective payment amount under the HH PPS to be an appropriate unit of service based on the number, type, and

duration of visits provided within that unit; and (3) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs. Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the HH applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of appropriate case-mix adjustment factors for significant variation in costs among different units of services. Lastly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to home health services furnished in a geographic area compared to the applicable national average level.

Section 1895(b)(3)(B)(iv) of the Act provides the Secretary with the authority to implement adjustments to the standard prospective payment amount (or amounts) for subsequent years to eliminate the effect of changes in aggregate payments during a previous year or years that were the result of changes in the coding or classification of different units of services that do not reflect real changes in case-mix. Section 1895(b)(5) of the Act provides the Secretary with the option to make changes to the payment amount otherwise paid in the case of outliers because of unusual variations in the type or amount of medically necessary care. Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to the annual applicable percentage increase. Section 50208 of the BBA of 2018 (Pub. L. 115-123) requires the Secretary to implement a new methodology used to determine rural add-on payments for CYs 2019 through 2022.

Section 1895(b)(2) of the Act and section 1895(b)(3)(A) of the Act, as amended by section 51001(a)(1) and 51001(a)(2) of the BBA of 2018 respectively, require the Secretary to implement a 30-day unit of service, effective for CY 2020, and calculate a 30-day payment amount for CY 2020 in a budget neutral manner, respectively. In addition, section 1895(b)(4)(B) of the Act, as amended by section 51001(a)(3) of the BBA of 2018, requires the Secretary to eliminate the use of the

number of therapy visits provided to determine payment, also effective for CY 2020.

Finally, the HHVBP Model applies a payment adjustment based on an HHA's performance on quality measures to test the effects on quality and expenditures.

2. Home Infusion Therapy

Section 1861(iii) of the Act, as added by the Cures Act, sets forth three elements for home infusion therapy suppliers in three areas: (1) Ensuring that all patients have a plan of care established and updated by a physician that sets out the care and prescribed infusion therapy necessary to meet the patient-specific needs, (2) having procedures to ensure that remote monitoring services associated with administering infusion drugs in a patient's home are provided, and (3) having procedures to ensure that patients receive education and training on the effective use of medications and equipment in the home. These provisions serve as the basis for suppliers to participate in Medicare.

Section 1834(u) of the Act serves as the basis for the establishment of a prospective payment system for home infusion therapy covered under Medicare. Section 1834(u)(7) of the Act, as added by BBA of 2018 requires the Secretary to provide a temporary transitional payment to eligible home infusion therapy suppliers for items and services associated with the furnishing of transitional home infusion drugs for CYs 2019 and 2020. Under this payment methodology (as described in section VI.D. of this final rule with comment period), the Secretary will establish three payment categories at amounts equal to the amounts determined under the Physician Fee Schedule established under section 1848 of the Act for services furnished during CY 2019 for codes and units of such codes, determined without application of the geographic adjustment.

Section 1834(u)(5)(B) of the Act requires the Secretary to designate organizations to accredit qualified home infusion therapy suppliers furnishing home infusion therapy no later than January 1, 2021. Qualified home infusion therapy suppliers must furnish infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; ensure the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis; be accredited by an accrediting organization designated and approved by the Secretary; and meet other such requirements as the Secretary deems appropriate.

B. Overall Impact

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). The net transfer impact related to the changes in payments under the HH PPS for CY 2019 is estimated to be \$420 million (2.2 percent). The net transfer impact in CY 2020 related to the change in the unit of payment under the PDGM is estimated to be \$0 million as section 51001(a) of the BBA of 2018 requires such change to be implemented in a budget-neutral manner. The net transfer impact in CY 2019 related to the Temporary Transitional Payment for Home Infusion

Therapy is estimated to be \$48 million. The savings impacts related to the HHVBP model as a whole are estimated at \$378 million for CYs 2018 through 2022. Due to the modifications to OASIS item collection as a result of the changes to the HH QRP and the changes to the HH PPS (PDGM), both effective on and after January 1, 2020, we estimate that this rule generates \$60 million in annualized cost savings, or \$46 million per year on an ongoing basis discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2020. Finally, the estimated cost impact to each potential home infusion therapy AO is \$35,711. The cost of \$12,453 would be incurred by the home infusion AO for the preparation and submission of their initial application to CMS seeking CMS approval of the AO's home infusion therapy accreditation program. The AO will incur this \$12,453 cost with the submission of their initial application and then every 6 years thereafter, with the submission of their renewal application. The remaining costs of \$23,258, which represents the costs associated with the home infusion therapy AO's participation in ongoing CMS AO overview, monitoring and program review activities will be incurred on a bi-yearly basis.

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 Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

C. Anticipated Effects

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 hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$7.5 million to \$38.5 million in any one year. For the purposes of the RFA, we estimate that almost all HHAs are small entities as that term is used in the RFA. Individuals and states are not included in the definition of a small entity. 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. The majority of HHAs' visits are Medicare paid visits and therefore the majority of HHAs' revenue consists of Medicare payments. Based on our analysis, we conclude that the policies in this final rule with comment period will result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs. Therefore, the Secretary has determined that this HH PPS final rule would have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a RIA 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 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 is not applicable to hospitals. Therefore, the Secretary has determined this final rule with comment period would not have a significant economic impact on the operations 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 2018, that threshold is approximately \$150 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 \$150 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final 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 final rule with comment period 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 with comment period, we must estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that would review the rule, we assume that the total number of unique commenters on this year's final rule would be the similar to the number of reviewers of

last year's final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this 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 believe 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 would review this final rule with comment period. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule with comment period, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is \$107.38 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 5.3 hours for the staff to review half of this final rule with comment period, which consists of approximately 160,000 words. For each HHA that reviews the rule, the estimated cost is \$569.11 (5.3 hours \times \$107.38). Therefore, we estimate that the total cost of reviewing this regulation is \$767,729.39 (\$569.11 \times 1,349 reviewers).

1. HH PPS

a. HH PPS for CY 2019

The update set forth in this rule applies to Medicare payments under HH PPS in CY 2019. Accordingly, the following analysis describes the impact in CY 2019 only. We estimate that the net impact of the policies in this rule is approximately \$420 million in increased payments to HHAs in CY 2019. We applied a wage index budget neutrality factor and a case-mix weight budget neutrality factor to the rates as discussed in section III.C.3 of this final rule with comment period. Therefore, the estimated impact of the 2019 wage index and the recalibration of the case-mix weights for CY 2019 is \$0 million. The \$420 million increase reflects the distributional effects of the CY 2019 home health payment update of 2.2 percent (\$420 million increase), a 0.1 percent increase in payments due to the new lower FDL ratio, which will increase outlier payments in order to target to pay no more than 2.5 percent

of total payments as outlier payments (\$20 million increase) and a 0.1 percent decrease in payments due to the new rural add-on policy mandated by the BBA of 2018 for CY 2019 (\$20 million decrease). The \$420 million in increased payments is reflected in the last column of the first row in Table 44 as a 2.2 percent increase in expenditures when comparing CY 2018 payments to estimated CY 2019 payments.

With regard to options for regulatory relief, the rural add-on policy for CYs 2019 through 2022 is statutory and we do not have the authority to alter the methodology used to categorize rural counties or to revise the rural add-on percentages.

b. HH PPS for CY 2020 (PDGM)

We estimate no net impact of the policies related to the implementation of the PDGM for the CY 2020 HH PPS, as the transition to the 30-day unit of payment is required to be budget neutral. However, since the PDGM eliminates the use of therapy thresholds as a factor in determining payment, HHAs that provide more nursing visits, and thus experience lower margins under the current payment system which may incentivize overutilization of therapy, may experience higher payments. Conversely, HHAs that provide more therapy visits compared to nursing visits, and thus may profit more from the current payment system, may experience lower payments.

c. Elimination of Recertification Requirement To Estimate How Much Longer Home Health Services Will Be Required

Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act require, as a condition of payment, that a physician must certify (and recertify, when home health services are furnished over a period of time) that the individual is eligible for home health services. The regulations at § 424.22(b)(2) set forth the content and basis for recertification requirements and states that the recertification statement must indicate the continuing need for services and estimate how much longer the services will be required. This requirement has been longstanding policy that predates the Paperwork Reduction Act of 1995 requirements. Therefore, there is no corresponding Collection of Information that was submitted to the Office of Management and Budget (OMB) for review and approval for the burden estimate for the recertification requirement that the certifying physician must estimate how much longer home health services will be required.

In section III.G. of this final rule with comment period, we eliminate the regulatory requirement as set forth at 42 CFR 424.22(b)(1), that the certifying physician, as part of the recertification process, include an estimate of how much longer home health services will be required at each home health recertification. While all other recertification content requirements under § 424.22 will remain unchanged, the certifying physician would not be required to provide his/her estimation as to how much longer the patient will require home health services on recertifications on and after January 1, 2019. Therefore, we believe this would result in a reduction of burden for certifying physicians by reducing the amount of time physicians spend on the recertification process and we are providing an estimate on the reduction in burden in this final rule with comment period. All salary information is based on the May 2017 wage data for physicians and surgeons from the Bureau of Labor Statistics (BLS) website at (<https://www.bls.gov/oes/current/oes291069.htm>) and includes a fringe benefits and overhead worth 100 percent of the base salary.

Using CY 2017 claims, we estimate that of the total number of Medicare home health claims (5.8 million), 37 percent were recertifications (2.1 million) completed by 284,615 certifying physicians.⁸⁶ Of those 2.1 million recertifications, we estimate that the time needed to recertify patient eligibility will decrease by 2 minutes per recertification with a total reduction of 69,930 physician hours for all recertifications as a result of eliminating the time estimation statement. Based on the physician's hourly wage of \$203.26 as described previously (\$101.63 with 100 percent fringe benefits and overhead), this results in an overall annualized cost savings of \$14.2 million beginning in CY 2019.

2. HHVBP Model

Under the HHVBP Model, the first payment adjustment applies in CY 2018 based on PY1 (2016) data and the final payment adjustment will apply in CY 2022 based on PY5 (2020) data. In the CY 2016 HH PPS final rule, we estimated that the overall impact of the HHVBP Model from CY 2018 through CY 2022 was a reduction of approximately \$380 million (80 FR 68716). In the CY 2017 HH PPS final rule, we estimated that the overall impact of the HHVBP Model from CY 2018 through CY 2022 was a reduction

of approximately \$378 million (81 FR 76795). We do not believe the changes finalized in this rule would affect the prior estimates.

3. Home Infusion Therapy

a. Health and Safety Standards

Section 5012 of the Cures Act (Pub. L. 114–255), which amended section 1861(s)(2) of the Social Security Act (the Act), established a new Medicare home infusion therapy benefit. Section 1861(iii) of the Act, as added by section 5012 of the Cures Act defines, the Medicare home infusion therapy benefit and covers professional services including nursing services, training and education, and remote monitoring and monitoring services associated with administering certain infusion drugs in a patient's home. This benefit would ensure consistency in coverage for home infusion benefits for all Medicare beneficiaries. Section 1861(iii) of the Act, as added by the Cures Act, sets forth elements for home infusion therapy suppliers in three areas: (1) Ensuring that all patients have a plan of care established and updated by a physician that sets out the care and prescribed infusion therapy necessary to meet the patient-specific needs; (2) having procedures to ensure that remote monitoring services associated with administering infusion drugs in a patient's home are provided; and (3) having procedures to ensure that patients receive education and training on the effective use of medications and equipment in the home.

We implement the following requirements for home infusion therapy suppliers—

- Ensure that all patients must have a plan of care established by a physician that prescribes the type, amount and duration of infusion therapy services that are furnished. The plan of care would specify the care and services necessary to meet the patient specific needs.
- Ensure that the plan of care for each patient is periodically reviewed by the physician.
- Ensure that patients have infusion therapy support services at all times through the provision of professional services, including nursing services, furnished in accordance with the plan of care on a 7-day-a-week, 24-hour-a-day schedule.
- Provide patient training and education.
- Provide remote monitoring and monitoring services for the provision of home infusion therapy and home infusion drugs.
- All home infusion therapy suppliers must provide home infusion

therapy services in accordance with nationally recognized standards of practice, and in accordance with all applicable state and federal laws and regulations (including the applicable provisions in the Federal Food, Drug, and Cosmetic Act).

All current standards established by AOs already address the requirements set forth in this rule. Furthermore, all existing home infusion therapy suppliers are already accredited by an existing AO for home infusion therapy to meet requirements established by private insurers and Medicare Advantage plans. Therefore, we assume that there would be no new burden imposed on home infusion therapy suppliers in order to meet the health and safety standards. Additionally, we assume that these health and safety provisions would not impose a new burden on home infusion therapy AOs that are likely to apply to be Medicare approved AOs for home infusion therapy because their existing standards would already meet or exceed those that would be established in this rule.

b. Home Infusion Therapy Payment

We estimate that the net impact of the policies in this rule is approximately \$48 million (not including \$12 million in beneficiary cost-sharing) in increased Medicare payments to home infusion suppliers in CY 2019. This increase reflects the cost of providing infusion therapy services to existing Medicare beneficiaries who are receiving DME home infusion therapy (at a 4-hour rate), as the temporary transitional payment applies only to existing Medicare eligible home infusion suppliers (that is, DME suppliers that are enrolled as pharmacies that provide external infusion pumps and supplies are considered eligible home infusion suppliers). Prior to the implementation of the temporary transitional payment, home infusion suppliers have not been separately paid for providing these services under the DME benefit. For the temporary transitional payment we do not anticipate an increase in beneficiaries receiving home infusion therapy services as referral patterns are not likely to change significantly due to the inability for other provider types (for example, physicians, HHAs) to become home infusion therapy suppliers prior to CY 2021 and given that existing DME suppliers already provide home infusion therapy services without separate reimbursement.

c. Accreditation of Quality Home Infusion Therapy Suppliers

The requirement for accreditation of home infusion therapy suppliers will

⁸⁶ CY 2017 OASIS assessments matched to Medicare FFS claims (as of March 2, 2018).

cause both the home infusion therapy AOs and the home infusion therapy suppliers to incur costs related to the accreditation process. This section provides a discussion of the estimated time and cost burdens that home infusion therapy suppliers may incur as part of the accreditation process. It also discusses the estimated time and cost burdens that may be incurred by the home infusion therapy AOs to comply with the home infusion therapy AO approval and oversight regulations at §§ 488.1010 through 488.1050. As the following discussion demonstrates, we have estimated that each home infusion therapy AO would incur an estimated cost burden in the amount of \$23,258 for compliance with the home infusion therapy AO approval and oversight regulations at §§ 488.1010 through 488.1050.

(1) Burden Incurred by Home Infusion Therapy AOs

Section 1834(u)(5)(B) of the Act requires the Secretary to designate AOs to accredit suppliers furnishing home infusion therapy not later than January 1, 2021. To date, we have not solicited nor approved any AOs to accredit home infusion therapy suppliers as required by section 1834(u)(5)(B) of the Act.

The AOs that respond to the solicitation notice would be required to submit an application to CMS requesting CMS-approval of a home infusion therapy accreditation program for Medicare. If CMS approves the AOs application, the home infusion therapy AO would also be required to meet, on an ongoing basis, the requirements set forth in §§ 488.1010 through 488.1050. The following is a discussion of the burden associated with specific sections of the home infusion therapy AO approval and oversight regulations at §§ 488.1010 through 488.1050.

(a) Burden for Home Infusion Therapy AOs Associated With § 488.1010

The AOs that accredit home infusion therapy suppliers would incur time and costs burdens associated with the preparation of the application they submit to CMS requesting approval of their home infusion therapy accreditation program. This would include the preparation, gathering or obtaining of all the documentation required in § 488.1010(a)(1) through (24).

If the AO has never submitted an application to CMS, we estimate that it would take approximately 70 hours of time to gather, obtain or prepare all documentation required by § 488.1010(a)(1) through (23). However, for an existing AO that has previously

submitted an application to CMS for any type of accreditation program, we estimate that it would take approximately 45 hours to gather, obtain or prepare all required documentation. We believe that it would take less time for an AO that has previously submitted an application to CMS to prepare an application requesting approval of a home infusion therapy accreditation program because this AO would already be familiar with the application process and requirements. The application requirements for home infusion therapy AOs, set forth at § 488.1010(a)(1) through (23), are consistent with those for Medicare-certified providers and suppliers which are set forth at § 488.5.

The home infusion therapy AO would incur costs associated with the preparation and submission of the home infusion therapy accreditation program application. The home infusion therapy AO would incur costs for the wages of all AO staff that work on the preparation of the application. We estimate that the AO would have 2 staff work on the preparation of the application. We believe that the AO staff that works on the AOs application would be clinicians such as registered nurses or medical or health services manager. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>) and the mean hourly wage for a medical or health services manager is \$53.69 (<https://www.bls.gov/oes/current/oes119111.htm>). Therefore, we estimate that the home infusion therapy AO would incur wages for 45 hours of time by a registered nurse and wages for 45 hours of time by a medical or health services manager in the amount of \$8,014.50 (45 hours × \$35.36 per hour = \$1,591.20) + (45 hours × \$53.69 = \$2,416.05 per hour) + (\$4,007.25 for fringe benefits and overhead).

As stated previously, we estimate that it would take approximately 70 hours for an AO that has never submitted an application before to prepare and submit their home infusion therapy accreditation program application to CMS. We estimate that the home infusion therapy AO would incur wages for 70 hours of time by a registered nurse and 70 hours of time by a medical or health services manager in the amount of \$12,453 (70 hours × \$35.36 per hour = \$2,475.20) + (70 hours × \$53.59 = \$3,751.30) + (\$6,226.50 for fringe benefits and overhead).

In addition, AOs are required to submit 2 hard copies of their application to CMS in notebooks with dividers and an electronic copy of their application on a thumb drive. Because

of this requirement, the home infusion therapy AO would incur costs for the notebooks, dividers, thumb drive, photocopying, paper and ink, and postage costs for mailing the notebooks with the hard copies of the application to the CMS Central Office. We estimate that these costs would be no more than \$250.

At this time, there are five HHA AOs that accredit home infusion therapy suppliers as part of the deeming accreditation of a home health accreditation program (that is, The Joint Commission (TJC), Accreditation Commission for Health Care (ACHC), The Compliance Team (TCT), Community Health Accreditation Partner (CHAP), Healthcare Quality Association on Accreditation (HQAA)). The other three home infusion therapy AOs are pharmacy associations that provide non-Medicare approved accreditation to home infusion therapy suppliers. (That is, the National Association of Boards of Pharmacy, the Center for Pharmacy Practice Accreditation (CPPA) and URAC). The home infusion therapy accreditation programs offers by these 8 AO have not been approved under the requirements of section 1834(u)(5)(A) of the Act. Therefore, in order for the home infusion therapy suppliers accredited by these AOs to continue to receive payment for the home infusion therapy services furnished to Medicare beneficiaries, these AOs must obtain Medicare approval for a home infusion therapy accreditation program. If all of these eight AOs were to submit applications to CMS for approval of a home infusion therapy accreditation program, the cost incurred across all of these potential home infusion therapy AOs for the preparation and submission of their applications would be \$64,116 (\$4,007.25 × 8 AOs = \$32,058) + (\$32,058 for fringe benefits and overhead).

To obtain this CMS approval, these AOs would be required to submit an application to CMS seeking approval of a home infusion therapy accreditation program that meets the requirements set forth in the new home infusion therapy AO approval and oversight regulations set forth at § 488.1010(a)(1) through (a)(24) and the new home infusion therapy health and safety regulations at 42 CFR part 466, subpart I. We have further that the home infusion therapy accreditation programs submitted to CMS for approval by the existing home infusion therapy AOs be consistent with the requirements of section 5102 of the 21st Century CURES Act and section 1861(iii) of the Act. We would also require that the home infusion therapy

programs submitted by these AOs be separate and distinct from the AOs home health deeming accreditation program.

The AOs that currently provide home infusion therapy accreditation would incur the time and costs associated with the preparation of the CMS application and required supporting documentation. We estimate that it would take these AOs approximately 45 hours to prepare their applications and supporting documentation because they have previously submitted applications for approval of their home health accreditation programs. The existing AOs that accredit home infusion therapy suppliers would also incur costs for the wages for all AO staff involved with the preparation and submission of the application. The AO would also incur costs for printing the hard copies of the application, ink and paper, notebooks and dividers, and postage.

(b) Burden for Home Infusion Therapy AOs Associated With § 488.1030

In accordance with § 488.1030(b) CMS would perform a comparability review if CMS makes changes to the home infusion therapy AO approval and oversight regulations or home infusion therapy health and safety regulation. The purpose of the comparability review is to allow CMS to assess the equivalency of a home infusion therapy AO's accreditation standards with the comparable Medicare home infusion therapy accreditation requirements after CMS imposes new or revised Medicare home infusion therapy accreditation requirements.

Section 488.1030(b)(1) would provide that if CMS were to make changes to the home infusion therapy AO approval and oversight accreditation regulations or the home infusion therapy health and safety regulations, CMS would send a written notice of the changes to the home infusion therapy AOs. Section 488.1030(b)(2) would provide that CMS would provide a deadline of not less than 30 day by which the AO must submit its revised home infusion therapy accreditation program standards to CMS.

Section 488.1030(b)(2) would require the home infusion therapy AOs to revise their home infusion therapy accreditation standards so as to incorporate the changes made by CMS. The AO must submit their revised home infusion therapy accreditation program standards to CMS by the deadline specified in CMS' written notice. The AO may submit a request for an extension of the submission deadline, so long as the request is submitted prior to the original submission deadline.

The home infusion therapy AOs would incur a time burden associated with the time required for the AO staff to review CMS' notice of the revisions to the home infusion therapy AO approval and oversight accreditation standards or home infusion therapy health and safety standards. We estimate that it would take no more than 1 hour for the AO to review the notice from CMS notifying the AO of the changes to the AO approval and oversight regulations or health and safety regulation.

The home infusion therapy AOs would incur a cost burden for the wages of the AO staff that are involved with reviewing the CMS notice and the preparation of the home infusion therapy AO's revised accreditation program standards. We believe that the AO staff that would review the notice from CMS regarding changes to the CMS home infusion therapy regulations would be clinicians such as registered nurses. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a non-industry specific registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the home infusion therapy AO would incur a cost burden in the amount of \$70.72 for the preparation of the response to CMS (1 hour × \$35.36 per hour = \$35.36) + (\$35.36 for fringe benefits and overhead).

The home infusion therapy would also incur a cost burden for the wages of the AO staff for the time spent preparing the AOs revised home infusion therapy accreditation standards. There is uncertainty around our estimate of this cost because the amount of wages incurred would be dependent on the amount of time spent by the AO staff preparing the AOs revised accreditation standards.

We believe that the AO staff that would prepare the home infusion therapy AOs revised home infusion therapy accreditation standards would be a clinician such as registered nurses. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a non-industry specific registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). If we were to estimate that it would take 5 hours for the home infusion therapy AO to prepare the revised home infusion therapy accreditation standards, the estimated cost burden to the AO would be \$353.60 (5 hours × \$35.36 per hour = \$176.80) + (\$176.80 for fringe benefits and overhead).

At this time, there are five HHA AOs that accredit home infusion therapy suppliers as part of the deeming accreditation of a home health

accreditation program (that is, The Joint Commission (TJC), Accreditation Commission for Health Care (ACHC), The Compliance Team (TCT), Community Health Accreditation Partner (CHAP), Healthcare Quality Association on Accreditation (HQAA)). The other three home infusion therapy AOs are pharmacy associations that provide non-Medicare approved accreditation to home infusion therapy suppliers (that is, the National Association of Boards of Pharmacy, the Center for Pharmacy Practice Accreditation (CPPA) and URAC). The home infusion therapy accreditation programs offers by these 8 AO have not been approved under the requirements of section 1834(u)(5)(A) of the Act. If all of these eight AOs were to submit applications to CMS for approval of a home infusion therapy accreditation program, the cost incurred across all of these AOs for the preparation of revised accreditation standards would be \$2,828.80 (\$176.80 × 8 AOs = \$1,414.40) + (\$1,414.40 for fringe benefits and overhead). As provided by § 488.1030(b)(4), a home infusion therapy AO may request an extension of the deadline by which they must submit their revised accreditation home infusion therapy standards, so long as the extension request is submitted prior to the submission deadline. If the home infusion therapy AO requested an extension of the submission deadline, the AO would incur burden for the time required to prepare and submit the deadline extension request, however, we believe this burden would be minimal. We believe that the extension request could be sent in the form of an email to CMS, would consist of no more than a few paragraphs and would take no more than 15 minutes to prepare and send.

The AO would incur a cost burden for the wages for the AO staff who prepares the extension request. We believe that this email would be sent by an administrative assistant. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for an executive administrative assistant is \$28.56 (<https://www.bls.gov/oes/current/oes436011.htm>). We estimate that the AO would incur a cost burden for wages related to the preparation and sending of the extension request to CMS in the amount of \$14.28. (\$28.56 × 15 minutes = \$7.14) + (\$7.14 for fringe benefits and overhead).

At this time, there are eight AOs that accredit home infusion therapy suppliers (that is—The Joint Commission (TJC), Accreditation Commission for Health Care (ACHC), The Compliance Team (TCT),

Community Health Accreditation Partner (CHAP), Healthcare Quality Association on Accreditation (HCAA), National Association of Boards of Pharmacy), the Center for Pharmacy Practice Accreditation (CPPA) and URAC. If all of these eight AOs were to submit applications to CMS for approval of a home infusion therapy accreditation program, they could become CMS-approved home infusion therapy AOs. It is unlikely that all of the AOs would submit a request for an extension of the deadline to submit their revised accreditation standards to CMS. However, if this were to occur, the cost incurred across all of these AOs for the preparation of the extension requests by each home infusion therapy AO would be \$114.24 ($\$7.14 \times 8 \text{ AOs} = \57.12) + ($\$57.12$ for fringe benefits and overhead).

Section § 488.1030(b)(7) would provide that if CMS were to make significant substantial changes to the home infusion therapy AO approval and oversight accreditation standards or the home infusion therapy health and safety standards, we may require the home infusion therapy AOs to submit a new application for approval of their revised home infusion therapy accreditation programs. If this were to occur, the home infusion therapy AOs would incur a time burden for the time associated the preparation of the AOs new application.

We estimate that it would take the home infusion therapy AO approximately 45 hours to prepare and submit their new application to CMS. This would include the time and costs required to gather and prepare the required supporting documentation to go with the application. We believe that the home infusion therapy AOs would already be familiar with the CMS application process and would be able to use their previous application and supporting documentation with updates, therefore, the reapplication process would be less burdensome.

The home infusion therapy AO would also incur costs associated with the preparation and submission of a new application. The home infusion therapy AO would incur costs for the wages of all AO staff that work on the preparation of the application. We estimate that the AO would have 2 staff persons work on the preparation of the application. Furthermore, we believe that the AO staff that works on the AOs application would be clinicians such as a registered nurse and a medical or health services manager. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a non-industry specific registered nurse is \$35.36 ([https://](https://www.bls.gov/oes/current/oes291141.htm)

www.bls.gov/oes/current/oes291141.htm) and the mean hourly wage for a medical or health services manager is \$53.69 (<https://www.bls.gov/oes/current/oes119111.htm>). Therefore, we estimate that the home infusion therapy AO would incur wages for 45 hours of time by a registered nurse and 45 hours of time by a medical or health services manager in the amount of $\$8,014.50$ (45 hours \times $\$35.36$ per hour = $\$1,591.20$) + (45 hours \times $\$53.69$ = $\$2,416.05$ per hour) + ($\$4,007.25$ for fringe benefits and overhead). The cost across all the 6 potential home infusion therapy AOs would be $\$48,087$ ($\$4,007.25 \times 6 \text{ AOs} = \$24,043.50$) + ($\$24,043.50$ for fringe benefits and overhead).

In addition, AOs are required to submit 2 hard copies of their application to CMS in notebooks with dividers and an electronic copy of their application on a thumb drive. Because of this requirement, the home infusion therapy AO would incur costs for the notebooks, dividers, thumb drive, photocopying, paper and ink, and postage costs for mailing the notebooks with the hard copies of the application to the CMS Central Office. We estimate that these costs would be no more than \$250.

In accordance with § 488.1030(c), CMS will perform a standards review when the home infusion therapy AO makes updates to its accreditation standards and surveys processes. Section 488.1030(c)(1) would require that when a home infusion therapy AO proposed to adopt new or revised accreditation standards, requirements or changes in its survey process, the home infusion therapy AO must submit its revised accreditation standards and survey processes to CMS for review, at least 60 days prior to the implementation date of the revised standards. Section 488.1030(c)(3) would require that the home infusion therapy AO provide CMS with a detailed description of the changes that are to be made to the AO's home infusion therapy accreditation standards, requirements and survey processes and a detailed crosswalk (in table format) that states the exact language of the organization's revised accreditation requirements and the applicable Medicare requirements for each. Section 488.1030(c)(4) would provide that CMS must provide a written notice to the home infusion therapy accrediting organization which states whether the home infusion therapy accreditation program, including the revisions, continues or does not continue to meet or exceed all applicable Medicare home infusion therapy requirements within 60 days of

receipt of the home infusion therapy accrediting organization's changes. Section 488.1030(c)(5) would provide that if a home infusion therapy AO implements changes that have neither been determined nor deemed by CMS to be comparable to the applicable Medicare home infusion therapy requirements, CMS may open a home infusion therapy accreditation program review in accordance with § 488.1030(c) or (d).

The burden to the home infusion therapy AO associated with the standards review includes the time required for the home infusion therapy AO to prepare its revised accreditation standards and detailed crosswalk for submission to CMS and submit them to CMS for review. This burden would also include the time required for the AO staff to read and respond to CMS' written response. It is important to note that we do not include in our burden estimate the time that would be spent by the home infusion therapy AO in making voluntary revisions to their accreditation standards that are not required by CMS nor prompted by a regulatory change.

The home infusion therapy AO would also incur costs for the wages of the AO staff involved with the preparation of the AO's revised home infusion therapy accreditation standards and the detailed crosswalk for submission to CMS. The AO would also incur costs for wages for the time the AO staff spent reviewing CMS' response. However, the AO could send their revised accreditation standards to CMS via email, therefore the AO would not incur costs for postage.

We are not able to accurately estimate the total time and cost burden associated with the standards review because the time required for the home infusion therapy AO to prepare its revised home infusion therapy accreditation standards and detailed crosswalk would depend on the extent of the revision the AO has made to its home infusion therapy accreditation standards or survey processes. The burden would also depend of the content and length of CMS' response letter. However, we do estimate that the preparation of the home infusion therapy AOs revised accreditation standard and detailed crosswalk for submission to CMS would take no less than 5 hours.

We believe that the AO staff that would prepare the home infusion therapy AOs revised home infusion therapy accreditation standards and detailed crosswalk for submission to CMS would be clinicians such as registered nurses. According to the U.S.

Bureau of Labor Statistics, the mean hourly wage for a non-industry specific registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, if we were to estimate that this task would take 5 hours to complete, the cost burden to the home infusion therapy would be \$353.60 (5 hours × \$35.36 per hour = \$176.80) + (\$176.80 for fringe benefits and overhead).

We further estimate that it would take the home infusion therapy AO approximately 30 minutes for the home infusion therapy AO to review the CMS response to their submission of the revised home infusion therapy accreditation standards and detailed crosswalk. We believe that a clinician such as a registered nurse would review the CMS response letter. Therefore, the cost burden to the home infusion therapy AO associated with this task would be \$53.04 (45 minutes × \$35.36 per hour = \$26.52) + (\$26.52 for fringe benefits and overhead).

It is important to note that we have not calculated this burden across all of the potential home infusion therapy AOs. We have not done so because the submission of revised home infusion therapy accreditation standards by a home infusion therapy AO would only occur on an occasional basis and would never be done by all 6 potential AOs at the same time.

In accordance with § 488.1030(d), CMS may perform a home infusion therapy accreditation program review if a comparability, performance, or standards review reveals evidence of substantial non-compliance of a home infusion therapy AO's CMS-approved home infusion therapy accreditation program with the requirements of the home infusion therapy AO approval and oversight regulation at 42 CFR part 488, subpart L. If a home infusion therapy accreditation program review is initiated, CMS will provide written notice to the home infusion therapy AO indicating that its CMS-approved accreditation program approval may be in jeopardy and that a home infusion therapy accreditation program review is being initiated. The notice would provide all of the following information:

- A statement of the instances, rates or patterns of non-compliance identified, as well as other related information, if applicable.
- A description of the process to be followed during the review, including a description of the opportunities for the home infusion therapy accrediting organization to offer factual information related to CMS' findings.
- A description of the possible actions that may be imposed by CMS

based on the findings of the home infusion therapy accreditation program review.

- The actions the home infusion therapy accrediting organization must take to address the identified deficiencies.

- A timeline for implementation of the home infusion therapy accrediting organization's corrective action plan, not to exceed 180 calendar days after receipt of the notice that CMS is initiating a home infusion therapy accreditation program review.

Section 488.1030(d)(3) would provide that CMS will monitor the performance of the AO's home infusion therapy and the implementation of the corrective action plan during a probation period of up to 180 days. Section 488.1030(d)(4) would provide that if CMS determines, as a result of the home infusion therapy accreditation program review or a review of an application for renewal of the accrediting organizations existing CMS-approved home infusion therapy accreditation program, that the home infusion therapy accrediting organization has failed to meet any of the requirements of the regulations at §§ 488.1010 through 488.1050, CMS may place the home infusion therapy AO's CMS-approved home infusion therapy accreditation program on an additional probation period of up to 180 calendar days subsequent to the period described in § 488.1030(d)(1)(iv).

The time burden associated with the home infusion therapy accreditation program review includes the time burden associated with the AO's review of CMS' written notice which indicates that the home infusion therapy AO's CMS-approved accreditation program approval may be in jeopardy and that a home infusion therapy accreditation program review is being initiated. The time required for the review of the CMS letter will depend on the length of CMS' finding. However, we estimate it would take no more than 60 minutes to review this letter.

The AO would incur costs for the wages of the AO staff who performs the review of the CMS letter. We believe that an AO staff person with a clinical background such as a registered nurse would review the CMS letter. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, we estimate that the cost burden to the home infusion therapy AO associated with the review of the CMS letter would be approximately \$70.72 (1 hour × \$35.36 = \$35.36) + (\$35.36 for fringe benefits and overhead).

There is further burden associated with the requirement that the AO prepare and submit a written response to the CMS letter and a corrective action plan. However, we are unable to accurately estimate the time burden associated with this task because the amount of time required for the home infusion therapy AO to prepare the response letter and corrective plan would be dependent on the number and type of findings identified in CMS' letter.

However, we believe that an AO staff person with a clinical background such as a registered nurse would prepare the home infusion therapy AO's written response to the CMS letter and a corrective action plan. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). If we were to estimate that it would take the home infusion therapy AO 3 hours to prepare and submit a written response to the CMS letter and a corrective action plan, the estimated cost burden to the home infusion therapy AO associated with this task would be \$212.16 (3 hours × \$35.36 = \$106.08) + (\$106.08 for fringe benefits and overhead). Section 488.1030(d)(2) provides that CMS would review and approve the AO's plan of correction within 30 days of receipt. If CMS requires the home infusion therapy AO to make changes to their corrective action plan as a condition of approval, the AO would incur burden for the time required to make the required revisions to their plan of correction and resubmit it to CMS.

The home infusion therapy AO would incur a time burden for the time spent by the AO staff making corrections to the AOs corrective action plan. We are unable to accurately estimate how long it would take for the AO to revise its corrective action plan because the revision to be made to the corrective action plan would be dependent on the extent of the correction requested by CMS.

However, we believe that an AO staff person with a clinical background such as a registered nurse would make the corrections to the AOs corrective action plan. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). So, if we were to estimate that it would take the home infusion therapy AO 2 hours to prepare and submit a written response to the CMS letter and make any necessary revision to the corrective action plan, the estimated cost burden to the home

infusion therapy AO associated with this task would be $\$141.44$ (2 hours \times $\$35.36$ per hour = $\$70.72$) + ($\70.72 for fringe benefits and overhead). During the 180 day probationary period, CMS is likely to require the home infusion therapy AO to submit periodic progress reports and participate in periodic telephone to monitor the home infusion therapy AOs progress. The home infusion therapy AO would incur burden for the time required to prepare and submit an initial progress report. We estimate that the initial progress report would take approximately one hour to prepare. We further estimate that the burden associated with the preparation and submission of subsequent progress reports would be less than that for the initial progress report because the AO would be able to modify or update their initial or previous progress report. We estimate that it would take approximately 1 hour for the AO staff to prepare the initial progress report and 30 minutes for the AO staff to prepare subsequent progress reports. If CMS were to require the AO to submit one progress report per month during the entire 180 day probation period (6 months), the AO would have to submit 1 initial progress report and 5 subsequent progress reports. Therefore, we estimate that the AO would incur a time burden in the amount of 3.5 hours for the submission of all progress reports during the 180 day probation period. The AO would also incur a cost burden for the wages of the AO staff person who is involved in the preparation and submission of the progress reports. We believe that the initial and subsequent progress reports would be prepared by person with a clinical background such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $\$35.36$ (<https://www.bls.gov/oes/current/oes291141.htm>). We estimate that the home infusion therapy AO would incur a cost burden in the amount of $\$247.52$ for the preparation of the progress reports during the 180 day probation period (3.5 hours \times $\$35.36$ per hour = $\$123.76$) + ($\123.76 for fringe benefits and overhead).

The home infusion therapy AO would also incur burden associated with the time required to participate in the periodic phone calls with CMS. We are not able to accurately estimate the amount of time that would be required for these periodic phone calls because we do not know how often the AO would be required to participate in phone calls with CMS or how long these phone calls would last. However, we do

not believe that these phone calls would be held more often than monthly or last more than one hour. The AO would incur costs for the wages of all AO staff that participate in the periodic telephone calls. We are not able to accurately estimate the total cost burden for wages that would be incurred by the home infusion therapy AO at this time, because we do not know who from the AO would be attending these meetings.

If we were to estimate that these phone calls were to be held on a monthly basis during the 180 day probation period for a period of one hour period per call, the home infusion therapy AO would incur a time burden in the amount of 6 hours per each staff member that participates in these phone calls. We believe that the AO would have a minimum of 3 staff that are clinicians, such as registered nurses, participate on the call. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $\$35.36$ (<https://www.bls.gov/ooh/healthcare/registered-nurses.htm>). Therefore, the cost burden to the home infusion therapy AO for participation in the monthly telephone calls would be $\$1,272.96$ (3 AO staff \times $\$35.36$ per hour = $\$106.08$ per call per all staff/ $\$106.08$ per call per all staff \times 6 calls = $\$636.48$ total wages per all staff per all calls) + ($\$636.48$ for fringe benefits and overhead).

At or near the end of the first 180 day probationary period, CMS will make a decision as to whether the home infusion therapy AO has successfully come into compliance with the home infusion therapy regulations, or whether the AO has failed to do so. Section 488.1030(d)(4) would provide that if CMS finds that the home infusion therapy AO has failed to properly implement the plan of correction and come into compliance with the requirements of the home infusion therapy AO approval and oversight regulation or the home infusion therapy health and safety regulations, CMS may place the home infusion therapy AO's on an additional probation period of up to 180 calendar days. If this were to occur, the AO would incur the same or similar time and cost burdens as in the initial 180 day probationary period. (See previous estimates for the estimated time and cost burden associated with the 180-day probationary period).

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under \S 488.1030(d) across all of the potential home infusion therapy AOs. We have not done so because the act of CMS placing a home infusion therapy AO on

an accreditation program review would only occur on a sporadic and as needed basis. There is unlikely to ever be a situation in which all 8 potential AOs would be under an accreditation program review at the same time.

(c) Burden for Home Infusion Therapy AOs Associated With \S 488.1035

Section 488.1035 titled "Ongoing responsibilities of a CMS-approved home infusion therapy accrediting organization" would require that the home infusion therapy AO carry out certain activities and submit certain documents to CMS on an ongoing basis. Section 488.1035(a) would require the home infusion therapy AO to submit the following documents to CMS: (1) Copies of all home infusion therapy accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of findings with respect to unmet CMS requirements); (2) notice of all accreditation decisions; (3) notice of all complaints related to providers or suppliers; (4) information about all home infusion therapy accredited suppliers against which the home infusion therapy accreditation organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the providers or suppliers accreditation; (5) the home infusion therapy accrediting organization must provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends; (6) notice of any changes in the home infusion therapy accrediting organization's accreditation standards or requirements or survey process.

We believe that there would be little burden associated with this requirements for several reasons. First, while the home infusion therapy AOs would be required to provide copies of all survey reports and any survey-related information that CMS may require, the AOs would only be required to provide this information upon request. CMS may not request the home infusion therapy AO to submit this information if there are no compliance concerns. Second, we believe the home infusion therapy AO would keep these records in the normal course of their business as a home infusion therapy AO and would store the survey records in electronic format. As the AO already has this information prepared and stored in an electronic format, it would place little if any burden on the home infusion therapy AO to provide this information to CMS. We believe that the AO could send this information to CMS

via email and attach the survey record electronic files to the email.

We estimate that it would take approximately 30 minutes to locate the required survey information files and approximately 15 minutes for the AO staff to prepare an email to CMS and attach the electronic files to the email. We believe that the person at the AO that would prepare the email sending the survey information to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/ooh/healthcare/registered-nurses.htm>). Therefore, the cost burden to the home infusion therapy AO associated with the preparation and submission of the survey reports and information to CMS would be \$53.04 (30 minutes to locate information requested by CMS \times \$35.36 per hour = \$17.68) + (15 minutes \times \$35.36 = \$8.84) + (\$26.52 for fringe benefits and overhead). The estimated cost across the potential 8 home infusion therapy AOs for these tasks would be \$424.32 (\$53.04 \times 8 home infusion therapy AOs = \$424.32).

Section 488.1035(a)(2) would require the home infusion therapy AO to provide CMS with notice of all accreditation decisions made for each home infusion therapy supplier that files an application for accreditation. This would consist of a list of each home infusion therapy supplier that had filed an application with the home infusion therapy AO for accreditation and the accreditation decision made by the AO.

We believe that these accreditation decisions would be made by the AO in the normal course of the AOs business of performing accreditation of home infusion therapy suppliers. We further believe that there would be little burden associated with the requirement that the AO provide CMS with a list of the accreditation decisions made by the AO as this is information that would be readily available to the AO and that could quickly and easily be provided to CMS via email. We estimate that it would take approximately 15 minutes for the home infusion AO to gather the required accreditation decision information in preparation for sending it to CMS.

We believe that this information can be sent to CMS via email and estimate that it would take an additional 15 minutes for the AO staff to prepare an email to CMS and attach the electronic files containing the accreditation decision information to the email. We believe that the person at the AO who would prepare the accreditation

decision information and prepare the email to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation and submission of the survey reports and information to CMS would be \$35.36 (15 minutes \times \$35.36 per hour = \$8.84) and (15 minutes \times \$35.36 = \$8.84) + (\$17.68 for fringe benefits and overhead). The estimated cost across the potential 8 home infusion therapy AOs for these tasks would be \$282.88 (\$35.36 \times 8 home infusion therapy AOs = \$282.88).

Section 488.1035(a)(3) would require the AO to report complaint information to CMS. Complaint information is typically reported to CMS by other AOs by email on a monthly basis for the previous month. The contents of the complaint information reported to CMS would depend on whether the AO had received any complaints during the previous month. For example, if the AO received no complaint during the previous month, this email could consist of a sentence stating that the AO had received no complaints. If the AO had received one or more complaints during the previous month, the AO would be required to provide information about the nature of each complaint, a description of the investigation performed, a description of how the complaint was resolved and the date resolved.

We believe that there would be little burden associated with the reporting of complaint information by the home infusion therapy AO to CMS for several reasons. First, we estimate that the home infusion therapy AOs will rarely receive complaints about their accredited home infusion therapy suppliers. Second, we believe that the home infusion therapy AO will store information about any complaints received in an electronic format. Therefore, complaint information can be reported by the home infusion therapy AO to CMS via email. We estimate that the preparation of the complaint information email would take only no more than 15 minutes to prepare and send.

We believe that the person at the AO who would prepare the complaint information email and send it to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/>

[current/oes291141.htm](https://www.bls.gov/oes/current/oes291141.htm)). Therefore, the estimated monthly cost burden to the home infusion therapy AO associated with the submission of complaint information to CMS would be \$17.68 (15 minutes \times \$35.36 per hour = \$8.84) + (\$8.84 for fringe benefits and overhead). The estimated yearly burden to the home infusion therapy AO for this task would be \$212.16 (\$17.68 per month \times 12 months per year = \$212.16 per year).

The estimated monthly cost across the potential 8 home infusion therapy AOs for these tasks would be \$141.44 (\$17.68 \times 8 home infusion therapy AOs = \$141.44). The estimated yearly cost across the 6 potential home infusion therapy AOs would be \$1,697.28 (\$17.68 \times 8 AOs = \$141.44 per all AOs per month and \$141.44 per year \times 12 months per year = \$1,697.28). Section 488.1035(a)(4) would require the AO to provide CMS with information about all home infusion therapy accredited suppliers against which the home infusion therapy AO has taken remedial or adverse action, including revocation, withdrawal, or revision of the providers or suppliers accreditation. The information to be sent to CMS would simply consist of a list of the home infusion therapy suppliers and the type of remedial or adverse action taken.

We expect that when a home infusion therapy AO takes remedial or adverse action against its accredited supplier, the AO would prepare documentation which states the action taken and the reason this action was taken. We further believe that the AO would store this information electronically. This would enable the AO to send the required information to CMS via email. Therefore, we believe that there would be little burden associated with this requirement.

We believe that the home infusion therapy AOs could send information about adverse or remedial actions they have taken against their accredited suppliers via email. We estimate that it would take approximately 30 minutes for a home infusion therapy AO to prepare a report about the adverse or remedial actions taken against its accredited suppliers and approximately 15 minutes to prepare an email to CMS, attach the electronic file with the required information and send it to CMS. The home infusion therapy AOs would be required to report this information to CMS on a monthly basis.

The AO would incur a cost burden for the wages of the AO staff for the time spent preparing the report of the adverse or remedial action taken against the AO's accredited home infusion therapy suppliers and the time spent preparing

the email to CMS. We believe that the person at the AO who would prepare the report of adverse or remedial action taken and prepare the email to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost monthly cost burden to the home infusion therapy AO associated with the submission of information about the adverse or remedial action taken by the home infusion therapy AO against its accredited home infusion therapy suppliers to CMS would be \$53.04 (30 minutes \times \$35.36 per hour = \$17.68 + (15 minutes \times \$35.36 per hour = \$8.84) + (\$26.52 for fringe benefits and overhead). The estimated yearly cost burden to the home infusion therapy AO for this task would be \$636.48 (\$53.04 per month \times 12 months per year = \$636.48 per year).

The estimated monthly cost across the potential 8 home infusion therapy AOs for these tasks would be \$424.32 (\$53.04 \times 8 home infusion therapy AOs = \$424.32). The estimated yearly cost across the 8 potential home infusion therapy AOs would be \$5,091.84 (\$53.04 \times 8 AOs = \$424.32 per all AOs per month and \$424.32 per year \times 12 months per year = \$5,091.84).

Section 488.1035(a)(5) would require the home infusion therapy accrediting organization to provide, on an annual basis, summary data specified by CMS that relates to the past year's accreditation activities and trends. This summary data might include information such as the total number of complaints received during the year, the total number of immediate jeopardy situations found during the year, and the total number of deficiencies cited. We believe this is information that the AO would collect and document throughout the year in the normal course of business. We further believe that the home infusion therapy AO would prepare this year end summary data for their own informational, quality improvement, and research purposes.

We believe that there would be little, if any time burden associated with the submission of the documents and information required by § 488.1035(a)(5) by the home infusion therapy AOs to CMS, because these are documents which the AO would keep in the normal course of business, therefore these documents would be easily accessible to the home infusion therapy AO. Title 5 CFR 1320.3(b)(2) states that the time, effort, and financial resources necessary to comply with a collection of

information that would be incurred in the normal course of their activities (for example in compiling and maintaining business records) will be excluded from the burden if the agency demonstrates that the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary. Further, we believe that most, if not all of the home infusion therapy AOs would store these documents electronically and would be able to send them electronically to CMS via email.

The home infusion therapy AO would incur a time burden for the preparation and submission of the annual summary data to CMS. We estimate that it would take approximately 60 minutes for the home infusion therapy AO to locate the required annual summary data information and prepare it for submission to CMS. We further estimate that it would take an additional 15 minutes to prepare an email to CMS and attach the electronic files containing the summary data.

The home infusion therapy AO would incur a cost burden for the wages of the AO staff who prepares that summary data for submission to CMS and prepares the email to in which the annual summary data are submitted to CMS. We believe that the person at the AO who would prepare the summary data for submission to CMS and also prepare the email to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the home infusion therapy AO associated with the submission of summary data to CMS would be \$88.40 (60 minutes \times \$35.36 per hour = \$35.36) + (15 minutes \times \$35.36 per hour = \$8.84) + (\$44.20 for fringe benefits and overhead). The estimate cost burden across the 8 potential home infusion therapy AOs for this task would be \$707.20 (\$88.40 \times 8 potential home infusion therapy AOs = \$707.20).

Section 488.1035(b) would require that within 30 calendar days after a change in CMS requirements, the home infusion therapy accrediting organization must submit an acknowledgment of receipt of CMS' notification to CMS. The time burden associated with this requirement would be the time required for an AO staff person to review the notification from CMS about the change in home infusion therapy accreditation program requirements and the time required for the AO staff person to compose and

send an acknowledgement email to CMS.

We estimate the time required for the AO staff to review the notice of a change in CMS requirements would be 1 hour. We further estimate that the time that would be required to prepare and submit the acknowledgement of receipt of the CMS notice would be approximately 15 minutes because this notice could be sent to CMS via email and would only consist of 1–2 paragraphs.

The home infusion therapy AO would incur a cost burden for the wages of the staff for the time required to review the notice from CMS of the change in CMS requirements. The home infusion therapy AO would incur a cost burden for the wages of the staff for the time required to prepare the acknowledgement and submits it to CMS. We believe that the person at the AO who would prepare the email to CMS acknowledging receipt of the CMS notice would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>).

The estimated cost burden to the home infusion therapy AO associated with the review of the notice from CMS of changes to the CMS requirements would be \$70.72 (1 hour \times \$35.36 per hour) + (\$35.36 for fringe benefits and overhead). The estimated cost burden associated with the preparation and submission of the acknowledgement by the home infusion therapy AO would be \$17.68 (15 minutes \times \$35.36 per hour = \$8.84) + (\$8.84 for fringe benefits and overhead). The estimates cost across the 8 potential home infusion therapy AOs would be \$707.20 (\$70.72 \times 8 = \$565.76) + (\$17.68 \times 8 = \$141.44).

It is important to note that the home infusion therapy AOs would only have to perform these tasks if CMS were to make a change to the home infusion therapy standards. We believe that this would occur on an infrequent basis, therefore, the home infusion therapy AOs would incur these time and cost burdens on an infrequent basis.

Section 488.1035(c) would require that the home infusion therapy AO permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings. An example in which a surveyor would be needed to testify as a witness would be if there was litigation about CMS' termination of a home infusion therapy supplier's participation in the Medicare program and the surveyor that had performed a survey of that home infusion therapy supplier was needed to

testify about the survey findings. The burden associated with this requirement would be the time the surveyor spent providing testimony, any travel expenses the home infusion therapy AO would be responsible to pay, and the wages paid to the surveyor during the time spent giving testimony.

The home infusion therapy AO would incur a time burden for the time required for the AO's surveyor to serve as a witness. This would include travel time to and from the location where the hearing is being held. The AO would also incur cost burdens for the wages paid to the surveyor during the time they are serving as a witness and also for any travel expenses the AO may be required to pay, that are not reimbursed.

It is important to note that the home infusion therapy AO surveyors would rarely, if ever, be required to act as a witness. Therefore, this is a burden that the home infusion therapy AOs would not be likely to incur.

Section 488.1035(d) would require that, within 2 business days of identifying a deficiency of an accredited home infusion therapy supplier that poses immediate jeopardy to a beneficiary or to the general public, the home infusion therapy AO must provide CMS with written notice of the deficiency and any adverse action implemented by the AO. The burden associated with this requirement is the time required to provide notice to CMS of the immediate jeopardy situation and the wages for the AO staff person for the time spent preparing and submitting this notice.

We believe that the AO would keep this information in the normal course of their business of providing home infusion therapy accreditation. Therefore, the AO should have these readily available. We further believe that the home infusion therapy AOs would keep records related to immediate jeopardy findings in an electronic format.

The AO would incur a time burden for the time required to report the immediate jeopardy information to CMS. We estimate that it would take the AO no more than 20 minutes to prepare an email to CMS in which they provide the required information about the immediate jeopardy situation that has been discovered. The AO can attach electronic files to the email that contain the required information. It is important to note that we do not count, as a burden, the time spent by the home infusion therapy AO in finding the immediate jeopardy situation or resolving it, because it is the duty of any CMS-approved AO to monitor its accredited providers or supplier to

ensure they are providing care that meets the accreditation standards and that they do not have any situation that put the patients or general public in imminent danger of harm. The home infusion therapy AO would incur a cost burden for the wages of the AO staff that prepares the email to CMS which notified CMS of the immediate jeopardy situation. We believe that the person at the AO who would prepare the immediate jeopardy notification email to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation and submission of the acknowledgement by the home infusion therapy AO would be \$23.60 ($\35.36 divided by 60 minutes per hour = \$0.59 per minute/20 minutes \times \$0.59 per minute = \$11.80) + (\$11.80 for fringe benefits and overhead).

The home infusion therapy AOs would have to perform these tasks and incur these time and costs burdens only if they discover an immediate jeopardy situation with an accredited home infusion therapy supplier. We would like to point out that this would not be a regular time and cost burden that would be incurred by the home infusion therapy AOs, as the discovery of immediate jeopardy situations by AOs do not occur frequently.

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under § 488.1035(d) across all of the potential home infusion therapy AOs. We have not done so because the need for a home infusion therapy AO to report an immediate jeopardy situation to CMS would only occur on a sporadic basis. Section 488.1035(e) would require that within 10 calendar days after CMS' notice to a CMS-approved home infusion therapy AO that CMS intends to withdraw approval of the AO's home infusion therapy accreditation program, the home infusion therapy AO must provide written notice of the withdrawal to all of the home infusion therapy AO's accredited suppliers. The time burden associated with this requirement would be the time spent by the AO staff to prepare the required notice that must be sent to all of the AOs accredited home infusion therapy suppliers and the time required for the AO to send this notice out to all of its accredited suppliers.

We estimate that it would take that home infusion therapy AO

approximately 45 minutes to prepare the notice that they must send out to their accredited suppliers. We believe it would take an additional 2 minutes per letter to be sent by the home infusion therapy AO to its accredited suppliers to prepare these letters for mailing (that is—fold letter, place in envelope, affix correct amount of postage and place the letter into the outgoing mail). We are not able to accurately estimate the amount of time it would take for the AO to send this notice out to all of its accredited suppliers because this would be dependent on the number of accredited suppliers the AO has at the time. However, if we were to assume that a home infusion therapy AO had 50 accredited home infusion therapy suppliers, this task would take the AO staff 1.7 hours to complete (2 minutes \times 50 letters = 100 minutes) and (100 minutes divided by 60 minutes per hour = 1.7 hours).

The home infusion therapy AO would incur a cost burden for the wages of the AO staff person that prepares the required notification. We believe that the person at the AO who would prepare the required notification would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the required notice which is to be sent to all of the AO's accredited suppliers would be \$53.04 (45 minutes \times \$35.36 per hour = \$26.52) + (\$26.52 for fringe benefits and overhead).

The home infusion therapy would also incur a cost burden for the wages of the staff person for the time spent preparing the required notices for mailing and mailing them. We are unable to accurately estimate this cost burden because the time required to perform this task would be dependent on the number of accredited home infusion therapy supplier the AO has at the time. However, if we were to assume that a home infusion therapy AO had 50 accredited home infusion therapy suppliers, this task would take the AO staff 1.7 hours to complete (2 minutes \times 50 letters = 100 minutes/100 minutes divided by 60 minutes per hour = 1.7 hours). We believe that the person that would perform this task would be an Administrative Assistant. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for an executive administrative Assistant is \$28.56 (<https://www.bls.gov/oes/current/oes436011.htm>). Therefore, the home infusion therapy AO would incur a cost burden in the amount of \$97.92 for the

completion of this task (\$28.56 per hour divided by 60 minutes per hour = \$0.48 per minute/60 minutes per hour divided by 10 = 6 minutes per 0.1 hour/6 minutes \times 7 = 42 minutes = 0.7 hour/60 minutes + 42 minutes = 102 minutes or 1.7 hours/\$0.48 per minute \times 102 minutes = \$48.96) + (\$48.96 for fringe benefits and overhead). The home infusion therapy AO would incur an additional cost burden for miscellaneous costs. These costs would include the cost of the paper used to print the notices on, the printer ink used, the cost of the envelopes used, and the postage required to mail all the notices. We are unable to accurately estimate these costs as they are dependent on the number of notices that would be sent. We believe that these costs would not exceed \$250.

It is important to note that the home infusion therapy AO surveyors would rarely, if ever, be required to perform the tasks required by § 488.1035(e) because we would rarely withdraw the CMS approval of a home infusion therapy AO. We would do so if there were serious, unresolved compliance concerns that the AO was unable or unwilling to rectify, even after being placed on an accreditation program probationary period.

(d) Burden for Home Infusion Therapy AOs Related to § 488.1040

Section 488.1040 would require that as part of the application review process, the ongoing review process, or the continuing oversight of a home infusion therapy AO's performance, CMS may conduct onsite inspections of the home infusion therapy AO's operations and offices at any time to verify the home infusion therapy AO's representations and to assess the home infusion therapy AO's compliance with its own policies and procedures. Section 488.1040(b) provides that the activities to be performed by CMS staff during the onsite inspections may include, but are not limited to the following: (1) Interviews with various AO staff; (2) review of documents, survey files, audit tools, and related records; (3) observation of meetings concerning the home infusion therapy accreditation process; (4) auditing meetings concerning the accreditation process; (5) observation of in-progress surveys and audits; and (6) evaluation of the AO's survey results and accreditation decision-making process.

We believe that there would be little burden associated with the onsite visits made by CMS to the home infusion therapy AO's operations and offices because most of the activities related to the onsite visit involve work performed

by the CMS staff, which would not impose burden on the AO staff (such as review of records or observation of meeting held at the AOs offices). We estimate that the time burden to the home infusion therapy AO associated with these onsite visits would include the time required for the AO staff to greet the CMS team upon arrival and show them to the conference room, the time required to locate the records the CMS team requests for review, and the time required for CMS to conduct interviews of AO staff members. If the home infusion therapy AOs records are electronic, an AO staff member may need to remain with the CMS team during their record review to assist them with access to the AO's records.

We are not able to accurately estimate the total time that would be required for these activities because we have not yet accredited any home infusion therapy AOs, nor have we had an opportunity to perform an onsite visit to a home infusion therapy AO. We do not yet know what type of accreditation standards and surveys processes the home infusion therapy AOs would use. Also, we do not know the amount and type of records we would seek to review during an onsite visit to a home infusion therapy AO or approximately how much time we would need to review these records. Likewise, we do not yet know how much interaction we would need to have with the home infusion therapy AO staff or which AO staff members we would choose to interview. The onsite AO visits we have performed for other types of AOs have lasted 1 to 2 days depending on the type of AO.

However, if we estimate that it would take 1 hour for the CMS team entrance conference, 8 hours for the CMS team to perform their records review and 1 hour for the CMS team conduct the exit conference, the home infusion therapy AO would incur a time burden in the amount of 1 hour for each AO staff person that attends the entrance conference, 8 hours for any staff that remains with the CMS team to assist them with the record review and 1 hour of time for each AO staff person that attends the exit conference. We believe that the AO staff that would be attending the entrance and exit conferences and assisting the CMS staff with their records review would most likely be clinicians such as registered nurses. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a non-industry specific registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). We estimate that approximately 4 AO staff persons would attend the entrance and exit conferences and that one AO staff

person would assist the CMS team with their record review.

Based on the a previously stated time estimate, we estimate that the home infusion therapy AO would incur a cost burden in the amount of \$282.88 for wages for four AO staff for attendance at the entrance conference. (\$35.36 per hour per each AO staff \times 1 hour = \$35.36/\$35.36 per hour \times 4 AO staff = \$141.44) + (\$141.44 for fringe benefits and overhead).

We further estimate that the AO would incur a cost burden in the amount of \$282.88 for the wages of the four AO staff for attendance at the exit conference. (\$35.36 per hour per each AO staff \times 1 hour = \$35.36/\$35.36 per hour \times 4 AO staff = \$141.44) + (\$141.44 for fringe benefits and overhead).

We also estimate that the AO would incur a cost burden in the amount of \$565.76 for the wages of the AO staff person that would remain with the CMS team to assist them with their record review. (8 hours \times \$35.36 = \$282.88) + (\$282.88 for fringe benefits and overhead).

The total estimated cost burden to the home infusion therapy AO associated with the CMS onsite visit is \$1,131.52 (\$282.88 for entrance conference + \$282.88 for exit conference + \$565.76 for assisting CMS staff with record review = \$1,131.52). The estimated cost burden across all of the potential eight home infusion therapy AOs would be \$9,052.16 (\$1,131.52 \times 8 potential AOs = \$9,052.16).

In this final rule with comment period, we have the eight AOs that currently provide accreditation to home infusion therapy suppliers must submit an application to CMS for approval of a separate and distinct home infusion therapy accreditation program. A corporate onsite visit to the home infusion therapy AOs office is a part of the application review and approval process. Therefore, each of the AOs that submit an application to CMS for approval of a home infusion therapy program would incur the previously stated estimated burden related to the corporate onsite visit. However, after the initial application process has been completed, CMS would only make additional corporate onsite visits every 6 years when the home infusion therapy AOs submit their renewal application. Therefore, this would not be a frequent or ongoing burden incurred by the home infusion therapy AOs.

(e) Burden for Home Infusion Therapy AOs Related to § 488.1045

Section § 488.1045 contains regulations related to the voluntary and involuntary termination of the CMS

approval of a home infusion therapy AO's home infusion therapy accreditation program. Section 488.1045(a) would provide that a home infusion therapy accrediting organization that decides to voluntarily terminate its CMS-approved home infusion therapy accreditation program must provide written notice at least 90 days in advance of the effective date of the termination to CMS and each of its accredited home infusion therapy suppliers.

The requirement that the home infusion therapy AO provide notice of its decision to voluntarily terminate its CMS approved home infusion therapy accreditation program to CMS and all of its accredited home infusion therapy suppliers would cause the AO to incur the following time burdens: (1) The time required to prepare and send the required notice to CMS; and (2) the time required to prepare and send the required notice to all of the AOs accredited home infusion therapy suppliers. We would require that the AO send the required notice of their decision to voluntarily terminate its CMS-approved accreditation program to CMS by U.S. mail. We would also require the AO to send the required notice to all of its accredited home infusion therapy suppliers by U.S. mail. We estimate that it would take approximately 60 minutes for the AO staff person to prepare the letter to CMS in which the AO notified CMS that the AO wishes to voluntarily terminate its CMS-approved home infusion therapy accreditation program, print the letter and mail it.

We further estimate that it would take the AO staff person another 4 hours to perform the following tasks: (1) Draft a letter its accredited home infusion therapy suppliers, giving notice that the AO is voluntarily terminating its CMS approved home infusion therapy accreditation program; (2) perform a mail merge to prepare a copy of the letter addressed to each accredited home infusion therapy supplier; (3) print out a letter to each accredited supplier and envelope; put the letters into the envelopes; (4) affix the correct amount of postage; and (5) put the envelopes in the outgoing mail. We believe that the person at the AO who would perform these tasks would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the required notice which

is to be sent to all of the AO's accredited suppliers would be \$35.36 (60 minutes \times \$35.36 per hour = \$35.36).

The home infusion therapy AO would also incur a cost burden for the wages of the staff person for the time spent preparing and mailing the required notices to be sent to the AO's accredited home infusion therapy suppliers. As stated previously, we estimate that it would take approximately 4 hours of time for an AO staff person to prepare the required notification letter to the AOs accredited providers, print out a copy of the letter for each accredited home infusion therapy supplier and put these letters into the mail. We believe that the person at the AO who would perform these tasks would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the required notice for mailing would be \$353.60 (4 hours \times \$35.36 per hour = \$176.80) + (\$176.80 for fringe benefits and overhead).

The home infusion therapy AO would incur an additional burden for miscellaneous costs associated with the preparation of the required notices to be sent to CMS and the AOs accredited home infusion therapy suppliers, including the cost of the paper on which the notices are printed, the printer ink used, the cost of the envelopes used, and the postage required to mail all of the notices. We are unable to accurately estimate these costs as they are dependent on the number of notices that would need to be sent. However we believe these costs would not exceed \$200. We seek comment on how to estimate this burden.

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under § 488.1045 across all of the potential home infusion therapy AOs. We have not done so because the need for a home infusion therapy AO to perform these tasks only arise if a home infusion therapy AO voluntarily decides to terminate its CMS approved home infusion therapy accreditation program. This would occur rarely, if ever.

Section 488.1045(b) states that once CMS publishes a notice in the **Federal Register** announcing the decision to involuntarily terminate the home infusion therapy AO's home infusion therapy accreditation program, the home infusion therapy AO must provide written notification to all suppliers

accredited under its CMS-approved home infusion therapy accreditation program by no later than 30 calendar days after the notice is published in the **Federal Register**. This notice would announce that CMS is withdrawing its approval of the AOs home infusion therapy accreditation program and the implications for the home infusion therapy suppliers payment status in accordance with the requirements at § 488.1010(f) once their current term of accreditation expires.

The time burden associated with § 488.1045(b) would be the time it takes for the home infusion therapy AO to prepare and send the required written notification to all accredited home infusion therapy suppliers which states that CMS is withdrawing the AOs approval of the home infusion therapy accreditation program and which also states the implications for the home infusion therapy suppliers payment status. We estimate that it would take no more than 4 hours for an AO staff person to perform the following tasks: (1) Draft the required notification letter; (2) perform a mail merge to prepare a copy of the letter that is addressed to each home infusion therapy supplier accredited by the AO; (3) print copies of the notification letters for each of the AOs accredited home infusion therapy suppliers; (4) put each notifications letter into an envelope; (5) affix the correct amount of postage to the envelope and (6) put the envelopes into the outgoing mail.

The home infusion therapy AO would incur a cost burden for the wages for the AO staff who performs the previously stated tasks. We believe that the person at the AO who would perform these tasks would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the required notice which is to be sent to all of the AO's accredited suppliers would be \$282.88 (4 hours \times \$35.36 per hour = \$141.44) + (\$141.44 for fringe benefits and overhead).

The home infusion therapy AO would incur an additional burden for miscellaneous costs associated with the preparation of the required notices to be sent to the AOs accredited home infusion therapy suppliers, including the cost of the paper on which the notices are printed, the printer ink used, the cost of the envelopes used, and the postage required to mail all of the notices. We believe that these costs would not exceed \$200.

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under § 488.1045 across all of the potential home infusion therapy AOs. We have not done so because the need for a home infusion therapy AO to perform these tasks required by § 488.1045(b) would only arise if CMS decides to involuntarily terminate the CMS approval of the AO's home infusion therapy accreditation program. This would occur rarely, if ever.

Section 488.1045(c)(3) would require that for both voluntary and involuntary terminations of a home infusion therapy AOs CMS approved home infusion therapy accreditation program, the home infusion therapy AO must provide a second written notification to all of its accredited home infusion therapy suppliers ten calendar days prior to the AO's accreditation program termination effective date. We estimate that the time and cost burdens associated with this requirement would be the same as our estimated burden for proposed § 488.1045(b) set forth previously.

Section 488.1045(d) sets forth the required steps that a home infusion therapy AO must take when one of its accredited home infusion therapy suppliers has requested a voluntary withdrawal from accreditation. The withdrawal from accreditation by the home infusion therapy supplier may not become effective until the AO completes all of the following 3 steps: (1) The home infusion therapy AO must contact the home infusion therapy supplier to seek written confirmation that the home infusion therapy supplier intends to voluntarily withdraw from the home infusion therapy accreditation program; (2) the home infusion therapy AO must advise the home infusion therapy supplier, in writing, of the statutory requirement for accreditation for all home infusion therapy suppliers and the possible payment consequences for a lapse in accreditation status; (3) the home infusion therapy AO must submit their final notice of the voluntary withdrawal of accreditation by the home infusion therapy supplier to CMS by no later than 5 business days after the request for voluntary withdrawal is ultimately processed and effective.

The burden associated with the requirement that the home infusion therapy AO contact the home infusion therapy supplier to seek written confirmation that the home infusion therapy supplier intends to voluntarily withdraw from the home infusion therapy accreditation program would include the time required for the AO to contact the home infusion therapy

supplier to request written confirmation that the home infusion therapy supplier does indeed want to terminate their home infusion therapy accreditation. We estimate that the AO would most likely contact the home infusion therapy supplier to make this request by telephone or email. We estimate this would take no more than 15 minutes.

The AO would incur a cost burden for the wages of the AO staff person for the time spent contacting the home infusion therapy supplier to confirm they intend to voluntarily withdraw from the home infusion therapy accreditation program. We believe that the person at the AO who would perform this task would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the home infusion therapy AO associated with contacting the home infusion therapy supplier to confirm that they do want to voluntarily terminate would be \$17.68 (15 minutes × \$35.36 per hour = \$8.84) + (\$8.84 for fringe benefits and overhead).

The home infusion therapy AO would also incur a time burden associated with the requirement that they send a written notice to the home infusion therapy supplier that is voluntarily terminating their home infusion therapy accreditation, which provides notice of the statutory requirement for accreditation for all home infusion therapy suppliers and the possible payment consequences for a lapse in accreditation status. We estimate that it would take the home infusion therapy no more than 60 minutes to prepare the written notification.

We believe that the person at the AO who would prepare the required written notice to be sent to the home infusion therapy supplier that is voluntarily terminating its home infusion therapy accreditation would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the required written notice would be \$70.72 (1 hours × \$35.36 per hour = \$35.36) + (\$35.36 for fringe benefits and overhead). We further estimate that the AO would incur postage costs in the amount of \$0.50 for each letter sent.

Finally, we estimate the burden associated with § 488.1045(d)(3) would

include the time required for the home infusion therapy AO staff to prepare a final notice of voluntary withdrawal of accreditation by the home infusion therapy supplier and the time required to send this notice to CMS. We estimate that it would only take the AO staff 15 minutes or less to prepare the required notice for CMS, because this notice could be sent to CMS by email. We estimate it would take an additional 10 minutes of time for the AO staff to prepare the email and attach the written notice to the email.

The AO would incur a cost burden for the wages of the AO staff for the time spent preparing the notice and sending it to CMS. We believe that the person at the AO who would prepare the required written notice to be sent to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the required written notice to be sent to CMS would be \$29.48 (15 minutes × \$35.36 per hour = \$8.84) + (10 minutes × \$35.36 per hour = \$5.90) + (\$14.74 for fringe benefits and overhead).

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under § 488.1045(d) across all of the potential home infusion therapy AOs. We have not done so because the need for a home infusion therapy AO to perform these tasks would only arise if a home infusion therapy supplier would decide to voluntarily terminate its accreditation with the home infusion therapy AO. This would occur on an infrequent basis. We do not believe that there would ever be a situation in which all 6 of the potential home infusion therapy AOs would have a home infusion therapy supplier decide to voluntarily terminate the accreditation with their home infusion therapy AOs simultaneously.

(f) Burden for Home Infusion Therapy AOs Associated With § 488.1050

Section 488.1050(a) would provide that a home infusion therapy AO that is dissatisfied with a determination, made by CMS, that its home infusion therapy accreditation requirements do not provide or do not continue to provide reasonable assurance that the suppliers accredited by the home infusion therapy AO meet the applicable quality standards is entitled to reconsideration.

Section 488.1050(b)(1) would require that a written request for reconsideration be filed within 30 calendar days of the receipt of CMS' notice of an adverse determination or non-renewal. Section 488.1050(b)(2) would provide that the written request for reconsideration must specify the findings or issues with which the home infusion therapy AO disagrees and the reasons for the disagreement. Section 488.1050(c)(1) provides the opportunity for a hearing to be conducted by a hearing officer appointed by the Administrator of CMS and § 488.1050(c)(2) provides that written notice of the time and place of the hearing will be provided at least 10 business days before the scheduled date.

We estimate that it would take approximately 2 hours for a home infusion therapy AO to prepare its request for reconsideration. We believe that the person at the AO who would prepare the request for reconsideration would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the request for reconsideration would be \$141.44 (2 hours × \$35.36 per hour = \$70.72) + (\$70.72 for fringe benefits and overhead).

The remaining information that would be submitted in connection with a request for reconsideration or a reconsideration hearing, including any evidence or testimony provided is not considered "information" in accordance with 5 CFR 1320.3(h)(8), which excludes as "information" any "facts or opinions obtained or solicited at or in connection with public hearings."

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under § 488.1050 across all of the potential home infusion therapy AOs. We have not done so because we believe that the filing of a request for reconsideration by a home infusion therapy AO would occur rarely, if ever. Further, we do not believe that there would ever be a situation in which all 6 of the potential home infusion therapy AOs would decide to file a request for reconsideration at the same time. Therefore, there would never be an occurrence where all the home infusion therapy AOs would incur the previously stated burden simultaneously.

(g) Burdens for Home Infusion Therapy AOs Related to Survey Activities and Accreditation of Home Infusion Therapy Suppliers

The home infusion therapy AO would incur time and cost associated the accreditation of home infusion therapy suppliers. These would include the time and costs required to perform an onsite survey, offsite survey or other type of survey activity for each home infusion therapy supplier that has hired that AO to provide accreditation. However, as we have not approved any home infusion therapy AOs, we do not yet know what type of home infusion therapy accreditation standards they will use, or what the home infusion therapy accreditation survey process will consist of. Therefore, we are unable to accurately estimate the time and cost burden associated with the survey of home infusion therapy suppliers.

However, we can state that if the home infusion therapy AO were to perform an onsite survey, it would incur wages for each of the surveyors that are sent to perform the survey for the amount of time spent performing the survey. The AO would also incur wages for the time spent by the surveyors or other home infusion therapy AO staff in reviewing the survey documents, making a decision about whether to grant accreditation to the home infusion therapy supplier that was surveyed and preparing the decision letter to the home infusion therapy supplier. The AO would also incur travel costs for the AO staff to travel to the home infusion therapy supplier's location to perform the survey.

If the home infusion therapy AO were to do an offsite records audit survey, the AO would request that the home infusion therapy supply the AO with specific records. The AO would incur costs for the wages of the AO staff that performed the audit of the documents provided by the home infusion therapy supplier. The AO would also incur wages for the time spent by the surveyors or other home infusion therapy AO staff in making a decision about whether to grant accreditation to the home infusion therapy supplier that was audited and preparing the decision letter to the home infusion therapy supplier.

We solicited comment on how to estimate this burden and receive none.

2. Burden to Home Infusion Therapy Suppliers Related to Home Infusion Therapy Health and Safety Standards

All existing home infusion therapy suppliers are already accredited by existing home infusion therapy AOs to

meet requirements established by private insurers and Medicare Advantage plans. We that, in order for the existing home infusion therapy suppliers accredited by these AOs to continue to receive payment for the home infusion therapy services provided, these AOs must obtain Medicare approval for a home infusion therapy accreditation program. To obtain this CMS approval, we that these AOs would be required to submit an application to CMS seeking approval of a home infusion therapy accreditation program that meets the requirements set forth in the new home infusion therapy AO approval and oversight regulations and new home infusion therapy health and safety regulations. We would also require that the home infusion therapy program submitted by these AOs be separate and distinct from the AOs home health deeming accreditation program.

It is likely that the home infusion therapy suppliers would need to be resurveyed after their home infusion therapy AO obtains CMS approval of a home infusion therapy accreditation program, under section 1861(iii)(3)(D)(i)(III) of the Act. We believe this resurvey would be necessary because the AOs would have to determine if the home infusion therapy suppliers they accredit meet their new Medicare-approved home infusion therapy accreditation program accreditation standards. However, if a current home infusion therapy AOs current home infusion therapy standards already meet or exceed the home infusion therapy health and safety standards, so that a revision of that AOs home infusion therapy accreditation standards is not required, then a resurvey of that AO's accredited home infusion therapy suppliers may not be necessary.

The home infusion therapy supplier would incur some time burden in order to come into compliance with the home infusion therapy AOs new home infusion therapy accreditation program requirements initially and thus prepare for the accreditation survey. However, all existing home infusion therapy suppliers are already accredited by existing home infusion therapy AOs to meet requirements established by private insurers and Medicare Advantage plans. Therefore, we assume that there would be little, if any new burden imposed on home infusion therapy suppliers in order to implement the new health and safety standards.

The home infusion therapy supplier would be charged a fee by the AO for providing accreditation services. Fees for the home infusion therapy

accreditation currently offered by the six AOs listed previously accreditation programs offered by the six AOs listed previously vary between \$5,950 and \$12,500 and, in general, currently cover all of the following items: Application fee, manuals, initial accreditation fee, onsite surveys or other auditing (generally once every 3 years), and travel, when necessary for survey personnel. Accreditation costs also vary by the size of the provider or supplier seeking accreditation, its number of locations, and the number of services it provides.

We recognize that cost and time burdens associated with becoming accredited may be a barrier for small suppliers such as home infusion therapy suppliers. We are implementing the following to minimize the burden of accreditation on suppliers, including small businesses:

- Multiple accreditation organizations—We expect that more than one AO would submit an application to become a designated Home Infusion Therapy AO. We believe that selection of more than one home infusion therapy AO would introduce competition resulting in reductions in accreditation costs.

- Required plan for small businesses—During the application process we would require prospective home infusion therapy AOs to include a plan that details their methodology to reduce accreditation fees and burden for small or specialty suppliers. This would need to include that the AO's fees are based on the size of the organization.

- Reasonable quality standards—The quality standards that would be used to evaluate the services rendered by each home infusion therapy supplier are being in this rule. Many home infusion therapy suppliers already comply with the standards and have incorporated these practices into their daily operations. It is our belief that compliance with the quality standards would result in more efficient and effective business practices and would assist suppliers in reducing overall costs.

There are at least two important sources of uncertainty in estimating the impact of accreditation on home infusion therapy suppliers. First, our estimates assume that all home infusion therapy suppliers with positive Medicare payments would seek accreditation. We assume that home infusion therapy suppliers who currently receive no Medicare allowed charges would choose not to seek accreditation. It is also possible that many of the home infusion therapy suppliers with allowed charges between

\$1 and \$1,000 may decide not to incur the costs of accreditation.

Second, it is difficult to predict what accreditation fees would be in the future. Our experience with other accreditation programs has led us to believe that the accreditation rates would go up, due to factors such as wage increases, and increased travel costs. To monitor accreditation fees, we proposed to require the AOs for home infusion therapy suppliers to submit their fees to CMS for review for reasonableness. We would require home infusion therapy AOs to notify CMS anytime there is an increase in accreditation fees.

(d) Medicare-Certified Accreditation Organizations—Proposed Changes to 42 CFR 488.5

We proposed to modify the AO approval and oversight regulations for Medicare-certified providers and suppliers by adding two new requirements. The first new requirement would have been to add to 42 CFR 488.5(a)(7) a requirement that in their application for CMS approval, the AOs that accredited Medicare-certified providers and suppliers include a statement acknowledging that all accrediting organization surveyors have completed or will complete the relevant program-specific CMS online trainings established for state surveyors, initially, and thereafter. As stated previously, after consideration of the numerous comments we received in response to this proposal, we decided not to finalize this proposal. Therefore the burden estimates provided in the proposed rule regarding the proposed time and cost burden related to the requirement that AO surveyors take the CMS online surveyor training are no longer relevant.

The second requirement was to add § 488.5(a)(18)(iii) to would require that the AOs for Medicare-certified providers and suppliers include a written statement in their application for CMS approval agreeing that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program, the accrediting organization must continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first. As stated previously, we have made a decision to finalize this proposal without change or modifications.

(1) Burden Associated With the Online Training Requirement for AO Surveyors

A number of commenters expressed concern that the requirement that AO surveyors take the CMS online training would impose significant burden on the surveyors. Other commenters stated the belief that the AO training was adequate and that it was similar to the CMS online training, therefore the training requirement would be duplicative. Therefore, after consideration of the comments received, we have decided not to finalize the proposal to require AO surveyors to take the CMS online surveyor training.

(2) Burden Associated With the Statement Requirement for AOs

We finalized that AOs approved in accordance with section 1865 of the Act, and regulated under part 488 subpart A, provide a written statement in their application in which they agree to continue a provider's or supplier's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

Section 488.5(a)(18)(iii) would require the AOs for Medicare-certified providers and suppliers to include a written statement in their application for CMS approval of their accreditation program, agreeing that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program, the accrediting organization must continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

We believe that the AOs that accredit Medicare-certified providers and suppliers would incur limited burden associated with this requirement, because this regulation simply requires that the AOs to include a statement in their application stating that they agree to continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first, if a provider or supplier provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program. We believe that this written statement to be provided by the AO would consist of

only 1 to 2 paragraphs and would take no more than 15 minutes to prepare.

We believe that a clinician such as a registered nurse would prepare the required statement to be included in the AOs application. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the AOs that accredit Medicare-certified providers and suppliers associated with the preparation of the required statement would be approximately \$17.68 (15 minutes \times \$35.36 per hour = \$8.84) + (\$8.84 for fringe benefits and overhead)).

There are nine AOs that accredit Medicare-certified providers and suppliers. The cost across all AOs for the completion of this task would be \$158.12 (($\8.84×9 AOs = \$79.56) + (\$79.56 for fringe benefits and overhead)). However, AOs for Medicare-certified providers and suppliers are required to submit a renewal application only every 6 years. Therefore, the existing AOs would be required to submit the statement stating that they agree to continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first, if a provider or supplier provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program with their next renewal application which is submitted after the publication of the final rule. While we have calculated the cost for the performance of this task across all AOs that accredit Medicare-certified providers and suppliers, it is important to note that the existing AOs are scheduled to submit their renewal applications at varying dates and times over a period of several years. Therefore

there will be no time period in which all of these AOs will incur these expenses simultaneously.

D. Detailed Economic Analysis

1. HH PPS

This rule finalizes updates for the CY 2019 HH PPS rates contained in the CY 2018 HH PPS final rule (82 FR 51676 through 51752). The impact analysis of this final rule with comment period presents the estimated expenditure effects of policy changes in this final rule with comment period. We use the latest data and best analysis available, but we do not make adjustments for future changes in such variables as number of visits or case-mix.

This analysis incorporates the latest estimates of growth in service use and payments under the Medicare HH benefit, based primarily on Medicare claims data from 2017. We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to errors resulting from other changes in the impact time period assessed. Some examples of such possible events are newly-legislated general Medicare program funding changes made by the Congress, or changes specifically related to HHAs. In addition, changes to the Medicare program may continue to be made as a result of the Affordable Care Act, or new statutory provisions. Although these changes may not be specific to the HH PPS, 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 HHAs.

a. HH PPS for CY 2019

Table 44 represents how HHA revenues are likely to be affected by the

policy changes in this rule for CY 2019. For this analysis, we used an analytic file with linked CY 2017 OASIS assessments and HH claims data for dates of service that ended on or before December 31, 2017. The first column of Table 44 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The second column shows the number of facilities in the impact analysis. The third column shows the payment effects of the CY 2019 wage index and revised labor share. The fourth column shows the payment effects of the CY 2019 case-mix weights. The fifth column shows the effects of the new rural add-on payment provision in statute. The sixth column shows the effects of the revised FDL ratio used to calculate outlier payments, and the seventh column shows the effects of the CY 2019 home health payment update percentage.

The last column shows the combined effects of all the policies in this rule. Overall, it is projected that aggregate payments in CY 2019 would increase by 2.2 percent. As illustrated in Table 44, the combined effects of all of the changes vary by specific types of providers and by location. We note that some individual HHAs within the same group may experience different impacts on payments than others due to the distributional impact of the CY 2019 wage index, the extent to which HHAs had episodes in case-mix groups where the case-mix weight decreased for CY 2019 relative to CY 2018, the percentage of total HH PPS payments that were subject to the low-utilization payment adjustment (LUPA) or paid as outlier payments, and the degree of Medicare utilization.

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TABLE 44: ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2019

	Number of Agencies	CY 2019 Wage Index and Labor Share ¹	CY 2019 Case-Mix Weights ²	Rural Add-On Revisions	Updated Outlier FDL Ratio 0.51	CY 2019 HH Payment Update Percentage ³	Total
All Agencies	10,582	0.0%	0.0%	-0.1%	0.1%	2.2%	2.2%
Facility Type and Control							
Free-Standing/Other Vol/NP	1,062	-0.4%	0.0%	0.0%	0.2%	2.2%	2.0%
Free-Standing/Other Proprietary	8,432	0.1%	0.0%	-0.1%	0.1%	2.2%	2.3%
Free-Standing/Other Government	252	0.3%	0.2%	-0.1%	0.2%	2.2%	2.8%
Facility-Based Vol/NP	590	-0.1%	0.1%	0.0%	0.2%	2.2%	2.4%
Facility-Based Proprietary	64	-0.5%	0.2%	-0.2%	0.2%	2.2%	1.9%
Facility-Based Government	182	0.0%	0.2%	-0.3%	0.2%	2.2%	2.3%
Subtotal: Freestanding	9,746	0.0%	0.0%	-0.1%	0.1%	2.2%	2.2%
Subtotal: Facility-based	836	-0.1%	0.1%	-0.1%	0.2%	2.2%	2.3%
Subtotal: Vol/NP	1,652	-0.3%	0.0%	0.0%	0.2%	2.2%	2.1%
Subtotal: Proprietary	8,496	0.1%	0.0%	-0.1%	0.1%	2.2%	2.3%
Subtotal: Government	434	0.1%	0.2%	-0.2%	0.2%	2.2%	2.5%
Facility Type and Control: Rural							
Free-Standing /Other Vol/NP	255	-0.2%	0.2%	-0.3%	0.2%	2.2%	2.1%
Free-Standing /Other Proprietary	836	0.7%	0.1%	-0.7%	0.1%	2.2%	2.4%
Free-Standing /Other Government	167	0.4%	0.2%	-0.2%	0.2%	2.2%	2.8%
Facility-Based Vol/NP	263	0.2%	0.3%	-0.3%	0.2%	2.2%	2.6%
Facility-Based Proprietary	33	0.1%	0.4%	-0.5%	0.1%	2.2%	2.3%
Facility-Based Government	140	0.3%	0.3%	-0.4%	0.2%	2.2%	2.6%
Facility Type and Control: Urban							
Free-Standing/Other Vol/NP	807	-0.4%	0.0%	0.0%	0.2%	2.2%	2.0%
Free-Standing /Other Proprietary	7,596	0.0%	0.0%	0.0%	0.1%	2.2%	2.3%
Free-Standing /Other Government	85	0.2%	0.1%	0.0%	0.1%	2.2%	2.6%
Facility-Based Vol/NP	327	-0.2%	0.1%	0.0%	0.2%	2.2%	2.3%
Facility-Based Proprietary	31	-0.9%	0.1%	0.0%	0.2%	2.2%	1.6%
Facility-Based Government	42	-0.3%	0.1%	-0.1%	0.1%	2.2%	2.0%
Facility Location: Urban or Rural							
Rural	1,694	0.5%	0.2%	-0.6%	0.1%	2.2%	2.4%
Urban	8,888	-0.1%	0.0%	0.0%	0.1%	2.2%	2.2%
Facility Location: Region of the Country (Census Region)							
New England	364	-1.0%	0.0%	0.0%	0.2%	2.2%	1.4%
Mid Atlantic	483	-0.3%	-0.1%	0.0%	0.2%	2.2%	2.0%
East North Central	2,037	-0.3%	0.1%	0.0%	0.1%	2.2%	2.1%
West North Central	708	-0.1%	0.0%	0.0%	0.2%	2.2%	2.3%
South Atlantic	1,649	0.0%	-0.3%	0.0%	0.1%	2.2%	2.0%
East South Central	423	0.1%	-0.2%	-0.5%	0.1%	2.2%	1.7%
West South Central	2,777	0.7%	0.3%	-0.3%	0.1%	2.2%	3.0%
Mountain	682	-0.5%	0.0%	0.1%	0.2%	2.2%	2.0%
Pacific	1,419	0.3%	0.3%	0.0%	0.1%	2.2%	2.9%
Other	40	0.8%	-0.5%	0.0%	0.2%	2.2%	2.7%
Facility Size (Number of First Episodes)							

	Number of Agencies	CY 2019 Wage Index and Labor Share ¹	CY 2019 Case-Mix Weights ²	Rural Add-On Revisions	Updated Outlier FDL Ratio 0.51	CY 2019 HH Payment Update Percentage ³	Total
< 100 episodes	2,866	0.0%	0.5%	0.0%	0.2%	2.2%	2.9%
100 to 249	2,266	0.1%	0.5%	-0.1%	0.1%	2.2%	2.8%
250 to 499	2,237	0.1%	0.3%	-0.1%	0.1%	2.2%	2.6%
500 to 999	1,678	0.1%	0.1%	-0.1%	0.1%	2.2%	2.4%
1,000 or More	1,535	-0.1%	-0.1%	-0.1%	0.1%	2.2%	2.0%

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 for which we had a linked OASIS assessment.

¹The impact of the CY 2019 home health wage index is offset by the wage index budget neutrality factor described in section III.C.4 of this final rule with comment period.

²The impact of the CY 2019 home health case-mix weights reflects the recalibration of the case-mix weights offset by the case-mix weights budget neutrality factor described in section III.B. of this final rule with comment period.

³The CY 2019 home health payment update percentage reflects the home health payment update of 2.2 percent as described in section III.C.2. of this final rule with comment period.

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

Other=Guam, Puerto Rico, Virgin Islands

b. HH PPS for CY 2020 (PDGM)

Table 45 represents how HHA revenues are likely to be affected by the policy changes in this rule for CY 2020. For this analysis, we used an analytic file with linked CY 2017 OASIS assessments and CY 2017 HH claims data (as of March 2, 2018) for dates of service that ended on or before December 31, 2017. The first column of Table 45 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The second column shows the number of HHAs in the impact analysis. The PDGM, as required by Section 51001(a)(2)(A) of the BBA of 2018, will be implemented in a budget neutral manner and the third column shows the total impact of the PDGM as outlined in section III.F of this final rule with comment period. As illustrated in Table 45, the effect of the PDGM varies by specific types of

providers and location. We note that some individual HHAs within the same group may experience different impacts on payments than others. This is due to distributional differences among HHAs with regards to the percentage of total HH PPS payments that were subject to the low-utilization payment adjustment (LUPA) or paid as outlier payments, the degree of Medicare utilization, and the ratio of overall visits that were provided as therapy versus skilled nursing.

As outlined in section III.F of this final rule with comment period, several OASIS items would no longer be needed to case-mix adjust the 30-day payment under the PDGM; therefore, we would make 19 current OASIS items (48 data elements) optional at the follow-up (FU) time point starting January 1, 2020. As also discussed in section III.F. of this final rule with comment period, in order to calculate the case-mix adjusted payment amount for the PDGM, we

would add the collection of two current OASIS items (10 data elements) at the FU time point starting January 1, 2020. Section X. of this final rule with comment period provides a detailed description of the net decrease in burden associated with these changes in conjunction with the changes in burden that result from OASIS item collection changes due to the removal of certain measures required under HH QRP, also effective for January 1, 2020 as outlined in section V.E. of this final rule with comment period. Due to the modifications to OASIS item collection as a result of the changes to the HH QRP and the changes to the HH PPS (PDGM), both effective on and after January 1, 2020, we estimate that this rule generates \$60 million in annualized cost savings, or \$46 million per year on an ongoing basis discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2020.

TABLE 45: IMPACTS OF PDGM, CY 2020

	Number of Agencies	PDGM
All Agencies	10,520	0.00%
Facility Type and Control		
Free-Standing/Other Vol/NP	1,055	1.8%
Free-Standing/Other Proprietary	8,377	-0.9%
Free-Standing/Other Government	252	0.6%
Facility-Based Vol/NP	590	2.8 %
Facility-Based Proprietary	64	4.0%
Facility-Based Government	182	3.9%
Subtotal: Freestanding	9,684	-0.3%
Subtotal: Facility-based	836	3.0%
Subtotal: Vol/NP	1,645	2.1%
Subtotal: Proprietary	8,441	-0.8%
Subtotal: Government	434	2.3%
Facility Type and Control: Rural		
Free-Standing/Other Vol/NP	256	3.3%
Free-Standing/Other Proprietary	836	4.1%
Free-Standing/Other Government	167	0.7%
Facility-Based Vol/NP	263	3.1%
Facility-Based Proprietary	33	11.1%
Facility-Based Government	140	5.1%
Facility Type and Control: Urban		
Free-Standing/Other Vol/NP	799	1.7%
Free-Standing/Other Proprietary	7,541	-1.5%
Free-Standing/Other Government	85	0.5%
Facility-Based Vol/NP	327	2.8%
Facility-Based Proprietary	31	0.3%
Facility-Based Government	42	2.8%
Facility Location: Urban or Rural		
Rural	1,695	3.8%
Urban	8,825	-0.6%
Facility Location: Region of the Country (Census Region)		
New England	355	2.0%
Mid Atlantic	480	2.4%
East North Central	2,019	-1.3%
West North Central	706	-4.2%
South Atlantic	1,647	-5.1%
East South Central	423	1.0%
West South Central	2,753	4.6%
Mountain	679	-5.0%
Pacific	1,417	3.8%
Outlying	41	10.6%
Facility Size (Number of 60-day Episodes)		
< 100 episodes	2,804	2.4%
100 to 249	2,267	1.4%
250 to 499	2,237	1.0%
500 to 999	1,677	-0.1%
1,000 or More	1,535	-0.4%

	Number of Agencies	PDGM
Nursing/Therapy Visits Ratio		
1st Quartile (Lowest 25% Nursing)	2,630	-9.6%
2nd Quartile	2,630	-1.0%
3rd Quartile	2,630	6.2%
4th Quartile (Top 25% Nursing)	2,630	17.3%

Source: CY 2017 Medicare claims data (as of June 30, 2018) for episodes ending on or before December 31, 2017 for which we had a linked OASIS assessment.

Notes: The "PDGM" is the 30-day version of the model with no behavioral assumptions applied. From the impact file, this analysis omits 358,219 60-day episodes not grouped under the PDGM (either due to a missing SOC OASIS, because they could be assigned to a clinical grouping, or had missing therapy/nursing visits). After converting 60-day episodes to 30-day periods for the PDGM, a further 29 periods were excluded with missing NRS weights, and 2,439 periods with a missing urban/rural indicator. These excluded episodes results overall in 67 fewer HHAs being represented than in the standard impact tables. The standard 30-day payment amount used to achieve impact neutrality is \$1,883.34, a 17.40% increase from the standard 2019 amount (\$1,604.24).

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

Other=Guam, Puerto Rico, Virgin Islands

In response to the CY 2019 case-mix adjustment methodology refinements proposed in the CY 2018 HH PPS proposed rule (82 FR 35270), a few commenters requested that CMS include more information in the impact table for

the PDGM, specifically how payments are impacted for patients with selected clinical conditions as was included in the Technical Report which is available at: <https://downloads.cms.gov/files/hhgm%20technical%20report>

[%20120516%20sxf.pdf](#). Therefore, we are including Table 46 which provides more information on the impact of the PDGM case-mix adjustment methodology for patients with selected clinical conditions.

TABLE 46: IMPACT OF THE PDGM FOR SELECTED PATIENT CHARACTERISTICS

	Ratio of Average PDGM Payment to Average Current (30-Day Equivalent) Payment
All Episodes (30-day Non-LUPA)	1.00
Clinical Group	
Behavioral Health	0.85
Complex	1.06
MMTA - Cardiac	0.99
MMTA - Aftercare	1.09
MMTA - Endocrine	1.09
MMTA - GI/GU	0.98
MMTA - Infectious	1.01
MMTA - Respiratory	0.97
MMTA - Other	0.96
MS Rehab	0.97
Neuro Rehab	0.93
Wound	1.25
Functional Impairment Level	
Low	0.95
Medium	0.99
High	1.06
Admission Source	
Community	0.89
Institutional	1.29
Timing	
Early	1.25
Late	0.87
Comorbidity Group	
No adjustment	0.97
Single Comorbidity	1.02
Comorbidity Interaction	1.15
Dual Status	
Not (Full) Dual Eligible	0.99
Yes (Full) Dual Eligible	1.03
Parenteral Nutrition	
No Parenteral Nutrition	1.00
Yes Parenteral Nutrition	1.12
Surgical Wounds	
No Known Surgical Wound	0.98
Yes Known Surgical Wound	1.10
Ulcers	
No Ulcers Recorded	0.99
Positive Number of Ulcers Recorded	1.15
Bathing	
Able to Bathe with some independence	0.98
Cannot bathe independently	1.08
Poorly-Controlled Cardiac Dysrhythmia	
No Poorly-Controlled Cardiac Dysrhythmia	1.00
Yes Poorly-Controlled Cardiac Dysrhythmia	1.05
Poorly-Controlled Diabetes	

	Ratio of Average PDGM Payment to Average Current (30-Day Equivalent) Payment
No Poorly-Controlled Diabetes	0.99
Yes Poorly-Controlled Diabetes	1.08
Poorly-Controlled Peripheral Vascular Disease	
No Poorly-Controlled Peripheral Vascular Disease	1.00
Yes Poorly-Controlled Peripheral Vascular Disease	1.07
Poorly-Controlled Pulmonary Disorder	
No Poorly-Controlled Pulmonary Disorder	1.00
Yes Poorly-Controlled Pulmonary Disorder	1.01
Open Wound/Lesion	
No Open Wound/Lesion	0.98
Yes Open Wound/Lesion	1.10
Temporary Health Risk	
No Temporary Health Risk	0.99
Yes Temporary Health Risk	1.02
Fragile/Serious Health Risk	
Yes Fragile/Serious Health Risk	0.99
No Fragile/Serious Health Risk	1.04

Notes: **For this table only**, payments are for normal episodes and do not include outlier payments. For comparability with the 30-day PDGM, current payments have been halved from 60-day amounts to simulate 30-day payments. PDGM payments have been normalized so that national average 30-day payments equaled the 30-day current system equivalent payment (\$1,604.24) to facilitate an understanding of reallocation of payments from the current system: for the ratio of PDGM to current payments in the right-most column, a value greater than one signifies that characteristic would receive increased payment and a value less than one would signify that characteristic would receive lesser payment, all else equal, in the PDGM. To be classified as Poorly Controlled Cardiac Dysrhythmia, Diabetes, Peripheral Vascular Disease, or Pulmonary Disorder required one of the following respective primary or secondary diagnosis codes with an accompanying recorded "poorly-controlled" degree of symptom control:

Cardiac Dysrhythmia: ICD-10 I-21-I22.9 & I47-I49

Diabetes: E08.0-E08.8, E09.0-E09.8, & E10-E14

Peripheral Vascular Disease: ICD-10 I73

Pulmonary Disorder: (I40-47, J84.01, J84.02, J84.03, J84.10, J96.0-J96.92, & J98.01-J98.3)

2. HHVBP Model

Table 47 displays our analysis of the distribution for possible payment adjustments at the maximum 7-percent and 8-percent rates that will be used in Years 4 and 5 of the Model. These analyses use performance year data from 2016, the first year of HHVBP, the most recent year for which complete performance year data are available. The estimated impacts are for the following finalized changes, each of which will take effect beginning with PY4 (2019):

- Remove two OASIS-based measures (Influenza Immunization Received for Current Flu Season and Pneumococcal Polysaccharide Vaccine Ever Received);
- Replace three OASIS-based measures (Improvement in Bathing, Improvement in Bed Transferring, and Improvement in Ambulation- Locomotion) with two composite measures (Total Change in Self Care, Total Change in Mobility);

- Reduce the maximum possible improvement points from 10 to 9 (13.5 for the two composite measures); and,
- Change the weights given to the performance measures used in the Model so that the OASIS and claims-based measures each count for 35 percent and the HHCAHPS measures count for 30 percent of the 90 percent of the Total Performance Score (TPS) that is based on performance on the Clinical Quality of Care, Care Coordination and Efficiency, and Person and Caregiver-Centered Experience measures. Data reporting for each New Measure will continue to have equal weight and account for the 10 percent of the TPS that is based on the New Measures collected as part of the Model. The weight of the unplanned hospitalization measure will also be increased so that it has three times the weight of the ED use without hospitalization measure.

We analyzed the payment adjustment percentage and the number of eligible HHAs under current policy to determine

the impacts of the changes finalized in this rule. We used PY1 (CY2016) data to measure the impacts. The data sources for these analyses are data from the QIES system for the existing OASIS and claims-based measures, OASIS assessments for the two composite measures, HHCAHPS data received from the HHCAHPS contractor, and New Measure data submitted by Model participants. HHAs are classified as being in the smaller or larger volume cohort using the 2016 Quality Episode File, which is created using OASIS assessments. We note that this impact analysis is based on the aggregate value across all nine Model states.

Table 48 displays our analysis of the estimated impact of the policies finalized in this rule on the number of eligible HHAs and the distribution of percentage change in payment adjustment percentage based on the same PY1 (CY2016) data used to calculate Table 47. We note that this impact analysis is based on the aggregate value across all nine Model

states. Note that all Medicare-certified HHAs that provide services in Massachusetts, Maryland, North Carolina, Florida, Washington, Arizona, Iowa, Nebraska, and Tennessee are required to compete in this Model. The analysis is calculated at the state and size cohort level. It is expected that a certain number of HHAs would not have a payment adjustment because they may be servicing too small of a population to report an adequate number of measures to calculate a TPS. Table 48 shows that there would be a reduction in the number of HHAs that would have a sufficient number of measures to receive a payment adjustment for performance year 4 of 31 HHAs (Change column), a decrease from 1,610 HHAs (Current column) to 1,579 HHAs (Simulated column) across the nine selected states.

This analysis reflects only HHAs that would have data for at least five measures that meet the requirements of § 484.305 and would be included in the Linear Exchange Function and would have a payment adjustment calculated. Value-based incentive payment adjustments for the estimated eligible 1,579 HHAs in the selected states that would compete in the HHVBP Model are stratified by size as described in section IV.B. of the CY 2017 HH PPS final rule. As finalized in section IV.B. of the CY 2017 final rule, there must be a minimum of eight HHAs in any cohort.

Those HHAs that are in states that do not have at least eight smaller-volume HHAs will not have a separate smaller-volume cohort and thus there will only be one cohort that will include all the HHAs in that state. As indicated in Table 48, Maryland, North Carolina, Tennessee, Washington, and Arizona would have only one cohort while Florida, Iowa, Massachusetts, and Nebraska would have both a smaller-volume cohort and a larger-volume cohort. For example, Iowa would have 17 HHAs eligible to be exempt from being required to have their beneficiaries' complete HHCAHPS surveys because they provide HHA services to less than 60 beneficiaries. Therefore, those 17 HHAs would be competing in Iowa's smaller-volume cohort for CY 2019 (PY4) under the Model.

Table 48 shows the distribution of percentage change in payment adjustment percentage resulting from the policies finalized in this rule. Using 2016 data and the maximum payment adjustment for performance year 4 of 7 percent (as applied in CY 2021), based on the six finalized OASIS quality

measures and two claims-based measures in QIES, the five HHCAHPS measures, and the three New Measures, we see that, across all nine states, 31 HHAs would no longer be eligible for a payment adjustment for PY4 because they would not have data on at least five measures that meet the requirements of § 484.305. The distribution of scores by percentile shows the distribution of the change in percent payment adjustment. For example, the distribution for HHAs in Florida in the smaller-volume cohort ranges from -2.5 percent at the 10th percentile to +2.9 percent at the 90th percentile. This means that, for 7 of the 77 HHAs in the smaller-volume cohort in Florida, the changes would decrease their payment adjustment percentage by -2.5 percent or more while, for another 7 HHAs these changes would increase their payment adjustment percentage by 2.9 percent or more. For half of the HHAs in Florida's smaller volume cohort, the impact of these changes on their payment adjustment percentage would be between -1.1 percent and +1.3 percent. These impact analyses suggest that, for most participating HHAs, the impacts of the changes would be modest.

Table 49 provides the payment adjustment distribution based on agency size, proportion of dually-eligible beneficiaries, average case mix (using the average case-mix for non-LUPA episodes), the proportion of the HHA's beneficiaries that reside in rural areas and HHA organizational status. HHAs with a higher proportion of dually-eligible beneficiaries and HHAs whose beneficiaries have higher acuity tend to have a more negative impact associated with the policies finalized in this rule based on the 50th percentile of the impact of the changes on payment adjustment percentage.

Table 50 shows the current and revised weights, as finalized in this rule, for individual performance measures by measure category and possible applicable measure category scenarios to demonstrate the weight of the individual measures when an HHA has scores on All Measures or if an HHA is missing all measures in a measure category. For example, for an HHA that has quality measure scores on All Measures in all the measure categories (OASIS-based, claims-based and HHCAHPS) under the current weighting method, the individual measures are weighted equally. The Finalized Weights columns show the revised weights for the individual performance measures based on the changes to the weighting methodology finalized in this

final rule with comment period; specifically, to weight the measure categories so that the OASIS-based measure category and the claims-based measure category will each count for 35 percent and the HHCAHPS measure category will count for 30 percent of the 90 percent of the TPS that is based on performance of the Clinical Quality of Care, Care Coordination and Efficiency, and Person and Caregiver-Centered Experience measures. For example, for HHAs with scores on All Measures, the OASIS-based measures account for 35 percent, with equal weighting given to the Improvement in Oral Medications, Improvement in Dyspnea, Improvement in Pain, and Discharge to Community measures. The Composite Self-Care and Composite Mobility measures will be weighted 1.5 times more than the other OASIS-based measures so that the maximum score for the two composite measures is the same as for the three functional OASIS-based measures that they are replacing (Improvement in Ambulation, Bathing and Bed Transferring). Under the revised weights, the two claims-based measures, which will collectively account for 35 percent, will not be weighted equally. We are finalizing that the weight of the acute care hospitalization measure will be three times higher than that of the ED Use measure. Thus, its weight will be 26.25 percent while the weight of the ED Use measure will be 8.75 percent for an HHA that reported on all measures. The HHCAHPS measures will account for 30 percent and each measure will be weighted equally.

Table 50 also shows the number of HHAs that would have enough measures to receive a payment adjustment under each possible scoring scenario under both the current and revised weighting methodologies. Most of the HHAs that would no longer receive a payment adjustment with the changes finalized in this rule are those with no claims or HHCAHPS measures. With only OASIS measures, these HHAs are more impacted by the finalized policy to remove the two immunization measures and the finalized policy to replace three OASIS functional measures with the two composite measures. The number of HHAs without claims or HHCAHPS measures that would have enough OASIS-based measures to receive a payment adjustment would drop from 99 to 73 (a decrease of 26 HHAs), and the majority of these HHAs would be smaller HHAs (16 of the 26 HHAs).

TABLE 47: ADJUSTMENT DISTRIBUTION BY PERCENTILE LEVEL OF QUALITY TOTAL PERFORMANCE SCORE AT DIFFERENT MODEL PAYMENT ADJUSTMENT RATES (PERCENTAGE)

Payment Adj. Distribution	Maximum Payment Adjustment Percentage	Percentile								
		10%	20%	30%	40%	Median	60%	70%	80%	90%
7% Payment Adj. For PY4 of the Model	7%	-3.3%	-2.4%	-1.7%	-0.9%	-0.2%	0.5%	1.2%	2.2%	3.7%
8% Payment Adj. For PY5 of the Model	8%	-3.8%	-2.8%	-1.9%	-1.0%	-0.3%	0.5%	1.4%	2.5%	4.2%

TABLE 48: HHA COHORT PAYMENT ADJUSTMENT DISTRIBUTIONS BY STATE/COHORT
 [Based on a 7-percent payment adjustment]

State	Cohort	Number of Eligible HHAs			Distribution of Percentage Change in Payment Adjustment Percentage Resulting From Finalized Changes				
		Current	Simulated	Change	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
	All	1610	1579	31	-2.1%	-1.0%	-0.1%	0.9%	1.9%
HHAs with no separate small HHA cohort									
AZ	All	113	112	1	-2.7%	-1.4%	-0.1%	0.7%	1.8%
MD	All	51	50	1	-1.7%	-0.6%	-0.3%	0.9%	1.6%
NC	All	163	163	0	-1.6%	-0.8%	0.0%	0.7%	1.9%
TN	All	122	122	0	-1.2%	-0.7%	0.2%	0.8%	1.7%
WA	All	57	57	0	-1.3%	-0.8%	0.0%	0.8%	2.0%
Large-volume HHA Cohort in states with small cohort									
FL	Large	706	703	3	-2.3%	-1.2%	-0.2%	1.0%	2.0%
IA	Large	99	97	2	-1.9%	-1.2%	-0.2%	0.8%	1.5%
MA	Large	123	119	4	-2.0%	-1.1%	-0.4%	0.5%	1.4%
NE	Large	45	45	0	-2.8%	-0.9%	-0.3%	0.6%	1.8%
Small-volume HHA Cohort in states with small cohort									
FL	Small	77	68	9	-2.5%	-1.1%	0.1%	1.3%	2.9%
IA	Small	25	17	8	0.1%	1.3%	2.9%	4.4%	6.4%
MA	Small	15	12	3	-1.4%	-0.5%	0.3%	1.5%	2.2%
NE	Small	14	14	0	-3.0%	-1.0%	0.0%	1.2%	2.2%

TABLE 49: PAYMENT ADJUSTMENT DISTRIBUTIONS BY CHARACTERISTICS FOR THE HHVBP MODEL
 [Based on a 7-percent payment adjustment ^{1,2}]

Cohort	Number of Eligible HHAs			Distribution of Percentage Change in Payment Adjustment Percentage Resulting From Finalized Changes				
	Current	Simulated	Change	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
Facility size (# of patients)								
Small HHA	136	117	19	-3.2%	-1.6%	-0.2%	1.1%	3.1%
Large HHA	1474	1462	12	-2.0%	-1.0%	-0.1%	0.9%	1.9%
Percentage of Medicaid patients								
No Medicaid	749	743	6	-2.2%	-1.1%	-0.1%	0.9%	2.0%
>0 and < 30% Medicaid	661	653	8	-1.7%	-0.9%	0.0%	0.9%	1.9%
30%+ Medicaid	200	183	17	-2.6%	-1.4%	-0.4%	0.6%	1.8%
Patient acuity								
Low Acuity	403	384	19	-2.2%	-1.0%	-0.1%	1.0%	2.0%
Medium Acuity	805	798	7	-1.8%	-0.9%	0.0%	0.9%	1.9%
High Acuity	402	397	5	-2.3%	-1.3%	-0.3%	0.9%	2.0%
Percentage of rural beneficiaries								
None	1482	1458	24	-2.1%	-1.1%	-0.1%	0.9%	1.9%
> 0 and < 90%	11	10	1	-4.1%	-1.1%	-0.4%	0.3%	1.7%
>=90%	117	111	6	-1.7%	-0.9%	0.2%	1.5%	2.7%
Facility type and control								
Non-profit	310	308	2	-1.4%	-0.8%	0.2%	1.0%	1.9%
For profit	1191	1169	22	-2.2%	-1.1%	-0.2%	0.8%	1.9%
Government	109	102	7	-1.9%	-0.9%	0.0%	1.2%	2.7%
Freestanding	1448	1419	29	-2.1%	-1.1%	-0.2%	0.9%	1.9%
Facility-based	162	160	2	-1.2%	-0.5%	0.2%	1.1%	2.0%

¹ Rural beneficiaries identified based on the CBSA code reported on the claim.

² Acuity is based on the average case-mix weight for non-LUPA episodes. Low acuity is defined as the bottom 25% (among HHVBP model participants); mid-acuity is the middle 50% and high acuity is the highest 25%.

TABLE 50: CURRENT AND FINALIZED WEIGHTS FOR INDIVIDUAL PERFORMANCE MEASURES FOR THE HHVBP MODEL ¹²³

	Current Weights				Finalized Weights: All Changes			
	All Measures (n=1,026)	No HHCAPHS (n=465)	No claims (n=20)	No claims or HHCAPHS (n=99)	All Measures (n=1,026)	No HHCAPHS (n=460)	No claims (n=20)	No claims or HHCAPHS (n=73)
<i>Large HHAs</i>	1023	382	20	49	1023	380	20	39
<i>Small HHAs</i>	3	83	0	50	3	80	0	34
OASIS (35% weight)¹								
Flu vaccine ever received ²	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%
Pneumococcal vaccine ²	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%
Improve Bathing ³	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%
Improve Bed Transfer ³	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%
Improve Ambulation ³	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%
Improve Oral Meds	6.25%	9.09%	7.14%	11.11%	5.00%	7.14%	7.69%	14.28%
Improve Dyspnea	6.25%	9.09%	7.14%	11.11%	5.00%	7.14%	7.69%	14.28%
Improve Pain	6.25%	9.09%	7.14%	11.11%	5.00%	7.14%	7.69%	14.28%
Discharge to Community	6.25%	9.09%	7.14%	11.11%	5.00%	7.14%	7.69%	14.28%
Composite self-care	0.00%	0.00%	0.00%	0.00%	7.50%	10.71%	11.53%	21.42%
Composite mobility	0.00%	0.00%	0.00%	0.00%	7.50%	10.71%	11.53%	21.42%
<i>Total weight for OASIS measures</i>	56.25%	81.82%	64.26%	100.00%	35.00%	49.98%	53.82%	99.96%
Claims (35% weight)								
Hospitalizations	6.25%	9.09%	0.00%	0.00%	26.25%	37.50%	0.00%	0.00%
Outpatient ED	6.25%	9.09%	0.00%	0.00%	8.75%	12.50%	0.00%	0.00%
<i>Total weight for claims measures</i>	12.50%	18.18%	0.00%	0.00%	35.00%	50.00%	0.00%	0.00%
HHCAPHS (30% weight)								
Care of patients	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
Communication between provider and patient	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
Discussion of specific care Issues	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
Overall rating of care	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
Willingness to recommend HHA to family or friends	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
<i>Total weight for HHCAPHS measures</i>	31.25%	0.00%	35.70%	0.00%	30.00%	0.00%	46.15%	0.00%

Notes:

¹ Under the finalized weights, the weights of the measure categories, when one category is removed, are based on the relative weight of each category when all measures are used. For example, if the two measure categories, Claims and OASIS, are expressed then each category represents 50% because each of these categories has the same weight (35%) when all 3 categories are represented (the OASIS percentage is shown as 49.98% in Table 50 due to rounding). However, if only OASIS and HHCAPHS are expressed, OASIS represents 53.82% while HHCAPHS represents 46.15%, which represents the same relative proportion as 35% and 30%, the OASIS and HHCAPHS weights, respectively, when all three categories are present.

² The flu vaccine ever received and pneumococcal polysaccharide vaccine measures are finalized to be removed from the applicable measure set beginning in CY 2019/PY4.

³ The Improvement in Bathing, Improvement in Bed Transfer and Improvement in Ambulation measures are finalized to be removed from the applicable measure set and replaced with the two new composite measures beginning in CY 2019/PY4. These new composite measures (Composite Self-Care and Composite Mobility) will be weighted 1.5 times more than the other OASIS-based measures so that the total weight for the functional-based OASIS measures is unchanged.

3. HH QRP

Failure to submit data required under section 1895(b)(3)(B)(v) of the Act with respect to a calendar year will result in the reduction of the annual home health market basket percentage increase otherwise applicable to a HHA for that calendar year by 2 percentage points. In section V.G. of this final rule with comment period, we revised our regulations at § 484.250(a) to clarify that not all OASIS data described in § 484.55(b) and (d) are needed for purposes of complying with the requirements of the HH QRP. There are no changes in this final rule with comment period in our method for applying the 2 percentage point reduction to HHAs that fail to meet the HH QRP requirements. For the CY 2018 annual payment update determination, 1,311 of the 11,776 active Medicare-certified HHAs, or approximately 11.1 percent, did not receive the full annual percentage increase. Information is not available to determine the precise number of HHAs that would not meet the requirements to receive the full annual percentage increase for the CY 2019 payment determination.

In section V.E. of this final rule with comment period, we are removing seven measures from the HH QRP: Depression Assessment Conducted, Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care, Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537), Pneumococcal Polysaccharide Vaccine Ever Received, Improvement in the Status of Surgical

Wounds, Emergency Department Use without Hospital Readmission during the First 30 Days of HH (NQF #2505), and Rehospitalization during the First 30 Days of HH (NQF #2380). Their associated burden decreases are for CY 2020 because HHAs will no longer be required to submit data on these measures beginning CY 2020. As noted previously, section X. of this final rule with comment period provides a detailed description of the net decrease in burden associated with these changes in conjunction with the changes in burden that result from the implementation of the PDGM for CY 2020. Due to the modifications to OASIS item collection as a result of the changes to the HH QRP and the changes to the HH PPS (PDGM), both effective on and after January 1, 2020; we estimate that this rule generates \$60 million in annualized cost savings, or \$46 million per year on an ongoing basis discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2020.

4. Home Infusion Therapy Payment

The following analysis applies to the Temporary Transitional Payment for Home Infusion Therapy as set forth in section 1834(u)(7) of the Act, as added by section 50401 of the BBA of 2018 (Pub. L. 115–123), and accordingly, describes the impact for CY 2019 only. Table 51 represents the estimated increased Medicare costs of existing beneficiaries who are furnished DME and are currently using home infusion therapy services. We used CY 2017 data

to identify beneficiaries with DME claims containing 1 of the 37 HCPCS codes identified in section 1834(u)(7)(C) of the Act, which are shown in column 2. In column 3, 2017 claims were again used to determine the total weeks of care, which is the sum of weeks of care across all beneficiaries found in each category. Weeks of care for payment categories 1 and 3 are defined as the week of the last infusion drug or pump claim minus the week of the first infusion drug or pump claim plus one. For Category 2, we used the median number of weeks of care, 47, as many patients use immune globulin for the whole year. Column four assumes the initial week of care requires two nurse visits, and all subsequent weeks only require one visit, in order to estimate the total visits of care per category. In general, nursing visits for payment category 2, subcutaneous immune globulin (SCIG) administration, occur once per month; therefore, we assume the estimated number of visits for these patients is 12. The fifth column multiplies the volume of nurse visits across beneficiaries by the payment rate (using the 2018 Physician Fee Schedule amounts) in order to estimate the increased cost per each of the three infusion drug categories.⁸⁷ At the time of publication, we did not have the 2019 Physician Fee Schedule rate in order to complete our impact analysis; however, actual payments starting on January 1, 2019 would be based on the Physician Fee Schedule amounts as specified in section 50401 of the BBA of 2018.

TABLE 51: ESTIMATED INCREASED MEDICARE COSTS OF EXISTING BENEFICIARIES WHO ARE FURNISHED DME AND ARE CURRENTLY USING HOME INFUSION THERAPY SERVICES, CY 2019

BBA of 2018 Category	Number of Beneficiaries	Total Weeks of Care	Estimated Total Visits of Care	Payment Rate	Estimated Cost
1	6,141	134,575	140,716	141.12	\$19,857,842
2	6,713	256,177	80,556	224.28	\$18,067,100
3	5,932	90,097	96,029	239.76	\$23,023,913
Estimated Medicare Costs				80%	\$48,759,084
Estimated Beneficiary Costs				20%	\$12,189,771
Total	18,786				\$60,948,855

Source: CY 2017 Medicare DME claims data as of June 30, 2018 containing HCPCS codes equal to one of the 37 codes listed in BBA of 2018.

Table 52 displays the estimated regional impacts using the beneficiary enrollment address reported in the Medicare Master Beneficiary Summary

File. Table 53 displays impacts based on rural or urban designations. All beneficiaries identified had at least one applicable home infusion claim (claims

with 1 of the 37 drug codes listed in section 1834(u)(7)(C) of the Act) in CY 2017. Unknown beneficiaries were those without valid state and county

⁸⁷ Based on the 2018 Medicare PFS these rates are \$141.12 (\$74.16 + 3 * \$22.32) for Category 1,

\$224.28 (\$176.76 + 3 * \$15.84) for Category 2, and \$239.76 (\$144.72 + 3 * \$31.68) for Category 3.

information in the Master Beneficiary Summary File. Additionally, the tables provide the estimated impacts by drug category.

TABLE 52: ESTIMATED IMPACTS OF THE TEMPORARY TRANSITIONAL PAYMENT FOR HOME INFUSION THERAPY SERVICES BY REGION, CY 2019

Census Division	Number of Home Infusion Patients	Total Estimated Costs [in \$]				Estimated Medicare Costs (80% of Total) [in \$]				Estimated Beneficiary Costs (20% of Total) [in \$]			
		Category 1	Category 2	Category 3	Total	Category 1	Category 2	Category 3	Total	Category 1	Category 2	Category 3	Total
New England	748	\$,060,799.04	906,988.32	266,373.36	2,234,160.72	848,639.23	725,590.66	213,098.69	1,787,328.58	212,159.81	181,397.66	53,274.67	446,832.14
Mid-Atlantic	3,620	2,792,764.80	1,663,260.48	8,922,428.64	13,378,453.92	2,234,211.84	1,330,608.38	7,137,942.91	10,702,763.13	558,552.96	332,652.10	1,784,485.73	2,675,690.79
East North Central	2,606	3,297,409.92	1,851,655.68	3,478,438.08	8,627,503.68	2,637,927.94	1,481,324.54	2,782,750.46	6,902,002.94	659,481.98	370,331.14	695,687.62	1,725,500.74
West North Central	1,350	1,212,220.80	1,442,568.96	1,685,273.04	4,340,062.80	969,776.64	1,154,055.17	1,348,218.43	3,472,050.24	242,444.16	288,513.79	337,054.61	868,012.56
South Atlantic	4,620	4,508,925.12	5,178,176.64	4,685,150.16	14,372,251.92	3,607,140.10	4,142,541.31	3,748,120.13	11,497,801.54	901,785.02	1,035,635.33	937,030.03	2,874,450.38
East South Central	1,267	1,363,219.20	1,647,112.32	693,625.68	3,703,957.20	1,090,575.36	1,317,689.86	554,900.54	2,963,165.76	272,643.84	329,422.46	138,725.14	740,791.44
West South Central	1,796	2,616,082.56	1,924,322.40	973,185.84	5,513,590.80	2,092,866.05	1,539,457.92	778,548.67	4,410,872.64	523,216.51	384,864.48	194,637.17	1,102,718.16
Mountain	888	994,896.00	1,474,865.28	297,062.64	2,766,823.92	795,916.80	1,179,892.22	237,650.11	2,213,459.13	198,979.20	294,973.06	59,412.53	553,364.79
Pacific	1,821	1,983,723.84	1,937,779.20	1,917,600.48	5,839,103.52	1,586,979.07	1,550,223.36	1,534,080.38	4,671,282.81	396,744.77	387,555.84	383,520.10	1,167,820.71
Other	70	27,800.64	40,370.40	104,775.12	172,946.16	22,240.51	32,296.32	83,820.10	138,356.93	5,560.13	8,074.08	20,955.02	34,589.23
Total	18,786	19,857,841.92	18,067,099.68	23,023,913.04	60,948,854.64	15,886,273.54	14,453,679.74	18,419,130.42	48,759,083.70	3,971,568.38	3,613,419.94	4,604,782.62	12,189,770.94

Source: CY 2017 Medicare DME claims data as of June 30, 2018 containing HCPCS codes equal to one of the 37 codes listed in BBA of 2018.

TABLE 53: ESTIMATED URBAN/RURAL IMPACTS OF THE TEMPORARY TRANSITIONAL PAYMENT FOR HOME INFUSION THERAPY SERVICES, CY 2019

CBSA Urban/Rural	Number of Home Infusion Patients	Total Estimated Costs				Estimated Medicare Costs (80% of Total)				Estimated Beneficiary Costs (20% of Total)			
		Category 1	Category 2	Category 3	Total	Category 1	Category 2	Category 3	Total	Category 1	Category 2	Category 3	Total
Urban	15,369	\$16,398,144.00	\$15,399,961.92	\$17,966,655.36	\$49,764,761.28	\$13,118,515.20	\$12,319,969.54	\$14,373,324.29	\$39,811,809.03	\$3,279,628.80	\$3,079,992.38	\$3,593,331.07	\$9,952,952.25
Rural	3,367	\$3,441,634.56	\$2,626,767.36	\$5,019,855.12	\$11,088,257.04	\$2,753,307.65	\$2,101,413.89	\$4,015,884.10	\$8,870,605.64	\$688,326.91	\$525,353.47	\$1,003,971.02	\$2,217,651.40
Unknown	50	\$18,063.36	\$40,370.40	\$37,402.56	\$95,836.32	\$14,450.69	\$32,296.32	\$29,922.05	\$76,669.06	\$3,612.67	\$8,074.08	\$7,480.51	\$19,167.26
Total	18,786	\$19,857,841.92	\$18,067,099.68	\$23,023,913.04	\$60,948,854.64	\$15,886,273.54	\$14,453,679.75	\$18,419,130.44	\$48,759,083.73	\$3,971,568.38	\$3,613,419.93	\$4,604,782.60	\$12,189,770.91

Source: CY 2017 Medicare DME claims data as of June 30, 2018 containing HCPCS codes equal to one of the 37 codes listed in BBA of 2018.<PHOTO>

E. Alternatives Considered

1. HH PPS

a. HH PPS for CY 2019

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2019 be increased by a factor equal to the applicable HH market basket update for those HHAs that submit quality data as required by the Secretary. For CY 2019, Section 1895(b)(3)(B)(vi) of the Act requires that the market basket update under the HHA prospective payment system be adjusted by changes in economy-wide productivity. The 0.8 percentage point multifactor productivity adjustment to the CY 2019 home health market basket update of 3.0 percent, is discussed in the preamble of this final rule with comment period and is not discretionary as it is a requirement in section 1895(b)(3)(B)(vi)(I) of the Act.

We considered not rebasing the home health market basket. However, we believe that it is desirable to rebase the home health market basket periodically so that the cost category weights reflect changes in the mix of goods and services that HHAs purchase in furnishing home health care. In addition, we considered not implementing the revision to the labor-related share of 76.1 percent in a budget neutral manner. However, we believe it is more prudent to implement the revision to the labor-related share in a manner that does not increase or decrease budgetary expenditures.

With regards to payments made under the HH PPS for high-cost outlier episodes of care (that is, episodes of care with unusual variations in the type or amount of medically necessary care), we did not consider maintaining the current FDL ratio of 0.55. As discussed in section III.E.3. of this final rule with comment period, we revise the FDL ratio to 0.51. Simulations using CY 2017 claims data and the CY 2019 HH PPS payment rates resulted in an estimated 2.32 percent of total HH PPS payments being paid as outlier payments using the existing methodology for calculating the cost of an episode of care. The FDL ratio and the loss-sharing ratio must be selected so that the estimated outlier payments do not exceed the 2.5 percent of total HH PPS payments (as required by section 1895(b)(5)(A) of the Act). Therefore, lowering the FDL ratio results in 2.32% in outlier payments that rises closer to but does not exceed the 2.5% in total outlier payments. We did not consider proposing a change to the loss sharing ratio (0.80) in order for the HH PPS to remain consistent with

payment for high-cost outliers in other Medicare payment systems (for example, IRF PPS, IPPS, etc.)

b. HH PPS for CY 2020 (PDGM)

For CY 2020, we did not consider alternatives to changing the unit of payment from 60 days to 30 days, eliminating the use of therapy thresholds for the case-mix adjustment, and requiring the revised payments to be budget neutral. Section 51001 of the BBA of 2018 requires the change in the unit of payment from 60 days to 30 days to be made in a budget neutral manner and mandates the elimination of the use of therapy thresholds for case-mix adjustment purposes. The BBA of 2018 also requires these measures to be implemented on January 1, 2020 and that we make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of payment and as a result of the case-mix adjustment factors that are implemented in CY 2020 in calculating a 30-day payment amount for CY 2020 in a budget neutral manner.

Alternatives to making 19 current OASIS items (48 data elements) optional at the FU time point as outlined in section X. of this final rule with comment period, would be to either not implement the case-mix adjustment methodology changes under the PDGM or to continue collecting the 19 current OASIS items at the FU time point, even though they would not be used to case-mix adjust payments under the PDGM. Similarly, an alternative to adding collection of two current OASIS items (10 data elements) at the FU time point as discussed in section X. of this final rule with comment period would be to either not adopt the PDGM or not to include the two current OASIS items (M1800 and M1033) as part of the case-mix adjustment methodology under the PDGM. As noted previously, we did not consider not implementing the case-mix methodology changes under the PDGM as a new case-mix adjustment methodology is required to be implemented in accordance with section 51001 of the BBA of 2018, which mandates the elimination of the use of therapy thresholds for case-mix adjustment purposes by January 1, 2020. We believe that continuing to require HHAs to report responses for the 19 current OASIS items at the FU time point that are no longer needed for case-mix adjustment purposes under the PDGM results in unnecessary burden for HHAs. While requiring HHAs to report responses for two current OASIS items at the FU time point results in a small increase in burden if CMS were to not make 19 current OASIS items optional

at the FU time point, those two OASIS items (M1800 and M1033) are correlated with increases in resource use and are used to determine the patient's functional impairment level under the HHGM, thus they are important for case-mix adjustment purposes in order to ensure accurate payments to HHAs under the PDGM.

We considered whether to continue using the wage-weighted minutes of care (WWMC) approach to estimate resource use under the PDGM, as described in section III.F.2. of this final rule with comment period. Although the relationship in relative costs between the WWMC approach and the cost-per-minute plus non-routine supplies (CPM+NRS) approach is very similar (correlation coefficient equal to 0.8512), the WWMC approach does not as evenly weight skilled nursing costs relative to therapy costs as evidenced in the cost report data and would require us to maintain a separate case-mix adjustment mechanism for NRS. If we were to maintain the current WWMC approach, skilled nursing and therapy costs would not be as evenly weighted and a certain level of complexity in calculating payments under the HH PPS would persist as we would need to continue with the current method of case-mix adjusting NRS payments separate from service costs (that is, skilled nursing, physical therapy, occupational therapy, speech-language pathology, home health aide, and medical social services) under the HH PPS.

In this final rule with comment period and to begin in CY 2020, we considered proposing a phase-out of the split percentage payment approach by reducing the percentage of the upfront payment over a period of time and requiring a notice of admission (NOA) to be submitted upon full elimination of the split-percentage payment. However, we wanted to take the opportunity in this year's rule to more clearly signal our intent to potentially eliminate the split percentage payment approach over time as a reduced timeframe for the unit of payment (30 days rather than 60 days) is now required in statute. Given that existing HHAs (certified with effective dates prior to January 1, 2019) would need to adapt to changes in cash flow with the elimination of the split percentage payment approach, we hope to receive additional feedback on the timeframes for a phase-out of the split percentage payment approach and whether there is a need for an NOA upon completion of a phase-out of the split percentage payment approach that we can take into consideration for potential future rulemaking.

2. HHVBP Model

We considered various alternatives to our proposals for the HHVBP Model. For the vaccination measures, we considered continuing to include them in the applicable measure set instead of removing them. However, for the reasons discussed in section IV of this final rule with comment period, we are finalizing our proposal to remove the two vaccination measures beginning with PY4.

With regard to our proposal to replace three OASIS-based measures with two composite measures, we also considered making no changes to the OASIS-based measures category.

Another alternative to this proposal would be to finalize one but not both composite measures. We discussed in the proposed rule the proposed scoring that would apply if we adopted this alternative. However, for the reasons discussed in section IV.B of this final rule with comment period, we are finalizing the replacement of the three OASIS-based measures with the two new composite measures.

An alternative to rescoring the maximum improvement points from 10 points to 9 points would be to keep the current scoring methodology. However, for the reasons discussed in section IV.B in this final rule with comment period, we are finalizing our proposal to rescore the maximum improvement points from 10 points to 9 points (or 13.5 points for the composite measures).

An alternative to reweighting the OASIS-based, claims-based and HHCAHPS measure categories would be to keep the current equally weighted methodology. For the reasons discussed in section IV.B of this final rule with comment period, we are finalizing reweighting of the OASIS-based measure category to 35 percent, the claims-based measure category to 35 percent and the HHCAHPS measure category to 30 percent in order to

encourage increased focus on the claims-based measures.

3. HH QRP

An alternative to removing seven measures from the HH QRP (Depression Assessment Conducted, Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care, Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537), Pneumococcal Polysaccharide Vaccine Ever Received, Improvement in the Status of Surgical Wounds, Emergency Department Use without Hospital Readmission during the First 30 Days of HH (NQF #2505), Rehospitalization during the First 30 Days of HH (NQF #2380)), as discussed in section V.E. of this final rule with comment period, would have been to retain these measures in the HH QRP.

4. Home Infusion Therapy

a. Health and Safety Standards

We considered establishing additional health and safety requirements related to patient assessment, infection control and quality improvement. However, according to the home infusion therapy supplier industry, and our research, we believe there are already some AOs that include requirements related to patient assessment, quality improvement, and infection control. To the extent that we subsequently determine that federal standards are necessary, we will propose them in subsequent notice and comment rulemaking.

b. Payment

We did not consider alternatives to implementing the home infusion therapy benefit for CY 2019 and 2020 because section 1834(u)(7) of the Act requires the Secretary to provide a temporary transitional payment to eligible home infusion therapy suppliers for items and services associated with the furnishing of transitional home infusion drugs.

c. Accreditation of Qualified Home Infusion Therapy Suppliers

AOs that accredit home infusion therapy suppliers must become accredited by an AO designated by the Secretary. In these options, we have attempted to minimize the burden of accreditation on home infusion therapy suppliers, which include approving home infusion therapy AOs that consider the unique needs of small home infusion therapy suppliers. Also, it is likely that the surveys of home infusion therapy suppliers would be performed as a desk review instead of an onsite survey. Doing a desk audit survey would prevent the travel time and cost that is required when the AO has to send a survey team to the home infusion therapy supplier's location to perform an onsite survey.

F. Accounting Statement and Tables

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4), in Table 54, we have prepared an accounting statement showing the classification of the transfers and costs associated with the CY 2019 HH PPS provisions of this rule. For CY 2020, due to the section 51001(a) of the BBA of 2018 requirement that the transition to the 30-day unit of payment be budget neutral, Table 55 displays a transfer of zero. Table 56 provides our best estimates of the changes to OASIS item collection as a result of the implementation of the PDGM and changes to the HH QRP. Table 57 provides our best estimate of the increase in Medicare payments to home infusion therapy suppliers related to the temporary transitional payment for home infusion therapy in CY 2019. Table 58 provides our best estimate of cost of AO compliance with our home infusion the Infusion Therapy application requirements.

TABLE 54: ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS DUE TO THE NET MARKET BASKET INCREASE, FROM CY 2018 TO 2019

Category	Transfers
Annualized Monetized Transfers	\$420 million
From Whom to Whom?	Federal Government to HHAs

TABLE 55: ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS DUE TO THE PDGM, FROM CY 2019 TO 2020 PDGM

Category	Transfers
Annualized Monetized Transfers	\$0 million
From Whom to Whom?	HHAs to Federal Government

TABLE 56: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS OF OASIS ITEM COLLECTION, FROM CY 2019 TO CY 2020

Category	Costs
Annualized Monetized Net Burden for HHAs' Submission of the OASIS	-\$60 million

TABLE 57: ACCOUNTING STATEMENT: TEMPORARY TRANSITIONAL PAYMENT FOR HOME INFUSION THERAPY CLASSIFICATION OF ESTIMATED TRANSFERS, FROM CY 2018 TO 2019

Category	Transfers
Annualized Monetized Transfers	\$48 million
From Whom to Whom?	Federal Government to Home Infusion Therapy Suppliers

TABLE 58: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS FOR HOME INFUSION THERAPY ACCREDITATION ORGANIZATIONS, FROM CY 2019 TO CY 2020

Category	Costs
Annualized Monetized Net Burden to Each Home Infusion Therapy AO for Compliance with the Regulations at §§488.1010 through 488.1050	\$12,453 - for preparing and submitting application to CMS \$23,258 – for participation in ongoing monitoring activities \$35,711 - Total

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G. Regulatory Reform Analysis Under E.O. 13771

Executive Order 13771, entitled “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.” Details on the estimated costs of this final rule with comment period, including limitations on the ability thus far to quantify some categories of impacts, can be found in the rule’s economic analysis. This final rule with comment period is considered an E.O. 13771 deregulatory action. Details on the estimated cost savings of this final rule with comment period can be found in the rule’s PRA and economic analysis. Due to the modifications to OASIS item collection as a result of the changes to the HH QRP and the changes

to the HH PPS (PDGM), both effective on and after January 1, 2020, we estimate that this rule generates \$60 million in annualized cost savings, or \$46 million per year on an ongoing basis discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2020.

H. Conclusion

1. HH PPS
 - a. HH PPS for CY 2019

In conclusion, we estimate that the net impact of the HH PPS policies in this rule is an increase of 2.2 percent, or \$420 million, in Medicare payments to HHAs for CY 2019. The \$420 million increase reflects the effects of the CY 2019 home health payment update of 2.2 percent (\$420 million increase), a 0.1 percent increase in payments due to decreasing the FDL ratio in order to target to pay no more than 2.5 percent of total payments as outlier payments (\$20 million increase), and a -0.1

percent decrease in CY 2019 payments due to the new rural add-on policy mandated by the BBA of 2018 (\$20 million decrease).

- b. HH PPS for CY 2020 (PDGM)

In conclusion, we estimate that Medicare payments to HHAs for CY 2020 will remain the same compared to CY 2019 as a result of the implementation of the PDGM. Section 51001(a) of the BBA of 2018 requires the Secretary to implement the 30-day unit of payment in a budget-neutral manner.

2. OASIS Changes Related to the HH QRP and HH PPS (PDGM) for CY 2020

In conclusion, we estimate that the changes to OASIS item collection as a result of the changes to the HH QRP and the changes to the HH PPS (PDGM), both effective on and after January 1, 2020, would result in a net \$60 million in annualized cost savings, discounted at 7 percent relative to year 2016, over

a perpetual time horizon beginning in CY 2020.

In conclusion, due to the modifications to OASIS item collection as a result of the changes to the HH QRP and the changes to the HH PPS (PDGM), both effective on and after January 1, 2020, we estimate that this rule generates \$60 million in annualized cost savings, or \$46 million per year on an ongoing basis discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2020.

4. Home Infusion Therapy

a. Health and Safety Standards

In summary, the health and safety standards would not have any economic impact on home infusion therapy suppliers or accreditation organizations.

b. Payment

In conclusion, we estimate that the net impact of the temporary transitional payment to eligible home infusion suppliers for items and services associated with the furnishing of transitional home infusion drugs would result in approximately \$48 million in additional Medicare payments to home infusion suppliers in CY 2019.

c. Accreditation of Qualified Home Infusion Therapy Suppliers

In summary, AOs that accredit HIT suppliers must become accredited by an AO designated by the Secretary. In these options, we have attempted to minimize the burden of accreditation on HIT suppliers, which include approving AOs that consider the unique needs of small HIT suppliers. Also, it is likely that the surveys of HIT suppliers will be performed as a desk review instead of an onsite survey. Doing a desk audit survey would prevent the travel time and cost that is required when the AO has to send a survey team to the HIT supplier's location to perform an onsite survey.

This analysis, together with the remainder of this preamble, provides an initial Regulatory Flexibility Analysis.

In accordance with the provisions of Executive Order 12866, this finalized rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 486

Grant programs-health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 488

Administrative practice and procedure, Health facilities, 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 409—HOSPITAL INSURANCE BENEFITS

■ 1. The authority citation for part 409 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§ 409.43 [Amended]

- 2. Section 409.43 is amended—
- a. By removing paragraph (c)(2);
- b. By resignating paragraphs (c)(3) and (4) as paragraphs (c)(2) and (3);
- c. In newly redesignated paragraph (c)(2)(ii) by removing the phrase “for services is submitted for the final percentage prospective payment” and adding in its place the phrase “(for episodes beginning on or before December 31, 2019) or 30-day period (for periods beginning on or after January 1, 2020) is submitted”; and
- d. In paragraph (e)(1)(iii) by removing the phrase “during the 60-day episode” and adding in its place the phrase “within 60 days”.
- 3. Section 409.46 is amended by adding paragraph (e) to read as follows:

§ 409.46 Allowable administrative costs.

* * * * *

(e) *Remote patient monitoring.* Remote patient monitoring is defined as the collection of physiologic data (for example, ECG, blood pressure, or glucose monitoring) digitally stored and transmitted by the patient or caregiver or both to the home health agency. If remote patient monitoring is used by the home health agency to augment the care planning process, the costs of the equipment, set-up, and service related to this system are allowable only as administrative costs. Visits to a beneficiary's home for the sole purpose of supplying, connecting, or training the patient on the remote patient monitoring equipment, without the provision of a skilled service are not separately billable.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 4. The authority citation for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 5. Section 424.22 is amended by revising paragraphs (b)(2) and (c) to read as follows:

§ 424.22 Requirements for home health services.

* * * * *

(b) * * *

(2) *Content and basis of recertification.* As a condition for payment of home health services under Medicare Part A or Medicare Part B, if there is a continuing need for home health services, a physician must recertify the patient's continued eligibility for the home health benefit as outlined in sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act, as set forth in paragraph (a)(1) of this section, and as specified in paragraphs (b)(2)(i) and (ii) of this section.

(i) Need for occupational therapy may be the basis for continuing services that were initiated because the individual needed skilled nursing care or physical therapy or speech therapy.

(ii) If a patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician must include a brief narrative describing the clinical justification of this need. If the narrative—

(A) Is part of the recertification form, then the narrative must be located immediately prior to the physician's signature.

(B) Exists as an addendum to the recertification form, in addition to the physician's signature on the recertification form, the physician must sign immediately following the narrative in the addendum.

(c) *Determining patient eligibility for Medicare home health services.* (1) Documentation in the certifying physician's medical records or the acute/post-acute care facility's medical records (if the patient was directly admitted to home health) or both must be used as the basis for certification of the patient's eligibility for home health as described in paragraphs (a)(1) and (b) of this section. Documentation from the HHA may also be used to support the basis for certification of home health eligibility, but only if the following requirements are met:

(i) The documentation from the HHA can be corroborated by other medical record entries in the certifying physician's medical record for the patient or the acute/post-acute care facility's medical record for the patient or both, thereby creating a clinically consistent picture that the patient is eligible for Medicare home health services.

(ii)(A) The certifying physician signs and dates the HHA documentation demonstrating that the documentation from the HHA was considered when certifying patient eligibility for Medicare home health services.

(B) HHA documentation can include, but is not limited to, the patient's plan of care required under § 409.43 of this chapter, or the initial or comprehensive assessment of the patient required under § 484.55 of this chapter.

(2) The documentation must be provided upon request to review entities or CMS or both. If the documentation used as the basis for the certification of eligibility is not sufficient to demonstrate that the patient is or was eligible to receive services under the Medicare home health benefit, payment is not rendered for home health services provided.

* * * * *

PART 484—HOME HEALTH SERVICES

■ 6. The authority citation for part 484 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh unless otherwise indicated.

■ 7. Section 484.202 is amended by revising the definitions of "Rural area" and "Urban area" to read as follows:

§ 484.202 Definitions.

* * * * *

Rural area means an area defined in § 412.64(b)(1)(ii)(C) of this chapter.

Urban area means an area defined in § 412.64(b)(1)(ii)(A) and (B) of this chapter.

■ 8. Section 484.205 is revised to read as follows:

§ 484.205 Basis of payment.

(a) *Method of payment.* An HHA receives a national, standardized prospective payment amount for home health services previously paid on a reasonable cost basis (except the osteoporosis drug defined in section 1861(kk) of the Act) as of August 5, 1997. The national, standardized prospective payment is determined in accordance with § 484.215.

(b) *Unit of payment—(1) Episodes before December 31, 2019.* For episodes beginning on or before December 31, 2019, an HHA receives a unit of

payment equal to a national, standardized prospective 60-day episode payment amount.

(2) *Periods on or after January 1, 2020.* For periods beginning on or after January 1, 2020, a HHA receives a unit of payment equal to a national, standardized prospective 30-day payment amount.

(c) *OASIS data.* A HHA must submit to CMS the OASIS data described at § 484.55(b) and (d) in order for CMS to administer the payment rate methodologies described in §§ 484.215, 484.220, 484.230, 484.235, and 484.240.

(d) *Payment adjustments.* The national, standardized prospective payment amount represents payment in full for all costs associated with furnishing home health services and is subject to the following adjustments and additional payments:

(1) A low-utilization payment adjustment (LUPA) of a predetermined per-visit rate as specified in § 484.230.

(2) A partial payment adjustment as specified in § 484.235.

(3) An outlier payment as specified in § 484.240.

(e) *Medical review.* All payments under this system may be subject to a medical review adjustment reflecting the following:

(1) Beneficiary eligibility.

(2) Medical necessity determinations.

(3) Case-mix group assignment.

(f) *Durable medical equipment (DME) and disposable devices.* DME provided as a home health service as defined in section 1861(m) of the Act is paid the fee schedule amount. Separate payment is made for "furnishing NPWT using a disposable device," as that term is defined in § 484.202, and is not included in the national, standardized prospective payment.

(g) *Split percentage payments.* Normally, there are two payments (initial and final) paid for an HH PPS unit of payment. The initial payment is made in response to a request for anticipated payment (RAP) as described in paragraph (h) of this section, and the residual final payment is made in response to the submission of a final claim. Split percentage payments are made in accordance with requirements at § 409.43(c) of this chapter.

(1) *Split percentage payments for episodes beginning on or before December 31, 2019—(i) Initial and residual final payments for initial episodes on or before December 31, 2019.* (A) The initial payment for initial episodes is paid to an HHA at 60 percent of the case-mix and wage-adjusted 60-day episode rate.

(B) The residual final payment for initial episodes is paid at 40 percent of

the case-mix and wage-adjusted 60-day episode rate.

(ii) *Initial and residual final payments for subsequent episodes before December 31, 2019.* (A) The initial payment for subsequent episodes is paid to an HHA at 50 percent of the case-mix and wage-adjusted 60-day episode rate.

(B) The residual final payment for subsequent episodes is paid at 50 percent of the case-mix and wage-adjusted 60-day episode rate.

(2) *Split percentage payments for periods beginning on or after January 1, 2020—(i) Initial and residual final payments for initial periods beginning on or after January 1, 2020.* (A) The initial payment for initial 30-day periods is paid to an HHA at 60 percent of the case-mix and wage-adjusted 30-day payment rate.

(B) The residual final payment for initial 30-day periods is paid at 40 percent of the case-mix and wage-adjusted 30-day payment rate.

(ii) *Initial and residual final payments for subsequent periods beginning on or after January 1, 2020.* (A) The initial payment for subsequent 30-day periods is paid to an HHA at 50 percent of the case-mix and wage-adjusted 30-day payment rate.

(B) The residual final payment for subsequent 30-day periods is paid at 50 percent of the case-mix and wage-adjusted 30-day payment rate.

(iii) *Split percentage payments on or after January 1, 2019.* Split percentage payments are not made to HHAs that are certified for participation in Medicare effective on or after January 1, 2019. An HHA that is certified for participation in Medicare effective on or after January 1, 2019 receives a single payment for a 30-day period of care after the final claim is submitted.

(h) *Requests for anticipated payment (RAP).* (1) HHAs that are certified for participation in Medicare effective by December 31, 2018 submit requests for anticipated payment (RAPs) to request the initial split percentage payment as specified in paragraph (g) of this section. HHAs that are certified for participation in Medicare effective on or after January 1, 2019 are still required to submit RAPs although no split percentage payments are made in response to these RAP submissions. The HHA can submit a RAP when all of the following conditions are met:

(i) After the OASIS assessment required at § 484.55(b)(1) and (d) is complete, locked or export ready, or there is an agency-wide internal policy establishing the OASIS data is finalized for transmission to the national assessment system.

(ii) Once a physician's verbal orders for home care have been received and documented as required at §§ 484.60(b) and 409.43(d) of this chapter.

(iii) A plan of care has been established and sent to the physician as required at § 409.43(c) of this chapter.

(iv) The first service visit under that plan has been delivered.

(2) A RAP is based on the physician signature requirements in § 409.43(c) of this chapter and is not a Medicare claim for purposes of the Act (although it is a "claim" for purposes of Federal, civil, criminal, and administrative law enforcement authorities, including but not limited to the following:

(i) Civil Monetary Penalties Law (as defined in 42 U.S.C. 1320a-7a(i)(2)).

(ii) The Civil False Claims Act (as defined in 31 U.S.C. 3729(c)).

(iii) The Criminal False Claims Act (18 U.S.C. 287)).

(iv) The RAP is canceled and recovered unless the claim is submitted within the greater of 60 days from the end date of the appropriate unit of payment, as defined in paragraph (b) of this section, or 60 days from the issuance of the RAP.

(3) CMS has the authority to reduce, disprove, or cancel a RAP in situations when protecting Medicare program integrity warrants this action.

§ 484.210 [Removed and Reserved]

■ 9. Section 484.210 is removed and reserved.

■ 10. Section 484.215 is amended—

■ a. By revising the section heading;

■ b. In paragraph (d) introductory text by removing the phrase "CMS calculates the" and adding in its place the phrase "For episodes beginning on or before December 31, 2019, CMS calculates the"; and

■ c. By adding paragraph (f).

The revision and addition reads as follows:

§ 484.215 Initial establishment of the calculation of the national, standardized prospective payment rates.

* * * * *

(f) For periods beginning on or after January 1, 2020, a national, standardized prospective 30-day payment rate applies. The national, standardized prospective 30-day payment rate is an amount determined by the Secretary, as subsequently adjusted in accordance with § 484.225.

■ 11. Section 484.220 is amended—

■ a. By revising the section heading and introductory text; and

■ b. In paragraph (a) introductory text by removing the phrase "national prospective 60-day episode" and adding in its place the phrase "national, standardized prospective".

The revisions read as follows:

§ 484.220 Calculation of the case-mix and wage area adjusted prospective payment rates.

CMS adjusts the national, standardized prospective payment rates as referenced in § 484.215 to account for the following:

* * * * *

■ 12. Section 484.225 is amended—

■ a. By revising the section heading and paragraph (a);

■ b. In paragraphs (b) and (c) by removing the phrase "national prospective 60-day episode" and adding in its place the phrase "national, standardized prospective"; and

■ c. By adding paragraph (d).

The revision and addition reads as follows:

§ 484.225 Annual update of the unadjusted national, standardized prospective payment rates.

(a) CMS annually updates the unadjusted national, standardized prospective payment rate on a calendar year basis (in accordance with section 1895(b)(1)(B) of the Act).

* * * * *

(d) For CY 2020, the national, standardized prospective 30-day payment amount is an amount determined by the Secretary. CMS annually updates this amount on a calendar year basis in accordance with paragraphs (a) through (c) of this section.

■ 13. Section 484.230 is revised to read as follows:

§ 484.230 Low-utilization payment adjustments.

(a) For episodes beginning on or before December 31, 2019, an episode with four or fewer visits is paid the national per-visit amount by discipline determined in accordance with § 484.215(a) and updated annually by the applicable market basket for each visit type, in accordance with § 484.225.

(1) The national per-visit amount is adjusted by the appropriate wage index based on the site of service of the beneficiary.

(2) An amount is added to the low-utilization payment adjustments for low-utilization episodes that occur as the beneficiary's only episode or initial episode in a sequence of adjacent episodes.

(3) For purposes of the home health PPS, a sequence of adjacent episodes for a beneficiary is a series of claims with no more than 60 days without home care between the end of one episode, which is the 60th day (except for episodes that have been PEP-adjusted), and the beginning of the next episode.

(b) For periods beginning on or after January 1, 2020, an HHA receives a national 30-day payment of a predetermined rate for home health services, unless CMS determines at the end of the 30-day period that the HHA furnished minimal services to a patient during the 30-day period.

(1) For each payment group used to case-mix adjust the 30-day payment rate, the 10th percentile value of total visits during a 30-day period of care is used to create payment group specific thresholds with a minimum threshold of at least 2 visits for each case-mix group.

(2) A 30-day period with a total number of visits less than the threshold is paid the national per-visit amount by discipline determined in accordance with § 484.215(a) and updated annually by the applicable market basket for each visit type, in accordance with § 484.225.

(3) The national per-visit amount is adjusted by the appropriate wage index based on the site of service for the beneficiary.

(c) An amount is added to low-utilization payment adjustments for low-utilization periods that occur as the beneficiary's only 30-day period or initial 30-day period in a sequence of adjacent periods of care. For purposes of the home health PPS, a sequence of adjacent periods of care for a beneficiary is a series of claims with no more than 60 days without home care between the end of one period, which is the 30th day (except for episodes that have been partial payment adjusted), and the beginning of the next episode.

■ 14. Section 484.235 is revised to read as follows:

§ 484.235 Partial payment adjustments.

(a) *Partial episode payments (PEPs) for episodes beginning on or before December 31, 2019.* (1) An HHA receives a national, standardized 60-day payment of a predetermined rate for home health services unless CMS determines an intervening event, defined as a beneficiary elected transfer or discharge with goals met or no expectation of return to home health and the beneficiary returned to home health during the 60-day episode, warrants a new 60-day episode for purposes of payment. A start of care OASIS assessment and physician certification of the new plan of care are required.

(2) The PEP adjustment does not apply in situations of transfers among HHAs of common ownership.

(i) Those situations are considered services provided under arrangement on behalf of the originating HHA by the receiving HHA with the common

ownership interest for the balance of the 60-day episode.

(ii) The common ownership exception to the transfer PEP adjustment does not apply if the beneficiary moves to a different MSA or Non-MSA during the 60-day episode before the transfer to the receiving HHA.

(iii) The transferring HHA in situations of common ownership not only serves as a billing agent, but must also exercise professional responsibility over the arranged-for services in order for services provided under arrangements to be paid.

(3) If the intervening event warrants a new 60-day payment and a new physician certification and a new plan of care, the initial HHA receives a partial episode payment adjustment reflecting the length of time the patient remained under its care based on the first billable visit date through and including the last billable visit date. The PEP is calculated by determining the actual days served as a proportion of 60 multiplied by the initial 60-day payment amount.

(b) *Partial payment adjustments for periods beginning on or after January 1, 2020.* (1) An HHA receives a national, standardized 30-day payment of a predetermined rate for home health services unless CMS determines an intervening event, defined as a beneficiary elected transfer or discharge with goals met or no expectation of return to home health and the beneficiary returned to home health during the 30-day period, warrants a new 30-day period for purposes of payment. A start of care OASIS assessment and physician certification of the new plan of care are required.

(2) The partial payment adjustment does not apply in situations of transfers among HHAs of common ownership.

(i) Those situations are considered services provided under arrangement on behalf of the originating HHA by the receiving HHA with the common ownership interest for the balance of the 30-day period.

(ii) The common ownership exception to the transfer partial payment adjustment does not apply if the beneficiary moves to a different MSA or Non-MSA during the 30-day period before the transfer to the receiving HHA.

(iii) The transferring HHA in situations of common ownership not only serves as a billing agent, but must also exercise professional responsibility over the arranged-for services in order for services provided under arrangements to be paid.

(3) If the intervening event warrants a new 30-day payment and a new physician certification and a new plan

of care, the initial HHA receives a partial payment adjustment reflecting the length of time the patient remained under its care based on the first billable visit date through and including the last billable visit date. The partial payment is calculated by determining the actual days served as a proportion of 30 multiplied by the initial 30-day payment amount.

■ 15. Section 484.240 is revised to read as follows:

§ 484.240 Outlier payments.

(a) For episodes beginning on or before December 31, 2019, an HHA receives an outlier payment for an episode whose estimated costs exceeds a threshold amount for each case-mix group. The outlier threshold for each case-mix group is the episode payment amount for that group, or the PEP adjustment amount for the episode, plus a fixed dollar loss amount that is the same for all case-mix groups.

(b) For periods beginning on or after January 1, 2020, an HHA receives an outlier payment for a 30-day period whose estimated cost exceeds a threshold amount for each case-mix group. The outlier threshold for each case-mix group is the 30-day payment amount for that group, or the partial payment adjustment amount for the 30-day period, plus a fixed dollar loss amount that is the same for all case-mix groups.

(c) The outlier payment is a proportion of the amount of imputed cost beyond the threshold.

(d) CMS imputes the cost for each claim by multiplying the national per-15 minute unit amount of each discipline by the number of 15 minute units in the discipline and computing the total imputed cost for all disciplines.

■ 16. Section 484.250 is amended by revising paragraph (a)(1) to read as follows:

§ 484.250 Patient assessment data.

(a) * * *

(1) Such OASIS data described at § 484.55(b) and (d) as is necessary for CMS to administer the payment rate methodologies described in §§ 484.215, 484.220, 484.230, 484.235, and 484.240; and such OASIS data described at § 484.55(b) and (d) as is necessary to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act.

* * * * *

■ 17. Section 484.320 is amended by revising paragraph (c) to read as follows:

§ 484.320 Calculation of the Total Performance Score.

* * * * *

(c)(1) For performance years 1 through 3, CMS will sum all points awarded for each applicable measure excluding the New Measures, weighted equally at the individual measure level to calculate a value worth 90 percent of the Total Performance Score.

(2) For performance years 4 and 5, CMS will sum all points awarded for each applicable measure within each category of measures (OASIS-based, claims-based and HHCAHPS) excluding the New Measures, weighted at 35 percent for the OASIS-based measure category, 35 percent for the claims-based measure category, and 30 percent for the HHCAHPS measure category when all three measure categories are reported, to calculate a value worth 90 percent of the Total Performance Score.

* * * * *

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 18. The authority citation for part 486 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 19. Add reserved subpart H and subpart I to read as follows:

Subpart H—[Reserved]

Subpart I—Requirements for Home Infusion Therapy Suppliers

General Provisions

Sec.
486.500 Basis and scope.
486.505 Definitions.

Standards for Home Infusion Therapy

486.520 Plan of care.
486.525 Required services.

Subpart I—Requirements for Home Infusion Therapy Suppliers

General Provisions

§ 486.500 Basis and scope.

Section 1861(s)(2)(iii) of the Act requires the Secretary to establish the conditions that home infusion therapy suppliers must meet in order to participate in the Medicare program and which are considered necessary to ensure the health and safety of patients.

§ 486.505 Definitions.

As used in §§ 486.520 and 486.525:

Applicable provider means a physician, a nurse provider, and a physician assistant.

Home means a place of residence used as the home of an individual, including an institution that is used as a home. An institution that is used as a home may not be a hospital, CAH, or

SNF as defined in section 1861(e)(1), 1861(mm)(1), or 1819(a)(1) of the Act, respectively.

Home infusion drug means a parental drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment. The term does not include insulin pump systems or a self-administered drug or biological on a self-administered drug exclusion list.

Infusion drug administration calendar day means the day on which home infusion therapy services are furnished by skilled professionals in the individual's home on the day of infusion drug administration. The skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel.

Qualified home infusion therapy supplier means a supplier of home infusion therapy that meets all of the following criteria which are set forth at section 1861(iii)(3)(D)(i) of the Act:

(1) Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs.

(2) Ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis.

(3) Is accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act.

(4) Meets such other requirements as the Secretary determines appropriate.

Standards for Home Infusion Therapy

§ 486.520 Plan of care.

The qualified home infusion therapy supplier ensures the following:

(a) All patients must be under the care of an applicable provider.

(b) All patients must have a plan of care established by a physician that prescribes the type, amount, and duration of the home infusion therapy services that are to be furnished.

(c) The plan of care for each patient must be periodically reviewed by the physician.

§ 486.525 Required services.

(a) The qualified home infusion therapy supplier must provide the following services on a 7-day-a-week, 24-hour-a-day basis in accordance with the plan of care:

(1) Professional services, including nursing services.

(2) Patient training and education not otherwise paid for as durable medical equipment as described in § 424.57(c)(12) of this chapter.

(3) Remote monitoring and monitoring services for the provision of home infusion therapy services and home infusion drugs.

(b) All home infusion therapy suppliers must provide home infusion therapy services in accordance with nationally recognized standards of practice, and in accordance with all applicable state and federal laws and regulations.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 20. The authority citation for part 488 is revised to read as follows:

Authority: 42 U.S.C 1302 and 1395hh.

■ 21. Section 488.5 is amended—

■ a. In paragraph (a)(17)(i) by removing the word “and” at the end of the paragraph;

■ b. In paragraph (a)(17)(ii) by removing the period and adding in its place “; and”; and

■ c. By adding paragraph (a)(17)(iii).

The additions read as follows:

§ 488.5 Application and re-application procedures for national accrediting organizations.

(a) * * *

(17) * * *

(iii) Include a written statement that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program, the accrediting organization must continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

* * * * *

■ 22. Add reserved subpart K and subpart L to read as follows:

Subpart K—[Reserved]

Subpart L—Accreditation of Home Infusion Therapy Suppliers

General Provisions

Sec.

488.1000 Basis and scope.

488.1005 Definitions.

Approval and Oversight of Home Infusion Therapy Supplier Accrediting Organizations

488.1010 Application and reapplication procedures for national home infusion therapy accrediting organizations.

488.1015 Resubmitting a request for reapproval.

488.1020 Public notice and comment.

488.1025 Release and use of home infusion therapy accreditation surveys.

488.1030 Ongoing review of home infusion therapy accrediting organizations.

488.1035 Ongoing responsibilities of a CMS-approved home infusion therapy accreditation organization.

488.1040 Onsite observations of home infusion therapy accrediting organization operations.

488.1045 Voluntary and involuntary termination.

488.1050 Reconsideration.

Subpart L—Accreditation of Home Infusion Therapy Suppliers

General Provisions

§ 488.1000 Basis and scope.

(a) *Regulatory basis for home infusion therapy services.* The home infusion therapy health and safety regulations are codified at part 486, subpart I, of this chapter.

(b) *Statutory basis for the accreditation of home infusion therapy suppliers.* (1) Sections 1102 and 1871 of the Act require that the Secretary prescribe such regulations as may be necessary to carry out the administration of the Medicare program.

(2) Section 1834(u)(5) of the Act require the Secretary to designate and approve independent organizations for the purposes of accrediting qualified home infusion therapy suppliers.

(c) *Scope.* This subpart sets forth the following:

(1) Application and reapplication procedures for national accrediting organizations seeking approval or re-approval of authority to accredit qualified home infusion therapy suppliers.

(2) Ongoing CMS oversight processes for approved accrediting organizations that accredit qualified home infusion therapy suppliers.

(3) Appeal procedures for accrediting organizations that accredit qualified home infusion therapy suppliers.

§ 488.1005 Definitions.

As used in this subpart—

Immediate jeopardy means a situation in which the provider's or supplier's non-compliance with one or more Medicare accreditation requirements has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient.

National accrediting organization means an organization that accredits provider or supplier entities under a specific program and whose accredited provider or supplier entities under each program are widely dispersed geographically across the United States. In addition, the specific program is

active, fully implemented, and operational.

National in scope means a program is fully implemented, operational, and widely dispersed geographically throughout the country.

Qualified home infusion therapy supplier means a supplier of home infusion therapy that meets all of the following criteria which are set forth at section 1861(iii)(3)(D)(i) of the Act:

(1) Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs.

(2) Ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis.

(3) Is accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act.

(4) Meets such other requirements as the Secretary determines appropriate.

Reasonable assurance means an accrediting organization has demonstrated to CMS' satisfaction that its accreditation program requirements meet or exceed the Medicare program requirements.

Rural area as defined at section 1886(d)(2)(D) of the Act.

Substantial allegation of non-compliance means a complaint from any of a variety of sources (such as patient, relative, or third party), including complaints submitted in person, by telephone, through written correspondence, or in the newspaper, magazine articles or other media, that would, if found to be present, adversely affect the health and safety of patients and raises doubts as to a qualified home infusion therapy supplier's compliance with the applicable Medicare accreditation requirements.

Approval and Oversight of Home Infusion Therapy Supplier Accrediting Organizations

§ 488.1010 Application and reapplication procedures for national home infusion therapy accrediting organizations.

(a) *Information submitted with application.* A national home infusion therapy accrediting organization applying to CMS for approval or re-approval of a designated home infusion therapy accreditation program must furnish CMS with information and materials that demonstrate that its home infusion therapy accreditation program requirements meet or exceed the applicable Medicare requirements for accrediting organizations, including the following:

(1) Documentation that demonstrates the organization meets the definition of

a national accrediting organization under § 488.1005 as it relates to the accreditation program.

(2) The Medicare provider or supplier type for which the organization is requesting approval or reapproval.

(3) Documentation that demonstrates the home infusion therapy accrediting organization's ability to take into account the capacities of rural home infusion therapy suppliers (as required by section 1834(u)(5)(A)(ii) of the Act).

(4) Information that demonstrates the home infusion therapy accrediting organization's knowledge, expertise, and experience in home infusion therapy.

(5) A detailed crosswalk (in table format) that identifies, for each of the applicable Medicare requirements, the exact language of the organization's comparable accreditation requirements and standards.

(6) A detailed description of the home infusion therapy accrediting organization's survey processes to confirm that a home infusion therapy supplier's processes are comparable to those of Medicare. This description must include all of the following:

(i) The types and frequency of surveys performed, and a rationale for which accreditation requirements will be evaluated via onsite surveys and which will be evaluated via offsite audits, or other strategies for ensuring accredited home infusion therapy suppliers maintain adherence to the home infusion therapy accreditation program requirements, including an explanation of how the accrediting organization will maintain the schedule it proposes.

(ii) Copies of the home infusion therapy accrediting organizations survey and audit forms, guidelines, and instructions to surveyors.

(iii) Documentation demonstrating that the home infusion therapy accrediting organization's onsite survey or offsite audit reports identify, for each finding of non-compliance with accreditation standards, the comparable Medicare home infusion therapy accreditation requirements, as applicable.

(iv) A description of the home infusion therapy accrediting organization's accreditation survey review process.

(v) A description of the home infusion therapy accrediting organization's procedures and timelines for notifying a surveyed or audited home infusion therapy supplier of non-compliance with the home infusion therapy accreditation program's standards.

(vi) A description of the home infusion therapy accrediting organization's procedures and timelines

for monitoring the home infusion therapy supplier's correction of identified non-compliance with the accreditation program's standards.

(vii) The ability of the home infusion therapy accrediting organization to conduct timely reviews of accreditation applications.

(viii) A statement acknowledging that, as a condition for CMS approval of a national accrediting organization's accreditation program, the home infusion therapy accrediting organization agrees to provide CMS with information extracted from each home infusion therapy accreditation onsite survey, offsite audit or other evaluation strategies as part of its data submissions required under paragraph (a)(19) of this section, and, upon request from CMS, a copy of the most recent accreditation onsite survey, offsite audit, or other evaluation strategy together with any other information related to the survey as CMS may require (including corrective action plans).

(ix) A statement acknowledging that the home infusion therapy accrediting organization will provide timely notification to CMS when an accreditation survey or complaint investigation identifies an immediate jeopardy as that term is defined at § 488.1005. Using the format specified by CMS, the home infusion therapy accrediting organization must notify CMS within 2 business days from the date the accrediting organization identifies the immediate jeopardy.

(7) Procedures to ensure that—

(i) Unannounced onsite surveys, as appropriate, will be conducted periodically, including procedures that protect against unannounced surveys becoming known to the provider or supplier in advance of the visit; or

(ii) Offsite survey audits are performed to evaluate the quality of services provided which may be followed up with periodic onsite visits.

(8) The criteria for determining the size and composition of the home infusion therapy accrediting organization's survey, audit and other evaluation strategy teams for individual supplier onsite surveys. The home infusion therapy accrediting organization's criteria should include, but not be limited to the following information:

(i) The expected number of individual home infusion therapy supplier locations to be surveyed using an onsite survey.

(ii) The number of home infusion therapy suppliers to be surveyed using off-site audits.

(iii) A description of other types of home infusion therapy accreditation review activities to be used.

(iv) The reasons for each type of survey (that is, initial accreditation survey, reaccreditation survey, and complaint survey).

(9) The overall adequacy of the number of the home infusion therapy accrediting organization's surveyors, auditors, and other staff available to perform survey related activities, including how the organization will increase the size of the survey, audit, and other evaluation staff to match growth in the number of accredited facilities or programs while maintaining re-accreditation intervals for existing accredited facilities or programs.

(10) Detailed information about the individuals who perform onsite surveys, offsite audits or other strategies for ensuring accredited home infusion therapy suppliers maintain adherence to the home infusion therapy accreditation program requirements, including all of the following information:

(i) The number and types of professional and technical staff available for conducting onsite surveys, offsite audits, or other strategies for ensuring accredited home infusion therapy suppliers maintain adherence to the home infusion therapy accreditation program requirements.

(ii) The education, employment, and experience requirements surveyors and auditors must meet.

(iii) The content and length of the orientation program.

(11) The content, frequency and types of in-service training provided to survey and audit personnel.

(12) The evaluation systems used to monitor the performance of individual surveyors, auditors and survey teams.

(13) The home infusion therapy accrediting organization's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys, audits or participate in accreditation decisions.

(14) The policies and procedures used when a home infusion therapy supplier has a dispute regarding survey or audit findings, or an adverse decision.

(15) Procedures for the home infusion therapy supplier to use to notify the home infusion therapy accrediting organization when the accredited home infusion therapy supplier does the either of the following:

(i) Removes or ceases furnishing services for which they are accredited.

(ii) Adds services for which they are not accredited.

(16) The home infusion therapy accrediting organization's procedures

for responding to, and investigating complaints against accredited facilities, including policies and procedures regarding referrals, when applicable, to appropriate licensing bodies, ombudsmen offices, and CMS.

(17) A description of the home infusion therapy accrediting organization's accreditation status decision-making process. The home infusion therapy accrediting organization must furnish the following:

(i) Its process for addressing deficiencies identified with accreditation program requirements, and the procedures used to monitor the correction of deficiencies identified during an accreditation survey and audit process.

(ii) A description of all types and categories of accreditation decisions associated with the program, including the duration of each of the organization's accreditation decisions.

(iii) Its policies and procedures for the granting, withholding or removal of accreditation status for facilities that fail to meet the accrediting organization's standards or requirements, assignment of less than full accreditation status or other actions taken by the organization in response to non-compliance with its standards and requirements.

(iv) A statement acknowledging that the home infusion therapy accrediting organization agrees to notify CMS (in a manner CMS specifies) of any decision to revoke, terminate, or revise the accreditation status of a home infusion therapy supplier, within 3 business days from the date the organization takes an action.

(18) A list of all currently accredited home infusion therapy suppliers, the type and category of accreditation, currently held by each, and the expiration date for each home infusion therapy supplier's current accreditation.

(19) A schedule of all survey activity (such as onsite surveys, offsite audits and other types of survey strategies) expected to be conducted by the organization during the 6-month period following submission of an initial or renewal application.

(20) A written presentation that demonstrates the organization's ability to furnish CMS with electronic data.

(21) A description of the home infusion therapy accrediting organization's data management and analysis system with respect to its surveys and accreditation decisions, including all of the following:

(i) A detailed description of how the home infusion therapy accrediting organization uses its data to assure the compliance of its home infusion therapy accreditation program with the

Medicare home infusion therapy accreditation program requirements.

(ii) A written statement acknowledging that the home infusion therapy accrediting organization agrees to submit timely, accurate, and complete data that CMS has determined is both necessary to evaluate the accrediting organization's performance and is not unduly burdensome for the accrediting organization to submit.

(A) The organization must submit necessary data according to the instructions and timeframes CMS specifies.

(B) Data to be submitted includes the following:

(1) Accredited home infusion therapy supplier identifying information.

(2) Survey findings.

(3) Quality measures.

(4) Notices of accreditation decisions.

(22) The three most recent annual audited financial statements of the home infusion therapy accrediting organization that demonstrate that the organization's staffing, funding, and other resources are adequate to perform the required surveys, audits, and related activities to maintain the accreditation program.

(23) A written statement acknowledging that, as a condition for approval, the home infusion therapy accrediting organization agrees to the following:

(i) *Voluntary termination.* Provide written notification to CMS and all home infusion therapy suppliers accredited under its CMS-approved home infusion therapy accreditation program at least 180 calendar days in advance of the effective date of a decision by the home infusion therapy accrediting organization to voluntarily terminate its CMS-approved home infusion therapy accreditation program and the implications for the suppliers' payment status once their current term of accreditation expires in accordance with the requirements at § 488.1045(a).

(ii) *Involuntary termination.* Provide written notification to all accredited home infusion therapy suppliers accredited under its CMS-approved home infusion therapy accreditation program no later than 30 calendar days after the notice is published in the **Federal Register** announcing that CMS is withdrawing its approval of its accreditation program and the implications for the home infusion therapy supplier's payment status in accordance with the requirements at § 488.1045(b) once their current term of accreditation expires.

(A) For both voluntary and involuntary terminations, provide a second written notification to all

accredited home infusion therapy suppliers 10 calendar days prior to the organization's accreditation program effective date of termination.

(B) Notify CMS, in writing (electronically or hard copy), within 2 business days of a deficiency identified in any accredited home infusion therapy supplier from any source where the deficiency poses an immediate jeopardy to the home infusion therapy supplier's beneficiaries or a hazard to the general public.

(iii) *Summary accreditation activity data and trends.* Provide, on an annual basis, summary accreditation activity data and trends including the following:

(A) Deficiencies.

(B) Complaints.

(C) Terminations.

(D) Withdrawals.

(E) Denials.

(F) Accreditation decisions.

(G) Other survey-related activities as specified by CMS.

(iv) *Termination of an accreditation organization.* If CMS terminates a home infusion therapy accrediting organization's approved status, the home infusion therapy accrediting organization must work collaboratively with CMS to direct its accredited home infusion therapy suppliers to the remaining CMS-approved accrediting organizations within a reasonable period of time.

(v) *Notification of proposed changes.* Notify CMS at least 60 days in advance of the implementation date of any significant proposed changes in its CMS-approved home infusion therapy accreditation program and that it agrees not to implement the proposed changes without prior written notice of continued program approval from CMS, except as provided for at § 488.1040(b)(2).

(vi) *Response to a written notice from CMS.* A statement acknowledging that, in response to a written notice from CMS to the home infusion therapy accrediting organization of a change in the applicable home infusion therapy accreditation requirements or survey process, the organization will provide CMS with proposed corresponding changes in the accrediting organization's home infusion therapy accreditation requirements for its CMS-approved home infusion therapy accreditation program to ensure that its accreditation standards continue to meet or exceed those of Medicare, or survey process remains comparable with that of Medicare. The home infusion therapy accrediting organization must comply with the following requirements:

(A) The proposed changes must be submitted within 30 calendar days of the date of the written CMS notice to the home infusion therapy accrediting organization or by a date specified in the notice, whichever is later. CMS gives due consideration to a home infusion therapy accrediting organization's request for an extension of the deadline as long as it is submitted prior to the due date.

(B) The proposed changes are not to be implemented without prior written notice of continued program approval from CMS, except as provided for at § 488.1040(b)(2)(ii).

(24) The organization's proposed fees for accreditation, including any plans for reducing the burden and cost of accreditation to small and rural suppliers.

(b) *Additional information needed.* If CMS determines that additional information is necessary to make a determination for approval or denial of the home infusion therapy accrediting organization's initial application or re-application for CMS-approval of an accreditation program, CMS requires that the home infusion therapy accrediting organization submit any specific documentation requirements and attestations as a condition of approval of accreditation status. CMS notifies the home infusion therapy accrediting organization and afford it an opportunity to provide the additional information.

(c) *Withdrawing an application.* A home infusion therapy accrediting organization may withdraw its initial application for CMS' approval of its home infusion therapy accreditation program at any time before CMS publishes the final notice described in § 488.1025(b).

(d) *Notice of approval or disapproval of application.* CMS sends a notice of its decision to approve or disapprove the home infusion therapy accrediting organization's application within 210 calendar days from the date CMS determines the home infusion therapy accrediting organization's application is complete. The final notice specifies the following:

(1) The basis for the decision.

(2) The effective date.

(3) The term of the approval (not exceed 6 years).

§ 488.1015 Resubmitting a request for reapproval.

(a) Except as provided in paragraph (b) of this section, a home infusion therapy accrediting organization whose request for CMS's approval or re-approval of an accreditation program has been denied, or a home infusion

therapy accrediting organization that has voluntarily withdrawn an initial application, may resubmit its application if the home infusion therapy accrediting organization satisfies all of the following requirements:

(1) Revises its home infusion therapy accreditation program to address the issues related to the denial of its previous request or its voluntary withdrawal.

(2) Resubmits the application in its entirety.

(b) If a home infusion therapy accrediting organization has requested, in accordance with § 488.1050, a reconsideration of CMS's disapproval, it may not submit a new application for approval of a home infusion therapy accreditation program until such reconsideration is administratively final.

§ 488.1020 Public notice and comment.

CMS publishes a notice in the **Federal Register** when the following conditions are met:

(a) *Proposed notice.* CMS publishes a notice after the receipt of a completed application from a national home infusion therapy accrediting organization seeking CMS's approval of a home infusion therapy accreditation program. The notice identifies the home infusion therapy accrediting organization, the type of suppliers covered by the home infusion therapy accreditation program, and provides at least a 30 day public comment period (beginning on the date of publication).

(b) *Final notice.* The final notice announces CMS decision to approve or deny a national accrediting organization application. The notice specifies the basis for the CMS decision.

(1) *Approval or re-approval.* If CMS approves or re-approves the home infusion therapy accrediting organization's home infusion therapy accreditation program, the final notice at a minimum includes the following information:

(i) A description of how the home infusion therapy accreditation program meets or exceeds Medicare home infusion therapy accreditation program requirements.

(ii) The effective date of approval (no later than the publication date of the notice).

(iii) The term of the approval (6 years or less).

(2) *Denial.* If CMS does not approve the home infusion therapy accrediting organization's accreditation program, the final notice describes the following:

(i) How the home infusion therapy accrediting organization fails to meet

Medicare home infusion therapy accreditation program requirements.

(ii) The effective date of the decision.

§ 488.1025 Release and use of home infusion therapy accreditation surveys.

The home infusion therapy accrediting organization must include, in its accreditation agreement with each supplier, an acknowledgement that the supplier agrees to release to CMS a copy of its most current accreditation survey and any information related to the survey that CMS may require, corrective action plans.

(a) CMS may determine that a home infusion therapy supplier does not meet the applicable Medicare conditions or requirements on the basis of its own investigation of the accreditation survey or any other information related to the survey.

(b) With the exception of home health agency surveys, general disclosure of an accrediting organization's survey information is prohibited under section 1865(b) of the Act. CMS may publically disclose an accreditation survey and information related to the survey, upon written request, to the extent that the accreditation survey and survey information are related to an enforcement action taken by CMS.

§ 488.1030 Ongoing review of home infusion therapy accrediting organizations.

(a) *Performance review.* CMS evaluates the performance of each CMS-approved home infusion therapy accreditation program on an ongoing basis. This review includes the review of the following:

(1) The home infusion therapy accrediting organization's survey activity.

(2) The home infusion therapy accrediting organization's continued fulfillment of the requirements at §§ 488.1010 and 488.1035.

(b) *Comparability review.* CMS assesses the equivalency of a home infusion therapy accrediting organization's CMS-approved program requirements with the comparable Medicare home infusion therapy accreditation requirements after CMS imposes new or revised Medicare accreditation requirements. When this occurs, the following takes place:

(1) CMS provides the home infusion therapy accrediting organizations with written notice of the changes to the Medicare home infusion therapy accreditation requirements.

(2) The home infusion therapy accrediting organization must make revisions to its home infusion therapy accreditation standards or survey processes which incorporate the new or

revised Medicare accreditation requirements.

(3) In the written notice, CMS specifies the deadline (no less than 30 calendar days) by which the home infusion therapy accrediting organization must submit its proposed revised home infusion therapy accreditation standard or survey process revisions, and the timeframe(s) for implementation of these revised home infusion therapy accreditation standards.

(4) CMS may extend the submission deadline by which the accrediting organization must submit its proposed revised home infusion therapy accreditation standards and survey processes, if both of the following occur:

(i) The accrediting organization submits a written request for an extension of the submission deadline.

(ii) The request for extension is submitted prior to the original submission deadline.

(5) After completing the comparability review of the home infusion therapy accrediting organizations revised home infusion therapy accreditation standards and survey processes, CMS shall provide written notification to the home infusion therapy accrediting organization regarding whether or not its home infusion therapy accreditation program, including the proposed revised home infusion therapy accreditation standards and implementation timeframe(s), continues to meet or exceed all applicable Medicare requirements.

(6) If, no later than 60 calendar days after receipt of the home infusion therapy accrediting organization's proposed changes, CMS does not provide the written notice to the home infusion therapy accrediting organization required, then the revised home infusion therapy accreditation standards and program is deemed to meet or exceed all applicable Medicare requirements and to have continued CMS-approval.

(7) If a home infusion therapy accrediting organization is required to submit a new application because CMS imposes new home infusion therapy regulations or makes significant substantive revisions to the existing home infusion therapy regulations, CMS provides notice of the decision to approve or disapprove the new application submitted by the home infusion therapy accrediting organization within the time period specified in § 488.1010(d).

(8) If a home infusion therapy accrediting organization fails to submit its proposed changes to its home infusion therapy accreditation standards

and survey processes within the required timeframe, or fails to implement the proposed changes that have been determined or deemed by CMS to be comparable, CMS may open an accreditation program review in accordance with paragraph (d) of this section.

(c) *Review of revised home infusion therapy accreditation standards submitted to CMS by an accrediting organization.* When a home infusion therapy accrediting organization proposes to adopt new or revised accreditation standards, requirements or changes in its survey process, the home infusion therapy accrediting organization must do the following:

(1) Provide CMS with written notice of any proposed changes in home infusion therapy accreditation standards, requirements or survey process at least 60 days prior to the proposed implementation date of the proposed changes.

(2) Not implement any of the proposed changes before receiving CMS's approval, except as provided in paragraph (c)(4) of this section.

(3) Provide written notice to CMS that includes all of the following:

(i) A detailed description of the changes that are to be made to the organization's home infusion therapy accreditation standards, requirements and survey processes.

(ii) A detailed crosswalk (in table format) that states the exact language of the organization's revised accreditation requirements and the applicable Medicare requirements for each.

(4) CMS must provide a written notice to the home infusion therapy accrediting organization which states whether the home infusion therapy accreditation program, including the proposed revisions, continues or does not continue to meet or exceed all applicable Medicare home infusion therapy requirements within 60 days of receipt of the home infusion therapy accrediting organization's proposed changes. If CMS has made a finding that the home infusion therapy accrediting organization's home infusion therapy accreditation program, accreditation requirements and survey processes, including the proposed revisions does not continue to meet or exceed all applicable Medicare home infusion therapy requirements. CMS must state the reasons for these findings.

(5) If, no later than 60 calendar days after receipt of the home infusion therapy accrediting organization's proposed changes, CMS does not provide written notice to the home infusion therapy accrediting organization that the home infusion

therapy accreditation program, including the proposed revisions, continues or does not continue to meet or exceed all applicable Medicare home infusion therapy requirements, then the revised home infusion therapy accreditation program is deemed to meet or exceed all applicable Medicare home infusion therapy requirements and to have continued CMS approval.

(6) If a home infusion therapy accrediting organization implements changes that have neither been determined nor deemed by CMS to be comparable to the applicable Medicare home infusion therapy requirements, CMS may open a home infusion therapy accreditation program review in accordance with paragraph (d) of this section.

(d) *CMS-approved home infusion therapy accreditation program review.* If a comparability, performance, or standards review reveals evidence of substantial non-compliance of a home infusion therapy accrediting organization's CMS-approved home infusion therapy accreditation program with the requirements of this subpart, CMS may initiate a home infusion therapy accreditation program review.

(1) If a home infusion therapy accreditation program review is initiated, CMS will provide written notice to the home infusion therapy accrediting organization indicating that its CMS-approved accreditation program approval may be in jeopardy and that a home infusion therapy accreditation program review is being initiated. The notice will provide all of the following information:

(i) A statement of the instances, rates or patterns of non-compliance identified, as well as other related information, if applicable.

(ii) A description of the process to be followed during the review, including a description of the opportunities for the home infusion therapy accrediting organization to offer factual information related to CMS' findings.

(iii) A description of the possible actions that may be imposed by CMS based on the findings of the home infusion therapy accreditation program review.

(iv) The actions the home infusion therapy accrediting organization must take to address the identified deficiencies

(v) The length of the accreditation program review probation period, which will include monitoring of the home infusion therapy accrediting organization's performance and implementation of the corrective action plan. The probation period is not to exceed 180 calendar days from the date

that CMS approves the AOs corrective action plan.

(2) CMS will review and approve the home infusion therapy accrediting organization's plan of correction for acceptability within 30 days after receipt.

(3) CMS will monitor the AO's performance and implementation of the plan of correction during the probation period which is not to exceed 180 days from the date of approval of the plan of correction.

(4) If CMS determines, as a result of the home infusion therapy accreditation program review or a review of an application for renewal of the accrediting organizations existing CMS-approved home infusion therapy accreditation program, that the home infusion therapy accrediting organization has failed to meet any of the requirements of this subpart, CMS may place the home infusion therapy accrediting organization's CMS-approved home infusion therapy accreditation program on an additional probation period of up to 180 calendar days subsequent to the 180-day probation period described in paragraph (d)(1)(v) of this section to implement additional corrective actions or demonstrate sustained compliance, not to exceed the home infusion therapy accrediting organization's current term of approval. In the case of a renewal application where CMS has already placed the home infusion therapy accreditation program on probation, CMS indicates that any approval of the application is conditional while the program is placed on probation.

(i) Within 60 calendar days after the end of any probationary period, CMS issues a written determination to the home infusion therapy accrediting organization as to whether or not its CMS-approved home infusion therapy accreditation program continues to meet the requirements of this subpart, including the reasons for the determination.

(ii) If CMS determines that the home infusion therapy accrediting organization does not meet the requirements, CMS may withdraw approval of the CMS-approved home infusion therapy accreditation program. The notice of determination provided to the home infusion therapy accrediting organization includes notice of the removal of approval, reason for the removal, including the effective date determined in accordance with paragraph (d)(4)(iii) of this section.

(iii) CMS publishes in the **Federal Register** a notice of its decision to withdraw approval of a CMS-approved accreditation program, including the

reasons for the withdrawal, effective 60 calendar days after the date of publication of the notice.

(e) *Immediate jeopardy.* If at any time CMS determines that the continued approval of a CMS-approved home infusion therapy accreditation program of any home infusion therapy accrediting organization poses an immediate jeopardy to the patients of the suppliers accredited under the program, or the continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of a CMS-approved home infusion therapy accreditation program of that home infusion therapy accrediting organization and publish a notice of the removal, including the reasons for it, in the **Federal Register**.

(f) *Notification to home infusion therapy suppliers of withdrawal of CMS approval status.* A home infusion therapy accrediting organization whose CMS approval of its home infusion therapy accreditation program has been withdrawn must notify each of its accredited home infusion therapy suppliers, in writing, of the withdrawal of CMS approval status no later than 30 calendar days after the notice is published in the **Federal Register**. The notification to the accredited home infusion therapy suppliers must inform them of the implications for their payment status once their current term of accreditation expires.

§ 488.1035 Ongoing responsibilities of a CMS-approved home infusion therapy accrediting organization.

A home infusion therapy accreditation organization approved by CMS must carry out the following activities on an ongoing basis:

(a) Provide CMS with all of the following in written format (either electronic or hard copy):

(1) Copies of all home infusion therapy accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of findings with respect to unmet CMS requirements).

(2) Notice of all accreditation decisions.

(3) Notice of all complaints related to providers or suppliers.

(4) Information about all home infusion therapy accredited suppliers against which the home infusion therapy accreditation organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the providers or suppliers accreditation.

(5) The home infusion therapy accrediting organization must provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

(6) Notice of any proposed changes in the home infusion therapy accrediting organization's accreditation standards or requirements or survey process. If the home infusion therapy accrediting organization implements the changes before or without CMS' approval, CMS may withdraw its approval of the accrediting organization.

(b) Within 30 calendar days after a change in CMS requirements, the home infusion therapy accrediting organization must submit an acknowledgment of receipt of CMS' notification to CMS.

(c) The home infusion therapy accrediting organization must permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(d) Within 2 business days of identifying a deficiency of an accredited home infusion therapy supplier that poses immediate jeopardy to a beneficiary or to the general public, the home infusion therapy accrediting organization must provide CMS with written notice of the deficiency and any adverse action implemented by the accrediting organization.

(e) Within 10 calendar days after CMS' notice to a CMS-approved home infusion therapy accrediting organization that CMS intends to withdraw approval of the home infusion therapy accrediting organization, the home infusion therapy accrediting organization must provide written notice of the withdrawal to all of the home infusion therapy accrediting organization's accredited suppliers.

§ 488.1040 Onsite observations of home infusion therapy accrediting organization operations.

(a) As part of the application review process, the ongoing review process, or the continuing oversight of a home infusion therapy accrediting organization's performance, CMS may conduct onsite inspections of the home infusion therapy accrediting organization's operations and offices at any time to verify the home infusion therapy accrediting organization's representations and to assess the home infusion therapy accrediting organization's compliance with its own policies and procedures.

(b) Activities to be performed by CMS staff during the onsite inspections may include, but are not limited to the following:

(1) Interviews with various accrediting organization staff.

(2) Review of documents, survey files, audit tools, and related records.

(3) Observation of meetings concerning the home infusion therapy accreditation process.

(4) Auditing meetings concerning the accreditation process.

(5) Observation of in-progress surveys and audits.

(6) Evaluation of the accrediting organization's survey results and accreditation decision-making process.

§ 488.1045 Voluntary and involuntary termination.

(a) *Voluntary termination by a CMS-approved accrediting program.* In accordance with § 488.1010(a)(23), a home infusion therapy accrediting organization that decides to voluntarily terminate its CMS-approved home infusion therapy accreditation program must provide written notice at least 180 days in advance of the effective date of the termination to CMS and each of its accredited home infusion therapy suppliers.

(b) *Involuntary termination of an accrediting organization's approval by CMS.* Once CMS publishes the notice in the **Federal Register** announcing its decision to terminate the home infusion therapy accrediting organization's home infusion therapy accreditation program, the home infusion therapy accrediting organization must provide written notification to all suppliers accredited under its CMS-approved home infusion therapy accreditation program no later than 30 calendar days after the notice is published in the **Federal Register** announcing that CMS is withdrawing its approval of its home infusion therapy accreditation program and the implications for the home infusion therapy suppliers payment status in accordance with the requirements at § 488.1010(f) once their current term of accreditation expires.

(c) *Voluntary and involuntary terminations.* For both voluntary and involuntary terminations—

(1) The accreditation status of affected home infusion therapy suppliers is considered to remain in effect until their current term of accreditation expires;

(2) If the home infusion therapy supplier wishes to avoid a suspension of payment, it must provide written notice to CMS at least 60-calendar days prior to its accreditation expiration date that it has submitted an application for home infusion therapy accreditation under another CMS-approved home infusion therapy accreditation program. Failure to comply with this 60-calendar day requirement prior to expiration of their

current home infusion therapy accreditation stations within could result in a suspension of payment; and

(3) The home infusion therapy accrediting organization provides a second written notification to all accredited home infusion therapy suppliers ten calendar days prior to the organization's accreditation program effective date of termination.

(d) *Voluntary withdrawal from accreditation requested by a home infusion therapy supplier.* If a voluntary withdrawal from accreditation is requested by the home infusion therapy supplier, the withdrawal may not become effective until the accrediting organization completes all of the following steps:

(1) The accrediting organization must contact the home infusion therapy supplier to seek written confirmation that the home infusion therapy supplier intends to voluntarily withdraw from the home infusion therapy accreditation program.

(2) The home infusion therapy accrediting organization must advise the home infusion therapy supplier, in writing, of the statutory requirement for accreditation for all home infusion therapy suppliers and the possible payment consequences for a lapse in accreditation status.

(3) The home infusion therapy accrediting organization must submit their final notice of the voluntary withdrawal of accreditation by the home infusion therapy supplier to CMS by 5 business days after the request for voluntary withdrawal is ultimately processed and effective.

§ 488.1050 Reconsideration.

(a) *General rule.* A home infusion therapy accrediting organization dissatisfied with a determination that its home infusion therapy accreditation requirements do not provide or do not continue to provide reasonable assurance that the suppliers accredited by the home infusion therapy accrediting organization meet the applicable quality standards is entitled to reconsideration.

(b) *Filing requirements.* (1) A written request for reconsideration must be filed within 30 calendar days of the receipt of CMS notice of an adverse determination or non-renewal.

(2) The written request for reconsideration must specify the findings or issues with which the home infusion therapy accrediting organization disagrees and the reasons for the disagreement.

(3) A requestor may withdraw its written request for reconsideration at

any time before the issuance of a reconsideration determination.

(c) *CMS response to a request for reconsideration.* In response to a request for reconsideration, CMS provides the accrediting organization with—

(1) The opportunity for a hearing to be conducted by a hearing officer appointed by the Administrator of CMS and provide the accrediting organization the opportunity to present, in writing and in person, evidence or documentation to refute the determination to deny approval, or to withdraw or not renew designation; and

(2) Written notice of the time and place of the hearing at least 10 business days before the scheduled date.

(d) *Hearing requirements and rules.*

(1) The reconsideration hearing is a public hearing open to all of the following:

(i) Authorized representatives and staff from CMS, including, but not limited to, the following:

(A) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts).

(B) Legal counsel.

(C) Non-technical witnesses with personal knowledge of the facts of the case.

(ii) Representatives from the accrediting organization requesting the reconsideration including, but not limited to, the following:

(A) Authorized representatives and staff from the accrediting organization.

(B) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts).

(C) Legal counsel.

(D) Non-technical witnesses, such as patients and family members that have personal knowledge of the facts of the case.

(2) The hearing is conducted by the hearing officer who receives testimony and documents related to the proposed action.

(3) Testimony and other evidence may be accepted by the hearing officer even though such evidence may be inadmissible under the Federal Rules of Civil Procedure.

(4) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(5) Within 45 calendar days after the close of the hearing, the hearing officer will present the findings and recommendations to the accrediting organization that requested the reconsideration.

(6) The written report of the hearing officer will include separate numbered findings of fact and the legal conclusions of the hearing officer.

(7) The hearing officer's decision is final.

Dated: October 19, 2018.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: October 22, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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Part III

National Credit Union Administration

12 CFR Part 701

Federal Credit Union Bylaws; Proposed Rule

**NATIONAL CREDIT UNION
ADMINISTRATION**

12 CFR Part 701

RIN 3313-AE86

Federal Credit Union Bylaws

AGENCY: National Credit Union Administration (NCUA).

ACTION: Proposed rule.

SUMMARY: The NCUA Board (Board) is proposing to update, clarify, and simplify the federal credit union bylaws (FCU Bylaws). The Board also is proposing changes that will update and conform the FCU Bylaws to legal opinions issued by the NCUA's Office of General Counsel and/or provide greater flexibility to FCUs. Finally, the Board is proposing other changes that are designed to remove outdated or obsolete provisions.

DATES: Comments must be received by January 14, 2019.

ADDRESSES: You may submit comments by any of the following methods (Please send comments by one method only):

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

- *NCUA Website:* http://www.ncua.gov/RegulationsOpinionsLaws/proposed_regs/proposed_regs.html. Follow the instructions for submitting comments.

- *Email:* Address to regcomments@ncua.gov. Include "[Your name] Comments on FCU Bylaws" in the email subject line.

- *Fax:* (703) 518-6319. Use the subject line described above for email.

- *Mail:* Address to Gerard Poliquin, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314-3428.

- *Hand Delivery/Courier:* Same as mail address.

Public inspection: All public comments are available on the agency's website at <http://www.ncua.gov/RegulationsOpinionsLaws/comments> as submitted, except as may not be possible for technical reasons. Public comments will not be edited to remove any identifying or contact information. Paper copies of comments may be inspected in NCUA's law library, at 1775 Duke Street, Alexandria, Virginia 22314, by appointment weekdays between 9:00 a.m. and 3:00 p.m. To make an appointment, call (703) 518-6540 or send an email to OGCMail@ncua.gov.

FOR FURTHER INFORMATION CONTACT: Benjamin M. Litchfield, Staff Attorney,

Office of General Counsel, 1775 Duke Street, Alexandria, Virginia 22314, or by telephone at (703) 518-6540.

SUPPLEMENTARY INFORMATION:

- I. Background
- II. Legal Authority
- III. Summary of the Proposed Rule
- IV. Article-by-Article Analysis
- V. Regulatory Procedures

I. Background

Section 108 of the Federal Credit Union Act (FCU Act) requires the Board to periodically prepare a form of bylaws to be used by FCU incorporators and to provide that form to FCU incorporators upon request.¹ FCU incorporators must submit proposed bylaws to the NCUA as part of the chartering process. Once the NCUA has approved an FCU's proposed bylaws, the FCU must operate according to its approved bylaws or seek agency approval for a bylaw amendment.²

The FCU Bylaws are set out in Appendix A to part 701 of the NCUA's regulations.³ The Board incorporated the FCU Bylaws into the NCUA's regulations to address concerns regarding bylaw enforcement.⁴ As the Board stated in the final rule incorporating the FCU Bylaws, the FCU Act only provides two mechanisms for correcting bylaw violations: (1) Suspension or revocation of an FCU's charter or (2) placing an FCU into conservatorship. Aside from these extreme remedies, when adopting the final rule, the Board was concerned about identifying what, if any, supervisory action the NCUA could take to protect fundamental member rights.⁵ By incorporating the FCU Bylaws into the NCUA's regulations, the Board believed that it could use additional regulatory tools, such as the issuance of a cease and desist order, to address material noncompliance with an FCU's bylaws.

FCUs often express concerns that the FCU Bylaws do not provide sufficient operational flexibility to allow an FCU to respond to changing market practices or to address basic corporate governance matters in a prompt and efficient manner. These arguments are well taken. Accordingly, the NCUA has engaged in an ongoing review of the FCU Bylaws to determine what, if any,

changes may be necessary to provide additional flexibility to FCUs.

In 2013, the NCUA's Office of General Counsel consulted with representatives from the credit union industry regarding the FCU Bylaws. The NCUA received many comments during the 2013 consultation, many of which focused on relatively narrow aspects of the FCU Bylaws. For example, FCUs recommended that the NCUA provide more staff commentary on the meaning and interpretation of specific bylaw provisions. They also encouraged the NCUA to make a concerted effort to modernize the FCU Bylaws by using consistent terms throughout and deleting inapplicable language that is no longer useful. Commenters specifically recommended that the NCUA update the preamble to the FCU Bylaws and ensure that the instructions are current.

On March 15, 2018, the Board issued an advance notice of proposed rulemaking (ANPR) soliciting comments on how to update, clarify, and simplify the FCU Bylaws.⁶ The Board solicited comment on five specific questions related to: (1) Improving the bylaw amendment process within the NCUA; (2) addressing ambiguities in the FCU Bylaws allowing for an FCU to limit services to a member and expel a member; (3) methods to facilitate recruitment and development of directors; (4) methods to encourage member attendance at annual and special meetings; and (5) eliminating regulatory overlaps between the FCU Bylaws and the NCUA's regulations. The Board also invited general comments on improvements to the FCU Bylaws.

The Board received a wide variety of comments to the ANPR from FCUs, federally insured, state-chartered credit unions, national credit union trade associations, state credit union trade associations, and law firms. Commenters generally appreciated the Board's efforts to provide an enhanced opportunity to participate in the rulemaking process. Nearly all of the commenters raised issues with specific aspects of the FCU Bylaws and requested that the Board provide the greatest amount of regulatory relief permissible under the FCU Act.

Based on the comments the Board has received in response to the ANPR and throughout its ongoing review of the FCU Bylaws, the Board is proposing to make significant revisions to modernize the FCU Bylaws.

¹ 12 U.S.C. 1758.

² 12 CFR 701.2(a).

³ 12 CFR 701, App. A.

⁴ 72 FR 61495, 61496 (Oct. 31, 2007).

⁵ Specifically, these rights include the right to: (1) Maintain a share account; (2) maintain FCU membership; (3) have access to credit union facilities; (4) participate in the director election process; (5) attend annual and special meetings; and (6) petition for removal of directors and committee members. See 72 FR 30984, 30986 (June 5, 2007) (proposed rule).

⁶ 83 FR 12283 (Mar. 21, 2018).

II. Legal Authority

The Board is issuing this proposed rule pursuant to its specific authority in the FCU Act to adopt a form of bylaws to be used by FCU incorporators when chartering an FCU,⁷ as well as its plenary authority to adopt rules and regulations for the administration of the FCU Act.⁸ Given the importance of proper corporate governance procedures to the safe and sound operation of FCUs, the Board believes this proposed rule is a necessary and proper exercise of this statutory rulemaking authority.

III. Summary of the Proposed Rule

The proposed rule incorporates many of the suggestions the Board received in response to the ANPR and throughout the NCUA's ongoing review of the FCU Bylaws. In addition, the proposed rule clarifies provisions that have created confusion in the past, as reflected by the numerous inquiries the NCUA has received from FCUs and members. In some instances, a proposed change offers more detail or further elaboration to help FCU officials, employees, and members better understand a provision.

The proposed rule also makes stylistic and grammatical changes throughout the FCU Bylaws, which provide for a much clearer and more readable document. For example, the proposed rule moves the entire body of staff commentary to the end of the FCU Bylaws, with corresponding references to the articles and section numbers that are the subject of the commentary.

However, the proposed rule does not permit an FCU to draft its own bylaws. The FCU Act requires the Board to develop a form of bylaws that "shall be used" by FCU incorporators and mandates that FCUs operate according to their NCUA-approved bylaws.⁹ While commenters to the ANPR and throughout the NCUA's ongoing review of the FCU Bylaws have advocated greater flexibility to develop their own bylaws, the Board continues to believe that having a uniform set of FCU Bylaws is more consistent with the spirit of the FCU Act¹⁰ and is necessary to protect fundamental member rights, to avoid confusion among FCUs, and to prevent

the adoption of illegal bylaw provisions.¹¹

IV. Article-by-Article Analysis

Introduction

This proposed rule modernizes the introductory language to the FCU Bylaws. It changes the instructions for bylaw amendments to reflect that the NCUA's Office of Credit Union Resources and Expansion (CURE) now is the primary office handling bylaw amendments, and consults with the NCUA's Office of General Counsel as necessary. The proposed rule also establishes an explicit 90 calendar day deadline for CURE to reach a decision on a bylaw amendment.

In the ANPR, the Board specifically requested comments on improving the bylaw amendment process. Commenters requested that the Board adopt a deadline for CURE to process bylaw amendments, with a majority favoring 30 calendar days. While the Board agrees that the NCUA should process bylaw amendments as expeditiously as possible to allow the FCU to address any pressing operational concerns, the Board remains concerned that 30 calendar days may be an insufficient amount of time. Accordingly, the proposed rule adopts a 90-calendar day deadline. The Board believes that this time period will provide CURE with sufficient time to consider the bylaw amendment without imposing an undue operational burden on the FCU. The Board requests specific comments on this aspect of the proposed rule including whether another time period, such as 60 calendar days, would be more appropriate to ensure that CURE processes proposed bylaw amendments in a timely manner.

Commenters to the ANPR also requested that the Board automatically approve any bylaw amendment that CURE does not approve within this deadline. The Board does not believe that it is appropriate to automatically approve proposed bylaw amendments, as this could result in adoption of a bylaw that has a material adverse effect on fundamental member rights, poses a safety and soundness risk to the FCU, or is otherwise contrary to law. Instead, the Board believes it is appropriate to treat the failure to approve a bylaw amendment within the prescribed deadline as a denial, which the FCU may then appeal to the Board pursuant to the appeals procedures set out in

subpart B to part 746 of the NCUA's regulations.¹²

Article I. Name—Purposes

Article I states the FCU's name and mission. The proposed rule amends section 2, which outlines the FCU's purposes, by changing the reference in the second sentence from "consumers" to "members." The Board is proposing to change this term because FCUs are not limited in their mission to serving consumers. There may be small businesses and other organizations within the field of membership that can benefit from the FCU's services, and this change is designed to reflect this benefit.

Article II. Qualifications for Membership

Article II outlines the requirements for obtaining and continuing FCU membership. The proposed rule includes an expanded discussion in the staff commentary of measures that an FCU may take to address abusive and disruptive members. In addition, to facilitate an FCU's implementation of any limitation of services policy, the proposed rule adds a new section 5, describing the concept of a "member in good standing." As long as a member remains in good standing, that member retains all of the rights and privileges associated with FCU membership. A member not in good standing, however, may be subject to an FCU's limitation of services policy.

In the ANPR, the Board specifically requested suggestions on ways to clarify an FCU's right to limit services or restrict access to credit union facilities to disruptive or abusive members. Some commenters recommended that the Board incorporate into the FCU Bylaws prior legal opinions by the NCUA's Office of General Counsel addressing this matter. Those legal opinions state that an FCU may limit services or access to credit union facilities to violent, belligerent, disruptive, or abusive members provided that there is a logical relationship between the objectionable conduct and the services to be suspended. The member must also receive adequate notice of the FCU's limitation of services policy.¹³

The Board agrees that incorporating these legal opinions into the FCU Bylaws is appropriate to provide additional clarity on an FCU's right to limit services or access to credit union facilities. Accordingly, the proposed rule includes staff commentary to Article II, based on these prior legal opinions, that details how an FCU may

⁷ 12 U.S.C. 1753.

⁸ 12 U.S.C. 1766(a).

⁹ 12 U.S.C. 1758.

¹⁰ See 71 FR 24551 (Apr. 26, 2006) ("NCUA's longstanding position has been that [the FCU Act] expresses a congressional desire for uniformity regarding FCU operations and member rights. Accordingly, NCUA views [the FCU Act] as providing authority to issue form bylaws that apply to all FCUs, not only newly chartered FCUs, and to review proposed bylaw amendments.")

¹¹ See 72 FR 30984, 30985 (June 5, 2007) (proposed rule) (uniform bylaws necessary to protect fundamental member rights, avoid confusion, and prevent adoption of illegal bylaws).

¹² 12 CFR 746, subpart B.

¹³ See OGC Op. No. 08-0431 (Aug. 12, 2008).

handle an abusive or disruptive member. The staff commentary notes that there is a reasonably wide range within which an FCU may fashion a limitation of services policy that is tailored to the needs of the individual FCU. An FCU has broad discretion to deny, as it deems appropriate, all or most credit union services such as ATM services, credit cards, loans, share draft privileges, preauthorized transfers, or access to credit union facilities to a member that has engaged in conduct that has caused a loss to the FCU or that threatens the safety of credit union staff, facilities, or other members in the FCU or its surrounding property. Accordingly, an FCU may take immediate action to address situations in which a member is violent, belligerent, disruptive, or poses a threat to the credit union, or other members, or its employees even if the FCU Act prohibits the FCU from immediately expelling the member.

The staff commentary also notes that the policy need not be identical or applied uniformly in all cases, provided that the FCU has a legitimate purpose for any disparate treatment of members. For additional clarity, the staff commentary contains cross references to procedures that FCUs must use to expel a member, and it refers to Article XVI, § 1 of the FCU Bylaws, which contains language reiterating that no member may access or utilize an FCU's services in furtherance of an illegal objective.

To facilitate an FCU's implementation of its limitation of services policy, the proposed rule amends Article II to distinguish between a member that retains all of the rights and privileges associated with FCU membership and a member that is subject to a limitation on services or a restriction on access to credit union facilities. As noted, the proposed rule adds a new section 5, describing the concept of a "member in good standing." A member in good standing retains all the rights of FCU membership. To remain in good standing, a member must be current on credit union loans, avoid engaging in any violent, belligerent, disruptive, or abusive behavior towards credit union staff or other credit union members in the FCU or its surrounding property, and not cause a financial loss to the credit union. A member that fails to observe any of these basic requirements may be subject to reasonable limitations of service or access to credit union facilities pursuant to the FCU's limitation of services policy.

The Board recognizes that terms such as "violent," "belligerent," "disruptive," and "abusive" are subjective and, therefore, may not

provide FCUs with absolute clarity regarding the circumstances under which a limitation of services or access to credit union facilities may be appropriate. The Board believes that, without question, certain actions warrant immediate limitations of service or access to credit union facilities, such as violence against other credit union members or credit union staff in the credit union facility or the surrounding property. In fact, the Board believes that an FCU has an obligation to take immediate action against such individuals. Other actions, such as rude behavior or potential threats of violence, may warrant limitations of service or restrictions of access to credit union facilities based on the specific facts and circumstances of that case. Accordingly, the Board requests comments on ways to clarify these terms, including specific examples of conduct that FCUs believe to be "disruptive," "abusive," and "belligerent." Based on the persuasiveness of the comments, the Board may incorporate examples of "violent," "belligerent," "disruptive," and "abusive" conduct into staff commentary to provide additional clarity for FCUs.

The Board notes that, in addition to the rights granted under Article II, an FCU may immediately take actions such as contacting local law enforcement, seeking a restraining order, or pursuing other lawful means, to protect the credit union, credit union members, and staff. Nothing in the FCU Act or the FCU Bylaws prevents an FCU from using whatever lawful means it deems necessary to address circumstances where a member poses a risk of harm to the FCU, its members, or its staff.

Article III. Shares of Members

Article III provides basic information about issues related to members' share accounts, including the par value of the membership share, trust accounts, and membership status of joint account holders. The proposed rule adds new language under Section 1 providing representative examples for FCUs to choose in establishing varying par values for different classes of membership (such as students, minors, or non-natural persons), provided that such differences conform to applicable legal requirements established by federal, state, or municipal anti-discrimination laws. The new language also clarifies that FCUs have options regarding whether to require all members to maintain a regular share account, or whether to permit members to base their qualification for membership on some other type of account. Additional staff commentary

elaborates more fully on this option. The proposed rule revises the text of Article III to incorporate plain English writing principles and delete unnecessary provisions.

Commenters to the ANPR requested that the Board provide additional guidance on trust accounts. New staff commentary addresses some of the considerations that apply in the context of trust accounts, including a discussion of the pertinent differences between revocable and irrevocable trusts. It also clarifies that, in the case of a revocable trust, the individual who establishes the trust (also known as the settlor) maintains ownership and control of the funds during that person's lifetime. Thus, the NCUA requires the settlor to join the FCU in order to establish a revocable trust account for that individual, thus requiring the settlor to be within the FCU's field of membership. The staff commentary notes that there is no requirement that the settlor first establish a regular share account to become a member. Rather, the settlor may satisfy the membership through the opening of the revocable trust account itself.

In contrast, the staff commentary clarifies that membership requirements for an irrevocable trust account may be met through the settlor, who is the original owner of the funds, or the beneficiary, who obtains an equitable, beneficial interest in the funds once the trust is established. So long as one or the other is eligible for membership and actually joins the FCU, then the FCU may accept the account. As with revocable trusts, the membership obligation can be satisfied through the opening of the trust account itself, so it is not necessary for the beneficiary or the settlor, as applicable, to establish a regular share account as a condition precedent to membership. Furthermore, the trustee need not actually be a member of the FCU. Many irrevocable trusts have a trustee and the NCUA often receives questions on whether membership requirements for an irrevocable trust may be met through the trustee. While the trustee has administrative responsibility for the account, the trustee has no ownership interest in the account and is, therefore, irrelevant for purposes of establishing membership.

The staff commentary also notes that a trust itself, whether revocable or irrevocable, may be a member of an FCU in its own right if all parties to the trust, including the settlors, beneficiaries and trustees, are within the field of membership and actually join the FCU.

Article IV. Meetings of Members

Article IV addresses procedures related to annual and special meetings of an FCU's membership. In the ANPR, the Board specifically requested comments on methods to encourage member attendance at annual and special meetings. The proposed rule makes several changes to Article IV to encourage greater member participation, including enhanced notice requirements and adjustments to quorum requirements.

To ensure that members receive adequate notice of an annual or special meeting, the proposed rule requires that the notice for the annual meeting be posted in a conspicuous place in the FCU's physical office of the FCU, such as at the teller windows or on the front door of the FCU's office, at least 30 calendar days before the meeting. The notice must also be prominently displayed on the FCU's website if the credit union then maintains a website. An FCU is not required to establish and maintain a website solely for this purpose, however. The proposed rule also deletes the option to waive prior notice if all members entitled to vote waived the notice requirement. The Board believes that these changes are appropriate because members are more likely to participate in annual and special meetings if the notice is widely announced.

In the staff commentary, the proposed rule encourages FCUs to provide a live webcast of annual and special meetings for interested members, as well as post a video of the annual meeting on the FCU's website. The NCUA encourages this policy only for FCUs with a website at the time of any such meeting; nothing requires FCUs to establish or maintain a website solely for this purpose. This policy encourages members to participate in the annual meeting, while also providing access to members who cannot attend meetings in person.

The proposed rule also adjusts the quorum requirement for meetings. It requires 12 members, excluding the board, credit union staff, and officials, for a quorum. The Board is proposing this adjustment to encourage FCUs to have wider participation from members, rather than allowing credit union staff and board members to control all corporate decision making within the credit union.

The proposed rule, however, does not change the total number of member signatures required to call a special meeting. During the 2013 consultation process with members of the credit union industry, commenters favored increasing the total number of member

signatures required to call a special meeting. They posited that special meetings are expensive and time-consuming to conduct and, thus, should be reserved only for matters of interest to a broad group of members. These comments are well taken. The Board does not believe that adopting a blanket increase is appropriate, however, given its potential to disenfranchise members of smaller FCUs. Accordingly, the Board is not proposing to make any changes to the provisions in Article IV that impose a limit on the total number of member signatures required to call a special meeting. Instead, the Board believes that a preferable approach is to continue the NCUA's current practice of considering requests from individual FCUs to increase this signature requirement on a case-by-case basis.

Furthermore, the proposed rule does not generally allow an FCU to conduct a virtual or hybrid (combined virtual and in-person) annual or special meeting. Commenters to the ANPR noted that at least 22 states currently permit corporations to host virtual or hybrid meetings, with several of those states extending the same flexibility to state-chartered financial institutions. The commenters argued that FCUs with the appropriate size, complexity, and sophistication should be allowed to take advantage of these solutions to provide greater flexibility for their members to attend annual or special meetings. The Board is sympathetic to the commenters' arguments. Due to its concerns about member disenfranchisement, however, the Board does not currently support adopting this position in a rulemaking that affects all FCUs. The Board is particularly concerned with the rights of members that do not have access to electronic devices or that may live in areas without access to broadband internet.

The NCUA will, however, consider bylaw amendment requests allowing for hybrid meetings on a case-by-case basis depending on, among other things, the FCU's size, nature, and field of membership. For example, the NCUA may grant such a bylaw amendment for an FCU that offers a majority of its financial services online or an FCU with a geographically dispersed field of membership. To avoid the possibility of member disenfranchisement, however, the Board does not believe it is appropriate to allow a virtual meeting to completely supplant a member meeting. Therefore, FCUs holding hybrid meetings must always offer an option for in-person attendance as well as online.

The FCU Bylaws already grant an FCU considerable discretion to hold

meetings in a location that is convenient for most of its members. Article IV allows an FCU to hold an annual or special meeting in the county in which any office of the FCU is located or within a radius of 100 miles of such an office, provided that the FCU does not pick a location designed to limit member participation or that has such an effect. Accordingly, the Board believes that an FCU has sufficient flexibility to ensure broad participation from members without the need for entirely virtual meetings and would be reluctant to approve any bylaw amendment allowing for entirely electronic voting. The Board encourages FCUs to be mindful when selecting a location for a member meeting to choose a location that maximizes member participation.

Article V. Elections

Article V addresses procedures for electing FCU Board members, and allows FCUs to select one of four options for conducting nominations and elections. During the 2013 consultation process with members of the credit union industry, the NCUA received comments that focused on several discrete aspects of this Article. Commenters suggested that, in regulating the voting process, the NCUA should take modern technology into consideration, including an option for electronic-only voting. Some commenters requested clarification on the appropriate procedures in cases of uncontested elections. Other commenters asked about the procedures for, and permissibility of, imposing additional director qualifications, and how to permit board-established qualifications.

The proposed rule provides staff commentary clarifying electronic voting. The staff commentary states that an FCU may use as many forms of electronic voting (e.g., mobile phone or internet) as it wishes for those members who choose to vote electronically. However, the proposed rule does not allow an FCU to adopt an entirely electronic voting process. While modern technological innovations have changed the way that corporations and other businesses conduct meetings and hold elections, the Board remains concerned that allowing electronic-only voting could disenfranchise those members that do not have access to electronic devices or that may live in areas without access to reliable internet. The NCUA will, however, consider bylaw amendment requests allowing for electronic-only voting on a case-by-case basis.

The proposed rule also provides staff commentary clarifying procedures for

uncontested elections. The staff commentary notes that three of the options for conducting nominations and elections provide for elections by acclamation or consensus when the number of nominees for board positions equals the number of positions to be filled. These options do not permit nominations from the floor at the meeting because members must be provided a ballot in advance of the member vote, so a petition is the only way to nominate a candidate not on the nominating committee's slate. The staff commentary also highlights that section 1(c) in each of these options requires the notice to members to include the fact that there are no nominations from the floor at the meeting, as well as a notice that the FCU will not conduct a vote by ballot if the number of nominees equals the number of positions to be filled.

Lastly, the proposed rule amends the staff commentary to encourage FCUs to take steps to increase the number of members who vote in FCU elections by increasing the range of voting options. The NCUA recently has approved several bylaw amendments that essentially combine the election options, for example, by adding a provision for mail or electronic ballots to one of the in-person voting options. The Board believes that, where possible, FCUs using one of the in-person voting options should consider offering mail or electronic ballots in addition to in-person voting. Similarly, FCUs conducting elections by mail and electronic means should consider also offering in-person voting. These changes currently require interested FCUs to pursue bylaw amendments individually. Accordingly, the Board seeks comment on whether the FCU Bylaws should include an additional option for conducting elections that would allow FCUs to use a combination of voting methods without needing to make individual requests to do so.

The Board seeks specific comments on whether the FCU Bylaws should require that the nominating committee widely publicize to all FCU members the call for nominations by any medium the FCU determines and interview every member who volunteers to serve. In addition, the Board asks whether the secretary should post the nominations by petition along with those of the nominating committee on the credit union's website (if the credit union maintains a website). The Board believes that widely publicizing the nomination process and posting the nominations by petition on the credit union's website will provide more opportunities for member participation

and is considering adopting such requirements in the final rule.

Article VI. Board of Directors

This Article provides the requirements related to the board of directors, such as the number of members, the composition of the board, the terms of office, and the responsibilities of the board. It also describes the regular and special meetings of the board. In addition, this Article provides the requirements for quorums, attendance and removal of board or credit committee members, and the suspension of supervisory committee members.

As part of the 2013 consultation process with members of the credit union industry, the NCUA received comments suggesting that the FCU Bylaws be revised to provide specific guidance to FCUs interested in establishing director emeritus and associate director positions. Commenters suggested that greater flexibility in regard to these types of arrangements will enable an FCU to better plan for vacancies in board positions and retirements among current directors. They also recommended enhanced flexibility regarding the composition of the board and reorganization of board duties. Moreover, commenters requested greater flexibility with regard to options concerning attendance by directors at meetings, and criteria and procedures by which incumbent directors may be removed. Commenters to the ANPR reiterated the need for additional guidance on associate director positions.

The Board agrees that an FCU should have the ability to establish, as a matter of FCU board policy, the position of director emeritus for former directors who faithfully fulfilled their responsibilities as members of the board for at least a specified minimum number of years. Accordingly, the proposed rule includes a new section 10 that an FCU may adopt to create such positions. It also includes specific staff commentary to this section that states that the decision to establish a director emeritus position, as well as any selection of individuals to become directors emeriti, is solely within the discretion of the FCU's board. The staff commentary clarifies that a director emeritus may attend and participate in board meetings, but may not vote on any matter before the board or exercise any official duties of a director.

To provide additional guidance to FCUs on associate director positions, the proposed rule clarifies, through staff commentary, that an FCU may establish associate director positions through

board policy. The staff commentary notes that the purpose of these positions is to provide qualified individuals with an opportunity to gain exposure to board meetings and discussions, but without formal director responsibility or the right to vote. As with the director emeritus position, the decision to establish an associate director position, as well as the selection of the individual(s) to become associate directors, is solely within the discretion of the FCU's board.

To provide FCUs with greater flexibility to address concerns regarding director and credit committee member attendance at monthly meetings, the proposed rule amends the option for FCUs to remove a director or a credit committee member for failure to attend regular meetings. The current bylaw language allows FCUs to remove a director or credit committee member that has missed 3 consecutive months, or 4 meetings in a calendar year. Under the proposed rule, an FCU may remove a director or credit committee member for missing 3 consecutive months or for missing 4 meetings within any 12 consecutive months. The Board believes this change provides FCUs with greater flexibility to address situations where a director or credit committee member misses a substantial number of consecutive meetings but would otherwise not qualify for removal because the missed meetings do not all occur within the same calendar year. In addition, the proposed rule adds language to allow FCUs to choose whether directors or credit committee members may be paid employees after such positions end.

The proposed rule also adds language that clarifies the existing restriction on the number of employees and family members of employees who may simultaneously serve on the board. The NCUA has received numerous questions regarding this issue since the FCU Bylaws were first incorporated into the NCUA's regulations in 2007. The current bylaw language prohibits FCU employees, their family members, or a combination of FCU employees and their family members from constituting a majority of the board. The purpose of this restriction is to prevent conflicts of interest that may arise when a majority of the board has a personal or pecuniary interest in a matter currently being reviewed by the board.

The Board has historically interpreted this provision of the FCU Bylaws to prohibit any combination of FCU employees, their family members, or FCU employees and their family members from constituting a majority of the board. To provide FCUs with

additional clarity, the proposed rule states that the total number of current voting directors serving who fall into the following categories must not constitute a majority of the board: (1) Management officials plus assistant management officials plus other employees; (2) immediate family members or persons in the same household as the management officials, assistant management officials, and other employees; or (3) management officials plus assistant management officials plus other employees, plus immediate family members or persons in the same household as management officials, assistant management officials, and other employees. The Board believes that this clarification will provide additional guidance to FCUs on this restriction.

For FCUs that elect not to have a specifically appointed credit committee, the proposed rule adds two new options to provide additional flexibility in addressing an applicant's request for review of a denied loan application. The FCU Act requires a board, at the request of the applicant, to review any application that has been denied by a loan officer.¹⁴ The FCU Bylaws allow the board, in its discretion, to establish subcommittees for the purpose of reviewing, at the request of an applicant, loan applications that have been rejected. These subcommittees are comprised of three members that serve a regular term of two years and function as mid-level appeal committees for the review of denials. The board itself must, at the request of an applicant, continue to review all applications denied by any such subcommittee. These two new options allow for FCUs to choose different ways to form the committee and select terms for the committee members.

Under the first new option, the board may elect to establish a subcommittee of three members and two alternates. The term of office of the subcommittee members may be for up to 3 years. Any number of lending professionals within the credit union may serve on the subcommittee, provided that no loan officer reviews any loan that the loan officer denied. At least 3 members of the subcommittee must review loan denials, none of whom have been a party to denying the loan. Under the second new option, the board may, by resolution, change the number of committee members to an odd number no less than 3 and no more than 7. The board has the

discretion to set the length of each subcommittee member's term upon appointment and stagger terms to prevent a complete turnover of subcommittee members. This option requires the board to file a copy of the resolution covering any increase or decrease in the number of subcommittee members with the official copy of the FCU's bylaws.

The proposed rule also adds staff commentary that encourages FCUs to form a board of directors that reflects the FCU's field of membership. This policy encourages FCUs to consider all members in its leadership. While the Board does not have specific concerns regarding board diversity or representativeness at this time, it believes in the importance of including such statements in the FCU Bylaws to remind stakeholders that credit unions are fundamentally different than many other depository financial institutions. Accordingly, the Board believes that credit unions should strive to have a board that reflects their membership to the greatest extent possible.

Finally, the proposed rule adds staff commentary that encourages FCUs to notify members, through a website posting (if the credit union then maintains a website), whenever the FCU's board adopts a resolution that changes the size of the FCU's board of directors. An FCU that does not then maintain a website can post such a notice in a conspicuous place in the FCU's offices, such as at the teller windows or on the FCU's front doors.

Article VII. Board Officers, Management Officials and Executive Committee

Article VII provides the requirements related to board officers, such as their election and their terms of office. It lists the duties of the chair, vice chair, financial officer, management officials, and secretary of the board. Article VII also explains the board powers regarding employees and the provisions for an executive committee and an investment committee.

The proposed rule makes certain clarifications and improvements to the readability of the language in this Article. For example, this Article utilizes the term "financial officer," and the NCUA has received comments that this term is confusing. The proposed rule, therefore, modifies the definition of "financial officer" in Article XVIII to mean "treasurer." The proposed rule also updates the language in section 8 to allow different options for addressing when directors or committee members may serve as paid employees of the credit union after their terms as

directors and/or committee members have ended.

The proposed rule adds more staff commentary under this Article, addressing procedural questions that arise in connection with specified board officer positions that may be held by directors, such as the president, vice president, and secretary of the board. The staff commentary clarifies that officers hold their respective board officer positions for a term of one year, until the first board meeting following the next annual meeting of the members. At that board meeting, board officer positions are again filled. Each board officer holds his or her position until the election and qualification of his or her successors. Thus, a board officer who is re-elected to the position the officer is currently holding serves for another year. Where another director is chosen to fill the position, the director takes office effective as of the date of the election, assuming the director is qualified.

The proposed rule adds additional staff commentary to address questions relating to temporary appointments of board officers, succession, replacement of director positions that may have become vacant between election cycles, and notifying members about membership on FCU committees. The staff commentary notes that, in the absence of both the chair and vice chair, those directors who are present at a meeting may select from among themselves an individual director to act as temporary chair for that particular meeting. Actions taken by the board under the direction of the temporary chair have the same validity and effect as if taken under the direction of the chair or the vice chair, provided a quorum of the board, including the temporary chair, is present. There is no requirement for the board to ratify actions taken under the temporary chair at a subsequent meeting of the board where either the chair or vice chair are present.

Article VIII. Credit Committee or Loan Officers

This Article provides the requirements for the credit committee, if an FCU elects to have one. This Article also lists the requirements for loan officers if an FCU does not have a credit committee. The proposed rule modernizes the language of this Article and incorporates plain English writing principles. In addition, the proposed rule incorporates into the FCU Bylaws several NCUA Office of General Counsel opinion letters permitting FCUs to use automated systems to process,

¹⁴ See 12 U.S.C. 1761c(b) ("If there is not a credit committee, a member shall have the right upon written request of review by the board of directors of a loan application which has been denied.").

underwrite, and fund loans under certain conditions.

Article IX. Supervisory Committee

Article IX provides the requirements for the supervisory committee, such as the appointment and membership of the committee, its duties, and the required officers. This Article also lists the powers of the supervisory committee. The FCU Act requires each FCU to have a supervisory committee. The supervisory committee must conduct or arrange for annual audits and verify members' deposits at least once every two years.¹⁵ The NCUA has assigned additional duties to FCUs' supervisory committees, including having them serve as an initial forum for hearing FCU members' complaints.¹⁶

The proposed rule modernizes the language of this Article. In addition, the proposed rule deletes paragraph (c) of section 3, as it is duplicative of paragraph (b). During the 2013 consultation process, commenters requested a number of changes to this Article to allow for greater flexibility. For example, one commenter requested that the Board amend section 3 to allow an FCU to call a special meeting 30 calendar days after all director positions become vacant, rather than the 7–14 calendar days currently set out in the FCU Bylaws. Another commenter requested that the Board amend section 6 to limit the actions members could take at a special meeting called to consider allegations of unsafe or illegal activity by a credit union director or credit committee member. These requested changes require statutory amendments to the FCU Act, so the proposed rule does not include any other substantive changes to this Article.

Article X. Organization Meeting

Some commenters have noted that the provisions in Article X, which govern the initial organizational meeting by which the FCU is established, effectively become obsolete and irrelevant after that initial organizational meeting. Although the Board acknowledges that this Article serves a limited purpose, it does not agree that the Article is necessarily irrelevant after the FCU has been established. Nevertheless, the proposed rule includes an option whereby FCUs may eliminate the Article after five years of operation. For FCUs electing this option, Article X will become "reserved" and its language inoperative.

Article XI. Loans and Lines of Credit to Members

Article XI lists loan purposes for members and addresses member delinquencies on loans. The proposed rule slightly edits the language of this Article for readability, but there are no other substantive changes.

Article XII. Dividends

Article XII establishes the power of the board to declare dividends. The proposed rule slightly edits the language of this Article for readability. There are no other substantive changes.

Article XIII. Reserved

The proposed rule makes no changes to this Article.

Article XIV. Expulsion and Withdrawal

Article XIV addresses the expulsion and withdrawal procedures for members. The Board notes that expulsion from membership is a very serious remedy that may only be accomplished in accordance with the procedures set forth in the FCU Act. An FCU may only expel a member upon a two-thirds majority vote of the membership at a special meeting called for that purpose or by operation of a board-approved nonparticipation policy.¹⁷ The FCU Act allows an FCU's board to adopt, by majority vote of a quorum of directors, and enforce a nonparticipation policy. If the FCU's board adopts such a policy, the FCU must provide written notice of the policy and its effective date to each member at least 30 calendar days prior to the policy's effective date. Each new member also must be provided a written notice of the policy prior to, or upon applying for, membership.

New staff commentary to this Article reiterates that the FCU Act provides only two methods for an FCU to expel a member and clarifies that only in-person voting is permitted in conjunction with a special meeting held for that purpose. This gives the affected member an opportunity to present his or her case against expulsion and an opportunity to respond to the FCU's concerns. The staff commentary clarifies that, short of expulsion, an FCU has a wide range of measures available to address abusive or disruptive members, and it specifically references Article XVI, Section 1 of the FCU Bylaws, which addresses situations when members use their accounts for unlawful purposes.

During the 2013 consultation process with representatives of the credit union industry, commenters pressed for ways

to make the expulsion of a disruptive member easier to accomplish. Commenters to the ANPR reiterated many of the same concerns. Many commenters requested that the Board either amend the FCU Bylaws or include staff commentary interpreting the FCU Act to allow an FCU to expel a member for actions such as filing for bankruptcy, habitual default, or misconduct under the FCU's board-approved nonparticipation policy. The FCU Act does not permit such an interpretation. A word used in a statute is given its ordinary or plain meaning unless context indicates otherwise.¹⁸ The term "nonparticipation" generally refers to a person not being involved with or participating in something. Accordingly, the Board believes that the term "nonparticipation" is best understood in a more limited sense to mean a failure to participate, or a lack of involvement, in credit union affairs. It does not refer to an act of malfeasance.

As the Board notes in the discussion of changes to Article II above, FCUs have the option to address violent, belligerent, disruptive, and abusive members by limiting their access to products and services provided that there is a logical relationship between the objectionable conduct and the services to be suspended and the member has received adequate notice of the FCU's limitation of services policy.¹⁹ Neither the FCU Act nor the NCUA's regulations prohibit an FCU, as it deems appropriate, from denying all or most credit union services such as ATM services, credit cards, loans, share draft privileges, preauthorized transfers, or access to credit union facilities to a member that has engaged in some objectionable conduct that has caused a loss to the FCU or that threatens the safety of credit union staff, facilities, or members. In fact, the Board believes that, without question, certain actions warrant immediate limitations of service or access to credit union facilities, such as violence against other credit union members or credit union staff in the credit union facility or the surrounding property. Consequently, even though the FCU Act does not permit an FCU to immediately expel a member under these circumstances, an FCU may still take immediate action to address situations in which a member is disruptive or poses a threat to the credit

¹⁸ *Sebelius v. Cloer*, 569 U.S. 369 (May 20, 2013) (absent evidence to the contrary, words must receive their ordinary meaning).

¹⁹ See OGC Op. No. 08–0431 (Aug. 12, 2008).

¹⁵ 12 U.S.C. 1761d.

¹⁶ See 12 CFR 715.3.

¹⁷ 12 U.S.C. 1764.

union, its employees, or other members in the FCU or its surrounding property.

Furthermore, as noted in the discussion of changes to Article II above, neither the FCU Act nor the NCUA's regulations prohibit an FCU from using lawful means to immediately protect the credit union, credit union members, and staff such as contacting local law enforcement, seeking a restraining order, or pursuing other forms of legal redress. The Board fully expects that an FCU would use these lawful means in addition to its limitation of services policy to proactively limit security threats or financial harm caused by violent, belligerent, disruptive, or abusive credit union members.

Article XV. Minors

This Article provides that minors are permitted to own shares and that the rights of minors to transact business with the FCU are governed by state law. The proposed rule slightly edits the language of this Article for readability, but there are no other substantive changes.

Article XVI. General

Article XVI addresses other general requirements, such as complying with other laws and regulations, confidentiality, and conflicts of interest. It also provides requirements related to records, indemnification, and the removal of directors and committee members.

During the 2013 consultation process with representatives of the credit union industry, the NCUA received comments regarding section 3, requesting a simplified procedure for confirmation by the membership of the suspension of a director or committee member by the supervisory committee. Commenters suggested that the confirmation of suspension be accomplished through balloting rather than a special meeting at which members must vote in person to accomplish the removal. The Board notes, in this respect, that these procedures are mandated by statute. The FCU Act requires that membership confirmation of supervisory committee suspension be accomplished only by majority vote of the members at a special meeting called for that purpose.²⁰ The proposed rule adds staff commentary explaining these requirements.

The staff commentary also adds new language regarding section 1 of this Article, which specifies that the credit union, its powers and duties, as well as the functions of its members, officers,

and directors, are all strictly circumscribed by law and regulation. It notes that, insofar as section 1 is included in the FCU Bylaws, an FCU need not adopt a specific policy or requirement that members use credit union products or services for lawful purposes. Furthermore, it confirms that this bylaw provision supports an FCU's decision to impose limits on products and services available to any individual who is found to be using the FCU in furtherance of unlawful purposes.

The proposed rule also amends section 6 to require FCUs with websites to post their bylaws on the website. The Board believes that adding this new requirement will ensure that members without access to an FCU's physical location where they can request a copy of the bylaws, can still have access to the FCU's corporate governance documents. Some FCUs operate over a wide geographic area, employing shared branch networks and/or online banking as a way to provide fast and reliable services to their members. It may be difficult for members of these FCUs, particularly in rural areas, to travel to the nearest branch office to request a copy of the FCU's bylaws. Accordingly, the Board believes that, to the extent an FCU maintains a website, an FCU should post its current bylaws on that website to provide these members with immediate access.

Finally, the proposed rule adds a new section 9 which clarifies the use of singular and plural terms as well as pronouns in the bylaws. The NCUA has received questions in the past in this regard. New section 9 clarifies that, unless the context requires otherwise, words denoting the singular may be construed as denoting the plural, words of the plural may be construed as denoting the singular, and words of one gender may be construed as denoting another gender as appropriate.

Article XVII. Amendments of Bylaws and Charter

Article XVII provides the requirements for amending an FCU's bylaws or charter. The proposed rule modernizes the language of this Article and incorporates plain English writing principles. In addition, in conjunction with the proposed rule's requirement for an FCU to post its current bylaws on its website (if the FCU maintains a website), the proposed rule requires an FCU to update the posting if it amends its bylaws.

Article XVIII. Definitions

Article XVIII lists the definitions applicable to all of the FCU Bylaws. The proposed rule makes a few technical

changes to this Article and adds several new definitions, which the Board believes are useful for purposes of clarification. These include new definitions for "Agency," "Charter," "Field of Membership," "Loans," and "Membership Officer." In addition, the definitions include a listing of approved board officers. This article also includes the term "Member," the definition of which identifies the characteristics and actions an individual must take to become a qualified member. Finally, the definitions include the term "Management," which is defined to include the Board, Financial Officer, and Management Official.

V. Regulatory Procedures

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA)²¹ requires the NCUA to provide an initial regulatory flexibility analysis with a proposed rule to certify that the rule will not have a significant economic impact on a substantial number of small entities (defined for the purpose of the RFA to include credit unions with assets less than or equal to \$100 million) and to publish its certification and a short explanatory statement in the **Federal Register** along with the proposed rule. The proposed new bylaw amendments are simply a resource that is available to all FCUs, regardless of size. Except for newly chartered FCUs, there is nothing prescriptive or mandatory about this proposed rule. All FCUs are free to adopt the proposed new bylaws, retain their current bylaws, or adopt some combination of the proposed bylaws and their current bylaws. If an FCU elects to adopt the new proposed version that FCU only needs to adopt a board resolution to that effect. Accordingly, the NCUA hereby certifies this proposed rule will not have a significant economic impact on a substantial number of small credit unions.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) applies to rulemaking in which an agency by rule creates a new paperwork burden on regulated entities or modifies an existing burden.²² For purposes of the PRA, a paperwork burden may take the form of a reporting, disclosure, or recordkeeping requirement, both referred to as information collection. The NCUA may not conduct or sponsor, and the respondent is not required to respond

²¹ 5 U.S.C. 601 *et seq.*

²² 44 U.S.C. 3507(d); 5 CFR part 1320.

²⁰ 12 U.S.C. 1761d.

to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The current proposal clarifies many bylaws provisions and adds a few substantive changes.

The amendments under this proposal would affect newly chartered FCUs or FCUs that choose to adopt these provisions. These provisions are:

- Article IV, § 2—The proposed rule would require FCUs to post annual meeting notices in a conspicuous place in the office of the credit union at least 30 days before the annual meeting, and to post the notice on the credit union's website, if the FCU has a website.

- Article V—The nominating committee must widely publicize the call for nominations to all members by any medium and interview each member who volunteers. The secretary must post the nominations by petition along with those of the nominating committee on the credit union's website, if the FCU has a website.

- Article XVI, § 6—If an FCU has a website, the FCU must post the bylaws on the website.

- Article XVII—After adopting amendments, a FCU must update the bylaws posted on its website, if the FCU has a website.

The information collection requirements under OMB control number 3133-0052 will be revised as follows due to the following program changes:

Article IV. Meetings of Members

The current information collection requirements under Article IV is related to notices related to member meetings. The NCUA estimated the current burden hours at 3,721. NCUA has determined that the new changes from the proposed rule would only increase the burden for each FCU by 15 minutes.

Each FCU is estimated to spend 10 minutes posting notices for an increase of 620 hours, and each FCU with a website is estimated to spend 5 minutes posting notices to their website for an increase of 301 hours. NCUA estimates that 3,617 of the total number of FCUs have websites. This new disclosure requirement will increase the burden hours associated with the information collection under Article IV by 921 hours; for a total of 4,642 hours.

Article V. Elections

The current information collection requirements under Article V covers the burden associated with the recordkeeping requirements for FCU elections. NCUA estimated the current burden hours to be 29,768. The NCUA

has determined that the new changes from the proposed rule would increase the burden for each FCU by 40 minutes. Each FCU is estimated to spend 30 minutes publicizing the call for nominations for an increase of 1,851 burden hours; and each FCU with a website is estimated to spend 10 minutes posting nominations to their website for an increase of 603 hours. The NCUA estimates that 3,617 of the total number of FCUs have websites. This new disclosure requirement will increase the burden hours associated with the information collection under Article V by 2,464 hours; for a total of 32,232 hours.

The information collection requirement associated with section 6 of Article V, Report of Officials, is cleared under OMB control number 3133-0004.

Article XVI. General

The current information collection requirements under Article XVI is FCU recordkeeping requirements specified in sections 5 and 6. The proposed rule does not affect the current recordkeeping requirements; however, under section 6 of Article XVI, a one-time burden of 1 hour will be reported for FCU's with a website to post their bylaws. This new disclosure requirements will increase the burden associated with Article XVI by 3,617 hours; for a total of 92,921 hours.

Article XVII. Amendments of Bylaws and Charter

A new information collection requirement proposed under Article XVII is that FCU, who maintains a website, would be required to update its bylaws on its website after adopting any amendments. The NCUA estimates that it would take an FCU 30 minutes to update its bylaws on its website annually; for a total of 1,809 burden hours.

The total increase in burden hours due to these proposed program changes is 8,810 and action will be taken to amend OMB control number 3133-0052 to reflect this increase.

Title of Information Collection: Federal Credit Union Bylaws, Appendix A to Part 701.

OMB Control Number: 3133-0052.

Estimated number of respondents: 3,721.

Estimated total annual responses: 1,276,965.

Estimated total annual burden: 445,424.

Affected Public: Private Sector: Not-for-profit institutions.

The Board invites comment on (a) whether the collections of information are necessary for the proper

performance of the agency's function, including whether the information has practical utility; (b) the accuracy of estimates of the burden of the information collections, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information being collected; (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

All comments are a matter of public record. Comments regarding the information collection requirements of this rule should be sent to (1) Dawn Wolfgang, NCUA PRA Clearance Officer, National Credit Union Administration, 1775 Duke Street, Suite 5080, Alexandria, Virginia 22314, or Fax No. 703-519-8572, or Email at PRAComments@ncua.gov and the (2) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for NCUA, New Executive Office Building, Room 10235, Washington, DC 20503, or email at OIRA_Submission@OMB.EOP.gov.

C. Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests. The NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order to adhere to fundamental federalism principles. This rule will not have a 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. This proposed rule will only apply to FCUs. Accordingly, the NCUA has determined this proposed rule does not constitute a policy that has federalism implications for purposes of the executive order.

D. Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this proposed rule will not affect family well-being within the meaning of Section 654 of the Treasury and General Government Appropriations Act, 1999, Public Law 105-277, 112 Stat. 2681 (1998).

List of Subjects in 12 CFR Part 701

Credit, Credit unions, Federal credit union bylaws.

By the National Credit Union Administration Board on October 18, 2018.

Gerard S. Poliquin,

Secretary of the Board.

For the reasons stated above, NCUA proposes to amend 12 CFR part 701, Appendix A as follows:

PART 701—ORGANIZATION AND OPERATION OF FEDERAL CREDIT UNIONS**■ 1.** The authority for part 701 continues to read as follows:

Authority: 12 U.S.C. 1752(5), 1755, 1756, 1757, 1758, 1759, 1761a, 1761b, 1766, 1767, 1782, 1784, 1785, 1786, 1787, 1788, 1789. Section 701.6 is also authorized by 15 U.S.C. 3717. Section 701.31 is also authorized by 15 U.S.C. 1601 *et seq.*; 42 U.S.C. 1981 and 3601–3610. Section 701.35 is also authorized by 42 U.S.C. 4311–4312.

■ 2. Appendix A to Part 701 is revised to read as follows:**Appendix A to Part 701—Federal Credit Union Bylaws****Introduction**

1. *Effective date.* The National Credit Union Administration (NCUA) Board first incorporated the Federal Credit Union (FCU) Bylaws as Appendix A to Part 701 of the NCUA's regulations on November 30, 2007. FCUs may retain previously adopted versions of the FCU Bylaws including the November 30, 2007 version. Unless an FCU has adopted bylaws before [insert effective date of final rule], it must adopt these revised bylaws.

2. *Adoption of all or part of these bylaws.* Although FCUs may retain any previously approved version of the FCU Bylaws, the NCUA Board encourages FCUs to adopt the revised bylaws because it believes they provide greater clarity and flexibility for credit unions and their officials and members. FCUs may also adopt portions of the revised bylaws and retain the remainder of previously approved bylaws, but the NCUA Board cautions FCUs to be extremely careful in making the decision. FCUs must be careful because they run the risk of having inconsistent or conflicting provisions because of the various options the revised bylaws provide, as well as other revisions in the text.

3. *Bylaw amendments.* a. The FCU Bylaws contain provisions allowing FCU boards to select from an option or range of options or to fill in a blank. The “fill-in-the-blank” provisions are changes to the FCU's bylaws. Thus, they require a two-thirds vote of the FCU's board of directors. As long as the board selects from the permissible options, the FCU does not need to submit the change to the NCUA for its approval.

b. FCUs continue to have the flexibility to request bylaw amendments. The NCUA must approve all bylaw amendments except for the provisions noted above. In the past, the

NCUA has published a “Standard Bylaw Amendments” booklet containing a list of “standard” preapproved and optional amendments not included in the FCU Bylaws. That document remains on the NCUA's website for historical purposes. However, FCUs may not adopt amendments from the “Standard Bylaw Amendments” booklet, as the FCU Bylaws include sufficient flexibility to make a separate list of standard bylaw amendments unnecessary. Thus, the NCUA no longer makes a distinction between “standard” and “nonstandard” bylaw amendments. Consequently, the NCUA considers any change to the FCU Bylaws that is not a “fill-in-the-blank” provision or part of a range of options to be a bylaw amendment that requires the NCUA approval.

c. The procedure for approval of a bylaw amendment is as follows:

i. The FCU must submit its request to the Office of Credit Union Resources and Expansion (CURE).

ii. The request must include:

1. The section of the FCU Bylaws to be amended;

2. The reason for, or purpose of, the amendment;

3. An explanation of why the amendment is desirable and what it will accomplish for the federal credit union; and

4. The specific wording of the proposed amendment.

iii. CURE will advise the credit union within 90 days if it approved the proposed amendment after its review and, if necessary, consultation with the NCUA's Office of General Counsel. If CURE denies a proposed amendment, the credit union may appeal that decision to the NCUA Board in accordance with the procedures set out in subpart B to part 746 of this chapter. For purposes of this provision, if CURE does not reach a decision within 90 days, the proposed amendment is considered to be denied.

d. Federal credit unions considering an amendment may find it useful to review the bylaws section of the agency website, which includes the NCUA's Office of General Counsel opinions on proposed bylaw amendments.²³ Opinions issued after April 2006 include the language of the approved amendment.

e. Because each decision by CURE is made on a case-by-case basis that depends on the unique facts and circumstances applicable to each FCU, the credit union must submit a proposed amendment to the NCUA for review under the procedure listed above, even if the NCUA previously approved an identical or similar amendment for another credit union.

4. *The nature of the FCU Bylaws.* a. The Federal Credit Union Act requires the NCUA Board to prepare bylaws for federal credit unions.²⁴ The FCU Bylaws address a broad range of matters concerning a credit union's organization and governance, the relationship of the credit union to its

members, and the procedures and rules a credit union follows.

b. The FCU Bylaws supplement the broad provisions of:

- A federal credit union's charter, which establishes the existence of a federal credit union;

- The Federal Credit Union Act, which establishes the powers of federal credit unions; and

- The NCUA's regulations, which implement the Federal Credit Union Act.

As a legal matter, a federal credit union's bylaws must conform to, and cannot be inconsistent with, any provision of its charter, the Federal Credit Union Act, the NCUA's regulations, or other laws or regulations applicable to the credit union's operations.

c. The NCUA expects federal credit unions and their members will make every effort to resolve bylaw disputes using the credit union's internal member complaint resolution process. If a bylaw dispute cannot be resolved internally, credit union officials or members should contact the regional office with oversight over the credit union for assistance in resolving the dispute.

d. The NCUA has discretion to take administrative actions when a credit union is not in compliance with its bylaws. If a potential violation is identified, the NCUA will carefully consider all of the facts and circumstances in deciding whether to take enforcement action. The NCUA will not generally take action against minor or technical violations, but emphasizes that it retains discretion to enforce the FCU Bylaws in appropriate cases, such as safety and soundness concerns or threats to fundamental, material credit union member rights.

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Bylaws

Federal Credit Union, Charter No. _____
(A corporation chartered under the laws of the United States)

Article I. Name—Purposes

Section 1. *Name.* The name of this credit union is as stated in Section 1 of

²³ <http://www.ncua.gov/Legal/Pages/BylawByYear.aspx>.

²⁴ 12 U.S.C. 1758.

its charter (approved organization certificate).

Section 2. *Purposes.* This credit union is a member owned, democratically operated, not-for-profit organization managed by a volunteer board of directors. Its stated mission is to meet the credit and savings needs of members, especially individuals of modest means. The purpose of this credit union is to promote thrift among its members by affording them an opportunity to accumulate their savings and to create a source of credit for provident or productive purposes. *The credit union may add business as one of its purposes by placing a comma after "provident" and inserting "business."*

Article II. Qualifications for Membership

Section 1. *Field of membership.* The field of membership of this credit union is limited to that stated in Section 5 of its charter.

Section 2. *Membership application procedures.* Persons eligible for membership under Section 5 of the charter must sign a membership application on approved forms. The applicant becomes a member upon approval of the application by a membership officer, after subscription to at least one share, payment of the initial installment, and payment of a uniform entrance fee if required by the board. If the membership officer denies a person's membership application, the credit union must explain the reasons for the denial in writing upon written request.

Section 3. *Maintenance of membership share required.* A member who withdraws all shareholdings or fails to comply with the time requirements for restoring his or her account balance to par value in Article III, Section 3, ceases to be a member. By resolution, the board may require persons readmitted to membership to pay another entrance fee.

Section 4. *Continuation of membership.* Once a member, always a member until the person or organization chooses to withdraw its membership or is expelled under the Act and Article XIV of these bylaws. The credit union may limit services and access to its facilities to a member who is disruptive to credit union operations.

Section 5. *Member in good standing.* A member in good standing retains all their rights and privileges in the credit union. A member in good standing is a member who maintains at least the minimum share set forth in Article III, Section 1 of these bylaws; who is not delinquent on any credit union loan; who has not had any account with this

credit union closed due to abuse or negligent behavior; who has not been belligerent or abusive to any duly elected or appointed official or employee when that official or employee is carrying out their duties as set in the Act, the rules and regulations, the charter, and bylaws of this credit union; and who has not caused a financial loss to this credit union. Subject to Article XIV of these bylaws and any applicable limitation of services policy approved by the board, members not in good standing retain their right to attend, participate, and vote at the annual and special meetings of the members and maintain a share account.

Article III. Shares of Members

Section 1. *Par value.* The par value of each share is \$ _____. Subscriptions to shares are payable at the time of subscription, or in installments of at least \$ ____ per month. *FCUs may establish differing par values for different classes of members or types of accounts (such as students, minors, or non-natural persons), provided this action does not violate any federal, state or local antidiscrimination laws. Below are some options an FCU can choose. The FCU may also establish differing par values for other classes of members not listed below. List all established par values in Section 1.*

_____ Option. *Par value for minors.* The par value of each share for members _____ years of age or younger is \$ _____. Subscriptions to shares are payable at the time of subscription, or in installments of at least \$ ____ per month.

_____ Option. *Par value for students.* The par value of each share for students is \$ _____. Subscriptions to shares are payable at the time of subscription, or in installments of at least \$ ____ per month. A student is defined as anyone enrolled full-time or part-time in _____.

_____ Option. *Par value for non-natural persons.* The par value of each share for non-natural persons is \$ _____. Subscriptions to shares are payable at the time of subscription, or in installments of at least \$ ____ per month.

Section 2. *Establishing membership.* To establish membership, the member must subscribe to one par value of share. The share does not have to be in a regular share account. The board may choose the best account for the characteristics of its membership. Below are some options an FCU can choose. Select one option and check the box corresponding to that option.

_____ Option A—*Regular Share account required to establish membership.* To

establish membership in the credit union, the member must subscribe to one share in a regular share account.

_____ Option B—_____ *account required to establish membership.* To establish membership in the credit union, the member must subscribe to one share in the stated account or accounts (note the account(s) in the blank above).

Section 3. *Cap on shares held by one person.* The board may establish, by resolution, the maximum amount of shares that any one member may hold.

Section 4. *Time periods for payment and maintenance of membership share.* The credit union will terminate from membership a member who:

- Fails to complete payment of one share within _____ of admission to membership, or
- Fails to complete payment of one share within _____ from the increase in the par value of shares, or
- Reduces the share balance below the par value of one share and does not increase the balance to at least the par value of one share within _____ of the reduction.

Section 5. *Transferability.* Members may transfer shares to another member in any form approved by the board. Shares that accrue credits for unpaid dividends retain those credits when transferred.

Section 6. *Withdrawals.* Members may withdraw money paid in on shares provided that:

(a) The board has the right, at any time, to require members, or a subset of members, to give up to 60 days written notice of intention to withdraw all or part of the amounts they paid in.

(b) Reserved.

(c) A member delinquent on any loan or obligation to the credit union may not withdraw their shares below the delinquent amount without the written approval of the credit committee or loan officer. This withdrawal restriction also applies if the member is a comaker, endorser, or guarantor of a delinquent loan. Coverage of overdrafts under an overdraft protection policy does not constitute delinquency for purposes of this paragraph. Shares issued in an irrevocable trust as provided in Section 6 of this article are not subject to withdrawal restrictions except as stated in the trust agreement.

(d) The share account of a deceased member (other than one held in joint tenancy with another member) may be continued until the close of the dividend period in which the administration of the deceased's estate is completed.

(e) The board can impose a fee for excessive share withdrawals from

regular share accounts. By resolution, the board can set the number of withdrawals not subject to a fee and the amount of the fee subject to regulations relevant to the advertising and disclosure of terms and conditions on member accounts.

Section 7. *Trusts*. Shares may be issued in a revocable or irrevocable trust, subject to the following:

(a) Shares issued in a revocable trust—the settlor must be a member of this credit union in his or her own right.

(b) Shares issued in an irrevocable trust—either the settlor or the beneficiary must be a member of this credit union.

(c) Both a revocable and irrevocable trust must state the name of the beneficiary.

A trust may be a member of the credit union as an entity if all parties to the trust, including all settlors, beneficiaries and trustees, are within the credit union's field of membership.

(d) Shares issued through a pension plan authorized by the rules and regulations will be treated as an irrevocable trust unless otherwise indicated in the rules and regulations.

Section 8. *Joint accounts and membership requirements*. Select one option and check the box corresponding to that option.

___ *Option A—Separate account not required to establish membership*

Owners of a joint account may both be members of the credit union without opening separate accounts. For joint membership, both owners are required to fulfill all of the membership requirements including each member purchasing and maintaining at least one share in the account and filling out the membership card.

___ *Option B—Separate account required to establish membership*

Each member must purchase and maintain at least one share in a share account that names the member as the sole or primary owner. Being named as a joint owner of a joint account is not sufficient to establish membership.

Article IV. Meetings of Members

Section 1. *Annual meeting*. The board must hold the annual meeting of the members [insert time for annual meeting, for example, “during the month of March/on the third Saturday of April/no later than March 31”], in the county in which any office of the credit union is located or within a radius of 100 miles of an office, at the time and place as the board determines and announces in the notice of the annual meeting.

Section 2. *Notice of meetings required*. a. The secretary must give

written notice to each member at least 30 but no more than 75 days before the date of any annual meeting. The secretary must give written notice to each member at least 7 days before the date of any special meeting of the members and at least 45 but no more than 90 days before the date of any meeting to vote on a merger with another credit union. The secretary may deliver the notice in person, by mail to the member's address, or, for members who have opted to receive statements and notices electronically, by electronic mail. The secretary must give notice of the annual meeting by posting the notice in a conspicuous place in the office of this credit union where members may read it at least 30 days before the meeting. The secretary must also prominently display the notice on the credit union's website if such credit union maintains a website.

b. All special meeting notices must state the purpose of the meeting. The officials and members may only transact business related to the stated purpose at the meeting.

Section 3. *Special meetings*. a. The board chair, the board of directors by majority vote, or the supervisory committee as provided in these bylaws may call a special meeting of the members. The chair must call and hold a special meeting within 30 days of the receipt of a written request from 25 members or 5% of the members as of the date of the request, whichever number is larger. However, a request of no more than 750 members may be required to call a special meeting.

b. The credit union may hold a special meeting at any location permitted for the annual meeting.

Section 4. *Items of business for annual meeting and rules of order for annual and special meetings*. The suggested order of business at annual meetings of members is—

(a) Ascertain that a quorum is present.

(b) Reading and approval or correction of the minutes of the last meeting.

(c) Report of directors, if there is one. For credit unions participating in the Community Development Revolving Loan Program, the directors must report on the credit union's progress on providing needed community services, if required by NCUA Regulations.

(d) Report of the financial officer or the chief management official.

(e) Report of the credit committee, if there is one.

(f) Report of the supervisory committee, as required by Section 115 of the Act.

(g) Unfinished business.

(h) New business other than elections.

(i) Elections, as required by Section 111 of the Act.

(j) Adjournment.

(k) To the extent consistent with these bylaws, the board will conduct all meetings of the members according to _____. The order of business for the annual meeting may vary from the suggested order, provided it includes all required items and complies with the rules of procedure adopted by the credit union.

The credit union must fill in the blank with one of the following authorities, noting the edition to be used: Democratic Rules of Order, The Modern Rules of Order, Robert's Rules of Order, or Sturgis' Standard Code of Parliamentary Procedure.

Section 5. *Quorum*. Except as otherwise provided, 12 members excluding the board, credit union staff, and officials, constitute a quorum at annual or special meetings. If a quorum is not present, the board may adjourn to a date at least 7 but not more than 14 days thereafter. The members present at any adjourned meeting will constitute a quorum, regardless of the number of members present. The board must give the same notice for the adjourned meeting as prescribed in Section 2 of this article for the original meeting, except that they must give notice at least 5 days before the date of the meeting fixed in the adjournment.

Article V. Elections

The Credit Union must select one of the four voting options. The board may print the credit union's bylaws with the option selected or retain this copy and check the box of the option selected. All options continue with Section 3 of this article.

Option A1—In-Person Elections; Nominating Committee and Nominations From Floor

Section 1. *Nomination procedures*. At least 30 days before each annual meeting, the chair will appoint a nominating committee of three or more members. The nominating committee will nominate at least one member for each vacancy, including any unexpired term vacancy, for which elections are being held, and determine that the members nominated are agreeable to the placing of their names in nomination and will accept office if elected. The nominating committee must widely publicize the call for nominations to all members by any medium and interview each member who volunteers.

Section 2. *Election procedures*. After placing the nominations of the nominating committee before the members, the chair calls for

nominations from the floor. When nominations are closed, the chair appoints election tellers. The election tellers distribute the ballots, collect the ballots and tally the votes, and the chair announces the results. Except when there is only one nominee for each open office, all elections are by ballot and determined by the plurality of vote. If there is only one nominee for each open office, the chair may take a voice vote or declare the election of each nominee by general consent or acclamation.

Option A2—In-Person Elections; Nominating Committee and Nominations by Petition

Section 1. *Nomination procedures.* a. At least 120 days before each annual meeting the chair will appoint a nominating committee of three or more members. The nominating committee will nominate at least one member for each vacancy, including any unexpired term vacancy, for which elections are being held, and determine that the members nominated are agreeable to the placing of their names in nomination and will accept office if elected. The nominating committee must widely publicize the call for nominations to all members by any medium and interview each member who volunteers.

b. At least 90 days before the annual meeting, the nominating committee files its nominations with the secretary of the credit union. At least 75 days before the annual meeting, the secretary notifies, in writing, all members eligible to vote that they may make nominations for vacancies by petition signed by 1% of the members with a minimum of 20 and a maximum of 500. The secretary may use electronic mail to notify members who have opted to receive notices or statements electronically.

c. The written notice must specify that the credit union will not conduct the election by ballot and there will be no nominations from the floor when the number of nominees equals the number of open positions.

d. The notice will include, in a form approved by the board of directors, a brief statement of qualifications and biographical data for each nominee submitted by the nominating committee. Each nominee by petition must submit a similar statement of qualifications and biographical data with the petition.

e. The written notice must state the closing date for receiving nominations by petition. At least 40 days before the annual meeting, nominee(s) must file the nomination petition with the secretary of the credit union. To be effective, nominee(s) must include a signed certificate with the nomination petition stating that they are agreeable to

nomination and will serve if elected to office.

f. At least 35 days before the annual meeting, the secretary will post the nominations by petition along with those of the nominating committee in a conspicuous place in each credit union office and on the credit union's website.

Section 2. *Election procedures.* a. The secretary must place all persons nominated by either the nominating committee or by petition before the members. When nominations are closed, the chair appoints the election tellers. The election tellers distribute the ballots, collect the ballots, and tally the votes, and the chair announces the results. Except when there is only one nominee for each open office, all elections are by ballot and determined by the plurality of vote.

b. There are no nominations from the floor if there are sufficient nominations by the nominating committee or by petition to provide at least one nominee for each open position. If there are nominations from the floor and they result in more nominees than open positions, the chair will close nominations, and appoint election tellers. The election tellers distribute the ballots, collect the ballots and tally the votes, and the chair announces the results. If there is only one nominee for each open office, the chair may take a voice vote or declare the election of each nominee by general consent or acclamation.

Option A3—Election by Ballot Boxes or Voting Machine; Nominating Committee and Nomination by Petition

Section 1. *Nomination procedures.* a. At least 120 days before each annual meeting, the chair will appoint a nominating committee of three or more members. The nominating committee will nominate at least one member for each vacancy, including any unexpired term vacancy, for which elections are being held, and determine that the members nominated are agreeable to the placing of their names in nomination and will accept office if elected. The nominating committee must widely publicize the call for nominations to all members by any medium and interview each member who volunteers.

b. At least 90 days before the annual meeting, the nominating committee files its nominations with the secretary of the credit union. At least 75 days before the annual meeting, the secretary notifies, in writing, all members eligible to vote that they may make nominations for vacancies by petition signed by 1% of the members with a minimum of 20 and a maximum of 500. The secretary may use electronic mail to notify members

who have opted to receive notices or statements electronically.

c. The written notice must specify that the credit union will not conduct the election by ballot and there will be no nominations from the floor when the number of nominees equals the number of open positions.

d. The notice will include, in a form approved by the board of directors, a brief statement of qualifications and biographical data for each nominee submitted by the nominating committee. Each nominee by petition must submit a similar statement of qualifications and biographical data with the petition.

e. The written notice must state the closing date for receiving nominations by petition. At least 40 days before the annual meeting, nominee(s) must file the nomination petition with the secretary of the credit union. To be effective, nominee(s) must include a signed certificate with the nomination petition stating that they are agreeable to nomination and will serve if elected to office.

f. At least 35 days before the annual meeting, the secretary will post the nominations by petition along with those of the nominating committee in a conspicuous place in each credit union office and on the credit union's website.

Section 2. *Election procedures.* The plurality of the vote determines all elections. The election is conducted by ballot boxes or voting machines, subject to the following conditions:

(a) The board of directors will appoint the election tellers;

(b) At least 10 days before the annual meeting, the secretary will direct the preparation and placement of ballot boxes, printed ballots, or voting machines if there are sufficient nominations made by the nominating committee or by petition to provide more nominees than open positions. The secretary will place the boxes or voting machines in conspicuous locations as determined by the board of directors. The secretary will post the names of the candidates near the boxes or voting machines. The posting will include a brief statement of the candidates' qualifications and biographical data in a form approved by the board of directors;

(c) The members have 24 hours to vote at conspicuous locations as the board determines. After 24 hours, election tellers will open the ballot boxes or voting machines, tally the vote, place the tally in the ballot boxes, and reseal the ballot boxes. The election tellers are responsible at all times for the integrity of the vote. The election tellers will keep a record of all persons voting

and must assure themselves that each person voting is entitled to vote; and

(d) The election tellers will take the ballot boxes to the annual meeting and place them in conspicuous locations with the names of the candidates posted near them. At the annual meeting, the election tellers will distribute printed ballots to those in attendance who have not voted. Members will deposit their votes in the ballot boxes placed by the election tellers. After giving the members an opportunity to vote at the annual meeting, the chair will close balloting. The election tellers will open the ballot boxes, tally the vote, and add the vote to the previous count. The chair will then announce the result of the vote.

Option A4—Election by Electronic Device (Including But Not Limited to Telephone and Electronic Mail) or Mail Ballot; Nominating Committee and Nominations by Petition

Section 1. *Nomination procedures.* a. At least 120 days before each annual meeting, the chair will appoint a nominating committee of three or more members. The nominating committee will nominate at least one member for each vacancy, including any unexpired term vacancy, for which elections are being held, and determine that the members nominated are agreeable to the placing of their names in nomination and will accept office if elected. The nominating committee must widely publicize the call for nominations to all members by any medium and interview each member who volunteers.

b. At least 90 days before the annual meeting, the nominating committee files its nominations with the secretary of the credit union. At least 75 days before the annual meeting, the secretary notifies, in writing, all members eligible to vote that they may make nominations for vacancies by petition signed by 1% of the members with a minimum of 20 and a maximum of 500. The secretary may use electronic mail to notify members who have opted to receive notices or statements electronically.

c. The written notice must specify that the credit union will not conduct the election by ballot and there will be no nominations from the floor when the number of nominees equals the number of open positions.

d. The notice will include, in a form approved by the board of directors, a brief statement of qualifications and biographical data for each nominee submitted by the nominating committee. Each nominee by petition must submit a similar statement of qualifications and biographical data with the petition.

e. The written notice must state the closing date for receiving nominations by petition. At least 40 days before the annual meeting, nominee(s) must file the nomination petition with the secretary of the credit union. To be effective, nominee(s) must include a signed certificate with the nomination petition stating that they are agreeable to nomination and will serve if elected to office.

f. At least 35 days before the annual meeting, the secretary will post the nominations by petition along with those of the nominating committee in a conspicuous place in each credit union office and on the credit union's website (if the credit union maintains a website).

Section 2. *Election procedures.* The plurality of vote determines all elections. The election is conducted by electronic device or mail ballot, subject to the following conditions:

(a) The board of directors will appoint the election tellers;

(b) At least 30 days before the annual meeting, the secretary will ensure either a printed ballot or notice of ballot is mailed to all members eligible to vote if there are sufficient nominations made by the nominating committee or by petition to provide more nominees than open positions. The secretary may use electronic mail to provide the notice of ballot to members who have opted to receive notices or statements electronically;

(c) If the credit union conducts its elections electronically, the secretary will ensure the transmission of the following materials to each eligible voter using the following procedures:

(1) One notice of balloting stating the names of the candidates for the board of directors and the candidates for other separately identified offices or committees. The notice must include a brief statement of qualifications and biographical data for each candidate in a form approved by the board of directors. The secretary may use electronic mail to provide the notice of ballot to members who have opted to receive notices or statements electronically.

(2) One mail ballot that conforms to Section 2(d) of this article, as well as instructions for the electronic election procedure, including how to access and use the system and the timeframe for voting. The instructions will state that members without the requisite electronic device necessary to vote on the system may vote by submitting the enclosed mail ballot and specify the date the mail ballot must be received by the credit union. For members who have opted to receive notices or statements electronically, the mail ballot is not

required and the secretary may use electronic mail to provide the instructions for the electronic election procedure.

(3) The election tellers verify, or cause to be verified, the name of the voter and their credit union account number as registered in the electronic balloting system. The election tellers will test the integrity of the balloting system at regular intervals during the election period.

(4) Election tellers must receive ballots no later than midnight, 5 calendar days before the annual meeting.

(5) Election tellers will tally the vote and the chair will make the result of the vote public at the annual meeting.

(6) If the electronic balloting system malfunctions, the board of directors may, in its discretion, hold the election by mail ballot only. The mail ballots must conform to Section 2(d) of this article and the secretary must mail them once more to all eligible members 30 days before the annual meeting. The board may make reasonable adjustments to the voting time frames above, or postpone the annual meeting when necessary, to complete the elections before the annual meeting.

(d) If the credit union conducts its election by mail ballot, the secretary will ensure the mailing of the following materials to each member using the following procedures:

(1) One ballot, clearly identified as the ballot, with the names of the candidates for the board of directors and the candidates for other separately identified offices or committees printed in random order. A brief statement of qualifications and biographical data for each candidate, in a form approved by the board of directors, will accompany the ballot;

(2) One ballot envelope, with instructions to place the completed ballot placed in the envelope and seal the envelope;

(3) One identification form the member completes that includes their name, address, signature and credit union account number;

(4) One mailing envelope that instructs the member to insert the sealed ballot envelope and the identification form. The mailing envelope must have prepaid postage and be preaddressed for return to the election tellers;

(5) When properly designed with features that preserve the secrecy of the ballot, the ballot, identification form, and prepaid postage and preaddressed return envelope may be combined;

(6) The election tellers will verify, or cause to be verified, the name and credit union account number of the voter as

appearing on the identification form. The tellers will retain the verified identification form and the sealed ballot envelope until the vote count is completed. In the event of a questionable or challenged identification form, the tellers must retain the identification form and sealed ballot envelope together until the verification or challenge is resolved;

(7) Election tellers must receive ballots mailed to them no later than midnight 5 days before the date of the annual meeting;

(8) The election tellers will tally the vote. They will verify the result at the annual meeting and the chair will make the result of the vote public at the annual meeting.

All Options Continue Here

Section 3. *Order of nominations.* Nominations may be in the following order:

(a) Nominations for directors.

(b) Nominations for credit committee members, if applicable. Elections may be by separate ballots following the same order as the above nominations or, if preferred, may be by one ballot for all offices.

Section 4. *Proxy and agent voting.* Members cannot vote by proxy. A member other than a natural person may vote through an agent designated in writing for the purpose.

Section 5. *One vote per member.* Respective of the number of shares, no member has more than one vote.

Section 6. *Submission of information regarding credit union officials to NCUA.* The secretary must forward the names and business addresses of board members, board officers, executive committee, credit committee members, if applicable, and supervisory committee members to the Administration in accordance with the Act and regulations in the manner as required by the Administration.

Section 7. *Minimum age requirement.* Members must be at least _____ years of age by the date of the meeting (or for appointed offices, the date of appointment) in order to vote at meetings of the members, hold elective or appointive office, sign nominating petitions, or sign petitions requesting special meetings.

The credit union may select the following option:

Section 7. Members must be at least _____ years of age by the date of the meeting in order to vote at meetings of the members, sign nominating petitions, or sign petitions requesting special meetings. Members must be at least _____ years of age to hold elective or appointive office.

The Credit Union's board should adopt a resolution inserting an age no greater than 18, or the age of majority under the state law applicable to the credit union, in the blank space for voting, or not greater than 21 for holding elective or appointive office.

The Credit Union may select the absentee ballot provision in conjunction with the selected voting procedure. The board may do this by printing the credit union's bylaws with this provision or by retaining this copy and checking the box.

____ Section 8. *Absentee ballots.* The board of directors may authorize the use of absentee ballots in conjunction with the other procedures authorized in this article, subject to the following conditions:

(a) The board of directors will appoint the election tellers;

(b) If there are sufficient nominations made by the nominating committee or by petition to provide more than one nominee for each open position, at least 30 days before the annual meeting, the secretary will ensure a printed ballot is mailed to all members of the credit union who are eligible to vote and who have submitted a written or electronic request for an absentee ballot;

(c) The secretary will ensure the following materials are mailed to each eligible voter who submitted a written or electronic request for an absentee ballot:

(1) One ballot, clearly identified as the ballot, with the names of the candidates for the board of directors and the candidates for other separately identified offices or committees printed in random order. A brief statement of qualifications and biographical data for each candidate, in a form approved by the board of directors, will accompany the ballot;

(2) One ballot envelope clearly marked with instructions to place the completed ballot placed in the envelope and seal the envelope;

(3) One identification form the member completes that includes their name, address, signature and credit union account number;

(4) One mailing envelope that instructs the member to insert the sealed ballot envelope and the identification form. The mailing envelope must have prepaid postage and be preaddressed for return to the election tellers;

(5) When properly designed with features that preserve the secrecy of the ballot, the ballot, identification form, and prepaid postage and preaddressed return envelope may be combined;

(d) The election tellers will verify, or cause to be verified, the name and credit

union account number of the voter as appearing on the identification form. The tellers will retain the verified identification and the sealed ballot envelope until the vote count is completed. In the event of a questionable or challenged identification form, the tellers must retain the identification form and the sealed ballot envelope together until the verification or challenge is resolved. If more than one voting procedure is used, the tellers must verify that no eligible voter voted more than one time;

(e) Election tellers must receive ballots mailed to them no later than midnight 5 days before the date of the annual meeting;

(f) Members or authorized personnel will deposit absentee ballots in the ballot boxes taken to the annual meeting or included in a precourt in accordance with procedures specified in Article V, Section 2; and

(g) If a member has chosen to receive statements and notices electronically, the credit union may provide notices required in this section by email and provide instructions for voting via electronic means instead of mail ballots.

Article VI. Board of Directors

Section 1. *Number of members.* The board consists of _____ directors, all of whom must be members. By resolution, the board may change the number of directors to an odd number not fewer than 5 or more than 15. The board may not reduce the number of directors unless there is a corresponding vacancy as a result of a death, resignation, expiration of a term of office, or other action provided by these bylaws. The board must file a copy of the resolution covering any increase or decrease in the number of directors with the official copy of the bylaws.

Section 2. *Composition of board and committees.* a. ____ (Fill in the number, which may be zero) director(s) may be a paid employee of the credit union. The board may appoint a management official who _____ (may or may not) be a member of the board and one or more assistant management officials who _____ (may or may not) be a member of the board. If the board permits the management official or assistant management official(s) to serve on the board, he or she may not serve as the chair.

b. ____ (Fill in the number, which may be zero) immediate family members, or those persons living in the same household, of a director may be a paid employee of the credit union.

c. The total number of directors serving who fall into each of the

categories below must not constitute a majority of the board:

- Management official plus assistant management official(s) plus other employees;
- Immediate family members or persons in the same household as the management official, assistant management official(s), and other employees; or
- Management official plus assistant management official(s) plus other employees, plus immediate family members or persons in the same household as management officials, assistant management officials and other employees.

d. ____ (Fill in the number, which may be zero) committee member(s) may be a paid employee of the credit union.

____ (Fill in the number, which may be zero) immediate family members, or those persons living in the same household, of a committee member(s) may be a paid employee of the credit union.

The board may also choose the option below:

____ No director or committee member, who is not then a paid employee of the credit union, may become a paid employee of this credit union for a minimum of ____ (Fill in the number, which may be zero) years from the date the official terminates his or her position as a director or committee member.

You can also add “unless the employee position to be filled exists as a result of a death or disability” after committee member.

For this section, you can correct the syntax by omitting the plural(s) if applicable.

Section 3. *Terms of office.* Terms for directors are for periods of 2 or 3 years as decided by the board. All terms must be for the same number of years and until the election and qualification of successors. Terms are set and staggered at the first meeting, or when the number of directors changes, so that approximately an equal number of terms expire at each annual meeting.

Section 4. *Vacancies.* The directors, by majority vote, will fill any vacancy on the board, credit committee, if applicable, or supervisory committee as soon as possible. If all director positions become vacant at once, the supervisory committee immediately becomes the temporary board of directors and must follow the procedures in Article IX, Section 3. Directors and credit committee members appointed to fill a vacancy hold office only until the next annual meeting. The FCU’s members then vote to select a candidate to fill the

remainder of the original director’s unexpired term. Members of the supervisory committee appointed to fill a vacancy on the supervisory committee hold office through the remainder of the unexpired term.

Section 5. *Regular and special meetings.* The board must hold a regular meeting each month at the time and place fixed by resolution. The board must conduct one regular meeting each calendar year in person. If a quorum of the board is present at the in person meeting, the remaining board members may participate by audio or video teleconference. The board may conduct the other regular meetings by audio or video teleconference. The chair, or in the chair’s absence the ranking vice chair, may call a special meeting of the board at any time and must do so upon written request of a majority of the directors. The chair, or in the chair’s absence the ranking vice chair, will fix the time and place of special meetings unless the board directs otherwise. The board will give notice of all meetings in the manner set by resolution. The board may conduct special meetings by audio or video teleconference. The board may take action and vote on resolutions without a meeting. The board must first obtain unanimous consent for the action in writing or by electronically recorded means.

Section 6. *Board responsibilities.* The board has the general direction and control of the affairs of this credit union. The board is responsible for performing all the duties customarily done by boards of directors. This includes but is not limited to:

(a) Directing the affairs of the credit union in accordance with the Act, these bylaws, the rules and regulations and sound business practices.

(b) Establishing programs to achieve the purposes of this credit union as stated in Article I, Section 2, of these bylaws.

(c) Establishing lending policies, a loan collection program, and authorizing the charge-off of uncollectible loans.

(d) Establishing policies to address training for directors and volunteer officials in areas such as ethics and fiduciary responsibility, regulatory compliance, and accounting.

(e) Ensuring that staff and volunteers who handle the receipt, payment or custody of money or other property of this credit union; or property in its custody as collateral or otherwise, are properly bonded in accordance with the Act and regulations.

(f) Performing additional acts and exercising additional powers as required

or authorized by applicable law and regulation.

If the credit union has an elected credit committee, you do not need to check a box. If the credit union has no credit committee check Option 1, and if it has an appointed credit committee check Option 2.

____ *Option 1. No Credit Committee.*

(g) Reviewing denied loan applications of members who file written requests for review.

(h) Appointing one or more loan officers and delegating to those officers the power to approve or disapprove loans, lines of credit or advances from lines of credit.

(i) In its discretion, appointing a loan review (the credit union may fill in another name if desired) committee to review loan denials and delegating to the committee the power to overturn denials of loan applications. The committee will function as a mid-level appeal committee for the board. The board must review all loans denied by the committee upon written request of the member.

The credit union may select one of three options for the makeup and term of the committee. Enter the option selected _____.

____ *Option A.* The committee must consist of three members with a term of office of ____ (enter no more than 3) years. The committee may not have more than one loan officer.

____ *Option B.* The committee must consist of three members and two alternates. The term of office of the committee members will be for ____ (enter no more than 3) years. The board may appoint any number of lending professionals within the organization to the committee, provided that no loan officer may review any loan that he or she denied. At least 3 members of the committee must review loan denials, none of whom have been a party to denying the loan.

____ *Option C.* The board may, by resolution, change the number of committee members to an odd number no less than three and no more than seven. The board will determine the length of each committee member’s term upon appointment and stagger terms as necessary to prevent a complete turnover of committee members. The board must file a copy of the resolution covering any increase or decrease in the number of committee members with the official copy of the bylaws of this credit union. The committee will act by majority vote of members present at a meeting. The committee may not have more than one loan officer.

____ *Option 2. Appointed Credit Committee.*

(g) Appointing an odd number of credit committee members as provided in Article VIII of these bylaws.

Section 7. *Quorum.* A majority of directors, including any vacant positions, constitutes a quorum for the transaction of business at any meeting. A majority of the directors holding office constitutes a quorum to fill any vacancies as stated in Section 4 of this article. Less than a quorum may adjourn from time to time until a quorum is in attendance.

Section 8. *Attendance and removal.* a. If a director or a credit committee member, if applicable, fails to attend regular meetings of the board or credit committee, respectively, for 3 consecutive months, (choose one of the following) _____ or 4 meetings within a calendar year, or _____ 4 meetings within any 12 consecutive meetings or otherwise fails to perform any significant duties as a director or a credit committee member, the board may declare the office vacant and fill the vacancy as provided in the bylaws.

b. The board may remove any board officer from office for failure to perform any significant duties as an officer. Prior to removal, the board must give the officer reasonable notice and an opportunity to respond to the issues.

c. When any board officer, membership officer, executive committee member or investment committee member is absent, disqualified, or otherwise unable to perform the duties of the office, the board may by resolution designate another member of this credit union to fill the position temporarily. The board may also, by resolution, designate another member or members of this credit union to act on the credit committee when necessary in order to obtain a quorum.

Section 9. *Suspension of supervisory committee members.* The board may suspend any member of the supervisory committee by a majority vote. In the event of a suspension, the board must hold a special meeting of the members at least 7 but no more than 14 days after any suspension. The members will decide whether to remove or to restore the suspended committee member of the supervisory committee.

The credit union may add the optional Section 10 if desired.

Section 10. *Director Emeritus.* The board of directors may appoint any former director who served on the board at least _____ (fill in the number) years as "Director Emeritus." The board may substitute suitable volunteer service

time for some of the board service time provided the candidate has served at least _____ (fill in the number) years on the board. The individuals appointed directors emeritus function as an advisory committee to the board of directors. Terms for directors emeritus are _____ (fill in the number) years. The board may increase or decrease the number of directors emeritus, or shorten or extend any director emeritus's term, by resolution. Unless separately elected or appointed, directors emeritus are not members of any other committee of the credit union. Directors emeritus are not a member or officer of the board of directors; they may not vote on any matter before the board or any other committee of the credit union; they may not receive any compensation from the credit union; and they are not required to attend any meetings or authorized to perform any duties other than providing advice to the credit union's board, staff and other committees as needed.

Article VII. Board Officers, Management Officials and Executive Committee

Section 1. *Board officers.* The board elects the following officers from their number: A chair, one or more vice chairs, a financial officer, and a secretary. The board determines the title and rank of each board officer and records them in the addendum to this article. The board may compensate one board officer, the _____, for services as they determine. If the board elects more than one vice chair, the board determines their rank as first vice chair, second vice chair, and so on. The same person may hold the offices of the financial officer and secretary. If the board permits a management official or assistant management official to serve on the board, he or she may not serve as the chair. Unless removed as provided in these bylaws, the board officers elected at the first meeting of the board hold office until the first annual meeting of the board following the first annual meeting of the members and until the election and qualification of their respective successors.

Section 2. *Election and term of office.* The board must hold a meeting not later than 7 days after the annual meeting to elect officers. Board officers hold office for a 1-year term and until the election and qualification of their respective successors. Any person elected to fill a vacancy caused by the death, resignation, or removal of an officer is elected by the board to serve only for the unexpired term of that officer and until a successor is duly elected and qualified.

Section 3. *Duties of Chair.* The chair presides at all meetings of the members and at all meetings of the board, unless disqualified through suspension by the supervisory committee. The chair also performs other duties customarily assigned to the office of the chair or duties directed to perform by resolution of the board that are not inconsistent with the Act, regulations, and these bylaws.

Section 4. *Approval required.* The board must approve all individuals authorized to sign all notes, checks, drafts, and other orders for disbursement of credit union funds.

Section 5. *Vice chair.* The ranking vice chair has and may exercise all the powers, authority, and duties of the chair during the chair's absence or inability to act.

Section 6. *Duties of financial officer.* i. The financial officer manages this credit union under the control and direction of the board unless the board has appointed a management official to act as general manager. Subject to limitations, controls and delegations the board may impose, the financial officer will:

(a) Have charge over all funds, securities, valuable papers and other assets of this credit union.

(b) Provide and maintain full and complete records of all the assets and liabilities of this credit union in accordance with prescribed law, regulation, and Administration guidance.

(c) Within 20 days after the close of each month, prepare and submit to the board a financial statement showing the condition of this credit union as of the end of the month, including a summary of delinquent loans; and post a copy of the statement in a conspicuous place in the office of the credit union where it will remain until replaced by the next month's financial statement.

(d) Ensure that financial and other reports the Administration may require are prepared and sent.

(e) Within standards and limitations set by the board, employ sufficient staff to run the credit union, and have the power to remove these employees.

(f) Perform other duties customarily assigned to the office of the financial officer or duties assigned by board resolution that are not inconsistent with the Act, regulations, and these bylaws.

ii. The board may employ one or more assistant financial officers, none of whom may also hold office as chair or vice chair. The board may authorize them, under the direction of the financial officer, to perform any of the duties falling to the financial officer, including the signing of checks. When

designated by the board, any assistant financial officer may also act as financial officer during the financial officer's temporary absence or temporary inability to act.

Section 7. *Duties of management official and assistant management official.* The board may appoint a management official who is under the direction and control of the board or of the financial officer as determined by the board. The board may assign any or all of the responsibilities of the financial officer described in Section 6 of this article. The board will determine the title and rank of each management official and record them in the addendum to this article. The board may employ one or more assistant management officials. The board may authorize assistant management officials under the direction of the management official, to perform any of the duties falling to the management official, including the signing of checks. When designated by the board, any assistant management official may also act as management official during the management official's temporary absence or temporary inability to act.

Section 8. *Board powers regarding employees.* The board employs, fixes the compensation, and prescribes the duties of employees as necessary, and has the power to remove employees, unless it has delegated these powers to the financial officer or management official. Management does not have the power or duty to employ, prescribe the duties of, or remove necessary clerical and auditing assistance employed or used by the supervisory committee or remove any loan officer appointed by the credit committee.

The credit union may select one of the following options and add it to the end of Section 8:

Option A. No director or committee member, who is not then a paid employee of the credit union, may become a paid employee of this credit union for a minimum of _____ (Fill in the number, which may be zero) years

from the date the official terminates his or her position as a director or committee member.

Option B. No director, committee member, immediate family member of a director or committee member, or person in the same household as a director or committee member, who is not then a paid employee of this credit union, may become a paid employee of the credit union for a minimum of _____ (Fill in the number, which may be zero) years from the date the official terminates his or her position as a director or committee member.

Option C. No director, committee member, immediate family member of a director or committee member, or person in the same household as a director or committee member, who is not then a paid employee of the credit union, may become a paid employee of this credit union for a minimum of _____ (Fill in the number, which may be zero) years from the date the official terminates his or her position as a director or committee member, unless the employee position to be filled exists as a result of a death or disability.

Option D. No official, who is not already a paid employee of this credit union, may become a paid employee of this credit union for a minimum of _____ (Fill in the number, which may be zero) years from the date the official terminates his or her position as a director or committee member, unless the employee position to be filled exists as a result of death or disability. The term "official" in this bylaw means a person who is a member of the board of directors, supervisory committee, or other volunteer committee established by the board of directors.

Section 9. *Duties of secretary.* The secretary prepares and maintains full and correct records of all meetings of the members and of the board. The secretary will prepare a record of each respective meeting within 7 days after its completion. The secretary must promptly inform the Administration in writing of any change in the address of

the office of this credit union or the location of its principal records. The secretary provides the proper notice of all meetings of the members in the manner prescribed in these bylaws. The secretary also performs other duties as directed by resolution of the board that are not inconsistent with the Act, regulation, and these bylaws. The board may employ one or more assistant secretaries, none of whom may also hold office as chair, vice chair, or financial officer, and may authorize them under direction of the secretary to perform any of the duties assigned to the secretary.

Section 10. *Executive committee.* As authorized by the Act, the board may appoint an executive committee of not fewer than three directors to serve at its pleasure, to act for it with respect to the board's specifically delegated functions. When making delegations to the executive committee, the board must be specific with regard to the committee's authority and limitations related to the particular delegation. The board may also authorize any of the following to act upon membership applications under conditions the board and these bylaws may prescribe: An executive committee; a membership officer(s) appointed by the board from the membership, other than a board member paid as an officer; the financial officer; any assistant to the paid officer of the board or to the financial officer; or any loan officer. The board may not compensate the executive committee member or membership officer as such.

Section 11. *Investment committee.* The board may appoint an investment committee composed of not less than two, to serve at its pleasure to have charge of making investments under rules and procedures established by the board. The board may not compensate any member of the investment committee as such.

Addendum: The board must list the positions of the board officers and management officials of this credit union. They are as follows:

Position	Credit union title	Officer or Official name
Board Chair. Vice Chair. Treasurer. Secretary. Management Official. Other 1. Other 2. Other 3. Other 4.		

Select Option 1 if the credit union has a credit committee and Option 2 if it does not have a credit committee.

Article VIII. Option 1 Credit Committee

Section 1. *Credit committee members.* The credit committee consists of _____ members. All the members of the credit committee must be members of this credit union. The board determines the number of members on the credit committee, which must be an odd number and may be fewer than 3 and no more than 7. The board may not reduce the number of members unless there is a corresponding vacancy as a result of a death, resignation, expiration of a term of office, or other action provided by these bylaws. The board must file a copy of the resolution covering any increase or decrease in the number of committee members with the official copy of the bylaws of this credit union.

Section 2. *Terms of office.* Regular terms of office for elected credit committee members are for periods of either 2 or 3 years as the board determines. All regular terms are for the same number of years and until the election and qualification of successors. The board will fix the regular terms at the beginning or upon any increase or decrease in the number of committee members so that approximately an equal number of regular terms expire at each annual meeting. The board determines the periods for the regular terms of office for appointed credit committee members and records these periods in the board's minutes.

Section 3. *Officers of credit committee.* The credit committee chooses from their number a chair and a secretary. The secretary of the committee prepares and maintains full and correct records of all actions taken by it. They must prepare those records within 3 days after the action. The same person may hold the offices of the chair and secretary.

Section 4. *Credit committee powers.* The credit committee may, by majority vote of its members, appoint one or more loan officers to serve at its pleasure. The committee may delegate to them the power to approve loan applications, share withdrawals, releases and substitutions of security, within limits specified by the committee and within limits of applicable law and regulations. The committee may not appoint more than one of its members as a loan officer. Each loan officer must furnish to the committee a record of each approved or not approved transaction within 7 days of the date of the filing of the application or request. This record becomes a part of the

committee's records. The committee must act on all applications or requests not approved by a loan officer. No individual may disburse funds of this credit union for any application or share withdrawal that the individual has approved as a loan officer.

Section 5. *Credit committee meetings.* The credit committee must hold at least one meeting a month and as frequently as required to complete the business of this credit union. The committee will give notice of meetings to its members in the manner it prescribes by resolution.

Section 6. *Credit committee duties.* For each loan, the credit committee or loan officer must review the character and financial condition of the applicant and their surety, if any. The credit committee or loan officer will ascertain the applicant's ability to fully and promptly repay the loan. The credit union may use an automated loan processing system to conduct this review, subject to the conditions set forth in Section 7, below. Where appropriate, the credit committee or loan officers should provide, or refer applicants to, financial counseling assistance.

Section 7. *Unapproved loans prohibited.* The credit committee must approve all loans. If the credit union uses an automated lending system, the credit committee must review all loan applications the system has denied and review at least a sample of approved loans to screen for fraud and ensure the automated system is functioning within the lending policies the board has established.

Section 8. *Lending procedures.* The credit committee, loan officer, or automated system determines the required security, if any, and the terms of repayment for each application. All lending decisions and loan terms must comply with applicable law and regulations, these bylaws, and board policy. The security furnished must be adequate in quality and character as well as consistent with sound lending practices. When the credit union does not have the funds available to make all the loans requested, the credit committee should give preference, in all cases, to the smaller applications if the need and credit factors are nearly equal.

Article VIII. Option 2 Loan Officers (No Credit Committee)

Section 1. *Records of loan officer; prohibition on loan officer disbursing funds.* Each loan officer must maintain a record of each approved or not approved transaction within 7 days of the filing of the application or request. This record then becomes a part of the

records of the credit union. No individual may disburse funds of this credit union for any application or share withdrawal that the individual has approved as a loan officer.

Section 2. *Loan officer duties.* For each loan, the loan officer must review the character and financial condition of the applicant and their surety, if any. The loan officer will ascertain the applicant's ability to fully and promptly repay the loan. The credit union may use an automated loan processing system to conduct this review, subject to the conditions set forth in Section 3, below. Where appropriate, the loan officer should provide, or refer applicants to, financial counseling assistance.

Section 3. *Unapproved loans prohibited.* The loan officer must approve all loans. Loan terms and rates must comply with applicable law and regulations. If the credit union uses an automated lending system, the loan officer must review all loan applications the system has denied, and review at least a sample of approved loans to screen for fraud and ensure the automated system is functioning within the lending policies the board has established.

Section 4. *Lending procedures.* The loan officer or automated lending system determine the required security, if any, and the terms of repayment for each application. All lending decisions and loan terms must comply with applicable law and regulation, these bylaws, and board policy. The security furnished must be adequate in quality and character as well as consistent with sound lending practices. When the credit union does not have the funds available to make all the loans requested, the loan officer should give preference, in all cases, to the smaller applications if the need and credit factors are nearly equal.

Article IX. Supervisory Committee

Section 1. *Appointment and membership.* The board appoints the supervisory committee from members of this credit union. One of the committee members may be a director other than the financial officer or the paid officer of the board. The board determines the number of members on the committee, which may not be fewer than 3 or more than 5. No member of the credit committee, if applicable, or employee of this credit union may be appointed to the committee. Terms of committee members are for periods of 1, 2, or 3 years as decided by the board. However, all terms are for the same number of years and until the appointment and qualification of successors. Terms are

set and staggered at the beginning, or on the increase or decrease in the number of committee members so that approximately an equal number of terms expire at each annual meeting.

Section 2. *Officers of supervisory committee.* The supervisory committee members choose from their number a chair and a secretary. The secretary prepares, maintains, and has custody of all records of the committee's actions. The same person may hold the offices of chair and secretary.

Section 3. *Duties of supervisory committee.*

a. The supervisory committee makes, or arranges for, the audits, and prepares and submits the written reports required by the Act and regulations. The committee may employ and use the clerical and auditing assistance required to carry out its responsibilities. The committee may request the board to provide compensation for this assistance. It will prepare and forward to the Administration required reports.

b. If all director positions become vacant at once, the supervisory committee immediately assumes the role of the board of directors. The supervisory committee acting as the board must generally call and hold a special meeting to elect a board. That board will serve until the next annual meeting. They must hold the special meeting at least 7 but no more than 14 days after all director positions became vacant. Nominations for the board at the special meeting are by petition or from the floor. However, the supervisory committee may forego the special meeting if the next annual meeting will occur within 45 days after all the director positions become vacant.

c. The supervisory committee acting as the board may not act on policy matters. However, directors elected at a special meeting have the same powers as directors elected at the annual meeting.

Section 4. *Verification of accounts.* The supervisory committee will cause the verification of the accounts of members with the records of the financial officer from time to time and not less frequently than as required by the Act and regulations. The committee must maintain a record of this verification.

Section 5. *Powers of supervisory committee—removal of directors and credit committee members.* By unanimous vote, the supervisory committee may suspend any director, board officer, or member of the credit committee. In the event of a suspension, the supervisory committee must call a special meeting of the members to act on the suspension. They must hold the

meeting at least 7 but no more than 14 days after the suspension. The chair of the committee acts as chair of the meeting unless the members select another person to act as chair.

Section 6. *Powers of supervisory committee—special meetings.* By majority vote, the supervisory committee may call a special meeting of the members to: Consider any violation of the provisions of the Act, the regulations, the credit union's charter or bylaws; or to consider any practice of this credit union the committee deems to be unsafe or unauthorized.

Article X. Organization Meeting

Section 1. *Initial meeting.* When making an application for a federal credit union charter, the subscribers to the organization certificate must meet to elect a board of directors and a credit committee, if applicable. The Agency may revoke the charter for failure to start operations within 60 days after receipt of the approved organization certificate unless the Agency approves an extension of time.

Section 2. *Election of directors and credit committee.* The subscribers elect a chair and a secretary for the meeting. The subscribers then elect a board of directors and a credit committee, if applicable. The elected directors or committee members will hold office until the first annual meeting of the members and until the election of their respective successors. Every person elected under this section or appointed under Section 3 of this article, must become a member within 30 days if they are not already. If any person elected as a director or committee member or appointed as a supervisory committee member does not become a member within 30 days of election or appointment, the office will automatically become vacant and be filled by the board.

Section 3. *Election of board officers.* Promptly after the elections held under the provisions of Section 2 of this article, the board must meet to elect the board officers. The officers will hold office until the first meeting of the board of directors after the first annual meeting of the members and until the election of their respective successors. The board also appoints a supervisory committee at this meeting as provided in Article IX, Section 1, of these bylaws and a credit committee, if applicable. The appointed members hold office until the first regular meeting of the board after the first annual meeting of the members and until the appointment of their respective successors.

After five years of operation, the credit union may select the following:

Article X of the bylaws shall be amended to read as follows:

Reserved

Article XI. Loans and Lines of Credit to Members

Section 1. *Loan purposes.* The credit union may make loans to members for provident or productive purposes in accordance with applicable law and regulations.

The credit union may add business as one of its purposes by placing a comma after "provident" and inserting "business."

Section 2. *Delinquency.* Any member whose loan is delinquent may be required to pay a late charge as determined by the board of directors.

Article XII. Dividends

Section 1. *Power of board to declare dividends.* The board sets dividend periods and declares dividends as permitted by the Act and applicable law and regulation.

Article XIII. Reserved

Article XIV. Expulsion and Withdrawal

Section 1. *Expulsion procedure; expulsion or withdrawal does not affect members' liability or shares.* To expel a member, the credit union must:

- Call a special meeting of the members;
- Provide the member the opportunity to be heard; and
- Obtain a two-thirds vote of the members present at the special meeting.

The credit union may also expel a member under a nonparticipation policy given to each member that follows the requirements found in the Act. Expulsion or withdrawal does not relieve a member of any liability to this credit union. The credit union will pay all of their shares upon their expulsion or withdrawal less any amounts due to this credit union.

Article XV. Minors

Section 1. *Minors permitted to own shares.* The credit union may issue shares in the name of a minor. State law governs the rights of minors to transact business with this credit union.

Article XVI. General

Section 1. *Compliance with law and regulation.* The members, directors, officers, and employees of this credit union must exercise all power, authority, duties, and functions according to the provisions of these bylaws in strict conformity with the provisions of applicable law and regulations, and the credit union's charter and bylaws.

Section 2. *Confidentiality.* The officers, directors, members of committees and employees of this credit union must keep all member transactions and all information respecting their personal affairs in confidence, unless otherwise directed by state or federal law.

Section 3. *Removal of directors and committee members.* Notwithstanding any other provisions in these bylaws, any director or committee member of this credit union may be removed from office by the affirmative vote of a majority of the members present at a special meeting called for the purpose, but only after an opportunity has been given to be heard. If member votes at a special meeting result in the removal of all directors, the supervisory committee immediately becomes the temporary board of directors and must follow the procedures in Article IX, Section 3.

Section 4. *Conflicts of interest prohibited.* a. No director, committee member, officer, agent, or employee of this credit union may participate in any manner, directly or indirectly, in the consideration or determination of any question affecting his or her pecuniary or personal interest or the pecuniary interest of any corporation, partnership, or association (other than this credit union) in which he or she is directly or indirectly interested.

b. If the board receives a matter affecting any director's interest, the director must withdraw from the consideration or determination of that matter. If the remaining qualified directors present at the meeting plus the disqualified director or directors constitute a quorum, the remaining qualified directors, by majority vote, may exercise with respect to this matter all the powers of the board. In the event of the disqualification of any member of the credit committee, if applicable, or the supervisory committee, that committee member must withdraw from the deliberation or determination.

Section 5. *Records.* The board must preserve copies of the organization certificate of this credit union, its bylaws, any amendments to the bylaws, and any special authorizations by the Administration. The board must attach copies of the organization certificate and field of membership amendments as an appendix to these bylaws. The board must record all returns of nominations, elections, and proceedings of all regular and special meetings of the members and directors in the minutes of this credit union. The respective chair or presiding officer and the person serving as secretary of the meeting must sign all minutes of the meetings of the members, the board, and the committees. All

copies and records maintained under this section may be stored physically or electronically provided that the information is readily accessible to the directors, committee members of this credit union, members, and the Administration. Moreover, signatures may be provided electronically where permissible under federal or state law.

Section 6. *Availability of credit union records.* All books of account and other records of this credit union must be available upon request at all times to the directors, committee members of this credit union, and members provided they have a proper purpose for obtaining the records. If this credit union maintains a website currently or in the future, the board must post the bylaws of this credit union on the website. The board must also make the charter and bylaws of this credit union available for inspection by any member, upon request. If the member requests a copy of the charter or bylaws, the board will provide a copy to the member. The board may provide this copy to the member in physical or electronic copy. If the member requests a physical copy, the board may charge a reasonable fee for the physical copy.

Section 7. *Member contact information.* Members must keep the credit union informed of their current mailing address or, if the member has elected to receive electronic communications, their current email address.

Section 8. *Indemnification.* (a) Subject to the limitations in § 701.33(c)(5) through (c)(7) of the regulations, the credit union may elect to indemnify to the extent authorized by (check one):

- Law of the State of ___:
- Model Business Corporation Act:

The following individuals from any liability asserted against them and expenses reasonably incurred by them in connection with judicial or administrative proceedings to which they are or may become parties by reason of the performance of their official duties (check as appropriate).

- Current officials.
- Former officials.
- Current employees.
- Former employees.

(b) The credit union may purchase and maintain insurance on behalf of the individuals indicated in (a) above against any liability asserted against them and expenses reasonably incurred by them in their official capacities and arising out of the performance of their official duties to the extent such insurance is permitted by the applicable State law or the Model Business Corporation Act.

(c) The term "official" in this bylaw means a person who is a member of the board of directors, credit committee, supervisory committee, other volunteer committee (including elected or appointed loan officers or membership officers), established by the board of directors.

Section 9. *Pronouns, Singular and Plural.* Unless the context requires otherwise, words denoting the singular may be construed as denoting the plural, words of the plural may be construed as denoting the singular, and words of one gender may be construed as denoting such other gender as is appropriate.

Article XVII. Amendments of Bylaws and Charter

Section 1. *Amendment procedures.* The board may adopt amendments of these bylaws by an affirmative two-thirds vote of the directors. Written NCUA approval is required for the amendment of the bylaws to become effective. After adopting amendments, the credit union will update the bylaws posted on its website (if such credit union maintains a website) and ensure that members seeking to inspect the bylaws receive the most current version of the bylaws. To adopt amendments to the credit union's charter, members must vote at a duly held meeting after receiving prior written notice of the meeting and a copy of the proposed amendment or amendments with the notice. Written NCUA approval is required for the amendment to the charter to become effective.

Article XVIII. Definitions

Section 1. *General definitions.* When used in these bylaws the terms:

"Act" means the Federal Credit Union Act, as amended.

"Administration" means the National Credit Union Administration.

"Agency" means the Regional Director, the Director of the Office of National Examinations and Supervision, or the Director of the Office of Credit Union Resources and Expansion.

"Applicable law and regulations" means the Federal Credit Union Act and rules and regulations issued thereunder or other applicable federal and state statutes and rules and regulations issued thereunder as the context indicates.

"Board" means board of directors of the federal credit union.

"Board officers" means:

1. "Chair" means Presiding Board officer, President of the Board, Presiding Board Officer, or Chairperson.
2. "Vice Chair" means Vice President.
3. "Financial Officer" means Treasurer.

4. “Secretary” means Recording Officer.

5. “Management Official” means General Manager, Manager, President, or Chief Executive Officer.

“Charter” means the approved organization certificate and field of membership issued by the National Credit Union Administration or one of its predecessors. It is the document that authorizes a group to operate as a credit union, defines the fundamental limits of its operating authority, and includes the persons the credit union is permitted to accept for membership.

“Field of membership” means the persons (including organizations and other legal entities) a credit union is permitted to accept for membership.

“Immediate family member” means spouse, child, sibling, parent, grandparent, grandchild, stepparents, stepchildren, stepsiblings, and adoptive relationships.

“Loans” means any type of loan product the credit union offers. This includes, but is not limited to, consumer loans, lines of credit, credit cards, member business loans, commercial loans, and real estate loans.

“Management” means the Board, Financial Officer, and Management Official.

“Member” means a person must:

1. Be eligible for membership under Section 5 of the charter;
2. Sign membership forms as approved by the credit union board;
3. Subscribe to at least one share (par value) of stock;
4. Pay the initial installment;
5. Pay an entrance fee, if required; and
6. Be eligible to vote upon reaching the minimum age the credit union establishes for voting and participation in the affairs of the credit union.

“Membership Officer” means a majority of the board of directors, a majority of the members of a duly authorized executive committee, or an individual(s) appointed by the board of directors to serve as such.

“NCUA Board” means the Board of the National Credit Union Administration.

“Person in the same household” means an individual living in the same residence maintaining a single economic unit.

“Regulation” or “regulations” means rules and regulations issued by the NCUA Board.

“Share” or “shares” means all classes of shares and share certificates that may be held in accordance with applicable law and regulations.

Official NCUA Commentary—Federal Credit Union Bylaws

Article II. Qualifications for Membership

i. Entrance fee: FCUs may not vary the entrance fee among different classes of members (such as students, minors, or non-natural persons) because the Act requires a uniform fee. FCUs may, however, eliminate the entrance fee for all applicants.

ii. Membership application procedures: Under section 113 of the Act,²⁵ the board acts upon applications for membership. However, the board can appoint membership officers from among the members of the credit union. Such membership officers cannot be a paid officer of the board, the financial board officer, any assistant to the paid officer of the board or to the financial officer, or any loan officer. As described under section 2 of this Article, an applicant becomes a member upon approval by a membership officer and payment of at least one share (or installment or uniform entrance fee).

iii. Violent, belligerent, disruptive, or abusive members: a. Many credit unions have confronted the issue of handling a violent, belligerent, disruptive, or abusive individual. Doing so is not a simple matter, insofar as it requires the credit union to balance the need to preserve the safety of individual staff, other members, and the integrity of the workplace, on one hand, with the rights of the affected member on the other. In accordance with the Act and applicable interpretations by the NCUA’s Office of General Counsel, there is a reasonably wide range within which FCUs may fashion a policy that works in their case. Thus, an individual that has become violent, belligerent, disruptive, or abusive may be prohibited from entering the premises or making telephone contact with the credit union, and the individual may be severely restricted in terms of eligibility for products or services. So long as the individual is not barred from exercising the right to vote at annual meetings and is allowed to maintain a regular share account, the FCU may fashion and implement a policy that is reasonably designed to preserve the safety of its employees and the integrity of the workplace.²⁶ The policy need not be identical nor applied uniformly in all cases—there is room for flexibility and a customized approach to fit the particular circumstances. In fact, the NCUA anticipates that some circumstances, such as violence against another member or credit union staff in

the FCU or its surrounding property, an FCU may take immediate action to restrict most, if not all, services to the violent member. In other situations, such as a member that frequently writes checks with insufficient funds, the FCU may attempt to resolve the matter with the member before limiting check writing services. Once adopted, the FCU must disclose the policy to new members when they join, and, as required by the Act,²⁷ notify existing members of the policy at least 30 days before it becomes effective. The FCU’s board has the option to adopt the optional amendment addressing members in good standing.

b. FCUs should also make specific note of Article XIV, § 1 of the bylaws, which spells out in detail the procedure required to expel an individual from membership. This procedure is mandated by the Act.²⁸ Furthermore, this Article specifies that the credit union, its powers and duties, and the functions of its members, officers and directors, are all strictly circumscribed by law and regulation. The commentary for this Article provides more details on members using accounts for unlawful purposes.

Article III. Shares of Members

i. Installments: FCUs may insert zero for the number of installments. The Act allows membership upon the payment of the initial installment of a membership share, but the NCUA no longer views this provision as requiring FCUs to offer the option of paying for the membership share in installments.

ii. Par value: FCUs may establish differing par values for different classes of members or types of accounts (such as students, minors, or non-natural persons), provided this action does not violate any federal, state or local antidiscrimination laws. For example, an FCU may want to establish a higher par value for recent credit union members, without requiring long-time members to bring their accounts up to the new par value. A differing par value may also be permissible for different types of accounts, such as requiring a higher par value for a member with only a share draft account. If a credit union adopts differing par values, all of the possible par values must be stated in section 1. The FCU Bylaws include several options for differing par values. The credit union may select one or more of these or establish its own.

iii. Regular share account: To establish membership, the member must subscribe to one par value of share. The

²⁵ See 12 U.S.C. 1761b.

²⁶ See OGC Op. No. 08–0431 (Aug. 12, 2008).

²⁷ See 12 U.S.C. 1764.

²⁸ *Id.*

share does not have to be in a regular share account. The bylaws include two options. One option requires the member to have a regular share account to open membership, and one option allows them to use any other account. The board may select which option to use. If the board does not select an option, the member must have a regular share account to open an account. Please note, if the board selects an account other than the regular share, the requirements of Article III, § 3 still apply. The member must maintain one share to remain a member. If the share balance falls below the par value and does not increase the balance within the time set by the board, membership is terminated. If the board decides to allow the members to use a share draft account, this section still applies if the member overdrafts the account below the par value.

iv. Reduction in share balance below par value: When a member's account balance falls below the par value, section 3 of this article requires FCUs to allow members a minimum time period to restore their account balance to the par value before membership is terminated. FCUs may not delete this requirement or delete references to this requirement in Article II, § 3.

v. Trusts: a. Trusts and shares issued in trust can be a complicated subject. For purposes of the FCU Bylaws, perhaps the main issue is the distinction between revocable and irrevocable trusts. In the case of a revocable trust, the individual who establishes the trust is essentially still in control of the funds during his lifetime. Thus, the account owner can change the designated beneficiary at any time, and he or she can determine whether the identified beneficiary actually receives any money simply by deciding to withdraw the funds before his or her own death. Accordingly, the requirement in the case of revocable trust accounts is simply that the owner of the funds be a member of the FCU. Furthermore, provided the owner of the funds is within the field of membership and eligible for membership, he or she may use the vehicle of the payable-on-death or revocable trust account itself as the method of becoming a member. There is no requirement that the account holder first establish a regular share account to become a member. In accordance with legal opinions issued by the NCUA's Office of General Counsel, an individual may fulfill the requirement of becoming a member by subscribing to the equivalent of the par value of one share, which can be done through the opening

of any type of account the credit union offers.²⁹

b. There is no requirement that the beneficiaries be members, since they may never actually come to own the funds or have a right to them. Furthermore, in the case of a revocable trust, since it is essentially indistinguishable from the member, there is no need for the trust to have a separate account number assigned or for it to be viewed as a legal entity separate from the member who set it up.

c. In the case of an irrevocable trust, the requirements are somewhat different. Membership requirements here may be met though either the settlor, who is the original owner of the funds, or the beneficiary, who obtains an equitable, beneficial interest in the funds once the trust is established. So long as one or the other is eligible for membership, the credit union may accept the account. Furthermore, as with revocable trusts, the membership obligation can be met through the opening of the trust account itself; it is not required that the beneficiary or the settlor have previously established a separate, regular share account. Most irrevocable trusts have a trustee who has administrative responsibility for the account, and so the credit union will typically deal with the trustee for purposes such as sending monthly statements and year-end tax reporting. However, the trustee need not actually be a member of the credit union, and the credit union need not necessarily view the trust account as a separate legal entity, with its own separate tax ID number. Instead, it need only verify and confirm the eligibility of either the settlor or the beneficiary (or all of the settlors or all of the beneficiaries in the case of multiple settlors or beneficiaries) to join the credit union.

d. A trust itself, either revocable or irrevocable, may be a member of the credit union in its own right if all parties to the trust, including all settlors, beneficiaries and trustees, are within the field of membership.³⁰ If all parties to the trust are within a credit union's field of membership, the trust will qualify as "an organization of such persons," which is a standard clause in FCU fields of membership.

Article IV. Meetings of Members

i. Annual and special meetings: FCUs are encouraged to provide a live webcast of annual and special meetings for interested members, and/or post a video of the annual meeting on the FCU's website. The NCUA Board encourages

this policy for FCUs that currently have a website.

Article V. Elections

i. Eligibility requirements: The Act and the FCU Bylaws contain the only eligibility requirements for membership on an FCU's board of directors, which are as follows:

(a) The individual must be a member of the FCU before distribution of ballots;

(b) The individual cannot have been convicted of a crime involving dishonesty or breach of trust unless the NCUA Board has waived the prohibition for the conviction; and

(c) The individual meets the minimum age requirement established under Article V, § 7 of the FCU Bylaws.

Anyone meeting the three eligibility requirements may run for a seat on the board of directors if properly nominated. It is the nominating committee's duty to ascertain that all nominated candidates, including those nominated by petition, meet the eligibility requirements.

ii. Nomination criteria for nominating committee: The Act and the FCU Bylaws do not prohibit a board of directors from establishing reasonable criteria, in addition to the eligibility requirements, for a nominating committee to follow in making its nominations, such as financial experience, years of membership, or conflict of interest provisions. The board's nomination criteria, however, applies only to individuals nominated by the nominating committee; they cannot be imposed on individuals who meet the eligibility requirements and are properly nominated from the floor or by petition.

iii. Candidates' names on ballots: When producing an election ballot, the FCU's secretary may order the names of the candidates on the ballot using any method for selection provided it is random and used consistently from year to year so as to avoid manipulation or favoritism.

iv. Secret ballots: An FCU must establish an election process that assures members their votes remain confidential and secret from all interested parties. If the election process does not separate the member's identity from the ballot, FCUs should use a third-party teller that has sole control over completed ballots. If the ballots are designed so that members' identities remain secret and are not disclosed on the ballot, FCUs may use election tellers from the FCU. In any case, FCU employees, officials, and members must not have access to ballots identifying members or to information that links members' votes to their identities.

²⁹ See OGC Op. No. 92-0522 (June 15, 1992).

³⁰ OGC Op. No. 99-1110 (Feb. 25, 2000).

v. Plurality voting: At least one nominee must be nominated for each vacant seat. When there are more nominees than seats open for election, the nominees who receive the greatest number of votes are elected to the vacant seats.

vi. Minimum age requirement: The age the board selects may not be greater than eighteen or the age of majority under the state law applicable to the credit union, whichever is lower.

vii. Electronic voting: Some members lack digital access or wish to have a choice to vote non-electronically. The FCU Bylaws protect members who cannot or choose not to vote electronically. For those members who vote electronically, credit unions have the flexibility to use as many forms of electronic voting (phone, internet, etc.) as they wish.

viii. Voting methods: Options A1, A2 and A3 provide for in-person voting at the annual meeting, or, for Option A3, by voting machine. Option A4 provides for remote voting via electronic device or mail ballot. The NCUA has approved several bylaw amendments for FCUs that combine in-person and remote options for member voting. The NCUA encourages FCUs using one of the first three options to consider whether they can also incorporate mail ballots or electronic voting. Likewise, the NCUA encourages FCUs using option A4 to consider whether they can also provide a means to vote for members who come to the annual meeting but have not voted in the election, such as a paper ballot.

ix. Uncontested elections: Options A2, A3 and A4 provide for election by acclamation or consensus when the number of nominees for board positions equals the number of positions to be filled. These options do not permit nominations from the floor at the meeting, so a petition is the only way for members to nominate a candidate not on the nominating committee's slate. Accordingly, section (1)(c) in each of these options requires the notice to members to include the fact that there are no nominations from the floor at the meeting, as well as a notice that the credit union will not conduct a vote by ballot if the number of nominees equals the number of positions to be filled. The FCU Bylaws do not require a particular procedure for uncontested elections.

The contents of the notice to members required in section (1)(c) does not alter the basic election procedures the credit union has selected. Should the number of the nominating committee nominees fall below the number of positions to be filled after the member notice is sent, this section does not permit

nominations from the floor. Only option A1 permits nominations from the floor.

x. Nomination procedures: Under all options under this Article, the nominating committee must widely publicize the call for nominations to all members by any medium. This requirement can be satisfied by publicizing the information to a large audience, whether by newsletter, email, or any other satisfactory medium that reaches as many members as possible. The NCUA emphasizes that member participation is important during an election, and FCUs must make sure that members are aware of the nomination process.

Article VI. Board of Directors

i. Vacancies: In accordance with the Act, when a vacancy on the board of directors occurs between annual elections, the remaining directors are to appoint a replacement. This replacement will serve as a director until the next annual meeting. The vacancy is then to be filled at the next annual meeting through the normal membership voting process, with the newly elected director serving out the remainder of the original term.³¹ The number of director positions may be changed to any odd number between 5 and 15, inclusive, but a position may not be eliminated if it is currently an occupied position. As the bylaw itself specifies, no reduction in the number of director positions may be made unless there is a corresponding vacancy, caused by death, resignation, expiration of term or other action permissible under the FCU Bylaws. In other words, the FCU may not arbitrarily propose to reduce the number of director positions and terminate one or more incumbent directors.

ii. Director emeritus: As a matter of board policy, the board may establish the position of director emeritus for former directors who faithfully fulfilled their responsibilities as members of the board for at least a specified minimum number of years. The board may determine that director emeritus status confers authority to attend board meetings and to participate in discussions and other board events; however, directors emeritus may not vote on any matter before the board or exercise any official duties of a director. The position is essentially an honorary title designed to recognize and reward the good service of those designated and to retain some of their institutional knowledge for the benefit of the board and the FCU. The decision to establish a director emeritus position, as well as

the selection of individuals to become directors emeritus, is solely within the discretion of the board. The board may establish a director emeritus position by adopting either the optional bylaw amendment or a board policy.

To assist them in providing advice, Directors emeriti have access to confidential information, including but not limited to the credit union's examination reports and CAMEL ratings, to the same extent as members of the board. Directors emeriti are also subject to the same confidentiality and conflict of interest standards applicable to directors.

iii. Associate directors: a. The board may also establish the position of associate director through board policy. This position is designed to provide qualified individuals with an opportunity to gain exposure to board meetings and discussions but without formal director responsibility or the right to vote. It may be thought of as an apprenticeship position in which the incumbent receives training and knowledge about the business of the board, with the expectation that the experience will prepare him or her for an eventual election to a director position. As with the director emeritus position, the decision to establish an associate director position, as well as the selection of individuals to become associate directors, is solely within the discretion of the board.

b. To assist their learning process, the board may determine to permit associate directors to have access to confidential information, including but not limited to the credit union's examination reports and CAMEL ratings, to the same extent as members of the board. Associate directors are also subject to the same confidentiality and conflict of interest standards applicable to directors.

iv. Composition of the board: The NCUA Board encourages the composition of the board of directors to reflect the field of membership of the FCU.

v. Notice to members of change in size of board: The NCUA encourages FCUs changing the size of their boards to post a notice of the change on the FCU's website (if the FCU maintains a website). An FCU is not required to establish and maintain a website solely for this purpose, however. An FCU that does not maintain a website can post such a notice in a conspicuous place in the office of the FCU, such as at the teller window or on the front door of the FCU.

Article VII. Board Officers, Management Officials and Executive Committee

³¹ 12 U.S.C. 1761(a).

i. Board officers: a. As specified in this bylaw, members of the board are elected by the credit union membership to the board itself. Once on the board, the directors themselves vote to select individuals from among their number to serve as officers of the board (chair, one or more vice chairs, secretary and financial officer). One board officer may be compensated as such for services he or she performs in that capacity. The offices of financial officer and secretary may be held by the same person.

b. Members of the board must hold the vote for the specified officer positions at the first board meeting following the annual meeting of the members. This board meeting should be held not later than seven days after the annual meeting. The Act requires the credit union to file a record of the names and addresses of the executive offices, members of the supervisory committee, credit committee, and loan officers be filed with the Administration within ten days after election or appointment.³² The NCUA's regulations also require federally insured credit unions to file NCUA Form 4501 or its equivalent within 10 days after an election or appointment of senior management or volunteer officials.³³

c. Officers hold their respective officer positions for a term of one year, until the first board meeting that follows the next annual meeting of the members. At that board meeting, officer positions are again filled. Each board officer holds his or her position until the election and qualification of his or her successor. Thus, a board officer who is re-elected to the position he or she is currently holding serves for another year. Where another director is chosen to fill the position, he or she takes office effective as of the date of the election, assuming he or she is qualified—meaning simply that he or she was properly elected by the membership to the board in the first place and is in good standing as a director.

d. As specified in this bylaw, the board chair presides at all board meetings. In the absence of the chair or his or her inability to act, the vice chair presides at the meeting. In the absence or inability to act of both the chair and the vice chair, those directors who are present may select from among their number an individual director to act as temporary chair for that particular meeting. Actions taken by the board under the direction of the temporary chair have the same validity and effect as if taken under the direction of the chair or the vice chair, provided a

quorum of the board, including the temporary chair, is present. If the board secretary is absent for any reason from a meeting, the chair (or acting chair) must select another director to fulfill the secretary's function at the meeting.

ii. Committee Membership: The NCUA encourages FCUs to publicize the names of the members of each FCU committee to FCU members. FCUs could provide this information either on the FCU's public website or to the portion of the website only accessible to members after logging in. The NCUA encourages this policy for FCUs that have a website. An FCU is not required to establish and maintain a website solely for this purpose, however. Providing a short description of the committee's duties also assists members in better understanding the leadership structure of the FCU.

Article VIII. Credit Committee or Loan Officers

i. Automated lending systems: Many FCUs now use automated systems for accepting loan applications, loan underwriting, and loan processing, as permitted by several of the NCUA Office of General Counsel's legal opinions. The bylaws reflect that FCUs may use automated lending systems, as long as the credit committee or a loan officer: (1) Reviews the loans the automated system granted for fraud and other purposes; and (2) reviews loans the automated system denied.

Article IX. Supervisory Committee

i. Nominations: The Act requires that the FCU's board appoint the members of the Supervisory Committee. It is permissible for the board to seek nominations from members before making Supervisory Committee appointments.

Article XIV. Expulsion and Withdrawal

i. Expulsion procedures: As noted in the commentary to Article II, there is a fairly wide range of measures available to the credit union in responding to abusive or disruptive members. However, in accordance with the Act, there are only two ways a member may be expelled: (1) A two-thirds vote of the membership present at a special meeting called for that purpose, and only after the individual is provided an opportunity to be heard; and (2) for non-participation in the affairs of the credit union, as specified in a policy adopted and enforced by the board.³⁴ Only in-person voting is permitted in conjunction with the special meeting, so that the affected member has an opportunity to present their case and

respond to the credit union's concerns. In addition, FCUs should consider the commentary under Article XVI about members using accounts for unlawful purposes.

Article XVI. General

i. Special meeting requirements: To remove a director under section 3 of this Article requires a majority vote of members present at a special meeting called for the purpose of voting on removal. The bylaw requires that the affected director have the "opportunity to be heard." NCUA interprets this provision as requiring the vote to occur at an in-person meeting rather than by mail ballot. At an in-person meeting, the director subject to the removal vote can make his or her case before the members. The director removal provisions derive from provisions of the Act, as follows:

- The bylaws govern the conduct of special meetings;³⁵
- Members must have the opportunity to vote, at a meeting, on the Supervisory Committee's suspension of a director;³⁶ and
- FCU members may be expelled by vote of members present at a meeting called for that purpose.³⁷

ii. Unlawful purposes: FCUs expressed concerns that some members may be using their accounts for unlawful purposes. Section 1 of this Article specifies that the credit union, its powers and duties, and the functions of its members, officers and directors, are all strictly circumscribed by law and regulation. Insofar as this provision is included in the bylaws, an FCU need not adopt a specific policy or requirement that members conform their use of credit union products or services to lawful purposes. Furthermore, the existence of this bylaw provides ample support should an FCU determine to impose strict limits on products and services available to any individual who is found to be using the FCU in furtherance of unlawful purposes.

iii. Posting of bylaws on website: FCUs that maintain a website must post a copy of the FCU's bylaws on the website. After adopting amendments, FCUs must post an updated copy of the bylaws. An FCU is not required to establish and maintain a website solely for this purpose, however.

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³² 12 U.S.C. 1761(b).

³³ 12 CFR 741.6.

³⁴ See 12 U.S.C. 1764.

³⁵ 12 U.S.C. 1760.

³⁶ 12 U.S.C. 1761d.

³⁷ 12 U.S.C. 1764(a).



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Part IV

Commodity Futures Trading Commission

17 CFR Part 1

De Minimis Exception to the Swap Dealer Definition; Final Rule

COMMODITY FUTURES TRADING COMMISSION**17 CFR Part 1**

RIN 3038-AE68

De Minimis Exception to the Swap Dealer Definition**AGENCY:** Commodity Futures Trading Commission.**ACTION:** Final rule.

SUMMARY: The Commodity Futures Trading Commission (“Commission” or “CFTC”) is amending the de minimis exception within the “swap dealer” definition in the Commission’s regulations by setting the aggregate gross notional amount threshold for the de minimis exception at \$8 billion in swap dealing activity entered into by a person over the preceding 12 months.

DATES: This rule is effective November 13, 2018.

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I. Background*A. Statutory and Regulatory Background*

1. Statutory Authority

Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act (“Dodd-Frank Act”) ¹ established a statutory framework to reduce risk, increase transparency, and promote market integrity within the financial system by regulating the swap market. Among other things, the Dodd-Frank Act amended the Commodity Exchange Act (“CEA”) ² to provide for the registration and regulation of swap dealers (“SDs”).³ The Dodd-Frank Act directed the CFTC and the U.S.

Securities and Exchange Commission (“SEC” and together with the CFTC, “Commissions”) to jointly further define, among other things, the term “swap dealer,”⁴ and to exempt from designation as an SD a person that engages in a de minimis quantity of swap dealing.⁵

CEA section 1a(49) defines the term “swap dealer” to include any person who: (1) Holds itself out as a dealer in swaps; (2) makes a market in swaps; (3)

regularly enters into swaps with counterparties as an ordinary course of business for its own account; or (4) engages in any activity causing the person to be commonly known in the trade as a dealer or market maker in swaps (collectively referred to as “swap dealing,” “swap dealing activity,” or “dealing activity”).⁶ The statute also requires the Commission to promulgate regulations to establish factors with respect to the making of a determination to exempt from designation as an SD an entity engaged in a de minimis quantity of swap dealing.⁷ CEA section 1a(49) further provides that in no event shall an insured depository institution (“IDI”) be considered to be an SD to the extent it offers to enter into a swap with a customer in connection with originating a loan with that customer.⁸

2. Regulatory History

Pursuant to the statutory requirements, in December 2010, the Commissions issued a proposing release (“SD Definition Proposing Release”) ⁹ further defining, among other things, the term “swap dealer.” Subsequently, in May 2012, the Commissions issued an adopting release (“SD Definition Adopting Release”) ¹⁰ further defining, among other things, the term “swap dealer” in § 1.3 of the CFTC’s regulations (“SD Definition”) and providing for a de minimis exception in paragraph (4) therein (“De Minimis Exception”).¹¹ The De Minimis Exception states that a person shall not be deemed to be an SD unless its swaps connected with swap dealing activities exceed an aggregate gross notional amount (“AGNA”) threshold of \$3 billion (measured over the prior 12-month period), subject to a phase-in period during which the AGNA

⁶ 7 U.S.C. 1a(49)(A). In general, a person that satisfies any one of these prongs is deemed to be engaged in swap dealing activity. See also the definitions of “swap” in CEA section 1a(47) and § 1.3 of Commission regulations. 7 U.S.C. 1a(47); 17 CFR 1.3.

⁷ 7 U.S.C. 1a(49)(D).

⁸ 7 U.S.C. 1a(49)(A).

⁹ Further Definition of “Swap Dealer,” “Security-Based Swap Dealer,” “Major Swap Participant,” “Major Security-Based Swap Participant” and “Eligible Contract Participant,” 75 FR 80174 (proposed Dec. 21, 2010).

¹⁰ Further Definition of “Swap Dealer,” “Security-Based Swap Dealer,” “Major Swap Participant,” “Major Security-Based Swap Participant” and “Eligible Contract Participant,” 77 FR 30596 (May 23, 2012).

¹¹ See 17 CFR 1.3. Swap dealer. As discussed in more detail in section II, the Commission notes that a joint rulemaking with the SEC is not required to amend the De Minimis Exception, pursuant to paragraph (4)(v) of the De Minimis Exception. See 17 CFR 1.3. Swap dealer, paragraph (4)(v); 77 FR at 30634 n.464.

¹ Public Law 111–203, 124 Stat. 1376 (2010), available at <https://www.gpo.gov/fdsys/pkg/PLAW-111publ203/pdf/PLAW-111publ203.pdf>.

² The CEA is found at 7 U.S.C. 1, et seq.

³ See generally 7 U.S.C. 6s.

⁴ Dodd-Frank Act section 712(d)(1). See the definitions of “swap dealer” in CEA section 1a(49) and § 1.3 of Commission regulations. 7 U.S.C. 1a(49); 17 CFR 1.3.

⁵ See Dodd-Frank Act section 721.

threshold is set at \$8 billion.¹² The phase-in period was originally scheduled to terminate on December 31, 2017, and the AGNA threshold was scheduled to decrease to \$3 billion at that time. However, as discussed below, pursuant to paragraph (4)(ii)(C)(1) of the De Minimis Exception, the Commission issued two successive orders to set new termination dates, and the phase-in period is currently scheduled to terminate on December 31, 2019.¹³

When the \$3 billion AGNA threshold was established, the Commissions explained that the information then available regarding certain portions of the swap market was limited, and that they expected more information to be available in the future (following the implementation of swap data reporting), which would enable the Commissions to make a more informed assessment of the De Minimis Exception and to revise it as appropriate.¹⁴ In recognition of these limitations and in anticipation of additional swap market data becoming available to the CFTC through the reporting of transactions to swap data repositories (“SDRs”), paragraph (4)(ii)(B) of the De Minimis Exception was adopted, which directed CFTC staff to complete and publish for public comment a report on topics relating to the definition of the term “swap dealer” and the de minimis threshold as appropriate, based on the availability of data and information.¹⁵ Paragraph (4)(ii)(C) of the De Minimis Exception provided that after giving due consideration to the staff report and any associated public comment, the CFTC may either set a termination date for the phase-in period or issue a notice of proposed rulemaking to modify the De Minimis Exception.¹⁶

¹² 17 CFR 1.3, Swap dealer, paragraph (4)(i)(A). Paragraph (4)(i)(A) also provides for a de minimis threshold of \$25 million with regard to swaps in which the counterparty is a “special entity” (excluding “utility special entities” as provided in paragraph (4)(i)(B) of the De Minimis Exception) as defined in CEA section 4s(h)(2)(C), 7 U.S.C. 6s(h)(2)(C). This final rule would not change the AGNA threshold for swaps with special entities.

¹³ See Order Establishing De Minimis Threshold Phase-In Termination Date, 81 FR 71605 (Oct. 18, 2016); Order Establishing a New De Minimis Threshold Phase-In Termination Date, 82 FR 50309 (Oct. 31, 2017).

¹⁴ See SD Definition Adopting Release, 77 FR 30632–34. In making their determination, the Commissions considered the limited and incomplete swap market data that was available at that time and concluded that the \$3 billion level appropriately considers the relevant regulatory goals. *Id.* at 30632. The Commissions found merit in determining the threshold by multiplying the estimated size of the domestic swap market by a 0.001 percent ratio suggested by several commenters. *Id.* at 30633.

¹⁵ 17 CFR 1.3, Swap dealer, paragraph (4)(ii)(B).

¹⁶ 17 CFR 1.3, Swap dealer, paragraph (4)(ii)(C).

In November 2015, staff issued a preliminary report concerning the De Minimis Exception (“Preliminary Staff Report”).¹⁷ After consideration of the public comments received in response to the Preliminary Staff Report,¹⁸ and further data analysis, in August 2016 staff issued a final staff report¹⁹ concerning the De Minimis Exception (“Final Staff Report,” and together with the Preliminary Staff Report, “Staff Reports”). The data analysis in the Staff Reports provided some insights into the effectiveness of the De Minimis Exception as currently implemented. For example, staff analyzed the number of swap transactions involving at least one registered SD,²⁰ which is indicative of the extent to which swaps are subject to SD regulation at the current \$8 billion AGNA threshold. Data reviewed for the Final Staff Report indicated that approximately 96 percent of swap transactions analyzed involved at least one registered SD.

To provide additional time for more information to become available to study the De Minimis Exception, in October 2016 the Commission issued an order, pursuant to paragraph (4)(ii)(C)(1) of the De Minimis Exception, establishing December 31, 2018, as the new termination date for the \$8 billion phase-in period.²¹ To enable staff to conduct additional analysis, in October 2017 the Commission further extended the phase-in period to December 31, 2019.²² Generally, the extensions provided additional time for Commission staff to conduct further data analysis regarding the De Minimis Exception, and gave market participants additional time to begin preparing for a change, if any, to the AGNA threshold.

¹⁷ See Swap Dealer De Minimis Exception Preliminary Report (Nov. 18, 2015), available at http://www.cftc.gov/idc/groups/public/@swaps/documents/file/dfreport_sddeminis_1115.pdf. For the Preliminary Staff Report, staff analyzed data from April 1, 2014 through March 31, 2015.

¹⁸ The comment letters are available on the Commission website at <http://comments.cftc.gov/PublicComments/CommentList.aspx?id=1634>.

¹⁹ See Swap Dealer De Minimis Exception Final Staff Report (Aug. 15, 2016), available at http://www.cftc.gov/idc/groups/public/@swaps/documents/file/dfreport_sddeminis081516.pdf. For the Final Staff Report, staff analyzed data from April 1, 2015 through March 31, 2016.

²⁰ Given that all of the CEA section 4s requirements have not yet been implemented by regulation, the term “registered SD” refers to an entity that is a provisionally registered SD. See 17 CFR 3.2(c)(3)(iii).

²¹ 81 FR 71605.

²² 82 FR 50309.

3. Policy Considerations

(i) Swap Dealer Registration Policy Considerations

The policy goals underlying SD registration and regulation generally include reducing systemic risk, increasing counterparty protections, and increasing market efficiency, orderliness, and transparency.

Reducing systemic risk: The Dodd-Frank Act was enacted in the wake of the financial crisis of 2008, in significant part, to reduce systemic risk, including the risk to the broader U.S. financial system created by interconnections in the swap market.²³ Pursuant to the Dodd-Frank Act, the Commission has adopted regulations designed to mitigate the potential systemic risk inherent in the previously unregulated swap market.²⁴

Increasing counterparty protections: Providing regulatory protections for swap counterparties who may be less experienced or knowledgeable about the swap products offered by SDs (particularly end-users who use swaps for hedging or investment purposes) is a fundamental policy goal advanced by the regulation of SDs.²⁵ The Commissions recognized that a narrower or smaller de minimis exception would increase the number of counterparties that could potentially benefit from those regulatory protections.²⁶

Increasing market efficiency, orderliness, and transparency: Increasing swap market efficiency, orderliness, and transparency is another goal of SD regulation.²⁷ Regulations

²³ Dodd-Frank Act, Preamble (indicating that the purpose of the Dodd-Frank Act was to promote the financial stability of the United States by improving accountability and transparency in the financial system, to end “too big to fail,” to protect the American taxpayer by ending bailouts, to protect consumers from abusive financial services practices, and for other purposes). See also De Minimis Exception to the Swap Dealer Definition, 83 FR 27444, 27446 (proposed June 12, 2018).

²⁴ For example, registered SDs have specific requirements for risk management programs and margin. See, e.g., 17 CFR 23.600; 17 CFR 23.150–23.161.

²⁵ For example, registered SDs are subject to external business conduct standard regulations designed to provide counterparty protections. See, e.g., 17 CFR 23.400–23.451.

²⁶ SD Definition Adopting Release, 77 FR 30628 (“On the one hand, a de minimis exception, by its nature, will eliminate key counterparty protections provided by Title VII for particular users of swaps and security-based swaps.”). See also 83 FR 27446.

²⁷ 77 FR 30629 (“The statutory requirements that apply to swap dealers . . . include requirements . . . aimed at helping to promote effective operation and transparency of the swap . . . markets.”). See *id.* at 30703 (“Those who engage in swaps with entities that elude swap dealer or major swap participant status and the attendant regulations could be exposed to increased

requiring SDs, for example, to keep detailed daily trading records, report trade information, and engage in portfolio reconciliation and compression exercises help achieve these market benefits.²⁸

(ii) De Minimis Exception Policy Considerations

Consistent with Congressional intent, “an appropriately calibrated de minimis exception has the potential to advance other interests.”²⁹ These interests include increasing efficiency, allowing limited swap dealing in connection with other client services, encouraging new participants to enter the market, and focusing regulatory resources.³⁰ The policy objectives underlying the de minimis exception are designed to encourage participation and competition by allowing persons to engage in a de minimis amount of dealing without incurring the costs of registration and regulation.³¹

Increasing efficiency: A de minimis exception based on an objective test with a limited degree of complexity enables entities to engage in a lower level of swap dealing with limited concerns about whether their activities would require registration.³² The de minimis exception thereby fosters efficient application of the SD Definition. Additionally, the Commission is of the view that the potential for regular or periodic changes to the de minimis threshold may reduce its efficacy by making it challenging for persons to calibrate their swap dealing activity as appropriate for their business models. Further, the Commission is mindful that objective, predictable standards in the de minimis exception

counterparty risk; customer protection and market orderliness benefits that the regulations are intended to provide could be muted or sacrificed, resulting in increased costs through reduced market integrity and efficiency. . . .”). See also 83 FR 27446.

²⁸ See, e.g., 17 CFR 23.200–23.205; 17 CFR parts 43 and 45; 17 CFR 23.502–23.503.

²⁹ See 77 FR 30628. See also 83 FR 27446.

³⁰ See 77 FR 30628–30, 30707–08. See also 83 FR 27446–47.

³¹ In considering the appropriate de minimis threshold, “exclud[ing] entities whose dealing activity is sufficiently modest in light of the total size, concentration and other attributes of the applicable markets can be useful in avoiding the imposition of regulatory burdens on those entities for which dealer regulation would not be expected to contribute significantly to advancing the customer protection, market efficiency and transparency objectives of dealer regulation.” 77 FR 30629–30. See also 83 FR 27446–47.

³² 77 FR 30628–29 (“[T]he de minimis exception may further the interest of regulatory efficiency when the amount of a person’s dealing activity is, in the context of the relevant market, limited to an amount that does not warrant registration. . . . In addition, the exception can provide an objective test . . .”). See also 83 FR 27446–47.

increase efficiency by establishing a simple test for whether a person’s swaps connected with swap dealing activity must be included in the de minimis calculation. On the other hand, more complexity in the de minimis calculation potentially results in less efficiency.³³

Allowing limited ancillary dealing: A de minimis exception allows persons to accommodate existing clients that have a need for swaps (on a limited basis) along with other services.³⁴ This enables end-users to continue transacting within existing business relationships, for example to hedge interest rate or currency risk.

Encouraging new participants: A de minimis exception also promotes competition by allowing a person to engage in some swap dealing activities without immediately incurring the regulatory costs associated with SD registration and regulation.³⁵ Without a de minimis exception, SD regulation could become a barrier to entry that may stifle competition. An appropriately calibrated de minimis exception could lower the barrier to entry of becoming an SD by allowing smaller participants to gradually expand their business until the scope and scale of their activity warrants regulation (and the costs involved with compliance).

Focusing regulatory resources: Finally, the de minimis exception also increases regulatory efficiency by enabling the Commission to focus its limited resources on entities whose swap dealing activity is sufficient in size and scope to warrant oversight.³⁶

As noted in the SD Definition Adopting Release, “implementing the de minimis exception requires a careful balancing that considers the regulatory interests that could be undermined by an unduly broad exception as well as those regulatory interests that may be promoted by an appropriately limited exception.”³⁷ A narrower de minimis exception would likely mean that a greater number of entities would be required to register as SDs and become subject to the regulatory framework applicable to registered SDs. However, a de minimis exception that is too narrow

³³ 77 FR 30707–08 (“On the other hand, requiring market participants to consider more variables in evaluating application of the de minimis exception would likely increase their costs to make this determination.”). See also 83 FR 27446–47.

³⁴ 77 FR 30629, 30707–08. See also 83 FR 27447.

³⁵ 77 FR 30629. See also 83 FR 27447.

³⁶ 77 FR 30628–29. See also 83 FR 27447.

³⁷ 77 FR 30628. See SD Definition Proposing Release, 75 FR 80179 (The de minimis exception “should apply only when an entity’s dealing activity is so minimal that applying dealer regulations to the entity would not be warranted.”). See also 83 FR 27447.

could, for example, discourage persons from engaging in limited swap dealing activity in order to avoid the burdens associated with SD regulation.

4. De Minimis Calculation

Generally, a person must count towards its AGNA threshold all swaps it enters into for dealing purposes over the preceding 12-month period. In addition, each person whose own swaps do not exceed the AGNA threshold must also include in its de minimis calculation the AGNA of swaps of any other unregistered affiliate controlling, controlled by, or under common control with that person (referred to as “aggregation”).³⁸

Pursuant to various CFTC regulations, certain swaps, subject to specific conditions, need not be considered in determining whether a person is an SD, including: (1) Swaps entered into by an IDI with a customer in connection with originating a loan to that customer;³⁹ (2) swaps between affiliates;⁴⁰ (3) swaps entered into by a cooperative with its members;⁴¹ (4) swaps hedging physical positions;⁴² (5) swaps entered into by floor traders;⁴³ (6) certain foreign exchange (“FX”) swaps and FX forwards;⁴⁴ and (7) commodity trade options.⁴⁵ In addition, the Commission understands that persons have applied CFTC interpretive guidance and staff letters so as not to count towards the AGNA threshold, subject to certain conditions, certain cross-border swaps⁴⁶ and swaps resulting from

³⁸ 17 CFR 1.3, Swap dealer, paragraph (4)(i)(A); Interpretive Guidance and Policy Statement Regarding Compliance With Certain Swap Regulations, 78 FR 45292, 45323 (July 26, 2013). See also 83 FR 27447.

³⁹ See 17 CFR 1.3, Swap dealer, paragraph (5); 77 FR at 30620–24. See also 83 FR 27447.

⁴⁰ See 17 CFR 1.3, Swap dealer, paragraph (6)(i); 77 FR at 30624–25. See also 83 FR 27447.

⁴¹ See 17 CFR 1.3, Swap dealer, paragraph (6)(ii); 77 FR at 30625–26. See also 83 FR 27447.

⁴² See 17 CFR 1.3, Swap dealer, paragraph (6)(iii); 77 FR at 30611–14. See also 83 FR 27447.

⁴³ See 17 CFR 1.3, Swap dealer, paragraph (6)(iv); 77 FR at 30614. See also 83 FR at 27447. The floor trader exclusion was also addressed in no-action relief. See CFTC Staff Letter No. 13–80, No-Action Relief from Certain Conditions of the Swap Dealer Exclusion for Registered Floor Traders (Dec. 23, 2013), available at <https://www.cftc.gov/idc/groups/public/@lrelettergeneral/documents/letter/13-80.pdf>.

⁴⁴ See Determination of Foreign Exchange Swaps and Foreign Exchange Forwards Under the Commodity Exchange Act, 77 FR 69694, 69704–05 (Nov. 20, 2012); Further Definition of “Swap,” “Security-Based Swap,” and “Security-Based Swap Agreement”; Mixed Swaps; Security-Based Swap Agreement Recordkeeping, 77 FR 48208, 48253 (Aug. 13, 2012).

⁴⁵ See 17 CFR 32.3; Commodity Options, 77 FR 25320, 25326 n.39 (Apr. 27, 2012).

⁴⁶ See 78 FR 45292; CFTC Letter No. 18–13, No-Action Position: Relief for Certain Non-U.S. Persons from Including Swaps with International Financial Institutions in Determining Swap Dealer and Major

multilateral portfolio compression exercises.⁴⁷ Further, certain inter-governmental or quasi-governmental international financial institutions are not included within the term “swap dealer.”⁴⁸

B. The Proposal

On June 12, 2018, the Commission published for public comment a Notice of Proposed Rulemaking (“NPRM”) to amend the De Minimis Exception by: (1) Setting the AGNA threshold for the De Minimis Exception at \$8 billion in swap dealing activity entered into by a person over the preceding 12 months; (2) adding new factors to the De Minimis Exception that would lead to excepting from the AGNA calculation: (a) Certain swaps entered into with a customer by an IDI in connection with originating a loan to that customer, (b) certain swaps entered into to hedge financial or physical positions, and (c) certain swaps resulting from multilateral portfolio compression exercises; and (3) providing that the Commission may determine the methodology to be used to calculate the notional amount for any group, category, type, or class of swaps, and delegating to the Director of the Division of Swap Dealer and Intermediary Oversight (“DSIO”) the authority to make such determinations (collectively, the “Proposal”).⁴⁹

In addition, the Commission sought comment on the following additional potential changes to the De Minimis Exception: (1) Adding as a factor a minimum dealing counterparty count threshold and/or a minimum dealing transaction count threshold; (2) adding as a factor whether a swap is exchange-traded and/or cleared; and (3) adding as a factor whether a swap is categorized

as a non-deliverable forward transaction.

The various aspects of the NPRM are discussed in further detail below. The Commission received 43 letters and Commission staff participated in four ex parte meetings⁵⁰ concerning the NPRM.⁵¹

⁵⁰ Comments were submitted by the following entities: 360 Trading Networks Inc. (“360 Trading”); American Bankers Association (“ABA”) (ABA also attached a report prepared by NERA Economic Consulting); American Gas Association (“AGA”); Americans for Financial Reform (“AFR”); Associated Foreign Exchange, Inc. and GPS Capital Markets, Inc. (“AFEX/GPS”); Association of Global Custodians (“AGC”); Better Markets, Inc. (“Better Markets”); Bond Dealers of America (“BDA”); Capital One Financial Corporation (“Capital One”); Cboe SEF, LLC (“Cboe SEF”); Citizens Financial Group, Inc. (“Citizens”); CME Group Inc. and Intercontinental Exchange, Inc. (“CME/ICE”); Coalition for Derivatives End-Users (“CDEU”); Coalition of Physical Energy Companies (“COPE”); Commercial Energy Working Group (“CEWG”); Commodity Markets Council (“CMC”) (CMC also expressed support for the CEWG comment letter); Covington & Burling LLP (“Covington”); Daiwa Securities Co. Ltd. (“Daiwa”); Edison Electric Institute and Electric Power Supply Association (“EEL/EPSA”); Foreign Exchange Professionals Association (“FXPA”); Frost Bank; Futures Industry Association and FIA Principal Traders Group (“FIA”); Institute for Agriculture and Trade Policy (“IATP”); Institute of International Bankers (“IIB”); International Energy Credit Association (“IECA”) (IECA also expressed support for the EEL/EPSA comment letter); International Swaps and Derivatives Association and Securities Industry and Financial Markets Association (“ISDA/SIFMA”); Japanese Bankers Association (“JBA”); M&T Bank (“M&T”); Managed Funds Association (“MFA”); National Council of Farmer Cooperatives (“NCFC”); National Rural Electric Cooperative Association and American Public Power Association (“NRECA/APPA”); Natural Gas Supply Association (“NGSA”); NEX Group plc (“NEX”); Northern Trust; Optiver US LLC (“Optiver”) (Optiver also expressed support for the FIA comment letter); Regions Financial Corp. (“Regions”); State Street; SVB Financial Group (“SVB”); Thomson Reuters (SEF) LLC (“TR SEF”); six U.S. Senators (“Senators”); Virtu Financial Inc. (“Virtu”); Western Union Business Solutions (USA), LLC and Custom House USA, LLC (“Western Union”); and TXM Markets Limited (“TXM”). Additionally, there were three meetings with Delta Strategy Group, DRW, Jump Trading, and Optiver, and one meeting with Better Markets. The comment letters and notice of the ex parte meetings are available at <https://comments.cftc.gov/PublicComments/CommentList.aspx?id=2885>.

⁵¹ Additionally, in March 2017, Chairman Giancarlo initiated an agency-wide internal review of CFTC regulations and practices to identify those areas that could be simplified to make them less burdensome and costly (“Project KISS”). See Remarks of then-Acting Chairman J. Christopher Giancarlo before the 42nd Annual International Futures Industry Conference in Boca Raton, FL (Mar. 15, 2017), available at <https://www.cftc.gov/PressRoom/SpeechesTestimony/opugiancarlo-20>. The Commission subsequently published in the **Federal Register** a Request for Information soliciting suggestions from the public regarding how the Commission’s existing rules, regulations, or practices could be applied in a simpler, less burdensome, and less costly manner. A number of responses submitted pursuant to the Project KISS Request for Information supported modifications to the De Minimis Exception. Project KISS, 82 FR 21494 (May 9, 2017), amended by 82 FR 23765

II. Final Rule—\$8 Billion Threshold

Given the more complete information now available regarding certain portions of the swap market, the data analytical capabilities developed since the SD regulations were adopted, five years of implementation experience, and comments received in response to the NPRM, in this adopting release the Commission is amending the De Minimis Exception by setting the AGNA threshold at \$8 billion in swap dealing activity. The CFTC may in the future separately propose or adopt rules addressing any aspect of the NPRM that is not finalized in this release.⁵²

This change to the De Minimis Exception is being adopted pursuant to the Commission’s authority under CEA section 1a(49)(D), which requires the Commission to exempt from designation as an SD an entity that engages in a de minimis quantity of swap dealing in connection with transactions with or on behalf of its customers, and to promulgate regulations to establish factors with respect to the making of this determination to exempt.⁵³ The Commissions issued the SD Definition Adopting Release pursuant to section 712(d)(1) of the Dodd-Frank Act, which requires the CFTC and SEC to jointly adopt rules regarding the definition of, among other things, the term “swap dealer.” The CFTC continues to coordinate with the SEC on SD and security-based swap dealer regulations. However, as discussed in the SD Definition Adopting Release, a joint rulemaking is not required with respect to the De Minimis Exception.⁵⁴ The Commission notes that it has consulted with the SEC and prudential regulators regarding the change to the De Minimis Exception adopted herein.⁵⁵

A. Proposal

The Commission proposed to amend paragraph (4)(i)(A) of the De Minimis Exception by setting the AGNA threshold at \$8 billion. For added clarity, the Commission also proposed

(May 24, 2017). The suggestion letters filed by the public are available at <https://comments.cftc.gov/KISS/KissInitiative.aspx>.

⁵² See *ICI v. CFTC*, 720 F.3d 370, 379 (D.C. Cir. 2013) (“[A]s the Supreme Court has emphasized, ‘[n]othing prohibits federal agencies from moving in an incremental manner.’”) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 522 (2009)).

⁵³ 7 U.S.C. 1a(49)(D). See also 17 CFR 1.3, Swap dealer, paragraph (4)(v).

⁵⁴ 77 FR 30634 n.464 (“We do not interpret the joint rulemaking provisions of section 712(d) of the Dodd-Frank Act to require joint rulemaking here, because such an interpretation would read the term “Commission” out of CEA section 1a(49)(D) (and Exchange Act section 3(a)(71)(D)), which themselves were added by the Dodd-Frank Act.”).

⁵⁵ As required by § 712(a)(1) of the Dodd-Frank Act.

Swap Participant Status (May 16, 2018), available at <https://www.cftc.gov/sites/default/files/idc/groups/public/%40rlrlettergeneral/documents/letter/2018-05/18-13.pdf>; CFTC Staff Letter No. 12–71, No-Action Relief: U.S. Bank Wholly Owned by Foreign Entity May Calculate De Minimis Threshold Without Including Activity From Its Foreign Affiliates (Dec. 31, 2012), available at <https://www.cftc.gov/idc/groups/public/%40rlrlettergeneral/documents/letter/12-71.pdf>; CFTC Staff Letter No. 12–61, No-Action Relief: U.S. Bank Wholly Owned by Foreign Entity May Calculate De Minimis Threshold Without Including Activity From Its Foreign Affiliates (Dec. 20, 2012), available at <https://www.cftc.gov/sites/default/files/idc/groups/public/@rlrlettergeneral/documents/letter/12-61.pdf>.

⁴⁷ CFTC Staff Letter No. 12–62, No-Action Relief: Request that Certain Swaps Not Be Considered in Calculating Aggregate Gross Notional Amount for Purposes of the Swap Dealer De Minimis Exception for Persons Engaging in Multilateral Portfolio Compression Activities (Dec. 21, 2012), available at <https://www.cftc.gov/idc/groups/public/@rlrlettergeneral/documents/letter/12-62.pdf>.

⁴⁸ See SD Definition Adopting Release, 77 FR 30693.

⁴⁹ 83 FR 27444.

to change the term “swap positions” to “swaps” in paragraph (4)(i)(A). Additionally, the Commission proposed to delete a parenthetical clause in paragraph (4)(i)(A) referring to the period after adoption of the rule further defining the term “swap,” and to remove and reserve paragraph (4)(ii) of the De Minimis Exception, which addresses the phase-in procedure and staff report requirements of the De Minimis Exception (discussed above in section I.A.2), since both of those provisions would no longer be applicable.

The Commission proposed to maintain the AGNA threshold at \$8 billion, and also solicited comment on whether to reduce the threshold to \$3 billion, or increase the threshold. The Commission cited as relevant an analysis of SDR data from January 1, 2017, through December 31, 2017 (the “review period”).⁵⁶ Given improvements in the quality of data being reported to SDRs since the Staff Reports were issued, Commission staff analyzed the AGNA of swaps activity for interest rate swaps (“IRS”), credit default swaps (“CDS”), FX swaps,⁵⁷ and equity swaps (whereas the analysis of AGNA data in the Staff Reports was limited to IRS and CDS).⁵⁸ However, given certain limitations discussed below, AGNA data was not available for non-financial commodity (“NFC”) swaps. In addition to now-available AGNA information for FX swaps and equity swaps, there were also continued improvements in the consistency of legal entity identifier (“LEI”) and unique swap identifier reporting.⁵⁹

⁵⁶ See 83 FR 27448–58. The data was sourced from data reported to the four registered SDRs: BSRD LLC, Chicago Mercantile Exchange Inc., DTCC Data Repository, and ICE Trade Vault. The analysis excluded inter-affiliate and non-U.S. transactions. The total size of the swap market that was analyzed, after excluding inter-affiliate and non-U.S. transactions, was approximately \$221.1 trillion in AGNA of swaps activity (excluding non-financial commodity swaps), approximately 4.4 million transactions, and 39,107 counterparties. The Proposal includes additional discussion regarding the methodology utilized to conduct the analysis. 83 FR 27449–50.

⁵⁷ The term “FX swaps” is used in this release to only describe those FX transactions that are counted towards a person’s de minimis calculation. The term “FX swaps” does not refer to swaps and forwards that are not counted towards the de minimis threshold pursuant to the exemption granted by the Secretary of the Treasury. See 77 FR at 69704–05; 77 FR 48253.

⁵⁸ See 83 FR 27449–50; Preliminary Staff Report, *supra* note 19, at 21–22; Final Staff Report, *supra* note 17, at 19.

⁵⁹ As discussed in the Proposal, certain data restrictions limited the usefulness of the SDR data to identify which swaps should be counted towards a person’s de minimis threshold, and the ability to precisely assess the current de minimis threshold or the impact of potential changes to the current exclusions. See 83 FR 27449–50.

Generally employing methodologies similar to those used for purposes of the Staff Reports, staff attempted to calculate persons’ swaps activity in terms of AGNA to assess how the swap market might be impacted by potential changes to the current De Minimis Exception. The reason an entity enters into a swap (e.g., dealing, hedging, investing, proprietary trading) is not collected under the reporting requirements in part 45 of the Commission’s regulations.⁶⁰ Accordingly, staff applied filters to the data to exclude from the analysis certain transactions and entities that were less likely to be connected to potential swap dealing activity. Entities such as funds, insurance companies, cooperatives, government-sponsored entities, most commercial end-users, and international financial institutions were excluded as potential SDs for the purpose of the analysis because these entities generally use swaps for investing, hedging, or proprietary trading, or otherwise enter into swaps that would not be included in determining whether the entity is an SD.⁶¹ Further, additional filters allowed for the exclusion of inter-affiliate⁶² and non-U.S. to non-U.S. swap transactions.⁶³

With the benefits of improved data quality and analytical tools, staff conducted a more granular analysis (as compared to the Staff Reports) to more accurately identify those entities that, based on their observable business activities, were potentially engaging in swap dealing activity (“In-Scope Entities”) ⁶⁴ versus those likely to be engaging in other kinds of transactions (e.g., entering into swaps for investment purposes). Further, for the purposes of the Proposal, a minimum unique counterparty count of 10 counterparties was utilized to better identify the entities that are likely to be engaged in transactions that have to be considered for the SD Definition. Adding this filter to the analysis reduced the likelihood of false positives—*i.e.*, reduced the potential that entities likely engaged in hedging or other non-dealing activity would be identified as potential SDs.⁶⁵

With respect to NFC swaps, Commission staff encountered a number

of challenges in calculating notional amounts, including: (1) The vast array of underlying commodities with differing characteristics; (2) the multiple types of swaps (e.g., fixed-float, basis, options, multi-leg, exotic); (3) the variety of data points required to calculate notional amounts (e.g., price, quantity, quantity units, location, grades, exchange rate); (4) locality-specific terms; and (5) lack of industry standards for notional amount-equivalent calculations.⁶⁶ Given the limitations in the AGNA data, counterparty counts and transaction counts were used as proxies to analyze likely swap dealing activity for participants in the NFC swap market.

The analysis conducted for the Proposal largely confirmed the analysis conducted for the Staff Reports;⁶⁷ however, there is greater confidence in the results given the improved data and refined methodology. Nonetheless, given the lack of a swap dealing indicator for individual swaps, and the lack of an indicator to identify whether a specific swap need not be considered in determining whether a person is an SD or counted towards the person’s AGNA threshold, staff’s analysis was based on a person’s AGNA of swaps activity, as opposed to AGNA of swap dealing activity.

To assess the relative impact on the swap market of potential changes to the De Minimis Exception, CFTC staff analyzed the extent to which the swap market was subject to SD regulation during the review period because at least one counterparty to a swap was a registered SD (“2017 Regulatory Coverage”). Specifically, with regard to 2017 Regulatory Coverage, staff identified the extent to which: (1) Swaps activity, measured in terms of AGNA or transaction count, was subject to SD regulation during the review period because at least one counterparty to a swap was a registered SD (“2017 AGNA Coverage” or “2017 Transaction Coverage,” as applicable); and (2) counterparties in the swap market transacted with at least one registered SD during the review period (“2017 Counterparty Coverage”).

Additionally, staff estimated regulatory coverage by assessing the extent to which the swap market would have been subject to SD regulation at different AGNA thresholds because at least one counterparty to a swap was identified as a “Likely SD” (“Estimated Regulatory Coverage”). For purposes of this analysis, the term “Likely SD”

⁶⁰ See 17 CFR part 45 app.1.

⁶¹ See *supra* section I.A.4 (discussing the de minimis threshold calculation). The Commission notes that the entity-based exclusions and transaction filters are not a determinative means of assessing whether any particular entity is engaged in swap dealing. See also 83 FR 27449 n.73.

⁶² See 17 CFR 1.3, Swap dealer, paragraph (6)(i).

⁶³ See generally 78 FR 45292.

⁶⁴ The majority of In-Scope Entities are banks, broker-dealers, non-bank financial entities, and affiliates thereof.

⁶⁵ See 83 FR 27449.

⁶⁶ See 83 FR 27449–50.

⁶⁷ See generally 83 FR 27449–58; Final Staff Report, *supra* note 19; Preliminary Staff Report, *supra* note 17.

refers to an In-Scope Entity that exceeded a specified AGNA threshold level, and traded with at least 10 unique counterparties. With regard to Estimated Regulatory Coverage, staff identified the extent to which: (1) Swaps activity, measured in terms of AGNA or transaction count, would have been subject to SD regulation during the review period, at a specified AGNA threshold, because at least one counterparty to a swap was identified as a Likely SD at that AGNA threshold (“Estimated AGNA Coverage” or “Estimated Transaction Coverage,” as applicable); and (2) counterparties in the swap market would have transacted with at least one Likely SD during the review period, at a specified AGNA threshold (“Estimated Counterparty Coverage”).

B. Summary of Comments

1. Set Threshold at \$8 Billion

Most commenters that addressed this aspect of the Proposal stated that the AGNA threshold should not decrease to \$3 billion, and/or supported setting the threshold at \$8 billion.⁶⁸ Some of those commenters also stated that the Commission could or should consider a higher threshold, as discussed in more detail in section II.B.2 below.⁶⁹ Commenters generally stated that the policy goals for SD registration—reducing systemic risk, increasing counterparty protections, and/or increasing market efficiency, orderliness, and transparency—and the policy goals for a de minimis exception—increasing efficiency, allowing limited ancillary dealing, encouraging new participants, and/or focusing regulatory resources—would be better advanced if the threshold did not decrease to \$3 billion.⁷⁰

⁶⁸ See ABA, AGA, AFEX/GPS, BDA, Capital One, Cboe SEF, Citizens, CDEU, COPE, CEWG, CMC, EEI/EPISA, FXPA, Frost Bank, FIA, IIB, IECA, ISDA/SIFMA, JBA, M&T, NCFC, NRECA/APPA, NGSA, Regions, SVB, Virtu, Western Union, and XTX comment letters.

⁶⁹ See ABA, AFEX/GPS, BDA, Capital One, Citizens, FIA, IIB, IECA, JBA, Regions, and SVB comment letters.

⁷⁰ Additionally, CDEU and CEWG referenced the Congressional Directive stating that the Commission should establish a threshold of \$8 billion or greater within 60 days of enactment of the Appropriations Act (*i.e.*, by February 16, 2016), while CEWG also cited to the recent recommendation from the U.S. Department of the Treasury to set the threshold at \$8 billion. See CDEU and CEWG comment letters; Accompanying Statement to the Consolidated Appropriations Act of 2016, Explanatory Statement Division A at 32 (Dec. 2015), available at <http://docs.house.gov/meetings/RU/RU00/20151216/104298/HMTG-114-RU00-20151216-SD002.pdf>; H. Rpt. 114–205 at 76 (July 14, 2015), available at <https://www.congress.gov/114/crpt/hrpt205/CRPT-114hrpt205.pdf>; U.S. Department of the Treasury, A Financial System That Creates Economic

Specifically, commenters stated that a reduced AGNA threshold could lead to some entities reducing or ceasing swaps activity to avoid registration and its related costs, which could lead to negative impacts for swap market participants. For example, fewer de minimis dealers could mean that small and mid-sized end-users and commercial entities who utilize swaps for hedging purposes, as well as NFC swap market participants, would have fewer dealers available to them.⁷¹ The potential negative impacts could include: (1) Increased concentration in the swap dealing market; (2) reduced availability of potential swap counterparties; (3) reduced liquidity; (4) increased volatility; (5) increased systemic risk; and/or (6) higher fees or reduced competitive pricing.⁷²

Several commenters also noted that the current \$8 billion threshold already subjects the vast majority of transactions to SD regulation, or that a reduced threshold would not capture significant additional dealing activity.⁷³

Some commenters stated that the nature of the swaps activity entered into by certain entities poses less systemic risk—*e.g.*, commercial banks that have swap dealing activity below \$8 billion and may be subject to prudential banking rules, and entities that primarily enter into NFC swaps.⁷⁴ More specifically, Citizens noted that prudential regulators examine the safety and soundness of middle-market banks’ swap businesses, and the swaps offered by these banks are structured conservatively to assist customers with hedging activities. Further, with respect to counterparty protections, Citizens stated that many middle-market banks that would potentially have to register at a lower threshold likely already perform, under applicable prudential banking rules, know-your-counterparty and suitability analyses of their counterparties prior to entering into swaps with them.⁷⁵

Several commenters stated that maintaining the \$8 billion threshold provides regulatory stability or

Opportunities—Capital Markets (available at <https://www.treasury.gov/press-center/press-releases/Documents/A-Financial-System-Capital-Markets-FINAL-FINAL.pdf>).

⁷¹ See ABA, AGA, AFEX/GPS, BDA, Capital One, Citizens, CDEU, COPE, CEWG, CMC, EEI/EPISA, Frost Bank, IIB, IECA, ISDA/SIFMA, JBA, M&T, NCFC, NRECA/APPA, NGSA, SVB, and Western Union comment letters.

⁷² See *id.*

⁷³ See ABA, BDA, Capital One, CDEU, CMC, Frost Bank, IECA, M&T, SVB, and Western Union comment letters.

⁷⁴ See Citizens, IECA, NRECA/APPA, NGSA, and SVB comment letters.

⁷⁵ See Citizens comment letter.

alleviates the uncertainty currently experienced by market participants with an AGNA of swap dealing activity between \$3 billion and \$8 billion.⁷⁶

Some commenters suggested that maintaining the \$8 billion threshold would enable the Commission to focus its limited resources on entities whose swap dealing is sufficient in size and scope to warrant oversight.⁷⁷ Two commenters also noted that Commission regulations not related to SD registration (*e.g.*, part 43 and 45 reporting requirements, and mandatory clearing and swap execution facility (“SEF”) trading requirements) already apply to unregistered entities, and therefore, many of the policy goals of SD registration are already being advanced with respect to swaps entered into by these unregistered entities.⁷⁸

With respect to NFC swaps, EEI/EPISA and NGSA expressed concern that a lower AGNA threshold would provide less accommodation for increasing NFC prices, which could lead to market participants reducing their swap dealing activity to remain below the threshold.⁷⁹ To address concerns regarding volatility in NFC prices, EEI/EPISA also suggested that the AGNA threshold be adjusted annually, consistent with the consumer price index.⁸⁰ NGSA also stated that the lower regulatory coverage for NFC swaps is appropriate given the characteristics of that market.⁸¹

A few commenters addressed the compliance costs associated with SD registration,⁸² stating that: (1) Establishing an \$8 billion threshold results in aggregate recurring compliance costs over a 10-year period, on a net present value basis, of approximately \$373 million;⁸³ and (2) the cost of SD registration (*e.g.*, systems build-out, external advisors, National Futures Association membership dues, compliance with margin rules) is underestimated,⁸⁴ with one commenter

⁷⁶ See AFEX/GPS, Capital One, COPE, EEI/EPISA, FXPA, FIA, IECA, ISDA/SIFMA, JBA, M&T, NGSA, and Regions comment letters.

⁷⁷ See Citizens, Virtu, and Western Union comment letters.

⁷⁸ See Citizens and Virtu comment letters.

⁷⁹ See EEI/EPISA and NGSA comment letters. As stated by EEI/EPISA, if NFC prices increase, the same level of swaps activity will potentially have a higher notional amount.

⁸⁰ See EEI/EPISA comment letter.

⁸¹ See NGSA comment letter.

⁸² See ABA, IECA, and SVB comment letters. Although addressed by ABA and SVB, the costs associated with SD regulatory requirements (*e.g.*, margin, reporting, technology, etc.) are not considered in the cost-benefit analysis below. See *infra* notes 249 and 286.

⁸³ See ABA comment letter.

⁸⁴ See IECA and SVB comment letters. Although outside of the scope of this rulemaking, IECA also

estimating that the initial cost would be approximately \$8 to \$10 million per entity, with ongoing costs to meet regulatory requirements of \$2 million per year thereafter.⁸⁵

BDA stated that the CFTC should clarify whether changes to the De Minimis Exception would be applicable to activity that occurred in the preceding 12 months.⁸⁶

2. Increase Threshold

Some commenters stated that the Commission should also consider a higher AGNA threshold, maintaining generally that the policy goals for SD registration and a de minimis exception would be better advanced if the threshold was higher than \$8 billion.⁸⁷

Specifically, several commenters stated that an increased threshold would not lead to a significant decrease in regulatory coverage of swap dealing activity.⁸⁸ ABA and AFEX/GPS asserted that a \$20 billion threshold would result in a trivial or non-consequential reduction in Estimated Regulatory Coverage,⁸⁹ and JBA stated that at a \$100 billion threshold, Estimated AGNA Coverage would be almost the same.⁹⁰ AFEX/GPS also asserted that the cumulative swaps activity conducted by SDs between \$8 billion and \$20 billion does not pose systemic risk, and entities would still be subject to reporting rules and recordkeeping requirements.⁹¹ Additionally, AFEX/GPS and Citizens asserted that a decrease in the number of registered SDs would focus the Commission's resources on SDs whose dealing activity is sufficient in size and scope to warrant greater oversight.⁹²

Further, a few commenters stated that given the costs of SD registration, a higher threshold would encourage new participants to engage in swap dealing activity, which SVB noted as important given the highly concentrated nature of the SD market, where the nation's largest banks control the vast majority of swap market share.⁹³

Additionally, ABA indicated that an increased threshold would result in

asserted that the Commission underestimates the negative impact on market development due to its failure to provide a workable capital rule for non-bank SDs.

⁸⁵ See SVB comment letter.

⁸⁶ See BDA comment letter.

⁸⁷ See ABA, AFEX/GPS, BDA, Capital One, Citizens, FIA, IIB, IECA, JBA, Regions, and SVB comment letters.

⁸⁸ See ABA, AFEX/GPS, BDA, Citizens, IIB, and SVB comment letters.

⁸⁹ See ABA and AFEX/GPS comment letters.

⁹⁰ See JBA comment letter.

⁹¹ See AFEX/GPS comment letter.

⁹² See AFEX/GPS and Citizens comment letters.

⁹³ See AFEX/GPS, BDA, Citizens, and SVB comment letters.

aggregate compliance cost savings for market participants. For example, AGNA thresholds of \$15 billion and \$50 billion would result in potential aggregate savings of \$81 million and \$170 million, respectively, on a net present value basis, as compared to an \$8 billion threshold.⁹⁴

3. Allow Threshold to Decrease

Better Markets and the Senators stated that the Commission should permit the AGNA threshold to decrease to \$3 billion, contending generally that the data insufficiently or misleadingly justifies maintaining the threshold at \$8 billion,⁹⁵ and arguing that the Proposal did not follow necessary administrative procedures or exceeded statutory authority.⁹⁶

The Senators stated that though notional amount data for NFC swaps was not used in considering the Proposal, the data that was available for NFC swaps shows significantly less regulatory coverage under an \$8 billion threshold than in other asset classes. The Senators commented that though the Proposal notes the "unique characteristics" of NFC swaps, the analysis provided to justify the \$8 billion threshold indicates a series of assumptions and possibilities rather than concrete data. The Senators also questioned why, given the lack of relevant notional amount data for NFC swaps, it is necessary to maintain the \$8 billion threshold for SDs involved with energy-related swaps.⁹⁷

Better Markets claimed that the regulatory coverage statistics are incomplete, misleading, and irrelevant to the Dodd-Frank Act's activities-based standard for SD registration, stating that the high AGNA and transaction coverage percentages are not indicative of the absolute level of swap dealing activities relevant to SD registration under CEA section 1a(49)(A). Further, in connection with the 680 additional counterparties that would potentially benefit from SD regulations under a lower \$3 billion threshold, Better Markets asserted that expanding counterparty protections to hundreds of market participants would have more than a "limited" effect on counterparty protection once relative statistics are abandoned.⁹⁸

Better Markets also asserted that the data filtering methodology was flawed and inadequately explained. Better

⁹⁴ See ABA comment letter.

⁹⁵ See Better Markets and Senators comment letters.

⁹⁶ See Better Markets comment letter.

⁹⁷ See Senators comment letter.

⁹⁸ See Better Markets comment letter.

Markets explained that, with respect to the 10 counterparty count filter, if a commodities affiliate of a large firm held itself out as an SD or stood ready to accommodate the demand of nine counterparties, that affiliate should have been treated, for purposes of the analysis, as an SD on account of its swap dealing activities, unless those activities did not exceed the AGNA threshold or otherwise were excluded from the SD registration analysis. Further, Better Markets argued that: (1) The CFTC should have provided an opportunity for public comment on the assumptions that were made in the CFTC's analysis; (2) there was some ambiguity in the terms used in the CFTC's analysis; (3) the CFTC's reliance upon a 10 unique counterparty filter was based on fatally flawed logic; (4) the data limitations demonstrate the benefits of better field-level and affiliate reporting of swaps, which would give the CFTC an informed basis to consider changes to the \$3 billion threshold; and (5) the CFTC must first amend its swap data and chief compliance officer reporting regulations to ensure it has sufficient data to provide an informed basis for administrative action.⁹⁹

Further, Better Markets commented that the de minimis threshold framework should be revised to focus on strict, observable measures like total notional amount or transactional activities, rather than a subset of such activities that potential registrants are able to interpret for themselves, and are not presently required by regulation to monitor, report, or internally track across the firm.¹⁰⁰

Better Markets also asserted that the statutory provision regarding the de minimis exception authorizes the CFTC to issue exemptive orders for individual or similarly-situated legal entities based upon generally applicable factors for determining whether such entities may be involved in a de minimis amount of swap dealing activities. Better Markets noted that it is unreasonable to conclude that Congress intended a wholesale exemption from registration that is divorced from the particular circumstances of any one petitioner. Further, Better Markets argued that the language in the exemptive mandate must be construed in a manner that is faithful to Congress' intent that the quantity of exempted swap dealing activities be minimal, a concept that has boundaries that can be drawn far short of billions of dollars and thousands of transactions by unregulated entities.¹⁰¹

⁹⁹ See *id.*

¹⁰⁰ See *id.*

¹⁰¹ See *id.*

AFR stated that, though the improved data adds weight to the claim that an \$8 billion threshold is appropriate for some financial swaps, arguments against the \$8 billion threshold are particularly strong in the case of NFC markets. Specifically, AFR asserted that the Commission should be willing to vary the de minimis threshold based on market characteristics, and in particular should reduce the \$8 billion threshold in NFC markets where \$8 billion in notional amount represents a different level of economic significance than in some other markets. AFR elaborated that the Commission continues to lack data on the notional amount for NFC swaps, making it difficult to draw definitive conclusions on the economic significance of the activity that is not subject to SD regulation, and stated that significant dealing activity in the NFC market is not subject to SD regulation since roughly half of all the entities with 10 or more NFC swap counterparties are not registered as SDs.¹⁰²

AFR also stated that the AGNA threshold analysis does not account for the numerous other exceptions proposed, which could exclude very large amounts of swaps activity from being considered in the de minimis calculation.¹⁰³

IATP stated that the data analysis does not support the idea that more ancillary dealing would promote greater competition, and thus more efficient and transparent price discovery. IATP asserted that the Commission's true motivation for maintaining an \$8 billion threshold is the regulatory compliance cost and burden reduction objective of Project KISS, rather than promoting improved price discovery. Further, IATP claimed that the AGNA of activity in the swap market has shrunk due to the clearing of swaps on centralized platforms and the migration of swaps to the futures markets, not because of constraints of the de minimis threshold or because of the lack of exemptions to the calculation of that threshold. IATP also stated that though it did not have a data-based argument for changing the \$8 billion threshold, it believed that maintaining the \$8 billion threshold because of potential administrative burdens involved in lowering the threshold is a poor, Project KISS-based, rationale that does not consider the benefits of SD registration for the financial integrity and price discovery of the swap market.¹⁰⁴

¹⁰² See AFR comment letter.

¹⁰³ See *id.*

¹⁰⁴ See IATP comment letter.

4. Other Comments

(i) Testing Frequency for Threshold

Some commenters addressed the testing frequency for the threshold. Commenters stated that the AGNA threshold calculation should continue to be based primarily on a rolling 12-month test of the AGNA of swap dealing activity.¹⁰⁵ Specifically, commenters indicated that: (1) Resources have been spent and systems have been built to comply with the current approach, and additional changes would add costs with no tangible benefit;¹⁰⁶ and (2) the current test is relatively simple to administer, and the 12-month testing period helps to smooth out any short-term aberrations in activity and allows for moderation of future swap dealing activity to avoid inadvertently triggering an SD registration requirement.¹⁰⁷ However, BDA stated that the CFTC should allow entities to test only at the end of every month, which would significantly reduce the compliance testing burdens for small and mid-sized firms.¹⁰⁸

(ii) Alternatives to Single AGNA Threshold

A number of commenters addressed whether the Commission should consider an alternative to a threshold based on the AGNA of swap dealing activity.

AFR and IECA noted that using AGNA as the relevant criterion for SD registration, as compared to other options, is beneficial because: (1) Resources have been expended to comply with the current approach, and changing that approach would add costs for no perceived benefit;¹⁰⁹ and (2) AGNA provides a stable metric of the gross size of swaps commitments that is not reliant on either current market valuations, model forecasts, or institutional arrangements such as bankruptcy procedures.¹¹⁰

AFR stated that controlling operational risk, not simply market risk, is a major reason for SD designation, and AGNA remains a good measure of the total operational risks incurred by an entity,¹¹¹ and Better Markets maintained that the de minimis exception must require consideration of the quantity of swap dealing, not net

¹⁰⁵ See ABA, CMC, Frost Bank, and IECA comment letters.

¹⁰⁶ See ABA, CMC, and IECA comment letters.

¹⁰⁷ See Frost Bank comment letter.

¹⁰⁸ See BDA comment letter.

¹⁰⁹ See IECA comment letter.

¹¹⁰ See AFR comment letter.

¹¹¹ See *id.*

exposures or other risk-based measures.¹¹²

However, IECA indicated that although using an alternative netting option (e.g., entity-netted notional amounts) is a reasonable idea and could be incorporated into existing analysis, in the NFC markets, netting would need to be done as a measure of credit exposure with physical and bilateral swaps being able to be offset against each other in connection with perceived "risk exposure" to a third party.¹¹³ Additionally, ABA and Citizens stated that the Commission should consider a risk-based de minimis exception.¹¹⁴ ABA asserted that a notional amount-based threshold is not the appropriate metric for the De Minimis Exception because it is not based on risk, and suggested that the Commission consider initial margin as the relevant metric.¹¹⁵

Commenters also stated that a tiered SD registration structure should not be considered, noting that a tiered structure could: (1) Create more uncertainty for situations where legal and regulatory certainty is important;¹¹⁶ and (2) subject entities to instability and inefficiency relative to a permanent, single AGNA de minimis threshold.¹¹⁷ On the other hand, IATP asserted that the Commission should propose, after further analytic work, a tiered SD registration for SDs with a certain threshold of NFC swaps activity (e.g., via commodity indexes).¹¹⁸

Several commenters also addressed whether the Commission should consider counterparty count and transaction count as additional metrics to be included in the de minimis threshold, as discussed in section IV.A below.

(iii) Additional Calculation Changes

Commenters addressed other calculation changes the Commission should consider for the de minimis threshold.

Virtu stated that the CFTC should exempt swap transactions where one party is a registered SD or one party holds their account with a registered SD since these transactions are already subject to the existing reporting

¹¹² See Better Markets comment letter.

¹¹³ See IECA comment letter.

¹¹⁴ See ABA and Citizens comment letters.

¹¹⁵ See ABA comment letter. ABA also suggested that the Commission could consider other market risk metrics, such as value at risk and sensitivities, as well as credit risk metrics, such as total swaps current exposure net of collateral received and largest fifteen swap counterparty current exposures net of collateral received.

¹¹⁶ See IECA comment letter.

¹¹⁷ See JBA comment letter.

¹¹⁸ See IATP comment letter.

requirements and, as such, Commission oversight.¹¹⁹

JBA stated that the CFTC should specify that the termination and modification of terms and conditions of existing transactions do not count towards the threshold, noting that termination of transactions mitigates counterparty credit risk and reduces the outstanding AGNA of swaps.¹²⁰

BDA argued that the CFTC should consider increasing the “special entity” threshold to \$100 million in order to provide special entities with more access to the marketplace. BDA maintained that the \$25 million threshold results in many mid-sized firms deciding not to enter into swaps with special entities, while an increase in that threshold could provide better market access for special entities while having no material impact on the overall regulation of SDs.¹²¹

Virtu asserted that transactions by market makers maintaining net open positions not exceeding \$1 billion (over a 12-month period) should be exempted from the de minimis threshold calculation.¹²² Virtu explained that certain market makers do not hold positions or carry risk for long periods of time, but rather seek to facilitate efficient risk transference to earn a spread and, in doing so, lower costs for investors through increased price competition and more transparency in the market.

IIB stated that entities that have discontinued new swap dealing activity should not have to count towards their AGNA threshold certain transactions that modify legacy swaps entered into by those entities, including: (1) Partial or full terminations; (2) modifications that shorten the duration of an outstanding swap; (3) partial or full novations of legacy swap transactions; or (4) swaps submitted for clearing.¹²³

(iv) Cross-Border Issues

With respect to cross-border issues, JBA stated that the market has been divided into two groups because non-SD entities outside of the U.S. avoid

transactions with U.S. persons, thereby undermining the diversity of U.S. markets.¹²⁴ Additionally, Western Union suggested that the Commission should also address the foreign consolidated subsidiary rules in the context of the De Minimis Exception rulemaking.¹²⁵ Further, IIB stated that the Commission should clarify that a swap between a non-U.S. person and a non-U.S. asset manager that is subject to post-trade allocation and submitted for clearing, or given up to a non-U.S. prime broker prior to being allocated, should not count towards the AGNA threshold in certain circumstances.¹²⁶

C. Final Rule and Commission Response

Upon consideration of the comments,¹²⁷ the Commission is adopting an amendment to paragraph (4)(i)(A) of the De Minimis Exception to set the AGNA swap dealing threshold at \$8 billion over the immediately preceding 12 months, as proposed. The Commission is also adopting the other conforming and clarifying changes as proposed.

1. Rationale for Not Reducing AGNA Threshold to \$3 Billion

As discussed in the Proposal,¹²⁸ as well as by most commenters that addressed this aspect of the Proposal,¹²⁹ the policy objectives underlying SD regulation—reducing systemic risk, increasing counterparty protections, and increasing market efficiency, orderliness, and transparency—would not be significantly advanced if the threshold decreased to \$3 billion. Additionally, the policy objectives furthered by a de minimis exception—increasing efficiency, allowing limited ancillary dealing, encouraging new participants, and focusing regulatory resources—would not be significantly advanced, and may be impaired to some extent, if the threshold decreased. Generally, as discussed in the Proposal

and as agreed with by most commenters, analysis of the data indicated that: (1) The current \$8 billion threshold subjects almost all swap transactions (as measured by AGNA or transaction count) to SD regulations; (2) at a lower threshold of \$3 billion, there would only be a small amount of additional AGNA and swap transactions subject to SD regulation, and there would potentially be reduced liquidity in the swap market, as compared to the \$8 billion threshold; and (3) a lower threshold could lead to reduced liquidity for NFC swaps, negatively impacting end-users who utilize NFC swaps for hedging purposes.¹³⁰

(i) High Regulatory Coverage at \$8 Billion Threshold

During the review period, almost all swap transactions involved at least one registered SD as a counterparty—greater than 99 percent for IRS, CDS, FX swaps, and equity swaps. For NFC swaps, approximately 86 percent of transactions involved at least one registered SD as a counterparty. Overall, approximately 98 percent of transactions involved at least one registered SD. Further, almost all AGNA of swaps activity included at least one registered SD—greater than 99 percent for IRS, CDS, FX swaps, and equity swaps. The Commission notes that the 2017 Counterparty Coverage was approximately 83.5 percent—*i.e.*, approximately 16.5 percent of the counterparties in the swap market did not transact with at least one registered SD on at least one swap (6,440 counterparties out of a total of 39,107), and therefore potentially did not benefit from the counterparty protection aspects of SD regulations.¹³¹ However, given the 2017 AGNA Coverage and 2017 Transaction Coverage statistics, these 6,440 entities had limited overall swaps activity. Accordingly, to the extent these 6,440 entities were engaged in swap dealing activities, such activity was likely ancillary and in connection with other client services, potentially advancing the policy rationales behind a de minimis exception. This data signifies that nearly all swaps already benefited from the policy considerations discussed above (*e.g.*, reducing systemic

¹¹⁹ See Virtu comment letter.

¹²⁰ See JBA comment letter.

¹²¹ See BDA comment letter.

¹²² See Virtu comment letter. Virtu noted that, while in aggregate the number of transactions engaged in by market makers might exceed the \$8 billion threshold, the net risk of these trades would not have the same potential impact to overall systemic risk because exempt market makers' open net positions in otherwise non-exempt transactions would be capped at \$1 billion over a rolling 12-month period. Additionally, certain market makers access the market through prime brokers—who are registered SDs—and, as such, these transactions would be included in the prime brokers' regulatory reports and subject to CFTC oversight.

¹²³ See IIB comment letter.

¹²⁴ See JBA comment letter.

¹²⁵ See Western Union comment letter (referring to Cross-Border Application of the Registration Thresholds and External Business Conduct Standards Applicable to Swap Dealers and Major Swap Participants, 81 FR 71946 (proposed Oct. 18, 2016)). Western Union also stated that the proposed application of the foreign consolidated subsidiary definition to SD registration is inconsistent with principles of international comity and would create an unfair competitive disadvantage for certain market participants.

¹²⁶ See IIB comment letter.

¹²⁷ The Commission also notes that the data analysis discussed in this adopting release and the Proposal confirmed the analysis conducted for the Staff Reports. See generally 83 FR 27449–58; Final Staff Report, *supra* note 19; Preliminary Staff Report, *supra* note 17.

¹²⁸ See generally 83 FR 27450–58.

¹²⁹ See *supra* section II.B.1.

¹³⁰ See generally *supra* section II.B.1; 83 FR 27450–58. See also Final Staff Report, *supra* note 19; Preliminary Staff Report, *supra* note 17.

¹³¹ The actual number of entities without a single transaction with a registered SD was likely lower than 6,440. Of the 6,440 entities, 1,780 had invalid identifiers that staff was unable to manually replace with a valid LEI. It is possible that these 1,780 invalid identifiers actually represented fewer than 1,780 distinct counterparties because one counterparty may be associated with multiple invalid identifiers. See 83 FR 27451.

risk, increasing counterparty protections, and increasing market efficiency, orderliness, and transparency) at the existing \$8 billion threshold.¹³²

(ii) Minimal Additional Regulatory Coverage at Lower Threshold

Given the high percentage of swaps that were subject to SD regulation at the existing \$8 billion threshold during the review period, a lower threshold of \$3 billion would result in only a small amount of additional activity being directly subjected to SD regulation. Specifically, the Estimated AGNA Coverage would have increased from approximately \$221,020 billion (99.95 percent) to \$221,039 billion (99.96 percent)—an increase of \$19 billion (a 0.01 percentage point increase). The Estimated Transaction Coverage would have increased from 3,795,330 trades (99.77 percent) to 3,797,734 trades (99.83 percent)—an increase of 2,404 trades (a 0.06 percentage point increase). The Estimated Counterparty Coverage would have increased from 30,879 counterparties (88.80 percent) to 31,559 counterparties (90.75 percent)—an increase of 680 counterparties (a 1.96 percentage point increase). These small increases in Estimated Regulatory Coverage indicate that the systemic risk mitigation, counterparty protection, and market efficiency benefits of SD regulation would be enhanced in only a very limited manner if the threshold decreased from \$8 billion to \$3 billion. Additionally, the limited regulatory and market benefits of a \$3 billion threshold should be considered in conjunction with the costs associated with a lower threshold (e.g., costs of implementing policies and procedures, technology systems, and training programs to address requirements imposed by SD regulations).¹³³

Additionally, as discussed by the Commission and most commenters, a \$3 billion AGNA threshold could lead certain entities to reduce or cease swap dealing activity to avoid registration and its related costs.¹³⁴ Generally, the costs associated with registering as an SD may exceed the profits from dealing swaps for entities with limited dealing activities. This could lead to negative impacts for swap market participants,

including, but not limited to, small and mid-sized end-users who use swaps for hedging purposes. Reduced swap dealing activity could lead to increased concentration in the swap dealing market, reduced availability of potential swap counterparties, reduced liquidity, increased volatility, increased systemic risk, and/or higher fees or reduced competitive pricing. The end-user counterparties of these smaller swap dealing entities may be adversely impacted by the above consequences and could face a reduced ability to use swaps to manage their business risks.¹³⁵ Additionally, as noted by some commenters, the nature of the swaps activity entered into by certain entities poses less systemic risk—e.g., commercial banks that have swap dealing activity below \$8 billion and entities that primarily enter into NFC swaps.¹³⁶

Further, although approximately 86 percent of NFC swaps involved at least one registered SD compared to approximately 99 percent for other asset classes, as discussed in the Proposal, the Commission is of the view that lower SD regulatory coverage is acceptable given the special characteristics of the NFC swap market. A reduced threshold likely would have negative impacts on NFC swap liquidity as some entities (e.g., small and mid-sized banks and/or non-financial entities) reduce dealing to avoid registration and its related costs. This would be detrimental to the end-users who do not have trading relationships with larger, financial-entity SDs, and who rely on small to mid-sized banks and/or non-financial entities to access liquidity in the wider swap market. Additionally, even if the threshold decreased, the available data leaves it unclear if or to what extent the 2017 Counterparty Coverage statistic of 86 percent would increase for NFC swaps since several of those entities may already have less than \$3 billion in AGNA of swap dealing activity. Further, many of the entities engaged in limited swap dealing activity for NFC swaps appear to have a specialized role in the market, in that their primary business is generally non-financial in nature and the swap dealing activity is ancillary to their primary role in the market.¹³⁷ Finally, entities that are active in the NFC swap market may utilize the existing physical position hedging

exemption, which is more directly applicable to the NFC asset class than to other swaps.¹³⁸

(iii) Response to Commenters Advocating Lower Threshold

The Commission disagrees with the few commenters that stated that the AGNA threshold should decrease to \$3 billion.¹³⁹

Better Markets stated that the high regulatory coverage ratios are not indicative of the absolute level of swap dealing activities relevant to SD registration, and asserted that maintaining an \$8 billion threshold would have more than a limited detrimental effect on counterparty protections.¹⁴⁰ The Commission notes that the statutory requirements do not dictate a specific methodology for assessing the de minimis exception, such as the focus on the absolute level of swap dealing suggested by Better Markets. Rather, the CEA requires the Commission to promulgate regulations to establish factors with respect to the making of a determination to exempt from designation as an SD an entity engaged in a de minimis quantity of swap dealing, without stating additional requirements.¹⁴¹

Additionally, as stated in the SD Definition Proposing Release and the SD Definition Adopting Release, the de minimis exception “should be interpreted to address amounts of dealing activity that are sufficiently small that they do not warrant registration to address concerns implicated by the regulations governing swap dealers and security-based swap dealers. In other words, the exception should apply only when an entity’s dealing activity is so minimal that applying dealer regulations to the entity would not be warranted.”¹⁴² This decision inherently requires judgment, and for that reason the Commission has considered whether entities that have less than \$8 billion in swap dealing activity meet this standard. Given the nature of the swap market and the Commission’s analysis of the data, requiring an entity that has less than \$8 billion in swap dealing activity to register as an SD is not warranted because it would not appreciably impact the systemic risk, counterparty protection, and market efficiency considerations of SD regulation, but

¹³² This analysis is discussed in greater detail in the Proposal, and was also addressed by commenters. See *supra* section II.B.1; 83 FR 27450–52.

¹³³ This analysis is discussed in greater detail in the Proposal, and was also addressed by commenters. See *supra* section II.B.1; 83 FR 27452–54.

¹³⁴ See *supra* section II.B.1; 83 FR 27452–54. See also Final Staff Report, *supra* note 19.

¹³⁵ See *supra* section II.B.1; 83 FR 27452–54.

¹³⁶ See *supra* section II.B.1; Citizens, IECA, NRECA/APPA, NGA, and SVB comment letters.

¹³⁷ This analysis is discussed in greater detail in the Proposal, and was also addressed by commenters. See *supra* section II.B.1; 83 FR 27452–57. See also CMC, IECA, and NGA comment letters.

¹³⁸ See 17 CFR 1.3, Swap dealer, paragraph (6)(iii); 83 FR 27456–57.

¹³⁹ See *supra* section II.B.3.

¹⁴⁰ See *supra* section II.B.3; Better Markets comment letter.

¹⁴¹ 7 U.S.C. 1a(49)(D).

¹⁴² SD Definition Adopting Release, 77 FR 30626; SD Definition Proposing Release, 75 FR 80179.

would negatively impact the policy considerations underlying the de minimis exception by reducing the amount of swap dealing allowed under the exception.¹⁴³ Thus, the Commission concludes that the \$8 billion threshold is consistent with a key rationale behind the de minimis exception because it would permit “amounts of dealing activity that are sufficiently small that they do not warrant registration.”¹⁴⁴ No individual policy factor was dispositive in the Commission’s analysis. Rather, the Commission considered all of the policy factors when assessing the regulatory coverage ratios.¹⁴⁵

As noted above in section II.B.3, Better Markets also asserted that the statutory provision regarding the de minimis exception authorizes the CFTC to issue exemptive orders for individual or similarly-situated legal entities based upon generally applicable factors for determining whether such entities may be involved in de minimis swap dealing activities. Better Markets contends that it is unreasonable to conclude that Congress intended a wholesale exemption from registration that is divorced from the particular circumstances of any one petitioner.¹⁴⁶ As noted, however, the CEA states that the Commission shall promulgate factors, through regulation, regarding the De Minimis Exception determination. Nothing in the statutory language prohibits the Commission from establishing a de minimis exception that is self-effectuating. The Commission believes that the \$8 billion threshold appropriately excludes entities “whose dealing activity is sufficiently modest in light of the total size, concentration and other attributes” of the swap market and for which SD regulation “would not be expected to contribute significantly to advancing the customer protection, market efficiency and transparency objectives of dealer regulation.”¹⁴⁷ The Commission sees no basis in the record or requirement in the statute to treat entities differently when they are similarly situated in this respect.

¹⁴³ As discussed, the analysis conducted in connection with the Proposal was consistent with the analysis conducted in connection with the Staff Reports. See generally 83 FR 27449–58; Final Staff Report, *supra* note 19; Preliminary Staff Report, *supra* note 17.

¹⁴⁴ 77 FR 30626. See also 75 FR 80179.

¹⁴⁵ As noted in the SD Definition Adopting Release, “implementing the de minimis exception requires a careful balancing that considers the regulatory interests that could be undermined by an unduly broad exception as well as those regulatory interests that may be promoted by an appropriately limited exception.” 77 FR 30628.

¹⁴⁶ See Better Markets comment letter.

¹⁴⁷ 77 FR 30629–30.

Also as noted above, with respect to the data analysis methodology, Better Markets and the Senators stated that the data insufficiently or misleadingly justifies maintaining the threshold at \$8 billion.¹⁴⁸ Better Markets also asserted that: (1) The CFTC should have provided an opportunity for public comment on alternative assumptions; (2) there is some ambiguity in the terms used in the CFTC’s analysis; (3) the CFTC’s reliance upon a 10 unique counterparty filter is based on fatally flawed logic; (4) the data limitations argue for better field-level and affiliate reporting of swaps, which would give the CFTC an informed basis to consider changes to a \$3 billion threshold; and (5) the CFTC must first amend its swap data and chief compliance officer reporting regulations to ensure it has sufficient data to provide an informed basis for administrative action.¹⁴⁹ Each of these comments will be addressed in turn.

First, with respect to Better Markets’ comment that the Commission should have provided an opportunity for public comment on alternative assumptions for the data analysis, the Commission notes that the methodology used by Commission staff to analyze data in relation to the de minimis threshold was first laid out in the Preliminary Staff Report, on which the public had the opportunity to comment. The Final Staff Report updated that analysis, and then the Proposal explained how the data related specifically to the proposal to maintain the \$8 billion threshold. As discussed in the Proposal, the updated analysis largely confirmed the analysis conducted for the Staff Reports. However, there is greater confidence in the results given the improved data and refined methodology. The Commission believes that the public has had an appropriate opportunity to comment on the data, the methodology, the assumptions about the data, and how the data relates to the maintenance of the \$8 billion threshold.

Second, the Commission cannot assess Better Markets’ comment that the analysis discussed in the Proposal contained ambiguous terms because Better Markets does not state which terms were ambiguous.

Third, the Commission disagrees with Better Markets’ comment that “the fact that CFTC-registered swap dealers, including every major Wall Street bank, tend to have more than 10

counterparties is irrelevant.”¹⁵⁰ The Commission notes that staff used the minimum 10 counterparty count only for analytical purposes, as a heuristic to help isolate those entities that appeared to be dealing. Lacking a dealing field in the data, for the reasons set forth above, staff selected a minimum of 10 counterparties as a conservative estimate to improve the analysis and better identify entities likely engaged in swap dealing.¹⁵¹

The Commission also believes that the 10 counterparty filter is appropriate for purposes of this analysis based on its observations of registered SDs and unregistered entities active in the swap market. As noted in the Proposal, data analysis showed that 83 percent of registered SDs had 10 or more counterparties, without weighting the results.¹⁵² In other words, since the analysis was performed using a non-weighted ranking, SDs with thousands of counterparties did not bias the results.

Fourth, the Commission does not believe that the data limitations warrant a delay in setting the threshold at \$8 billion. As discussed, the data has improved since the analysis in the Staff Reports. Further, the Commission believes its analysis was appropriately conservative, particularly given that the volume of activity it analyzed was over-inclusive (since hedging and other non-dealing activity could not be excluded), and given that its entity-level exclusions were based on an informed assessment of the likely activity of swap market participants.

In the SD Definition Adopting Release, the Commission noted that “comprehensive information regarding the total size of the domestic swap market is incomplete, with more information available with respect to certain asset classes than others.”¹⁵³ In 2012, the Commission evaluated the appropriateness of the initial \$3 billion AGNA threshold using three primary sources of data: (1) Index CDS; (2) the Quarterly Report on Bank Trading and Derivatives Activities issued by the Office of the Comptroller of the Currency (“OCC”); and (3) public comments to the 2010 SD Definition Proposing Release.¹⁵⁴ At the time, granular, transaction-level swaps data across all swap asset classes was not yet available for review by the Commission. The data now available is significantly more detailed than what was available

¹⁵⁰ See Better Markets comment letter.

¹⁵¹ See *supra* section II.A.; 83 FR 27449–50.

¹⁵² See 83 FR 27449.

¹⁵³ 77 FR 30632.

¹⁵⁴ *Id.* at 30632–33.

¹⁴⁸ See *supra* section II.B.3; Better Markets and Senators comment letters.

¹⁴⁹ See *supra* section II.B.3; Better Markets comment letter.

to the Commission when the \$3 billion threshold was originally established. The data now includes details such as counterparty pairs, product identifiers, transaction-level data for those market participants active in more asset classes than only index CDS, and transaction-level data (not just quarterly position data) involving market participants beyond banks subject to OCC reporting. In light of the additional, more detailed data, the Commission believes that the \$8 billion threshold continues to be appropriately calibrated to the policy goals of SD registration and the de minimis exception.¹⁵⁵

Fifth, for similar reasons, the Commission does not believe it should wait to amend its swap data and chief compliance officer reporting regulations before setting the threshold at \$8 billion. As noted above, the Commission believes that it does have sufficient data to support this action, so it is not necessary to wait for future changes to the data reporting regime.¹⁵⁶

As noted above, Better Markets also commented that the de minimis threshold framework should be revised to focus on strict, observable measures like total notional amount or transactional activities, rather than a subset of such activities that potential registrants are able to interpret for themselves, and are not presently required by regulation to monitor, report, or internally track across the firm.¹⁵⁷ However, the Commission notes that the statutory definition of “swap dealer” itself limits the scope to swap dealing activity, and therefore, using total notional amount would not be appropriate.

As noted, the Senators stated that the data that was available for NFC swaps shows significantly less coverage for that asset class under an \$8 billion threshold compared to other asset classes.¹⁵⁸ In justifying the \$8 billion proposal, the Senators commented that

¹⁵⁵ Additionally, Commission staff attempted to accurately identify those entities that, based on their observable business activities, are potentially engaged in swap dealing activity versus those likely engaged in other kinds of transactions. See *supra* section II.A; 83 FR 27449.

¹⁵⁶ The Commission also notes that it recently adopted amendments to its chief compliance officer requirements. See Chief Compliance Officer Duties and Annual Report Requirements for Futures Commission Merchants, Swap Dealers, and Major Swap Participants, 83 FR 43519 (Aug. 27, 2018).

¹⁵⁷ See *supra* section II.B.3; Better Markets comment letter.

¹⁵⁸ See *supra* section II.B.3; Senators comment letter. As noted above, for NFC swaps, approximately 86 percent of transactions involved at least one registered SD as a counterparty, compared to greater than 99 percent for IRS, CDS, FX swaps, and equity swaps. See *supra* section II.C.1.i.

though the Proposal noted the “unique characteristics” of NFC swaps, the analysis provided indicated a series of assumptions and possibilities rather than concrete data. The Senators also questioned whether, given the lack of relevant data for NFC swaps, it is necessary to reduce the threshold for SDs involved with energy-related swaps. However, as discussed in section II.C.1.ii, the Commission believes that a reduced threshold would have a negative impact on NFC swap market liquidity as some entities may reduce dealing to avoid registration and its related costs. Additionally, as noted, entities active in the NFC swap market may utilize the existing physical position hedging exemption, which is more directly applicable to the NFC asset class than other swaps.¹⁵⁹

Further, AFR stated that, though the improved data adds weight to the claim that an \$8 billion threshold is appropriate for some financial swaps, arguments against the \$8 billion threshold are particularly strong in the case of NFC swaps.¹⁶⁰ The Commission does not believe a lower threshold for NFC swaps would advance the policy goals of SD registration or the de minimis exception. As noted by the Commission and several commenters, the nature of the NFC swap market poses less systemic risk than financial swaps.¹⁶¹ Additionally, the Commission notes the concerns of reduced liquidity if the threshold is reduced for NFC swaps, including an increased concentration in the market, which could adversely affect end-users who rely on small and mid-sized SDs that do not have to register at an \$8 billion threshold.

Lastly, the Commission disagrees with IATP’s assertion that promoting improved price discovery is not the true rationale for maintaining an \$8 billion threshold, and that rather, the motivation is the regulatory compliance cost and burden reduction objective of Project KISS.¹⁶² The Commission has laid out above the various policy-related considerations that justify maintaining an \$8 billion threshold; these relate to the regulatory goals of both SD registration in general and of the de minimis exception in particular. Additionally, these goals were discussed in the Staff Reports, well in

¹⁵⁹ See 17 CFR 1.3, Swap dealer, paragraph (6)(iii); *supra* section II.C.1.ii; 83 FR 27456–57.

¹⁶⁰ See *supra* section II.B.3; AFR comment letter.

¹⁶¹ See *supra* section II.B.1. See, e.g., IECA and NCSA comment letters. See also 83 FR 27456–57; Final Staff Report, *supra* note 19, at 12 (citing comment letters submitted in response to Preliminary Staff Report, *supra* note 17).

¹⁶² See *supra* section II.B.3; IATP comment letter.

advance of any comments submitted in response to Project KISS.¹⁶³

2. Rationale for Not Increasing AGNA Threshold

Although several commenters suggested a higher threshold, the Commission is declining to increase the AGNA threshold from the current \$8 billion level. As discussed in the Proposal,¹⁶⁴ at a \$100 billion threshold: (1) The Estimated AGNA Coverage would have decreased from approximately \$221,020 billion (99.95 percent) to \$220,877 billion (99.88 percent)—a decrease of \$143 billion (a 0.06 percentage point decrease);¹⁶⁵ (2) the Estimated Transaction Coverage would have decreased from 3,795,330 trades (99.77 percent) to 3,773,440 trades (99.20 percent)—a decrease of 21,890 trades (a 0.58 percentage point decrease);¹⁶⁶ and (3) the Estimated Counterparty Coverage would have decreased from 30,879 counterparties (88.80 percent) to 28,234 counterparties (81.19 percent)—a decrease of 2,645 counterparties (a 7.61 percentage point decrease).¹⁶⁷

As the Commission and commenters have stated, the small decrease in Estimated AGNA Coverage and Estimated Transaction Coverage at higher thresholds potentially indicates that increasing the threshold to up to \$100 billion may have a limited adverse effect on the systemic risk and market efficiency policy considerations of SD regulation.¹⁶⁸ Additionally, a higher threshold could enhance the benefits associated with a de minimis exception, for example by allowing entities to increase ancillary dealing activity. However, the Commission is of the view that the decrease in Estimated Counterparty Coverage indicates that fewer entities would be transacting with registered SDs, reducing the counterparty protection benefits of SD regulation if the AGNA threshold increased from \$8 billion to \$20 billion, \$50 billion, or \$100 billion.¹⁶⁹ The

¹⁶³ See Final Staff Report, *supra* note 19; Preliminary Staff Report, *supra* note 17.

¹⁶⁴ See 83 FR 27454–56.

¹⁶⁵ The decrease would be lower at thresholds of \$20 billion and \$50 billion, at 0.01 percentage points and 0.04 percentage points, respectively.

¹⁶⁶ The decrease would be lower at thresholds of \$20 billion and \$50 billion, at 0.05 percentage points and 0.42 percentage points, respectively.

¹⁶⁷ The decrease would be lower at thresholds of \$20 billion and \$50 billion, at 2.80 percentage points and 5.71 percentage points, respectively.

¹⁶⁸ See *supra* section II.B.2; 83 FR 27455.

¹⁶⁹ As noted, the decrease in Estimated Counterparty Coverage would be 2.80 percentage points, 5.71 percentage points, 7.61 percentage points, at thresholds of \$20 billion, \$50 billion, and \$100 billion, respectively.

Commission also notes that increasing the threshold could result in changes in market behavior that could lead to the regulatory coverage decreasing more than the analysis indicated.

Further, maintaining the status quo signals long-term stability of the de minimis threshold, and should provide for the efficient application of the SD Definition, as it allows for long-term planning based on the current AGNA threshold.¹⁷⁰

3. Response to Other Comments

With respect to BDA's comment regarding permitting month-end only testing for the de minimis threshold, the Commission notes that several commenters indicated that the market has adapted to the current requirements and that changes would not be beneficial.¹⁷¹ In particular, the Commission agrees with commenters that the current test is relatively simple to administer, and the 12-month testing period helps to smooth out any short-term variations in activity. The Commission does not believe that allowing month-end only testing would reduce burdens since persons should already have systems in place to regularly track the level of their swap dealing activity. Therefore, the Commission is not adopting this alternative. Additionally, in response to BDA, the Commission notes that for purposes of the \$8 billion threshold calculation, an entity must count activity that took place in the immediately preceding 12 months.

Similarly, in response to the commenters that recommended alternatives to the single AGNA threshold or other calculation changes,¹⁷² the Commission points out that systems and processes have been established for the current requirements,¹⁷³ and therefore the Commission is not adopting the proposed adjustments at this time. The Commission may take subsequent action or conduct further study with respect to alternative approaches to the single AGNA threshold, including moving toward a risk-based SD registration metric in the future. The Commission

would expect that a change could entail costs as market participants adjust their de minimis threshold calculation processes.

Additionally, any modification to the special entity threshold is outside of the scope of the Proposal,¹⁷⁴ but as with other suggestions, the Commission may consider this in the future. Lastly, with respect to comments asking that the Commission address cross-border issues,¹⁷⁵ this issue is also outside of the scope of this rulemaking.

III. Proposed Rule Amendments Not Adopted

A. Swaps Entered Into by Insured Depository Institutions in Connection With Loans to Customers

1. Proposal

The Commission proposed adding an IDI loan-related factor in the De Minimis Exception (the "IDI De Minimis Provision") to address concerns that there are circumstances where swaps not covered by the IDI loan-related swap exclusion in paragraph (5) of the SD Definition (the "IDI Swap Dealing Exclusion") should be excluded from the de minimis calculation. Specifically, the Commission proposed to add specific characteristics that an IDI can consider when assessing whether swaps entered into with customers in connection with loans to those customers must be counted towards the IDI's de minimis calculation. The proposed IDI De Minimis Provision would have encompassed a broader scope of loan-related swaps than the IDI Swap Dealing Exclusion. The proposed IDI De Minimis Provision included: (1) A lengthier timing requirement for when the swap must be entered into; (2) an expansion of the types of swaps that are eligible; (3) a reduced syndication percentage requirement; and (4) an elimination of the notional amount cap. The IDI could exclude qualifying swaps from the de minimis calculation pursuant to the IDI De Minimis Provision regardless of whether the swaps would qualify for the IDI Swap Dealing Exclusion.

2. Summary of Comments

Almost all commenters that addressed the IDI De Minimis Provision expressed general support for the proposed amendment.¹⁷⁶ Commenters often compared the IDI De Minimis Provision to the IDI Swap Dealing Exclusion. In

that regard, commenters generally stated that the IDI De Minimis Provision better aligns the regulatory framework with the risk mitigation demands of bank customers.¹⁷⁷

Commenters generally supported proposed new paragraph (4)(i)(C)(1),¹⁷⁸ which provided that a swap must be entered into no earlier than 90 days before execution of the loan agreement, or before transfer of principal to the customer, unless an executed commitment or forward agreement for the applicable loan exists. In that event, the 90-day restriction does not apply. In comparison, the IDI Swap Dealing Exclusion in paragraph (5) of the SD Definition requires that a swap must be entered into no more than 90 days before or 180 days after the date of execution of the loan agreement (or date of transfer of principal to the customer).¹⁷⁹ On the other hand, three commenters recommended removing the 90-day restriction because it would be detrimental to the IDIs and/or borrowers.¹⁸⁰ Additionally, two commenters suggested revisions to the "executed commitment" or "forward agreement" exception to the 90-day restriction.¹⁸¹

Proposed new paragraph (4)(i)(C)(2) stated that for purposes of the IDI De Minimis Provision, a swap is "in connection with" a loan if: (1) The rate, asset, liability or other term underlying such swap is, or is related to, a financial term of such loan; or (2) if such swap is required as a condition of the loan, either under the IDI's loan underwriting criteria or as is commercially appropriate, in order to hedge risks incidental to the borrower's business (other than for risks associated with an excluded commodity) that may affect the borrower's ability to repay the loan. Two commenters requested clarification regarding the proposed "condition of the loan" language.¹⁸²

Proposed new paragraph (4)(i)(C)(3) stated that the termination date of the swap cannot extend beyond termination of the loan. A few commenters stated that circumstances can be anticipated at the time of loan origination that would support permitting the termination date of the swap to extend beyond

¹⁷⁰ See 83 FR 27456–57.

¹⁷¹ See *supra* section II.B.4.i. Potentially, month-end only testing could marginally encourage competition because newly-established swap dealing businesses (as contrasted to the existing businesses that have adapted to current requirements) could set up only month-end testing as opposed to regular testing. However, the Commission believes that maintaining the current requirements is appropriate even in view of any marginal encouragement of competition that could result from the suggested change.

¹⁷² See *supra* sections II.B.4.ii and II.B.4.iii.

¹⁷³ See, e.g., *supra* sections II.B.4.i and II.B.4.ii.

¹⁷⁴ See *supra* section II.B.4.iii; *supra* note 12; 83 FR 27445 n.14.

¹⁷⁵ See *supra* section II.B.4.iv.

¹⁷⁶ See ABA, BDA, Capital One, CDEU, Citizens, Frost Bank, IIB, ISDA/SIFMA, JBA, M&T, and Regions comment letters.

¹⁷⁷ See Capital One, Frost Bank, M&T, Regions comment letters.

¹⁷⁸ See Capital One, Citizens, Frost Bank, M&T, and Regions comment letters.

¹⁷⁹ 17 CFR 1.3, Swap dealer, paragraph (5)(i)(A).

¹⁸⁰ See BDA, CDEU, and ISDA/SIFMA comment letters.

¹⁸¹ See Capital One and Frost Bank comment letters.

¹⁸² See ABA and Regions comment letters.

termination of the loan.¹⁸³ Additionally, in response to a question in the Proposal, a few commenters stated that in order to qualify for the IDI De Minimis Provision, IDIs should not be required to terminate loan-related swaps if a loan is called, put, accelerated, or goes into default before scheduled termination.¹⁸⁴

Proposed new paragraph (4)(i)(C)(4)(i) required an IDI to be, under the terms of the agreements related to the loan, the source of at least five percent of the maximum principal amount under the loan for a related swap not to be counted towards its de minimis calculation, and proposed new paragraph (4)(i)(C)(4)(ii) stated that if an IDI is a source of less than a five percent of the maximum principal amount of the loan, the notional amount of all swaps the IDI enters into in connection with the financial terms of the loan cannot exceed the principal amount of the IDI's loan in order to qualify for the IDI De Minimis Provision. A few commenters stated that the five percent participation requirement should be eliminated from the IDI De Minimis Provision,¹⁸⁵ while two commenters generally supported the five percent requirement.¹⁸⁶

The proposed IDI De Minimis Provision did not include the requirement in the IDI Swap Dealing Exclusion that the AGNA of swaps entered into in connection with the loan not exceed the principal amount outstanding,¹⁸⁷ and two commenters agreed that there are circumstances where the AGNA of loan-related swaps can exceed the outstanding principal amount of the loan.¹⁸⁸

In response to a question in the Proposal, three commenters stated that the CFTC should not impose any prior notice requirement or other conditions on the ability of IDIs to rely on the proposed IDI De Minimis Provision.¹⁸⁹ In response to another question in the Proposal, three commenters stated that there should not be a requirement that

swap confirmations reference a specific loan because doing so would add operational complexity for little or no benefit.¹⁹⁰

Two commenters discussed whether the IDI De Minimis Provision could be promulgated without a joint rulemaking.¹⁹¹ ABA stated that the Commission is not required to promulgate the IDI De Minimis Provision through joint rulemaking with the SEC.¹⁹² However, Better Markets asserted that the CFTC's position that a "joint rulemaking is not required with respect to changes to the de minimis exception-related factors" is invalid and "would impermissibly enable the CFTC to conduct an end-run around the statutory joint rulemaking requirement." In particular, Better Markets stated that language potentially permitting unilateral action on the de minimis threshold itself does not permit unilateral regulatory actions affecting core definitional issues that must be accomplished through joint rulemaking.¹⁹³

3. Commission Response

The Commission has determined not to adopt the IDI De Minimis Provision at this time. The Commission continues to consider the issues raised by commenters. For example, the various contexts in which IDIs enter into swaps with their loan customers, and the relation between those swaps and the larger swap market, may merit further consideration.

B. Swaps Entered Into to Hedge Financial or Physical Positions

1. Proposal

The Commission proposed adding a provision in new paragraph (4)(i)(D) of the De Minimis Exception, to include as a factor whether a swap was entered into primarily for the purpose of hedging and met certain related conditions (the "Hedging De Minimis Provision").¹⁹⁴ As proposed, to qualify for the Hedging De Minimis Provision, the primary purpose for the swap would need to be to reduce or otherwise mitigate one or more specific risks to which the person is subject. Proposed paragraph (4)(i)(D)(2) provided that the person entering into the hedging swap could not be the price maker of the hedging swap and receive or collect a bid/ask spread, fee, or other commission for entering into the hedging swap (the

"price maker condition"). In addition, the proposed Hedging De Minimis Provision included in paragraphs (D)(3) through (D)(5) the following conditions that are similar to conditions in the physical hedging exclusion in paragraph (6)(iii) of the SD Definition: (1) The swap must be economically appropriate to the reduction of risks that may arise in the conduct and management of an enterprise engaged in the type of business in which the person is engaged; (2) the swap must be entered into in accordance with sound business practices; and (3) the swap must not be entered into in connection with activity structured to evade designation as an SD.

2. Summary of Comments

Most commenters supported including an express hedging exception that would clarify which physical and financial hedging swaps do not need to be included in the AGNA threshold calculation.¹⁹⁵ These commenters agreed with the Commission that there is currently some uncertainty and confusion among market participants regarding this determination. However, many of these commenters raised issues with the particular conditions identified in the proposed Hedging De Minimis Provision, and two other commenters objected to inclusion of the Hedging De Minimis Provision.¹⁹⁶ Among other issues, the two commenters viewed the Hedging De Minimis Provision as a major expansion of the De Minimis Exception.

Generally, commenters supported adding the Hedging De Minimis Provision to the De Minimis Exception to provide more certainty and/or clarity regarding the treatment of hedging activity.¹⁹⁷ On the other hand, AFR and Better Markets stated that excepting hedges of swap dealing positions from the de minimis threshold could exclude swaps that appear to be hedges, but are actually dealing swaps.¹⁹⁸ Furthermore, Better Markets asserted that a hedge of client facing swap is "inextricably" tied to accommodating customer demands.¹⁹⁹

Several commenters noted that the price maker condition included in the proposed Hedging De Minimis Provision could be viewed as more

¹⁸³ See ABA, BDA, CDEU, Citizens, and M&T comment letters.

¹⁸⁴ See ABA, BDA, Capital One, CDEU, IIB, and ISDA/SIFMA comment letters.

¹⁸⁵ See ABA, BDA, Citizens, and ISDA/SIFMA comment letters.

¹⁸⁶ See Capital One and M&T comment letters.

¹⁸⁷ 17 CFR 1.3, Swap dealer, paragraph (5)(i)(E). However, as discussed, pursuant to proposed paragraph (4)(i)(C)(4)(ii), if an IDI is a source of less than a five percent of the maximum principal amount of the loan, the notional amount of all swaps the IDI enters into in connection with the financial terms of the loan cannot exceed the principal amount of the IDI's loan. See also 83 FR 27461.

¹⁸⁸ See Capital One and M&T comment letters.

¹⁸⁹ See ABA, Capital One, and M&T comment letters.

¹⁹⁰ See ABA, BDA, and Capital One comment letters.

¹⁹¹ See ABA and Better Markets comment letter.

¹⁹² See ABA comment letter.

¹⁹³ See Better Markets comment letter.

¹⁹⁴ See 83 FR 27462-63.

¹⁹⁵ See ABA, AGA, AFEX/GPS, BDA, Capital One, CDEU, COPE, CMC, EEI/EPISA, Frost Bank, FIA, IIB, IECA, ISDA/SIFMA, JBA, NRECA/APPA, NGSA, Virtu, and Western Union comment letters.

¹⁹⁶ See AFR and Better Markets comment letters.

¹⁹⁷ See ABA, AGA, BDA, Capital One, Citizens, CDEU, EEI/EPISA, Frost Bank, FIA, NGSA, NRECA/APPA, Virtu, and Western Union comment letters.

¹⁹⁸ See AFR and Better Markets comment letters.

¹⁹⁹ See Better Markets comment letter.

limiting than the existing physical swap hedging exclusion.²⁰⁰ Many commenters expressed concern that the proposed condition would be overly prescriptive, ambiguous, and/or could inadvertently require certain hedging activity to be treated as swap dealing activity.²⁰¹ In particular, commenters asked that the bid/ask spread limitation be deleted or clarified.²⁰² Conversely, two commenters expressed some support for this condition as proposed.²⁰³

ISDA/SIFMA was of the view that the requirement that the primary purpose for entering into the swap must be to reduce or otherwise mitigate one or more “specific” risks is unreasonably restrictive.²⁰⁴ ISDA/SIFMA suggested that the Commission should remove the term “specific” from the regulatory text to better achieve the Commission’s policy objective of encouraging greater use of swaps to hedge risks. On the other hand, NRECA/APPA noted that the specific, but non-exclusive, risks identified in paragraph (4)(i)(D)(1) are consistent with the types of commercial risks that an end-user would hedge.²⁰⁵

AFR and Better Markets objected to the Hedging De Minimis Provision, stating that it could allow even large dealers to escape registration, and that the exclusion of anticipatory hedges allows too much discretion to institutional judgment.²⁰⁶

Better Markets expressed concern that the Hedging De Minimis Provision promotes unregulated swap dealing and is therefore “not a valid statutory objective.” Furthermore, Better Markets stated that the Commission does not need to provide clarity for the existing hedging exemption because the existing standard of using facts and circumstances to distinguish dealing swaps is a “well-settled framework.”²⁰⁷ Better Markets also asserted that the

Commission misinterpreted its prior statements about the use of swaps to hedge dealing positions. However, in doing so, Better Markets cited to language in the joint SD Definition Adopting Release that addressed the definition of “security-based swap dealer,” not “swap dealer.”²⁰⁸

AFR and Better Markets also asserted that the Hedging De Minimis Provision should not be included in the De Minimis Exception because enforcement of the conditions would be impractical.²⁰⁹

3. Commission Response

The comments generally confirmed that nuanced facts and circumstances may be relevant to determining whether a swap that hedges financial risk, but also has dealing characteristics or is connected to dealing activities, should be counted toward the AGNA threshold. However, the comments also raised specific implementation and compliance issues. For these reasons, the Commission has determined not to adopt the Hedging De Minimis Provision at this time.

The Commission confirms that the “relevant facts and circumstances” test established in the SD Definition Adopting Release and further discussed in the DSIO FAQ Guidance²¹⁰ continues to be in effect. In doing so, the Commission emphasizes that market participants should continue to evaluate such swaps without consideration of the proposed Hedging De Minimis Provision.

C. Swaps Resulting From Multilateral Portfolio Compression Exercises

1. Proposal

The Commission proposed new paragraph (4)(i)(E) of the De Minimis Exception, which would add as a factor in the de minimis calculation whether a swap results from multilateral portfolio compression exercises (“MPCE De Minimis Provision”). Specifically, the Proposal stated that for purposes of determining whether a person has exceeded the AGNA threshold set forth in paragraph (4)(i)(A), the person may exclude swaps that result from multilateral portfolio compression exercises, as defined in § 23.500 of Commission regulations, to the extent

the person does not enter into the multilateral portfolio compression exercise in connection with activity structured to evade designation as an SD. The Proposal was consistent with DSIO no-action relief issued on December 21, 2012 (“Staff Letter 12–62”).²¹¹

2. Summary of Comments

Most commenters addressing this aspect of the Proposal supported exempting from the de minimis threshold swaps that result from multilateral portfolio compression exercises,²¹² stating that multilateral portfolio compression: (1) Advances the Commission’s policy goals of reducing counterparty credit risks by allowing swap market participants with large portfolios to net down the size and number of swaps among them, thus lowering the AGNA of outstanding swaps;²¹³ and (2) does not involve dealing activity, but rather allows market participants to reduce their risk without implicating any of the other considerations related to SD regulation.²¹⁴

Several commenters also stated that, given the policy-related similarities between bilateral and multilateral portfolio compression, the Commission should also exclude from counting towards the De Minimis Exception swaps that result from bilateral portfolio compression exercises.²¹⁵ One commenter asserted that reliance on the “multilateral portfolio compression exercise” definition in § 23.500(h) of Commission regulations may be too limiting.²¹⁶

On the other hand, AFR and IATP expressed concerns with the MPCE De Minimis Provision.²¹⁷ AFR stated that the definition of portfolio compression appears overbroad since it goes beyond the termination of fully offsetting swaps to include any exercise which would result in the reduction of current market risks for a set of swaps, even if the exercise might actually increase credit exposure or market risk under stressed market conditions.²¹⁸ IATP noted that entities should be required to document and report the results of multilateral compression exercises to qualify for the exception. Additionally, IATP stated

²⁰⁰ See CEWG, CMC, FIA, and IECA comment letters.

²⁰¹ See CDEU, EEI/EPISA, IECA, and Western Union comment letters.

²⁰² See ABA, BDA, EEI/EPISA, IECA, IIB, NRECA/APPA, and Western Union comment letters.

²⁰³ See COPE and NRECA/APPA comment letters.

²⁰⁴ See ISDA/SIFMA comment letter.

²⁰⁵ See NRECA/APPA comment letter.

²⁰⁶ See AFR and Better Markets comment letters.

²⁰⁷ See Better Markets comment letter. Better Markets noted that, in October 2012, DSIO addressed whether hedging activity is included in calculating the de minimis amount when it stated that “a person must consider the swap in light of all other relevant facts and circumstances to determine whether such hedging activity is swap dealing activity. . . .” See Frequently Asked Questions (FAQ)—[DSIO] Responds to FAQs About Swap Entities (Oct. 12, 2012) (“DSIO FAQ Guidance”), available at https://www.cftc.gov/idc/groups/public/newsroom/documents/file/swapentities_faq_final.pdf.

²⁰⁸ 77 FR 30619 n.280 (stating that security-based swaps activity for hedging purposes “unrelated to activities that constitute dealing” would not be expected to lead the person to be a security-based swap dealer).

²⁰⁹ See AFR and Better Markets comment letters. AFR described the potential need for a swap-by-swap analysis and the potential for disputes regarding the proposed anti-evasion provision.

²¹⁰ See *supra* note 207.

²¹¹ CFTC Staff Letter No. 12–62, *supra* note 47.

²¹² See ABA, IIB, ISDA/SIFMA, JBA, and NEX comment letters.

²¹³ See ABA, ISDA/SIFMA, and NEX comment letters.

²¹⁴ See IIB comment letter.

²¹⁵ See ABA, IIB, ISDA/SIFMA, and JBA comment letters.

²¹⁶ See IIB comment letter.

²¹⁷ See AFR and IATP comment letters.

²¹⁸ See AFR comment letter.

that any de minimis exception-related exemption must be in the public interest, and asked questions regarding the legal authority for the Commission to propose the amendments included in the NPRM.²¹⁹

3. Commission Response

The Commission has determined not to adopt the MPCE De Minimis Provision at this time. The Commission believes that further action on this provision may require additional consideration of the various relevant issues.²²⁰

D. Methodology for Calculating Notional Amounts

1. Proposal

Given the variety of potential methods that could be used to calculate the notional amount for certain swaps, particularly for swaps where notional amount is not a contractual term of the transaction (e.g., certain NFC swaps), the Commission proposed new paragraph (4)(vii) of the De Minimis Exception, which sets out a mechanism for the Commission, on its own or upon written request by a person, to determine the methodology to be used to calculate the notional amount for any group, category, type, or class of swaps for purposes of whether a person exceeds the AGNA threshold. The proposed rule required that such methodology be economically reasonable and analytically supported, and that any such determination be posted on the CFTC website. Further, to ensure timely clarity to market participants, the Commission proposed to delegate to the Director of DSIO the authority to make such determinations.

2. Summary of Comments

Several commenters generally supported Commission efforts to provide certainty and clarity regarding calculation of notional amounts.²²¹ Some of these commenters supported providing the Commission with the explicit authority to approve or establish methodologies for calculating notional amount.²²² Citizens specifically noted that the lack of clarity regarding notional amount interpretations has persisted for too long, and what little guidance that exists

does not provide the certainty that market participants need in order to run their businesses efficiently.²²³ Further, FIA stated that the DSIO FAQ left open a multitude of questions for market participants attempting to calculate notional amount.²²⁴ Additionally, NGSAs requested that the CFTC provide a safe harbor for reliance on a notional amount calculation methodology that is based on standard industry practice unless and until CFTC publishes notice that invalidates such a methodology or prescribes a different methodology.²²⁵

NRECA/APPA suggested that the Commission should not determine the methodology for calculating notional amounts, stating that the word “determine” in proposed new paragraph (4)(vii) of the De Minimis Exception should be changed to “provide guidance with respect to.”²²⁶

Several commenters did not support the proposal to delegate to the Director of DSIO the authority to make notional calculation determinations.²²⁷ Specifically, some commenters stated that the Commission, rather than the Director of DSIO, should determine the methodology for calculating notional amounts because the methodology used to determine the AGNA is a critical component of the de minimis threshold, as it impacts which entities will be designated as SDs.²²⁸ Commenters also noted that the delegation, as proposed, would permit Commission staff to make substantive, and potentially critical, policy determinations in an informal process,²²⁹ and that Commissioners should not remove themselves from that decision-making process, particularly given that one of the challenges related to NFC swaps was lack of a standard for calculation of notional amount.²³⁰

On the other hand, several commenters supported the proposal to delegate to the Director of DSIO the authority to make notional calculation determinations.²³¹ However, many of these commenters supported delegation only if determinations were subject to a public notice and comment process.²³² A few commenters noted that if the Commission believes that delegation is

proper, it should add safeguards, such as an appeal to the Commission, coupled with a stay of any contested staff determination, pending Commission action.²³³ One commenter suggested that DSIO should be granted authority to respond to individual dealer requests for guidance on how the notional amount would be calculated for a given transaction, and dealers should be able to rely on any response from DSIO.²³⁴

Several commenters stated that notional calculation methodologies should be subject to a formal public notice and comment process.²³⁵ A few commenters also noted that notional calculation methodologies should be evaluated pursuant to a cost-benefit analysis.²³⁶ A few commenters suggested that notional calculations be guided by international standards, industry group comment letters, and the DSIO FAQ Guidance.²³⁷

Commenters also provided feedback regarding specific notional amount calculation methodologies.²³⁸

3. Commission Response

The comments raised a number of issues with the proposed authority and delegation regarding the methodology for calculating notional amounts. Given the nature and significance of these issues, the Commission has determined to not adopt this provision at this time.

IV. Other Matters Discussed in NPRM

In the NPRM, the Commission did not propose, but sought comment on the following additional potential changes to the De Minimis Exception: (1) Adding a minimum dealing counterparty count threshold and/or a minimum dealing transaction count threshold; (2) establishing as a factor in the de minimis determination whether a given swap was exchange-traded and/or cleared; and (3) establishing as a factor in the de minimis determination whether a given swap is a non-deliverable forward transaction. The Commission did not propose rule text for any of these topics.

At this time, the Commission is not adopting final rules regarding any of these three potential changes. The Commission may take subsequent action

²¹⁹ See IATP comment letter.

²²⁰ The Commission notes that Staff Letter 12-62 is not affected by the Commission's determination not to adopt the MPCE De Minimis Provision at this time.

²²¹ See ABA, Citizens, CEWG, CMC, EEI/EPISA, FIA, Frost Bank, IIB, NGSAs, and Western Union comment letters.

²²² See Citizens, EEI/EPISA, FIA, Frost Bank, and Western Union comment letters.

²²³ See Citizens comment letter.

²²⁴ See FIA comment letter.

²²⁵ See NGSAs comment letter.

²²⁶ See NRECA/APPA comment letter.

²²⁷ See AGA, AFR, COPE, EEI/EPISA, FIA, IATP, ISDA/SIFMA, JBA, NRECA/APPA, and Senators comment letters.

²²⁸ See AFR, AGA, and FIA comment letters.

²²⁹ See COPE comment letter.

²³⁰ See Senators comment letter.

²³¹ See Citizens, CDEU, CEWG, CMC, Frost Bank, IIB, NGSAs, and Western Union comment letters.

²³² See CDEU, CEWG, CMC, IIB, and NGSAs comment letters.

²³³ See COPE, EEI/EPISA, and IECA comment letters.

²³⁴ See BDA comment letter.

²³⁵ See ABA, AGA, BDA, CDEU, CMC, EEI/EPISA, FIA, IECA, IIB, ISDA/SIFMA, NRECA/APPA, and NGSAs comment letters.

²³⁶ See AGA, FIA, and ISDA/SIFMA comment letters.

²³⁷ See ABA, EEI/EPISA, NRECA/APPA, and NGSAs comment letters.

²³⁸ See BDA, CEWG, CMC, EEI/EPISA, and IECA comment letters.

or conduct further study with respect to any of these issues. The Commission recognizes the public interest in moving forward with the aspects of the NPRM that it is adopting in this release, rather than delaying action on the NPRM as a whole in order to further consider any of these additional topics.

A. Dealing Counterparty Count and Dealing Transaction Count Thresholds

The Commission sought comment on whether an entity should be able to qualify for the de minimis exception if its level of swap dealing activity is below any of the following three criteria: (1) An AGNA threshold, (2) a proposed dealing counterparty count threshold, or (3) a proposed dealing transaction count threshold. Although a few commenters expressed general support for adding a dealing counterparty or dealing transaction count threshold to the De Minimis Exception,²³⁹ most commenters did not support the idea.²⁴⁰

B. Exception for Exchange-Traded and/or Cleared Swaps

The Commission sought comment on whether an exception from the de minimis calculation for swaps that are executed on an exchange (e.g., a SEF or designated contract market (“DCM”)) and/or cleared by a derivatives clearing organization is appropriate. Most commenters supported including an exception for exchange-traded and/or cleared trades,²⁴¹ though two commenters were opposed to the idea.²⁴²

C. Exception for Non-Deliverable Forwards

The Commission sought comment on whether an exception from the de minimis calculation for non-deliverable forwards is appropriate. Most commenters generally supported including an exception for NDFs,²⁴³ though one commenter was opposed to the idea.²⁴⁴

²³⁹ See generally BDA, IIB, and JBA comment letters.

²⁴⁰ See generally Citizens, CEWG, EEI/EPISA, IATP, IECA, ISDA/SIFMA, and NGSA comment letters.

²⁴¹ See generally 360 Trading, ABA, BDA, Daiwa, Cboe SEF, Citizens, CME/ICE, EEI/EPISA, FXPA, Frost Bank, FIA, IIB, IECA, JBA, MFA, Optiver, TR SEF, Virtu, and XTX comment letters.

²⁴² See generally AFR and Better Markets comment letters.

²⁴³ See generally 360 Trading, ABA, AFEX/GPS, AGC, BDA, Capital One, Cboe SEF, Citizens, CDEU, CMC, Covington, FXPA, FIA, IIB, IECA, ISDA/SIFMA, JBA, Northern Trust, Optiver, Regions, State Street, SVB, TR SEF, Virtu, Western Union, and XTX comment letters.

²⁴⁴ See Better Markets comment letter.

V. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (“RFA”) requires that agencies consider whether the regulations they propose will have a significant economic impact on a substantial number of small entities.²⁴⁵ As noted in the Proposal, the regulations adopted herein only affect certain entities that are close to the AGNA threshold in the De Minimis Exception. For example, the regulations would affect entities with a relevant AGNA of swap dealing activity between \$3 billion and \$8 billion. Moreover, they would affect IDIs that enter into loan-related swaps. That is, the regulations are relevant to entities that engage in swap dealing activity with a relevant AGNA measured in the billions of dollars. The Commission does not believe that these entities would be small entities for purposes of the RFA. Additionally, the Commission received no comments on the Proposal’s RFA discussion. Therefore, the regulations being adopted herein will not have a significant economic impact on a substantial number of small entities, as defined in the RFA.

Accordingly, the Chairman, on behalf of the Commission, hereby certifies pursuant to 5 U.S.C. 605(b) that these regulations will not have a significant economic impact on a substantial number of small entities.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (“PRA”)²⁴⁶ imposes certain requirements on Federal agencies, including the Commission, in connection with their conducting or sponsoring any collection of information, as defined by the PRA. The Commission may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (“OMB”) control number. As discussed in the Proposal, the final regulations will not impose any new recordkeeping or information collection requirements, or other collections of information that require approval of OMB under the PRA.

The Commission notes that all reporting and recordkeeping requirements applicable to SDs result from other rulemakings, for which the CFTC has sought OMB approval, and

²⁴⁵ 5 U.S.C. 601 *et seq.*

²⁴⁶ 44 U.S.C. 3501 *et seq.*

are outside the scope of rulemakings related to the De Minimis Exception.²⁴⁷

C. Cost-Benefit Considerations

Section 15(a) of the CEA requires the Commission to consider the costs and benefits of its actions before promulgating a regulation under the CEA or issuing certain orders.²⁴⁸ Section 15(a) further specifies that the costs and benefits shall be evaluated in light of five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. In this section, the Commission considers the costs and benefits resulting from its determinations with respect to the Section 15(a) factors.

In this adopting release, the Commission is amending the De Minimis Exception by setting the AGNA threshold at \$8 billion in swap dealing activity. The Proposal requested public comment on the costs and benefits of the proposed regulations, and specifically invited comments on: (1) The costs and benefits to market participants associated with each change; (2) the direct costs associated with SD registration and compliance; (3) the indirect benefits to registering as an SD; (4) the indirect costs to becoming a registered SD; (5) whether entities with dealing activity between \$3 billion and \$8 billion incur similar registration and compliance costs as compared to entities with dealing activity above \$8 billion; (6) the costs and benefits to the public associated with each proposed change; (7) how each proposed change affects each of the Section 15(a) factors; (8) whether the Commission identified all of the relevant categories of costs and benefits in its preliminary consideration of the costs and benefits; and (9) whether the costs and benefits of the proposed changes, as applied in cross-border contexts, differ from those costs and benefits resulting from their domestic application, and, if so, in what ways and to what extent.

As part of this cost-benefit consideration, the Commission will discuss the costs and benefits of the adopted change and analyze the amendment as it relates to each of the

²⁴⁷ Parties wishing to review the CFTC’s information collections on a global basis may do so at www.reginfo.gov, at which OMB maintains an inventory aggregating each of the CFTC’s currently approved information collections, as well as the information collections that presently are under review.

²⁴⁸ 7 U.S.C. 19(a).

15(a) factors. The Commission notes that this consideration of costs and benefits is based on the understanding that the swap market functions internationally, with many transactions involving U.S. firms occurring across different international jurisdictions, with some prospective Commission registrants organized outside the U.S., and other entities operating both within and outside the U.S., and commonly following substantially similar business practices wherever located. Where the Commission does not specifically refer to matters of location, the discussion below of the costs and benefits of the regulations being adopted refers to their effects on all subject swaps activity, whether by virtue of the activity's physical location in the United States or by virtue of the activity's connection with or effect on U.S. commerce under CEA section 2(i).

As discussed above, the De Minimis Exception provides an exception from the SD Definition for persons who engage in a de minimis amount of swap dealing activity. Currently, a person shall not be deemed to be an SD unless swaps entered into in connection with swap dealing activity exceed an AGNA threshold of \$3 billion (measured over the prior 12-month period), subject to a phase-in period that is currently in effect, during which the AGNA threshold is set at \$8 billion. The Commission is amending the De Minimis Exception to set the AGNA threshold at the current \$8 billion phase-in level.

There are market-wide costs and benefits associated with setting the AGNA threshold at \$8 billion. In addition, setting the threshold at \$8 billion would have specific monetary costs and benefits as compared to a lower or higher threshold. The current \$8 billion phase-in level threshold, along with the prospect that the threshold would decrease to \$3 billion after December 31, 2019, in the absence of further Commission action, sets the baseline for the Commission's consideration of the costs and benefits of the proposed alternatives. Accordingly, the Commission considers the costs and benefits that would result from maintaining the current \$8 billion phase-in level threshold, or alternatively, a threshold level below or above the current \$8 billion threshold. The status quo baseline also includes other aspects of existing rules related to the De Minimis Exception. The analysis also takes into account any relevant no-action relief, to the extent such relief is being relied upon. As the Commission is of the belief that existing no-action relief related to the De Minimis

Exception is being fully relied upon by market participants, the cost-benefit discussion that follows also considers the effects of that relief.

1. General Costs and Benefits

There are several policy objectives underlying SD regulation and the de minimis exception to SD registration, which have associated with them general costs and benefits depending on the level of the AGNA threshold. As discussed above in section I.A.3, costs and benefits may be associated with the primary policy objectives of SD regulation, which include reducing systemic risk, increasing counterparty protections, and increasing market efficiency, orderliness, and transparency.²⁴⁹ The Commission also considers the costs and benefits associated with the policy objectives furthered by a de minimis exception, which include increasing efficiency, allowing limited ancillary dealing, encouraging new participants to enter the swap dealing market, and focusing regulatory resources.²⁵⁰

As noted by the Commission and a few commenters, generally, the lower the threshold, the greater the number of entities that are subject to the SD-related regulatory requirements, which could decrease systemic risk, increase counterparty protections, and promote swap market efficiency, orderliness, and transparency.²⁵¹ However, the Commission and most commenters recognize that a lower threshold could have offsetting costs for the market. For example, it is likely that a lower threshold would discourage new participants from entering into the swap market, and reduce the amount of dealing activity in which swap market participants engage in connection with their other businesses.²⁵²

On the other hand, and as discussed further below, the higher the threshold, the greater the number of entities that are able to engage in dealing activity

²⁴⁹ See also SD Definition Adopting Release, 77 FR 30628–30, 30707–08. To achieve these policy objectives, registered SDs are subject to a broad range of requirements which may carry their own costs and benefits. These requirements include, among other things, registration, internal and external business conduct standards, reporting, recordkeeping, risk management, posting and collecting margin on uncleared swaps, and chief compliance officer designation and responsibilities. However, costs associated with regulatory requirements applicable to SDs result from other rulemakings and are outside the scope of rulemakings related to the De Minimis Exception.

²⁵⁰ See *id.*

²⁵¹ See *supra* sections I.A.3 and II.B.3; 83 FR 27471–72; 77 FR 30628–30, 30703, 30707.

²⁵² See *supra* sections I.A.3, II.B.1, and II.C.1; 83 FR 27448–58, 27471–72; 77 FR 30628–30, 30703, 30707.

without being required to register, which could increase competition and liquidity in the swap market. However, a higher AGNA threshold could potentially decrease the number of registered SDs, which could have a negative impact on achieving the general benefits associated with the policy objectives of SD regulation. This might adversely affect the swap market to some extent.²⁵³

(i) Maintaining the \$8 Billion Threshold

The comments received for this proposed amendment were generally supportive.²⁵⁴ As discussed in section II.C.1.i, at the \$8 billion threshold the 2017 Transaction Coverage and 2017 AGNA Coverage ratios indicate that nearly all swaps were covered by SD regulation, generally giving rise to the benefits of SD regulation discussed above. Almost all swap transactions involved at least one registered SD as a counterparty, approximately 99 percent or greater for IRS, CDS, FX swaps, and equity swaps. For NFC swaps, approximately 86 percent of transactions involved at least one registered SD as a counterparty. Overall, approximately 98 percent of all swap transactions involved at least one registered SD. Further, almost all AGNA of swaps activity included at least one registered SD, approximately 99 percent or greater for IRS, CDS, FX swaps, and equity swaps. Further, the Commission notes that the 6,440 entities that did not enter into any transactions with a registered SD had limited activity overall. As discussed in the Proposal, the 6,440 entities entered into 77,333 transactions, representing approximately 1.7 percent of the overall number of transactions during the review period.²⁵⁵ Additionally, collectively, the 6,440 entities had \$68 billion in AGNA of swaps activity, representing approximately 0.03 percent of the overall AGNA of swaps activity during the review period.

The Commission believes that this limited activity indicates that to the extent these entities are engaging in swap dealing activities, such activity is likely ancillary and in connection with other client services, potentially indicating that the benefits associated with the policy objectives of SD registration and the de minimis

²⁵³ See *supra* sections II.B.2 and II.C.2; 83 FR at 27454–56.

²⁵⁴ See *supra* section II.B.1. See also ABA, AGA, AFEX/GPS, BDA, Capital One, Cboe SEF, Citizens, CDEU, COPE, CEWG, CMC, EEI/EPFA, FXPA, Frost Bank, FIA, IIB, IECA, ISDA/SIFMA, JBA, M&T, NCFC, NRECA/APPA, NGSAs, Regions, SVB, Virtu, Western Union, and XTX comment letters.

²⁵⁵ 83 FR 27451.

exception are being advanced at the current \$8 billion threshold. Additionally, setting the AGNA at \$8 billion would foster efficiency and potentially reduce costs by allowing persons to continue to use existing calculation procedures and business processes that are geared towards the \$8 billion threshold.

Commenters generally agreed with the Commission's position. For example, many commenters noted that the current \$8 billion threshold already subjects the vast majority of transactions to SD regulation, or that a reduced threshold would not capture significant additional dealing activity.²⁵⁶ Some commenters stated that the nature of the swaps activity entered into by certain entities poses less systemic risk (e.g., commercial banks that have swap dealing activity below \$8 billion, and entities that primarily enter into NFC swaps).²⁵⁷

However, as discussed above, Better Markets stated that the high regulatory coverage ratios are not indicative of the absolute level of swap dealing activities relevant to SD registration, and noted that maintaining an \$8 billion threshold would have more than a limited effect on counterparty protections.²⁵⁸ The Commission believes that while either percentage of the market or absolute level of swaps activity are valid considerations, it is more relevant in this context of achieving a desirable balance of policy goals to consider the level of activity as a percentage of the whole.

Additionally, the Senators stated that though notional amount data for NFC swaps was not used in considering the Proposal, the data that was available for NFC swaps shows significantly less coverage for NFC swaps under an \$8 billion threshold than in other asset classes.²⁵⁹ The Commission notes that with respect to NFC swaps, registered SDs still entered into the significant majority (86 percent) of the overall market's total transactions and, as noted in the Proposal, faced 83 percent of counterparties in at least one transaction, indicating that the existing \$8 billion threshold has helped extend the benefits of SD registration to much of the NFC swap market.²⁶⁰ The trading activity of the 42 unregistered entities

with 10 or more NFC swap counterparties represents approximately 13 percent of the overall NFC swap market by transaction count. However, as compared to the existing 44 registered SDs with at least 10 counterparties, these 42 In-Scope Entities have significantly lower mean transaction and counterparty counts, indicating that they may only be providing ancillary dealing services to accommodate commercial end-user clients, also potentially indicating that the benefits associated with the policy objectives of the de minimis exception are being advanced at the current \$8 billion threshold.²⁶¹ The Commission believes these market-wide benefits demonstrate that maintaining an \$8 billion threshold is also appropriate with respect to the NFC swap asset class.

(ii) \$3 Billion Threshold

The Commission is of the view that the systemic risk mitigation, counterparty protection, and market efficiency benefits of SD regulation would be enhanced in only a very limited manner if the AGNA threshold decreased from \$8 billion to \$3 billion, as would be the case if the current regulation and the existing Commission order establishing an end to the phase-in period on December 31, 2019 were left unchanged. As discussed, Estimated AGNA Coverage would increase from approximately \$221,020 billion (99.95 percent) to \$221,039 billion (99.96 percent), an increase of \$19 billion (a 0.01 percentage point increase); Estimated Transaction Coverage would increase from 3,795,330 trades (99.77 percent) to 3,797,734 trades (99.83 percent), an increase of 2,404 trades (a 0.06 percentage point increase); and Estimated Counterparty Coverage would increase from 30,879 counterparties (88.80 percent) to 31,559 counterparties (90.75 percent), an increase of 680 counterparties (a 1.96 percentage point increase).²⁶² The effect of these limited increases is further mitigated by the fact that at the current \$8 billion phase-in threshold, the substantial majority of transactions are already covered by SD regulation—and related counterparty protection requirements—because they include at least one registered SD as a counterparty. For NFC swaps, as discussed in the Proposal, without notional-equivalent data, it is unclear how many of the 42 In-Scope Entities with 10 or more counterparties that are not registered SDs would actually be subject to SD registration at a \$3 billion

threshold.²⁶³ It is possible that a portion of the swaps activity for some or all of these entities qualifies for the physical hedging exclusion in paragraph (6)(iii) of the SD Definition, and therefore would not be considered swap dealing activity, regardless of the AGNA threshold level.²⁶⁴

As discussed, a lower AGNA threshold could lead to certain entities reducing or ceasing swaps activity to avoid registration and its related costs.²⁶⁵ Although the magnitude of this effect is unclear, reduced swap dealing activity could lead to increased concentration in the swap dealing market, reduced availability of potential swap counterparties, reduced liquidity, increased volatility, higher fees, wider bid/ask spreads, or reduced competitive pricing. Systemic risk could actually increase as a result. The end-user counterparties of these smaller swap dealing entities may be adversely impacted by the above consequences and could face a reduced ability to use swaps to manage their business risks.

Most commenters generally agreed with the Commission's position. For example, commenters indicated that there would be a market-wide costs associated with a lower threshold given that if entities reduced or ceased swaps activity to avoid registration and its related costs, the small and mid-sized end-users and commercial entities who utilize swaps for hedging purposes and NFC swap market participants would have fewer dealers available to them.²⁶⁶ Two commenters indicated that the market-wide benefit of a lower threshold would be limited because Commission regulations not related to SD registration already apply to unregistered entities, and therefore, many of the policy goals of SD registration are already being advanced with respect to swaps entered into by these unregistered entities.²⁶⁷

IATP suggested that contrary to the assumption that small banks may avoid the swap market due to the costs of SD registration at a \$3 billion threshold, the costs and obligations of SD registration would not discourage swap dealing

²⁶³ See 83 FR 27456. Hypothetically, if all 42 entities registered, the percentage of all NFC swaps facing at least one registered SD would rise from approximately 86 percent to 98 percent.

²⁶⁴ See 17 CFR 1.3, Swap dealer, paragraph (6)(iii); *supra* section II.C.1.ii; 83 FR 27456–57.

²⁶⁵ See *supra* sections II.B.1 and II.C.1.ii; 83 FR 27452–54.

²⁶⁶ See *supra* section II.B.1. See also ABA, AGA, AFEX/GPS, BDA, Capital One, Citizens, CDEU, COPE, CEWG, CMC, EEI/EPISA, Frost Bank, IIB, IECA, ISDA/SIFMA, JBA, M&T, NCFE, NRECA/APPA, NGS, SVB, Virtu, and Western Union comment letters.

²⁶⁷ See Citizens and Virtu comment letters.

²⁵⁶ See *supra* section II.B.1. See also AGA, BDA, Capital One, CDEU, CMC, Frost Bank, IECA, M&T, SVB, and Western Union comment letters.

²⁵⁷ See *supra* section II.B.1. See also Citizens, IECA, NRECA/APPA, NGS, and SVB comment letters.

²⁵⁸ See *supra* section II.B.3.

²⁵⁹ See *supra* section II.B.3; Senators comment letter.

²⁶⁰ 83 FR 27456.

²⁶¹ *Id.*

²⁶² See *supra* section II.C.1.ii; 83 FR 27452–54.

when there is strong market demand for innovative swap market risk management products. IATP stated that the lack of participation in the swap market by smaller banks may be due to the smaller banks preferring the price transparency of the futures and options markets as compared to the swap market.²⁶⁸ However, as discussed, the Commission believes, and most commenters agree, that a lower threshold could lead to certain entities reducing or ceasing swaps activity.

However, the Senators questioned why, given the lack of relevant data for NFC swaps, it is necessary to remove the phase-in reduction of the AGNA threshold for energy-related SDs.²⁶⁹ The Commission believes, and commenters generally agreed, that a reduced threshold would have a cost in terms of a decrease in NFC swap market liquidity because some entities may reduce dealing to avoid registration.²⁷⁰ For example, with respect to NFC swaps, EEI/EPISA and NGSAs expressed concern that a lower AGNA threshold would provide less accommodation for increasing NFC prices, which could lead to market participants reducing their swap dealing activity to remain below the threshold.²⁷¹ Further, NGSAs stated that a lower threshold may reduce ancillary swap dealing in commodity markets and reduce counterparty diversity for end-users.²⁷²

The Commission notes that although AGNA data was not available for NFC swaps, the OCC publishes the Quarterly Report on Bank Derivatives Activities, including end-of-quarter gross notional amount position data from call reports filed by insured U.S. commercial banks and savings associations. Although point-in-time position data is not directly comparable to the transaction volume calculations that are required for evaluating AGNA threshold calculations, the report does provide outstanding commodity notional amount position totals in comparison with IRS, CDS, FX swaps, and equity swaps. According to the OCC, as of the end of 2017, NFC swaps represented \$1,373 billion out of the \$171,964 billion total notional amount reported outstanding, or approximately 0.8 percent of the total.²⁷³ Although the

number of transactions involving at least one registered SD is lower in the NFC swap market than other asset classes (86 percent compared to over 99 percent for the other four asset classes), the Commission believes it would be inappropriate to lower the AGNA threshold to \$3 billion only to potentially increase the registered SD coverage rate (as measured by transaction count) for the smallest of the five asset classes as measured by outstanding notional amount per the OCC Quarterly Report on Bank Derivatives Activities.

(iii) Higher Threshold

Conversely, a higher AGNA threshold would potentially decrease the number of registered SDs, which could have a negative impact on achieving the general benefits associated with the policy objectives of SD regulation. For example, a higher threshold would allow a greater amount of swap dealing to be undertaken without certain counterparty protections.²⁷⁴ This might impact the integrity of the swap market to some extent. However, the Commission is unable to quantify how the integrity of swap market might be harmed. On the other hand, as noted by the Commission and commenters, the higher the AGNA threshold, the greater the number of entities that are able to engage in dealing activity without being required to register, which could increase competition and liquidity in the swap market.²⁷⁵ A higher threshold could also allow the Commission to expend its resources on entities with larger swap dealing activities that warrant more oversight.

Some commenters agreed that the small decrease in Estimated AGNA Coverage and Estimated Transaction Coverage at higher thresholds potentially indicates that increasing the threshold to up to \$100 billion may have a limited effect on the systemic risk and market efficiency-related benefits of SD regulation.²⁷⁶

available at [https://www.occ.gov/topics/capital-markets/financial-markets/derivatives/dq318.pdf](https://www OCC.gov/topics/capital-markets/financial-markets/derivatives/dq318.pdf).

²⁷⁴ See *supra* section II.C.2; 83 FR 27454–56.

²⁷⁵ See *supra* sections II.B.2 and II.C.2; 83 FR 27454–56.

²⁷⁶ See *supra* section II.B.2. As discussed, in comparison to an \$8 billion threshold, a \$100 billion threshold would reduce the Estimated AGNA Coverage from approximately \$221,020 billion (99.95 percent) to \$220,877 billion (99.88 percent), a decrease of \$143 billion (a 0.06 percentage point decrease). In comparison to an \$8 billion threshold, a \$100 billion threshold would reduce the Estimated Transaction Coverage from 3,795,330 trades (99.77 percent) to 3,773,440 trades (99.20 percent), a decrease of 21,890 trades (a 0.58 percentage point decrease). The decreases would be more limited at higher thresholds of \$20 billion or \$50 billion. See *supra* section II.C.2; 83 FR 27455.

Additionally, a higher threshold could enhance the benefits associated with a *de minimis* exception, for example by allowing entities to increase ancillary dealing activity.²⁷⁷ However, the decrease in Estimated Counterparty Coverage indicates that fewer entities would be transacting with registered SDs, reducing the counterparty protection benefits of SD regulation if the threshold increased from \$8 billion to \$20 billion, \$50 billion, or \$100 billion.²⁷⁸ The Commission also notes that increasing the threshold could result in changes in market behavior that could lead to the regulatory coverage decreasing more than the analysis indicated.

Additionally, though it did not conduct an analysis of AGNA activity for NFC swaps, the Commission is of the view that increasing the AGNA threshold could potentially lead to fewer registered SDs participating in the NFC swap market, similar to its observations with respect to IRS, CDS, FX swaps, and equity swaps discussed above in section II.C.2. This could reduce the number of entities transacting with registered SDs.

The cost of reduced protections for counterparties would be realized to the extent that a higher threshold would result in fewer swaps involving at least one registered SD. Additionally, depending on how the swap market adapts to a higher threshold, it is also possible that the reduction in Estimated Regulatory Coverage would be greater than the data indicates to the extent that a higher threshold leads to an increased amount of swap dealing activity between entities that are not registered SDs. In such a scenario, Estimated Regulatory Coverage could potentially decrease more than the data indicates, increasing the general costs associated with the *De Minimis* Exception.

2. Direct Cost and Benefits

As discussed in the Proposal, for any AGNA threshold, some firms will have AGNA of swap dealing activity sufficiently close to the threshold so as to require analysis to determine whether their activity qualifies as *de minimis*. Hence, (1) with a \$3 billion threshold,

²⁷⁷ See *supra* sections II.B.2 and II.C.2; 83 FR 27455.

²⁷⁸ As discussed, the data also indicates that at higher thresholds, there is a more pronounced decrease in Estimated Counterparty Coverage. The Estimated Counterparty Coverage would decrease from 30,879 counterparties (88.80 percent) to 28,234 counterparties (81.19 percent), a decrease of 2,645 counterparties (a 7.61 percentage point decrease). The decrease would be lower at thresholds of \$20 billion and \$50 billion, at 2.80 percentage points and 5.71 percentage points, respectively. See *supra* section II.C.2; 83 FR 27455.

²⁶⁸ See IATP comment letter.

²⁶⁹ See *supra* section II.B.3; Senators comment letter.

²⁷⁰ See *supra* sections II.B.1 and II.C.1.ii.

²⁷¹ See *supra* section II.B.1; EEI/EPISA and NGSAs comment letters. As stated by EEI/EPISA, if NFC prices increase, the same level of swaps activity would potentially have a higher notional amount.

²⁷² See NGSAs comment letter.

²⁷³ See OCC, Quarterly Report on Bank Trading and Derivatives Activities (Fourth Quarter 2017),

some set of entities would likely have to incur the direct costs of analyzing whether they would exceed the threshold, (2) with an \$8 billion threshold, a (mostly) different set of entities would have to continue to incur costs of analyzing their activity, and (3) with a higher threshold, some entities would no longer need to conduct an ongoing analysis of whether they would be above the new threshold, while other entities may begin conducting such an analysis.

Based on the available data, the Commission estimates that if the AGNA threshold were set at \$3 billion, approximately 22 currently unregistered entities would need to conduct an initial analysis of whether they would be above the threshold.²⁷⁹ The Commission estimates that the potential total direct cost of conducting the initial analysis for the 22 entities would average approximately \$79,000 per entity, or approximately \$1.7 million in the aggregate.²⁸⁰

Certain of those entities with ongoing swap dealing activity that is near a \$3 billion threshold may also need to conduct periodic de minimis calculation analyses to assess whether they qualify for the exception. The Commission estimates that approximately 11 entities may need to conduct such analyses.²⁸¹ Further, the

²⁷⁹ Commission staff analyzed the swaps activity of market participants over a one-year period to develop this estimate. The estimate includes 22 In-Scope Entities that had 10 or more counterparties and between \$1 billion and \$5 billion in AGNA of swaps activity in IRS, CDS, FX swaps, and equity swaps. Entities that were already registered SDs were excluded. The estimate does not account for entities that primarily are entering into NFC swaps because notional amount information was not available for that asset class. See 83 FR 27474 n.191.

²⁸⁰ This estimate is based on the following staff requirements for this determination: 25 hours for an OTC principal trader at \$695/hour, 40 hours for a compliance attorney at \$335/hour, 35 hours for a chief compliance officer at \$556/hour, 80 hours for an operations manager at \$290/hour, and 20 hours for a business analyst at \$273/hour. These individuals would be responsible for identifying, analyzing, and aggregating the swap dealing activity of a firm and its affiliates. The estimates of the number of personnel hours required have been updated from the SD Definition Adopting Release in light of the Commission's experience in implementing the SD Definition.

The estimates of the hourly costs for these personnel are from SIFMA's Management & Professional Earnings in the Securities Industry 2013 survey, modified to account for an 1800-hour work-year and multiplied by 5.35 to account for firm size, employee benefits, and overhead, which is the same multiplier that was used when the SD Definition was adopted. See 77 FR 30712 n.1347.

The Commission recognizes that particular entities may, based on their circumstances, incur costs substantially greater or less than the estimated averages. See 83 FR 27474 n.192.

²⁸¹ The estimate of 11 entities is approximately 50 percent of the 22 entities that would need to undertake an initial analysis. This estimate assumes

Commission estimates that the potential annual direct cost of conducting these ongoing analyses for those 11 entities would be approximately \$40,000 per entity, or \$440,000 in the aggregate.²⁸² The projected 11 entities that may conduct periodic de minimis calculations represents a net figure, as some entities may need to conduct a periodic de minimis calculation, while on the other hand, some entities with AGNA near \$8 billion might be able to avoid periodic de minimis calculation costs because they will be certain that their AGNA exceeds the \$3 billion threshold.

Conversely, the Commission assumes that a higher threshold would permit certain entities to no longer incur ongoing costs of assessing whether they are above the threshold. The Commission estimates the savings that would result from a higher AGNA threshold of \$20 billion. Based on the available data, the Commission estimates that if the threshold were set at \$20 billion, approximately 29 entities would no longer need to conduct an ongoing analysis of whether they would be above the new threshold, while 4 entities may begin conducting such an analysis.²⁸³ The Commission estimates that the ongoing cost savings for the net 25 entities that would no longer be conducting periodic de minimis threshold analyses would average approximately \$40,000 per entity, or \$1 million in the aggregate per year.²⁸⁴

The Commission notes that ABA submitted a study that evaluated the costs and benefits of SD registration for member banks at various AGNA thresholds, prepared by NERA Economic Consulting ("NERA").²⁸⁵ NERA's study provided cost estimates for initial and ongoing testing of

that many entities would, following the initial analysis, determine that they would either need to register or choose not to engage in enough dealing activity to require ongoing monitoring. See 83 FR 27474 n.193.

²⁸² The Commission estimates that the ongoing analysis would be streamlined as a result of the initial analysis, and therefore would be less costly. For purposes of this calculation, the Commission estimates that the cost of the ongoing analysis would be approximately 50 percent of the cost of the initial analysis. See 83 FR 27474 n.194.

²⁸³ Commission staff analyzed the swaps activity of market participants over a one-year period to develop this estimate. The estimate includes 29 In-Scope Entities that had between \$3 billion and \$15 billion, and 4 In-Scope Entities that had between \$15 billion and \$25 billion, in AGNA of swaps activity in IRS, CDS, FX swaps, and equity swaps, and at least 10 counterparties. The estimate does not account for entities that primarily are entering into NFC swaps because notional amount information was not available for that asset class. See 83 FR 27474 n.195.

²⁸⁴ See *supra* note 282.

²⁸⁵ See ABA comment letter (attaching NERA study).

whether a bank holding company has exceeded the AGNA threshold, under various scenarios.²⁸⁶ To arrive at aggregate estimates, NERA estimated the per entity costs of initial and ongoing SD registration determination analyses, and also provided its estimates of the number of registrants at various AGNA thresholds, which Commission staff used to estimate the additional costs or cost savings at different AGNA thresholds, as compared to an \$8 billion threshold.

First, to estimate initial and ongoing SD registration determination costs, NERA sent a survey to 22 bank holding companies that participate in the swap market and received eight responses.²⁸⁷ Based on these responses, NERA estimated average, one-time, upfront SD determination costs of \$657,696 per entity²⁸⁸ (as compared to the Commission's estimate of approximately \$79,000 per entity on average). Further, NERA estimated average, ongoing, SD determination costs of \$89,209 per entity²⁸⁹ (as compared to the Commission's estimate of approximately \$40,000 per entity on average).²⁹⁰

NERA's survey of banking entities indicates significantly higher initial and ongoing SD determination monitoring costs than the Commission's cost estimates on a per entity annualized basis. NERA's per entity cost estimates were based on the eight responses to their survey, while the Commission's estimates were based on: (1) Estimates

²⁸⁶ Although addressed by the NERA study, the costs associated with SD regulatory requirements (e.g., margin, reporting, technology, etc.) are not considered in this analysis. Costs associated with regulatory requirements applicable to SDs result from other rulemakings and are outside the scope of rulemakings related to the De Minimis Exception.

²⁸⁷ See ABA comment letter (attaching NERA study). To estimate activity, NERA applied a 1.5 assumed turnover ratio to swap position data from the Federal Reserve Bank of Chicago's "Holding Company Data" for bank holding companies with greater than \$10 billion in assets on a consolidated basis. The 1.5 adjustment factor was based on NERA's estimate of the typical turnover/notional holdings ratio to convert periodic position data into an annualized estimate of AGNA transaction volume.

²⁸⁸ NERA estimated median, one-time, upfront SD determination costs of \$188,095 per entity, significantly lower than the average cost of \$657,696. NERA noted that initial SD determination costs were distributed widely, but the variation did not appear related to institution size or magnitude of annual swaps activity.

²⁸⁹ NERA estimated median, ongoing, SD determination costs of \$83,430 per entity.

²⁹⁰ NERA also calculated a 10 year net present value estimate of the ongoing monitoring costs. NERA estimated the present value of ongoing determination costs to be \$723,562 per bank holding company using the average estimate. Additionally, NERA's analysis included 10 year net present value estimates of business conduct and margin costs, which was outside of the scope of the CFTC's analysis.

of the number of personnel hours required in light of the Commission's experience in implementing the SD Definition; and (2) modified costs from SIFMA's Management & Professional Earnings in the Securities Industry 2013 survey.²⁹¹ Additionally, NERA's analysis evaluated bank holding companies on a consolidated basis, while the Commission's analysis included subsidiaries of banks prior to consolidation and firms unrelated to banks.

Second, to estimate the number of entities that would be required to register at different AGNA thresholds, NERA evaluated four different scenarios, including various combinations of an AGNA threshold, a risk-based threshold, and amendments to date restrictions related to the IDI Swap Dealing Exclusion. At various AGNA thresholds—including \$3 billion, \$8 billion, and \$15 billion—NERA estimated the number of bank holding companies expected to register as SDs for each scenario it evaluated. To allow for a more direct comparison with the Commission's estimates, the Commission made an assumption that the difference in the number of entities

required to register at \$3 billion and \$15 billion thresholds, as compared to an \$8 billion threshold, would also be the number of entities that would incur ongoing costs or cost savings related to assessing whether they would be required to register as SDs. Depending on the scenario evaluated, the Commission believes that NERA estimated that 13 to 17 additional bank holding companies would conduct ongoing SD registration-related analyses at the \$3 billion threshold as compared to the \$8 billion threshold.²⁹² Conversely, depending on the scenario, the Commission believes that NERA estimated that 7 to 10 bank holding companies would no longer incur ongoing monitoring costs at a \$15 billion threshold compared to an \$8 billion threshold.²⁹³

In general, the Commission believes that its per entity estimated costs reflect the broader nature of the types of entities that would need to conduct such an analysis. For example, NERA's analysis focused on survey responses from consolidated bank holding companies, whereas the Commission's estimates also account for smaller financial institutions and non-financial

entities that may have less operational complexity and therefore may incur lower costs in making determinations. Additionally, the Commission's estimates of the number of entities that would incur costs related to SD registration analyses are based on non-public SDR data on AGNA activity, while NERA's implied estimates are based on publicly available swap position data from the Federal Reserve Bank of Chicago's "Holding Company Data" for bank holding companies with greater than \$10 billion in assets on a consolidated basis.

However, given the different methods and sources of information utilized, the Commission is providing a range of estimated costs or cost savings that combine the per entity costs and the counts of the number of entities required to conduct SD registration analyses, as estimated by the Commission and NERA. The tables below summarize the estimates for initial and ongoing SD determination costs. Since NERA conducted estimates using four different scenarios, the tables below include information based on the highest and lowest number of entities estimated by NERA at given thresholds.

TABLE 1—ESTIMATE OF ADDITIONAL COSTS INCURRED FOR INITIAL SD DETERMINATION ANALYSES
[\$3 Billion threshold]²⁹⁴

Per entity average cost estimate	CFTC (22 entities)	NERA low estimate (13 entities)	NERA high estimate (17 entities)
CFTC—\$79,000	\$1,738,000	\$1,027,000	\$1,343,000
NERA—\$657,696	14,469,312	8,550,048	11,180,832

TABLE 2—ESTIMATE OF ADDITIONAL COSTS INCURRED FOR ONGOING SD DETERMINATION ANALYSES
[\$3 Billion threshold]

Per entity average cost estimate	CFTC (11 entities)	NERA low estimate (13 entities)	NERA high estimate (17 entities)
CFTC—\$40,000	\$440,000	\$520,000	\$680,000
NERA—89,209	981,299	1,159,717	1,516,553

TABLE 3—ESTIMATE OF COST SAVINGS FOR NOT CONDUCTING ONGOING SD DETERMINATION ANALYSES
[\$15 Billion or \$20 billion threshold]²⁹⁵

Per entity average cost estimate	CFTC (\$20 billion) (25 entities)	NERA low estimate (\$15 billion) (7 entities)	NERA high estimate (\$15 billion) (10 entities)
CFTC—\$40,000	\$1,000,000	\$280,000	\$400,000

²⁹¹ See *supra* note 280.

²⁹² This is based on NERA's "Number of Banks Required To Register As Swap Dealer" estimates at \$3 billion compared to \$8 billion under the various scenarios. NERA did not explicitly calculate the number of entities that may yet incur initial determination costs, but instead estimated the number of entities that would be required to register at various thresholds.

²⁹³ This is based on NERA's "Number of Banks Required To Register As Swap Dealer" estimates at \$15 billion compared to \$8 billion under the various scenarios. Note that NERA did not provide estimates at a \$20 billion threshold, and its estimates at the \$15 billion threshold are the closest for relevant comparison with Commission estimates at \$20 billion.

²⁹⁴ For Tables 1 through 3, aggregate cost or cost savings estimates are calculated using a given scenario's per entity average cost estimate multiplied by the relevant entity count. For example, in Table 1, \$79,000 multiplied by 22 entities equals \$1,738,000.

²⁹⁵ As discussed, the Commission considered a higher threshold of \$20 billion, while NERA considered a higher threshold of \$15 billion.

TABLE 3—ESTIMATE OF COST SAVINGS FOR NOT CONDUCTING ONGOING SD DETERMINATION ANALYSES—Continued
 [\$15 Billion or \$20 billion threshold]²⁹⁵

Per entity average cost estimate	CFTC (\$20 billion) (25 entities)	NERA low estimate (\$15 billion) (7 entities)	NERA high estimate (\$15 billion) (10 entities)
NERA—89,209	2,230,225	624,463	892,090

Based on its analysis, and incorporating information provided by NERA, the Commission estimates that for the 13 to 22 entities at a \$3 billion AGNA threshold that may need to conduct an initial SD registration analyses, at per entity average costs of \$79,000 to \$657,696, the estimated aggregate initial determination cost ranges from \$1,027,000 to \$14,469,312, as indicated in Table 1.²⁹⁶

Additionally, for the 11 to 17 entities at a \$3 billion AGNA threshold that may need to conduct ongoing SD registration analyses, at per entity average costs of \$40,000 to \$89,209, the estimated aggregate annual ongoing monitoring cost ranges from \$440,000 to \$1,516,553, as indicated in Table 2.

Lastly, for the 7 to 25 entities at a \$15 billion or \$20 billion AGNA threshold that would no longer need to conduct ongoing SD registration analyses, at per entity average cost savings of \$40,000 to \$89,209, the estimated aggregate annual ongoing monitoring cost savings ranges from \$280,000 to \$2,230,225, as indicated in Table 3.

The Commission notes that the aggregate estimates of initial and ongoing SD determination and monitoring costs, based on either the Commission or NERA's per entity cost estimates or marginal entity count estimates, buttress the Commission's decision to adopt an \$8 billion threshold and not let it decrease to \$3 billion. Additionally, the Commission is of the view that the cost savings at \$15 billion or \$20 billion thresholds would not sway its decision to maintain the threshold at \$8 billion given the general costs and benefits discussed above. Lastly, in light of all the considerations, the Commission would come to the same conclusion, regardless of where the most accurate cost falls in the range of potential initial and ongoing costs.

3. Section 15(a)

Section 15(a) of the CEA requires the Commission to consider the effects of its

²⁹⁶ Using a different methodology, NERA estimated \$2,623,925 (median estimate) to \$9,174,855 (average estimate) in remaining aggregate initial determination costs. The Commission notes that this estimate is within the \$1,027,000 to \$14,469,312 range calculated above.

actions in light of the following five factors:

(i) Protection of Market Participants and the Public

Providing regulatory protections for swap counterparties who may be less experienced or knowledgeable about the swap products offered by SDs (particularly end-users who use swaps for hedging or investment purposes) is a fundamental benefit advanced by registration of SDs. For example, registered SDs are required to provide mid-mark quotes and perform scenario analyses. However, these requirements are not in standard ISDA agreements and are not required of entities that deal a de minimis amount of swaps.

The Commission is maintaining the current de minimis phase-in threshold of \$8 billion in AGNA of swap dealing activity. As discussed above, the Commission recognizes that a \$3 billion threshold may result in more entities being required to register as SDs compared to the proposed (and currently in-effect) \$8 billion threshold, thereby extending counterparty protections to a greater number of market participants. However, this benefit is relatively small because, at the current \$8 billion phase-in threshold, the substantial majority of transactions are already covered by SD regulation—and related counterparty protection requirements—since they include at least one registered SD as a counterparty.²⁹⁷

On the other hand, as noted above, a threshold above \$8 billion may result in fewer entities being required to register as SDs, thus extending counterparty protections to a fewer number of market participants. Although the Estimated Transaction Coverage and Estimated AGNA Coverage would not decrease much at higher thresholds of up to \$100 billion, the decrease in Estimated Counterparty Coverage is more pronounced at higher AGNA thresholds, potentially indicating that the benefit of SD counterparty protections requirements could be reduced at higher thresholds.

²⁹⁷ As discussed in section II.C.1.i, the 2017 Transaction Coverage ratio was approximately 98 percent.

SD registration is also intended to reduce systemic risk in the swap market. Pursuant to the Dodd-Frank Act, the Commission has proposed or adopted regulations for SDs, including margin and risk management requirements, designed to mitigate the potential systemic risk inherent in the swap market. Therefore, the Commission recognizes that a lower threshold may result in more entities being required to register as SDs, thereby potentially further reducing systemic risk. Conversely, a higher threshold may result in fewer entities being required to register an SD and, thus, possibly increase systemic risk.

However, the data appears to indicate that the additional entities that would need to register at the \$3 billion threshold are engaged in a comparatively smaller amount of swap dealing activity. Many of these entities might be expected to have fewer counterparties and smaller overall risk exposures as compared to the SDs that engage in swap dealing in excess of the \$8 billion level. Accordingly, the Commission believes that the incremental reduction in systemic risk that may be achieved by registering dealers that engage in dealing between the \$3 billion and \$8 billion thresholds is limited.

The data also indicates that at higher thresholds of \$20 billion, \$50 billion, or \$100 billion, fewer entities would be required to register as SDs, though the change in regulatory coverage as measured by Estimated AGNA Coverage and Estimated Transaction Coverage would be small. Thus, the Commission believes that the increase in systemic risk that may occur due to a higher threshold would not be significant. However, depending on how the market adapts to a higher threshold, the level of regulatory coverage could potentially decrease more than the data indicates.

The Commission believes that setting the AGNA threshold at \$8 billion will not substantially diminish the protection of market participants and the public as compared to a \$3 billion threshold. Further, as discussed, the Commission does not expect that an increase in the threshold would

substantially increase the protection of market participants and the public.

(ii) Efficiency, Competitiveness, and Financial Integrity of Markets

Another goal of SD registration is swap market efficiency, orderliness, and transparency. These market benefits are achieved through regulations regarding, for example, recordkeeping, reporting, disclosure, and risk management.

As compared to a \$3 billion threshold, an \$8 billion threshold may have a negative effect on the efficiency and integrity of the markets as fewer entities are required to register as SDs and fewer transactions become subject to SD-related regulations. However, the Commission also recognizes that the efficiency and competitiveness of the swap market may be negatively impacted if the AGNA threshold is set too low, by potentially increasing barriers to entry that may stifle competition and reduce swap market efficiency. For example, if entities choose to reduce or cease their swap dealing activities in response to the \$3 billion threshold, the number or availability of market makers for swaps may be reduced, which could lead to increased costs for potential counterparties and end-users. Conversely, a higher threshold may increase market liquidity, efficiency, and competition as more entities engage in swap dealing without SD registration as a barrier to entry. However, a higher threshold may also result in fewer swaps being subject to SD-related regulations, potentially reducing the financial integrity of markets.

Considering these countervailing factors, the Commission believes that setting the AGNA threshold at \$8 billion will not significantly diminish the efficiency, competitiveness, and financial integrity of markets as compared to a \$3 billion threshold. Further, as discussed, an increase in the threshold would potentially have both positive and negative effects to the efficiency, competitiveness, and financial integrity of the markets.

(iii) Price Discovery

All else being equal, the Commission believes that price discovery will not be harmed and might be improved if there are more entities engaging in ancillary dealing due to increased competitiveness among swap counterparties. The Commission is of the view that, as compared to a \$3 billion threshold, an \$8 billion threshold would encourage participation of new swap dealing businesses and promote ancillary dealing because those entities engaged

in swap dealing activities below the threshold would not need to incur the direct costs of registration until they exceeded a higher threshold.

Similarly, raising the threshold above \$8 billion could lead to even more entities engaging in ancillary dealing.

The Commission notes that some counterparties might be more likely to transact at off-market prices if they trade with an entity that does not provide mid-market quotes or scenario analyses, as would be required if the entity were a registered SD. If so, such transactions might harm post-trade price discovery since these transactions would occur at off-market prices.

(iv) Sound Risk Management

The Commission notes that a higher AGNA threshold could lead to impaired risk management practices because a lower number of entities would be required by regulation to: (1) Develop and implement detailed risk management programs; (2) adhere to business conduct standards that reduce operational and other risks; and (3) satisfy margin requirements for uncleared swaps. For the same reason, a lower threshold could positively impact risk management since more entities would be required to comply with the above mentioned risk-related SD regulations. The Commission also notes that to the extent an entity that is not required to register as an SD at a higher threshold is a prudentially regulated bank, that entity would be subject to the risk management requirements of its prudential regulator.

(v) Other Public Interest Considerations

The Commission has not identified any other public interest considerations with respect to setting the AGNA threshold at \$8 billion in swap dealing activity.

D. Antitrust Considerations

Section 15(b) of the CEA requires the Commission to take into consideration the public interest to be protected by the antitrust laws and endeavor to take the least anticompetitive means of achieving the purposes of the CEA, in issuing any order or adopting any Commission rule or regulation (including any exemption under section 4(c) or 4c(b)), or in requiring or approving any bylaw, rule, or regulation of a contract market or registered futures association established pursuant to section 17 of the CEA.²⁹⁸ The Commission believes that the public

interest to be protected by the antitrust laws is generally to protect competition.

The Commission has considered this final rule to determine whether it is anti-competitive and has identified no anti-competitive effects. Because the Commission has determined that the final rulemaking is not anti-competitive and has no anti-competitive effects, the Commission has not identified any less anti-competitive means of achieving the purposes of the CEA.

List of Subjects in 17 CFR Part 1

Commodity futures, Definitions, De minimis exception, Insured depository institutions, Swaps, Swap dealers.

For the reasons stated in the preamble, the Commodity Futures Trading Commission amends 17 CFR part 1 as follows:

PART 1—GENERAL REGULATIONS UNDER THE COMMODITY EXCHANGE ACT

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

Authority: 7 U.S.C. 1a, 2, 5, 6, 6a, 6b, 6c, 6d, 6e, 6f, 6g, 6h, 6i, 6k, 6l, 6m, 6n, 6o, 6p, 6r, 6s, 7, 7a–1, 7a–2, 7b, 7b–3, 8, 9, 10a, 12, 12a, 12c, 13a, 13a–1, 16, 16a, 19, 21, 23, and 24 (2012).

■ 2. In § 1.3, amend the definition of the term “Swap dealer” by revising paragraph (4)(i)(A) and removing and reserving paragraph (4)(ii).

The revision reads as follows:

§ 1.3 Definitions.

* * * * *

Swap Dealer. * * *

(4) *De minimis exception*—(i)(A) *In general.* Except as provided in paragraph (4)(vi) of this definition, a person that is not currently registered as a swap dealer shall be deemed not to be a swap dealer as a result of its swap dealing activity involving counterparties, so long as the swaps connected with those dealing activities into which the person—or any other entity controlling, controlled by or under common control with the person—enters over the course of the immediately preceding 12 months have an aggregate gross notional amount of no more than \$8 billion, and an aggregate gross notional amount of no more than \$25 million with regard to swaps in which the counterparty is a “special entity” (as that term is defined in section 4s(h)(2)(C) of the Act, 7 U.S.C. 6s(h)(2)(C), and § 23.401(c) of this chapter), except as provided in paragraph (4)(i)(B) of this definition. For purposes of this definition, if the stated notional amount of a swap is leveraged or enhanced by the structure of the

²⁹⁸ 7 U.S.C. 19(b).

swap, the calculation shall be based on the effective notional amount of the swap rather than on the stated notional amount.

* * * * *

Issued in Washington, DC, on November 6, 2018, by the Commission.

Robert Sidman,

Deputy Secretary of the Commission.

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

Appendices to De Minimis Exception to the Swap Dealer Definition—Commission Voting Summary, Chairman’s Statement, and Commissioners’ Statements

Appendix 1—Commission Voting Summary

On this matter, Chairman Giancarlo, and Commissioners Quintenz, Behnam, Stump, and Berkovitz voted in the affirmative. No Commissioner voted in the negative.

Appendix 2—Statement of Chairman J. Christopher Giancarlo

Today’s final rule on the numeric threshold for swap dealer *de minimis* will provide the market with certainty that the threshold will not fall from \$8 billion to \$3 billion. I fully support the proposed final rule.

The action before us is without prejudice to all other items in the Commission’s June 2018 NPRM. That includes various proposed rule amendments and other topics for consideration. Those proposals and considerations are clearly of wide ranging interest as evidenced by the public comments received. They remain under staff consideration pending further Commission action.

Indeed, I will direct CFTC staff to continue their analysis of the range of matters raised in the June 2018 NPRM and comments submitted by the public.

I will specifically ask staff to conduct a study on possible alternative metrics for the calculation of the swap dealer *de minimis* threshold drawing upon proposals in the June 2018 NPRM, including the feasibility of: (i) Removing cleared swaps from the current *de minimis* calculation; (ii) haircutting cleared swaps included in the current *de minimis* calculation; (iii) adopting a new, bifurcated *de minimis* calculation that uses initial margin amounts for cleared swaps and entity-netted notional amounts for uncleared swaps; and (iv) applying other risk-based approaches that the staff may recommend. I will be asking the staff for specific deadlines and deliverables for this work. Once staff has reviewed and analyzed the data, I expect that the study will be made public for further discussion and possible Commission consideration.

I deliberately decline at this time to express any view on the appropriateness of whether any of the proposals in the June 2018 NPRM not before us today should be addressed by CFTC unilateral rulemaking or

joint consideration with the U.S. Securities and Exchange Commission (SEC).

Be assured that SEC Chairman Clayton and I—and our fellow CFTC and SEC Commissioners—are committed to working together on robust harmonization where appropriate and working jointly where necessary on these and other matters.

With respect to IDIs, staff has informed me that they would consider no-action relief for IDIs pending formal Commission action should they receive a meritorious request.

In sum, I am hopeful that we will today provide market certainty that the *de minimis* threshold will not fall below its current level.

Surely, it has taken a while to reach this point. Yet, I am hopeful that we may achieve it with a good degree of consensus across the full Commission. Assuming so, then we have increased market certainty—a very good thing in trading markets.

Sometimes it’s worth the wait.

Appendix 3—Statement of Commissioner Brian D. Quintenz

I support today’s final rule to rescind the *de minimis* threshold’s scheduled reduction to \$3 billion of gross notional swap dealing activity. Every iteration of data analysis completed by CFTC staff on this issue, from the 2015 Preliminary Report,¹ to the 2016 Final Report,² to the updated data and analysis in the 2018 June proposed rule, and to the data presented in this final rule, clearly and unequivocally supported eliminating this ill-conceived reduction. I am pleased that today’s action will remove a large source of negative regulatory uncertainty for market participants in managing their swaps business and serving their customers.

However, this is just the first of many necessary steps toward correcting what I believe is a flawed swap dealer registration policy. Therefore, it is my hope that today’s final rule should be viewed with finality only in this one regard.

The Dodd-Frank Act advanced three main and substantial policy objectives for swap dealer registration: Systemic risk reduction, counterparty protection, and enhanced swap market transparency and efficiency. As I have emphasized on many prior occasions, given the significant costs of swap dealer regulation, it is critical that the *de minimis* exception be appropriately calibrated to ensure that the correct market group—those best situated to realize the corresponding policy goals of registration—shoulders the burdens of swap dealer regulations.

As I have also said repeatedly in the past, notional value is a poor measure of activity, and it is a meaningless measure of risk. Therefore, by itself, notional value is an incredibly deficient metric by which to impose large costs and achieve substantial policy objectives. A one-size-fits-all notional value test for swap dealer registration

captures entities that engage in low volume, low risk activity with high notional amounts, and places those firms under the same regulatory regime as the world’s largest, most complex financial institutions that deal in *trillions of dollars’* worth of swaps.³ The end result is that smaller firms are disincentivized from engaging in lower risk activity when faced with justifying the cost of swap dealer registration.

I have heard anecdotally from certain small to mid-sized players in the swap markets that the breakeven point of the costs of swap dealer registration as measured by a level of notional swap dealing activity is much higher than the \$8 billion level in this rule. If that is the case, the current \$8 billion notional threshold effectively forces these smaller players to curtail their swap dealing business, thereby limiting competition and further concentrating swaps activity with their larger competitors.⁴

In my view, an appropriately calibrated *de minimis* exception would better align the criteria of the *de minimis* threshold with the costs of swap dealer regulation, particularly the largest costs tied to mitigating systemic risk, like capital and margin. A *de minimis* threshold based on metrics more closely correlated with the risk of the products traded, as opposed to the current risk-insensitive notional value metric, would better measure dealing activity and more appropriately capture the entities warranting Commission oversight.

I am pleased the Chairman continues to recognize this and has directed staff to study many of the alternative risk-based registration metrics that were suggested in the proposed rule. The staff report will provide the Commission with additional data and insights into the impact that alternative approaches may have on swap dealer registration. For example, staff’s analysis should show how removing or haircutting cleared swaps from the *de minimis* calculation would impact the number and composition of firms required to register as swap dealers. The report will also provide staff with an opportunity to consider, for the first time, how a registration threshold tied to initial margin for cleared swaps could better represent a *de minimis* quantity of swap dealing activity. For uncleared products, staff can examine the impact of using entity-netted notional amounts, a more accurate measure of a firm’s risk and market size, as a metric of swap dealing activity. The results of the staff report will be critical to any future Commission consideration of a

³ See Office of the Comptroller of the Currency, “Quarterly Report on Bank Trading and Derivatives Activities, Second Quarter 2018,” available at: <https://www.occ.gov/topics/capital-markets/financial-markets/derivatives/dq218.pdf>.

⁴ For further discussion, see comment letter to CFTC from Financial Services Roundtable dated January 19, 2016 (“We do not see a benefit to requiring an entity that enters into a small number of swaps with a large notional amount but little exposure to choose between exiting the market or registering as a swap dealer, nor should entities that are taking on very large exposures without crossing a notional threshold, or a trade or counterparty count metric, be unregulated because they have concentrated risk in a small number of trades.”).

¹ See Swap Dealer *De Minimis* Exception Preliminary Report (“Preliminary Report”), http://www.cftc.gov/idc/groups/public/@swaps/documents/file/dfreport_sddeminis_1115.pdf.

² See Swap Dealer *De Minimis* Exception Final Report (“Final Report”), https://www.cftc.gov/sites/default/files/idc/groups/public/@swaps/documents/file/dfreport_sddeminis081516.pdf.

more risk-sensitive swap dealer registration threshold.

In addition, many of the policy recommendations discussed in the proposed rule, such as better allowing insured depository institutions to assist their customers in hedging loan-related risks and excluding non-deliverable forwards from an entity's *de minimis* count—would advance the policy goals of the *de minimis* exception by encouraging greater participation and competition in the swap markets. I would eagerly anticipate the Commission's action on these important reforms. As the Commission's recent no-action letter to a Main Street bank this past August shows, the deficiencies of the current *de minimis* exception are beginning to squeeze firms' activity and constrain their ability to serve clients.⁵

Any *de minimis* threshold must always be put into context of the broader swaps market regulatory regime. The Commission is not establishing the *de minimis* exception in a vacuum. Since the swap dealer definition was adopted in 2012, a broad range of rigorous regulatory requirements have gone into effect which also advance the goals of swap dealer registration, such as mandatory clearing, SEF trading, swap data reporting, and margin requirements for uncleared swaps.

The Commission's regulatory framework for the swap market has greatly evolved from its state six years ago; it is only common sense that the swap dealer registration threshold should evolve as well. It will be a great day when financial regulators, including the CFTC, finally move away from gross notional value as any sort of metric or test of derivatives exposure, activity, or risk. I look forward to that day, and I am committed to working with the Chairman, my fellow Commissioners, and our staff to make sure we get the swap dealer *de minimis* exception policy right.

Appendix 4—Concurring Statement of Commissioner Rostin Behnam

Today, the Commission acts decisively to set the aggregate gross notional amount ("AGNA") threshold for the *de minimis* exception at \$8 billion in swap dealing activity entered into by a person over the preceding 12 months. I am comfortable supporting today's final rule because it is limited to establishing a clear and certain *de minimis* threshold. While I was unable to support the proposed rule—which moved the Commission far beyond the task before it towards unilaterally redefining swap dealing activity absent meaningful, congressionally-required collaboration with the Securities and Exchange Commission ("SEC")—I am gratified that the Commission is not moving forward with aspects of the Proposal which would have further complicated the distinction between dealing and non-dealing activities.¹ Such action would have been

⁵ CFTC No-Action Letter 18–20 (August 28, 2018), <https://www.cftc.gov/PressRoom/PressReleases/7775-18>.

¹ De Minimis Exception to the Swap Dealer Definition, 83 FR 27444, 27481–2 (proposed June 12, 2018).

detrimental to market participants. To the extent the Commission continues to consider addressing long standing concerns with the IDI Swap Dealing Exclusion,² ambiguity regarding the treatment of swaps used for hedging, or relief applicable to swaps that result from multilateral portfolio compression exercises, it should do so jointly with the SEC.

NFC Swap Data

Today's decision to maintain the AGNA threshold at \$8 billion follows a period of prolonged uncertainty during which Commission staff conducted more complete data analysis regarding the *de minimis* exception.³ While swap data repository ("SDR") data quality has improved, AGNA data was unavailable for non-financial commodity ("NFC") swaps.⁴ Nevertheless, Commission staff used counterparty and transaction counts and a series of assumptions to analyze likely swap dealing activity in the NFC swap market and concluded that reducing the \$8 billion AGNA threshold could lead to reduced liquidity in NFC swaps, negatively impacting end-users and commercial entities who utilize NFC swaps for hedging.⁵ The Commission further relied upon findings and comments that the unique characteristics of the NFC swap market pose less systemic risk than financial swaps.⁶

It is my hope that Commission staff will continue to examine and monitor data and activities in the NFC swap market to ensure that concentrated activity by unregistered NFC counterparties in segments of that swap market, such as in energy-related swaps, do not present outsized risk or harm to end-users, and most importantly, the general public.

Appendix 5—Statement of Commissioner Dan M. Berkovitz

I support amending the swap dealer *de minimis* exception to set the threshold at \$8 billion. This limited amendment relies on extensive data analysis to achieve a balance between the policy objectives of the *de minimis* exception and the registration of swap dealers.

At the outset, I would like to acknowledge the leadership of Chairman Giancarlo and the efforts of my fellow Commissioners to achieve consensus on this rulemaking. I look forward to working together to continue to find areas of agreement where it makes sense for our markets and the American people.

Data-Driven Rulemaking

Title VII of the Dodd-Frank Act directed the Commodity Futures Trading Commission

² If the proposed IDI Minimis Provision truly better aligns the swap dealer regulatory framework with the risk mitigation demands of bank customers, as commenters suggested, then it would seem that there should be few hurdles in the way of the CFTC and SEC engaging to reconsider the parameters of the IDI Swap Dealing Exclusion.

³ 83 FR 27445–6.

⁴ 83 FR 27445.

⁵ 83 FR 27450, 27456–7.

⁶ 83 FR 27457; Final Rule, *De Minimis* Exception to the Swap Dealer Definition, section II.C.1.ii (to be codified at 17 CFR pt. 1).

("Commission") and the U.S. Securities and Exchange Commission ("SEC") to jointly further define, among other things, the term "swap dealer."¹ At the same time, Congress enacted Section 1a(49)(D) of the Commodity Exchange Act ("CEA"), which directed the Commission to exempt from designation as a swap dealer entities that engage in a *de minimis* quantity of swap dealing.

In 2012, the Commission—jointly with the SEC—adopted the further definition of the term swap dealer. In this rulemaking, the *de minimis* swap dealing threshold was set at \$3 billion. However, recognizing that a lack of swap trading data made it difficult to set an appropriate threshold, the Commission implemented a long phase-in period during which the threshold was set at \$8 billion.² The regulation directed Commission staff to study the data on swap dealing activity that would be collected through swap data repositories ("SDRs") and publish a report for public comment, enabling the Commission at a later time to make a data-based judgment regarding the *de minimis* quantity threshold.³

To this end, the staff built a comprehensive database to aggregate data from all four SDRs. Over several years, the staff developed and refined new techniques to sort and evaluate the data, published two reports on the *de minimis* exception, and continued to revise its analysis in response to public comments. This process was not without considerable challenges, but the staff worked diligently to produce meaningful, data-driven information to guide the Commission's decision-making regarding the appropriate *de minimis* threshold.

This effort provided a highly significant data point: Approximately 98 percent of all swap transactions involved at least one registered swap dealer. We now know that at the \$8 billion threshold, nearly all swap transactions benefit from swap dealer regulation.

The staff's analysis also showed that reducing the threshold to \$3 billion would have a minimal impact on the amount of swaps activity that would be subject to swap dealer regulation. Indeed, based on the analysis, reducing the threshold to \$3 billion would only add swap dealer coverage to less than one-tenth of one percent of reported swaps. By the same token, the analysis demonstrated that increasing the threshold quantity above \$8 billion would have almost no impact on the amount of swaps subject to dealer regulation until that threshold reaches a significantly higher level. At those levels, the effect on specific categories of swaps—notably non-financial commodity swaps ("NFC")—becomes much more significant.

When considering amending a rule, the Commission should consider both the

¹ Dodd-Frank Wall Street Reform and Consumer Protection Act, section 712(d)(1), Public Law 111–203, 124 Stat. 1376 (2010) (the "Dodd-Frank Act").

² See 17 CFR 1.3, Swap dealer, paragraph (4)(i)(A); see also Further Definition of "Swap Dealer," "Security-Based Swap Dealer," "Major Swap Participant," "Major Security-Based Swap Participant" and "Eligible Contract Participant," 77 FR 30596, 30633–34 (May 23, 2012) ("SD Adopting Release").

³ 17 CFR 1.3, Swap dealer, paragraph (4)(ii)(B).

benefits and costs from those rule changes. Here, data analysis has shown that the benefits of changing the current \$8 billion threshold are relatively small because nearly all swap activity is already covered by dealer regulation.

On the other hand, decreasing the threshold from its current level would impose tangible costs on market participants. If the threshold were lowered to \$3 billion, unregistered dealers that are currently under the \$8 billion level, but that could exceed the \$3 billion threshold, would have to re-evaluate whether swap dealing in excess of \$3 billion would continue to make business sense. The *de minimis* rulemaking proposal⁴ noted that this issue is particularly important in the NFC swap market. The staff's data analysis showed that many of the smaller swap dealers for physical commodities are physical commodity producers, distributors, consumers, or merchandizers. Swap dealing is an ancillary business for them. Where the costs of registering as a swap dealer exceed anticipated benefits, it is likely that many of these entities would withdraw from providing swap dealing services to their customers. That would leave many end users looking to hedge their risks with either no dealers available, or very few dealers to provide competitive pricing.

The Commission should seek to preserve and foster competition for swap dealer services. One of the fundamental purposes of the CEA is to "promote . . . fair competition among boards of trade, other markets and market participants."⁵ American businesses throughout the country that need to use swaps to hedge their risks should not be forced to rely solely on large Wall Street banks. Retaining the *de minimis* threshold at \$8 billion will help preserve competition and choice for American businesses for these swap dealing services.

It is important to note that this rulemaking represents one of the first times in which the Commission has relied on SDR data to set policy, and the staff that undertook this principled and thorough analysis should be commended for their efforts. Given the technological advancements in data collection and analysis, effective use of data to inform policy making is critical for the Commission to meet its policy objectives of fostering open, transparent, competitive, and financially sound markets.

In sum, the data demonstrates that the current *de minimis* threshold level is largely accomplishing its intended purposes. Where the current regulations are working, regulatory stability also is an important objective. Accordingly, after considering the results of the swap data analysis, relevant policy implications, and limited benefits and potential costs of altering the *de minimis* threshold quantity, I believe that maintaining the threshold at \$8 billion is appropriate and sound public policy.

Physical Commodity Swaps

The proposal noted that Commission staff encountered challenges in measuring the

aggregate gross notional amount of NFC swaps. Instead, the staff used counterparty and transaction counts to approximate swap dealing activity for NFC swaps. The staff's analysis indicated that fewer NFC swap transactions—86 percent—involved at least one registered swap dealer, as opposed to 99 percent for other swap categories.

The market participants who use physical commodity swaps to hedge their risks typically include farmers, ranchers, farm product processors, energy producers and consumers, manufacturers, and other end users. These consumer-facing businesses need a properly functioning physical commodity derivatives marketplace to maintain consistent prices for their customers. Ultimately, the American people benefit from stable prices on the products that these businesses produce and distribute.

I am therefore calling on the Commission to continue to focus on improving our data collection and analysis for NFC swaps. More robust data collection will help us improve regulation in this space, including considering ways to balance the benefits of *de minimis* swap dealing in physical commodities with the need for customer protections and the other benefits of swap dealer registration.

Joint Rulemaking Required for Swap Dealer Definition

I am voting today solely in favor of setting the *de minimis* exception threshold quantity at \$8 billion because it is within the Commission's authority to do so. Looking forward, however, I will not support other amendments to the swap dealer definition without a joint rulemaking with the SEC, as required by the Dodd-Frank Act.

In addition to setting the threshold level, the proposal sought to alter the swap dealer definition by excluding from counting toward that *de minimis* threshold: (1) Swaps entered into by an insured depository institution ("IDI") in connection with originating loans; (2) swaps hedging financial or physical positions; and (3) swaps resulting from multilateral portfolio compression exercises. The proposal also asked questions about excluding from the threshold calculation swaps that are cleared and/or exchange traded and non-deliverable forwards.

Although the Commission is not adopting these provisions today, my view is that any such changes would effectively amount to an amendment of the swap dealer definition, not the *de minimis* exception. Doing so unilaterally and not as a joint rulemaking with the SEC would be contrary to the statutory language and inconsistent with Congressional intent.

When Congress enacted Title VII of the Dodd-Frank Act, its intent was clear: "[T]he [Commission] and the [SEC], in consultation with the Board of Governors, shall further define the term[] . . . 'swap dealer,'" among other terms.⁶ Congress clarified that the Commission must use the joint rulemaking process to make any other rules regarding these definitions that it and the SEC determine are necessary for the protection of

investors.⁷ To underscore this point, Congress noted that rules prescribed jointly by the Commission and the SEC under Title VII must be "comparable to the maximum extent possible," and that any interpretation of, or guidance regarding, a provision of the Dodd-Frank Act would be effective only if issued jointly by the Commission and the SEC.⁸ Pursuant to this statutory directive, the agencies adopted a joint rulemaking to define "swap dealer" and "security-based swap dealer."

Congress created one exception to the joint rulemaking requirement. CEA subsection 1a(49)(D) authorizes "the Commission" to exempt from designation as a swap dealer "an entity that engages in a *de minimis* quantity of swap dealing" and "to establish factors with respect to the making of this determination to exempt."⁹ The Commission included this *de minimis* exception in paragraph 4 of the swap dealer definition, notably separate from other provisions in the definition addressing the IDI exclusion (paragraph 5) and the physical hedging exclusion (paragraph 6).

By its terms, the *de minimis* exception relates solely to exempting a numerical quantity of swap dealing activity. Under the statutory structure, the Commission and the SEC must jointly determine which activities are dealing activities and therefore must be counted toward the threshold; the Commission itself may set a numerical quantity of such dealing as a threshold for registration. Put simply, deciding "which" activity gets counted must be done jointly; deciding "how much" of that activity triggers the registration requirement may be done singly.

The proposal framed these additional proposed changes to the swap dealer definition as "factors" in the *de minimis* threshold determination. In doing so, the proposal sought to use the Commission's unilateral authority to "establish factors" as provided in the second sentence in CEA subsection 1a(49)(D). However, that interpretation is a misreading of the statutory provision. The second sentence in CEA subsection 1a(49)(D) authorizes the Commission to promulgate regulations to "establish factors with respect to the making of this determination to exempt."¹⁰ The words "this determination" clearly refer to the quantity determination in the first sentence of the subsection: "[t]he Commission shall exempt from designation as a swap dealer an entity that engages in a *de minimis* quantity of swap dealing in connection with transactions with or on behalf of its customers."¹¹ In other words, the "factors" referred to in the second sentence relate to the numerical quantity determination in the first sentence; this sentence does not create a distinct directive authorizing the Commission to independently determine what constitutes swap dealing.¹²

⁷ Dodd-Frank Act, section 712(d)(2)(A).

⁸ Dodd-Frank Act, section 712(d)(2)(D).

⁹ 7 U.S.C. 1a(49)(D) (emphasis added).

¹⁰ *Id.*

¹¹ *Id.* (emphasis added).

¹² In the preamble of the SD Adopting Release, the Commission discussed the factors envisioned by

⁴ Notice of proposed rulemaking, *De Minimis Exception to the Swap Dealer Definition*, 83 FR 27444 (June 12, 2018).

⁵ 7 U.S.C. 5(b).

⁶ Dodd-Frank Act, section 712(d)(1).

This point is clear when we examine what would happen if each of the five categories of swap dealing activity identified in the proposal as “factors” (*i.e.*, IDI, physical hedging, multilateral portfolio compression

Section 1a(49)(D). For example, the preamble provided that the Commission could consider whether the de minimis exception would “lead[] to an undue amount of dealing activity to fall outside the ambit of Title VII regulatory framework, or lead[] to inappropriate reductions in counterparty protections (including protections for special entities).” SD Adopting Release, 77 FR 30635.

exercises, cleared and/or exchange traded, and non-deliverable forwards) were removed from the definition of swap dealing through this interpretation of the de minimis exception. Combined, these five categories of swaps likely total *more than half* of the notional amount traded. There would appear to be no limit to what dealing activity could be excluded from dealer regulation through the de minimis exception by framing whole categories of swaps to be excluded as “factors.” The Commission could effectively determine unilaterally what constitutes swap

dealing. The de minimis exception would swallow the swap dealer definition. This result cannot be reconciled with the Dodd-Frank Act’s joint rulemaking requirement.

For these reasons, while I am amenable to considering further refinements to the swap dealer definition and what gets counted as dealing, I am of the view that this cannot be accomplished without joint rulemaking with the SEC.

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Part V

The President

Memorandum of October 29, 2018—Delegation of Authority Under Section 1244 of the National Defense Authorization Act for Fiscal Year 2019

Presidential Documents

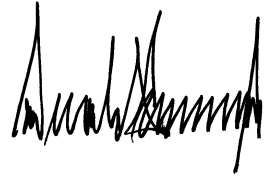
Title 3—**Memorandum of October 29, 2018****The President****Delegation of Authority Under Section 1244 of the National Defense Authorization Act for Fiscal Year 2019**

Memorandum for the Secretary of State[,] the Secretary of the Treasury[,] the Secretary of Defense[,] the Secretary of Commerce[,] and] the Director of National Intelligence

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, I hereby delegate to the Secretary of State, in coordination with the Secretary of the Treasury, the Secretary of Defense, the Secretary of Commerce, and the Director of National Intelligence, the authority to submit to the Congress the certification required by section 1244 of the National Defense Authorization Act for Fiscal Year 2019 (Public Law 115–232).

The delegation in this memorandum shall apply to any provision of any future public law that is the same or substantially the same as the provision referenced in this memorandum.

The Secretary of State is authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, October 29, 2018

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